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Report on Home Use Medical Device Meetings



June 6 & 7, 2002

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On Thursday, June 6 and Friday, June 7, 2002, two separate meetings were conducted at the office of the Food and Drug Law Institute (FDLI) for the purpose of discussing the issue of the safety and effectiveness of medical devices used in the home environment. The participants were invited from relevant government agencies, non-profit organizations, health practitioners, patient caretakers, academia, and industry. The meetings were held at the request of Center for Devices and Radiological Health (CDRH) which is the Food and Drug Administration's component responsible for assuring the safety and effectiveness of

medical devices. This report summarizes the results of those meetings.

I. Background

For several years, CDRH has had an intensive program to review and revise many of its policies and procedures, and it has done so through the use of teams composed of CDRH and other FDA staff. One such team, The Home Health Care Committee, is studying how medical devices used in the home environment by patients and lay caregivers can be made more safe and effective. The Home Health Care Committee was formed as part of CDRH's strategic planning to understand the impediments to the safe and effective operation of medical devices used in the home environment and to recommend appropriate Center actions within its legislative mandates and public health responsibility. The committee also wanted to see how the home environment influenced the use, functioning, and safety of devices that were not necessarily intended for use outside of clinical facilities by trained health care practitioners.

The use of sophisticated medical devices in the home environment has evolved as significant changes in medical care delivery have occurred over the past few decades. Prior to World War II, medical care was primarily a home affair, with doctors and nurses visiting the patient in the home, and hospital-based care reserved primarily for the severely ill. However, after World War II, as medical diagnosis and therapy became more sophisticated and intensive, of necessity it was delivered primarily in medical care facilities, such as hospitals, medical offices, and clinics. However, as health care delivery has become more sophisticated, it has become considerably more expensive especially since the 1970's. Changes in health care economics, as well as demographic changes, have stimulated a significant evolution of the "hospital" model, with more and more patients being cared for at home or at other non-clinical places for their convalescence, after the patient's acute medical status has been stabilized. And inevitably, their care has been performed or maintained more and more by patients' parents, spouses, or other non-clinical personnel. As patients have been moved to the home and other non-medical facilities for their recuperation or long term care, the medical devices needed for their care (e.g., respiratory and intravenous therapy devices) have followed them. But many such medical devices were given CDRH approval for marketing under the expectation that they would be used by trained health care practitioners in controlled health care delivery facilities. Thus sophisticated medical devices are being used under conditions that neither their manufacturers nor the regulatory system had necessarily contemplated or intended. This in turn has had consequences for the safe and effective operation of these medical devices, especially those with sophisticated requirements for proper operation, maintenance, calibration, electrical power, etc.. Anecdotal reports of patient deaths or injuries as a result of problems with these factors are increasing.

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As part of its study of how the safety and effectiveness of medical devices used in the home environment can be improved, CDRH desires the input of individuals, companies, and organizations that are familiar with this use. To help obtain this input, CDRH asked FDLI to convene and facilitate a small meeting ² of invited participants on Thursday, June 6, 2002, and a similar meeting on Friday, June 7, 2002, at FDLI's office in Washington DC. Invited organizations and individuals were asked to select which meeting they would like to attend.

Holding these meetings is consistent with Section 406(b) of the Food and Drug Administration Modernization Act, which charges FDA with consulting with "appropriate scientific and academic experts, health care professionals, representatives of patient and advocacy groups and the regulatory industry" when developing its plans for statutory compliance with the law. CDRH does not seek advice or consensus at such meetings, but the staff looks for opinions from invited individuals on an ad hoc, one-time basis. Once CDRH develops its specific plans regarding the home use of medical devices, it will

conduct other activities in order to obtain broad public input on this issue.

²This work was conducted under the auspices of FDA/CDRH Service Order No. C45917-00-02-SE-00 with FDLI. Mr. Arcarese's participation in the project was under the auspices of a separate agreement between him and FDLI.

II. Process

The idea for the two June meetings derived from the success of previous meetings conducted by FDLI for other CDRH topics, in which a relatively small number of invited experts were convened at FDLI for facilitated discussions. The conversations between invited experts and CDRH staff proved remarkably fruitful in identifying issues and ideas which CDRH staff could use in formulating new program initiatives. In every case, CDRH followed up with public meetings, Federal Register publications, or other means of assuring broad public input prior to mounting a formal program to deal with the issues about which it had sought opinions.

These facilitated conversations are unlike typical conferences. Typical conferences are usually characterized by speakers at a podium addressing a listening audience, with little provision for debate and interaction between speakers and audience other than a few questions and answers. Thus conferences primarily consist of a process of one-way communication from speaker to audience, and the audience for the most part does not actively interact with the speaker or with each other, except for what might incidentally occur informally between individuals during breaks. Unlike conferences, there are no "speakers at a podium" in these facilitated conversational meetings. All the participants are invited specifically for the purpose of actively discussing and interacting with each other, probing each other's experiences, questioning claims and preconceived notions, and posing and debating suggested alternatives, under the general guidance of a facilitator. In this kind of environment, where the total number of participants is small enough to allow all participants to have sufficient "air time" to discuss their points of view, the accumulated wisdom and experience of all the participants is tapped. This process honors the contribution of the participants, who donate their valuable time and incur expenses to attend the meeting without recompense from FDA or FDLI, by giving them a sufficient opportunity to express themselves and to interact with other participants. This produces a very intellectually enriching experience for all. Unlike typical so-called "focus-group testing," these facilitated meetings are not recorded, nor is there a one-way wall separating participants from silent and unseen observers. Consequently, participants feel free to express themselves candidly. Notes taken by FDA participants are used for the purpose of compiling a report which makes no individual attributions.

CDRH staff familiar with those previous meetings felt that the same approach would be helpful at this stage in the home use program, and they contacted FDLI about the idea of holding similar meetings for the home care issue. Specific planning for the meetings was conducted between members of the CDRH Home Use Committee and Mr. Joseph S. Arcarese, who would be the facilitator of the planned meetings. Although now retired from full time employment with FDLI, Mr. Arcarese continues to facilitate meetings under an agreement with FDLI. He facilitated a large number of FDLI/CDRH meetings during his seven year tenure in FDLI, and facilitated many similar meetings during his 26 year tenure in FDA's CDRH. Planning was conducted over a series of meetings, phone calls, and e-mail communications, starting with a meeting on Friday, December 7 between Mr. Arcarese and members of the Committee. Committee members expressed their desire for information and comment from relevant communities (including government agencies dealing with health care, and non-government entities and individuals with experience relevant to the home care topic).

It was agreed that Mr. Arcarese would draft an invitation letter to be sent to a variety of organizations and individuals known to be involved with the home use issue. Between March 28 and April 19, the language and format of an invitation letter was drafted, reviewed by the Home Use Committee, and revised

accordingly (final copy attached). Individually addressed invitation letters were mailed to 82 recipients. In many instances, invitation letters initially addressed to particular people were passed on to others who subsequently contacted Mr. Arcarese. The list of initial addressees and those who subsequently received copies is attached. In addition, on May 5, reminder e-mail invitations were sent to 52 recipients who had not responded to the mailed invitations. The invitation letters offered recipients the choice of attending either the June 6 or June 7 meeting. Positive responses were ultimately received from 29 individuals. Of the positive respondents, 26 actually attended and three did not. The lists of attendees at each meeting are attached.

The invitation letters included a request that the respondent fill out a brief survey form, consisting of six questions, and send their answers to Mr. Arcarese. A number of participants did so, and he compiled their responses (copy attached).

The six questions were:

1. How would you define "home care devices"?
2. What, in general, do you see as "challenges" or problems to the safe and effective use of medical devices in the home?
3. What challenges to successful maintenance and repair of home care medical devices are you aware of?
4. How can communication between the user and the manufacturer be improved?
5. What future technology do you anticipate having an impact on home care?
6. What process would you like to see for safely managing the migration of professional use devices into the home?

Copies of the anonymous responses submitted by the respondents were provided to all attendees, and the discussions at the meetings were organized around the six questions.

During the meetings, notes were taken by several CDRH staff attending in attendance, and the following summary was prepared based upon those notes. Subsequently, all attendees were asked to review a draft of this summary, and the final version reflects the comments received.

III. Summary of Meetings

(Note: This section summarizes comments from both the June 6 and the June 7 meetings)

A. General Comments

The use of medical devices for home care is widespread and increasing. Most care is going on outside of the control or supervision of regulated agencies.

Although the early years of regulation of medical devices by FDA was characterized by a more rigorous approach with a great many devices classified so that health care practitioners were needed to prescribe their use, this last decade has been characterized by many devices being reclassified, so that prescriptions are not necessary for the general public to have access to them. Consequently, a growing number of medical devices are available for the general public to purchase over the counter. Although Class II and Class III devices are prescription devices, and thus are not directly available over the counter for use by the general public, prescriptions for their use in the home are now more readily provided by licensed health care practitioners.

Although manufacturers are required to provide labeling and other information to give health care practitioners sufficient information in order for them to use the devices safely and effectively, devices that are not labeled for "over-the-counter" use are not required to be accompanied by training and education

for use by non-clinical users. There has been the assumption that the prescribing health care practitioners will assure that such necessary education will be provided to lay caregivers, but in fact, a major problem with the current system is that the education and training of homecare users is woefully deficient. The use of some sophisticated devices places unrealistic expectations on the capabilities of lay caregivers. Furthermore, the home environment is devoid of the safety and support systems found in hospitals.

Thus, training and education of the lay user is a major issue. Current labeling and instructional materials are inadequate for use by lay persons, and may be quite difficult to understand. Although some home healthcare organizations do instruct the lay caregivers, it frequently happens that the devices are delivered for use with little or no instruction or supervision by trained professionals.

The current system of health care in this country leaves much to be desired. Due to reimbursement limitations, the hospital may order the attending physician to discharge a patient for home care. The physician signs an order for the use of a particular device type. However, the distributor ordinarily chooses the specific brand and model. The attending physician may receive little or no feedback about the specific circumstances at home into which the patient is released. Three quarters of the home healthcare industry is not accredited by the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) for assessment of patients/home caregivers regarding their capability for use of medical devices in the home. The current reimbursement system does not provide adequate funding to assure that such assessments occur.

Device design is also a major issue. Design of the same generic kinds of products are inconsistent from manufacturer to manufacturer. Included in the design issue is the related issue of standardization of user interfaces. There are no regulatory requirements for the application of human factors principles in the design of medical devices.

B. Home Care Device Definition

CDRH operationally defines home use medical devices as: “medical devices used in the home environment by persons who are ill or disabled and need, or whose providers of care need, education and/or other related health care services to use and maintain the devices safely and effectively”.

However, there are several problems with this definition. First, it may be incompatible with telemedicine and telemetry. Second, it doesn't take into account those people who are recovering (i.e., not presently “ill” per se) and who may need to be monitored during their recuperation. One person thought that adding the term “at risk” might also help characterize that not all home care users are presently ill. Third, the word “home” is too limiting and “home use” is an inaccurate characterization, because there are other non-clinical venues besides the home where medical devices are used (e.g., car or other transport). Some monitoring or therapeutic devices are used on the person wherever he/she might go, inside or outside. To deal with this, it was suggested that the definition be changed to speak about the use of devices outside of controlled environments (or outside of “traditional health care settings”), where the concept of controlled environments is understood to mean those venues under relevant regulatory and professional control.

It was emphasized that neither the home health agency nor a visiting health professional actually controls the “home” environment where medical devices may be installed, at least not to the extent that a hospital's environment is controlled (for example, with reference to the consistency and suitability of electrical power, minimizing the existence of extraneous electric and magnetic fields, preventing children or animals from having physical access to devices, circumventing any stairs, narrow doorways, and other barriers impeding movement, having quick and ready access to professional maintenance and repair, etc.). Although many homes are modern and have adequate electrical power, plumbing, and other modern physical characteristics, not all homes are so well endowed. Some homes have very old wiring and inadequate electrical power, or no power at all. Some homes even have dirt floors and lack indoor plumbing. Some homes are in rural areas with very limited access. Thus, the range of “homes” is

extremely broad with respect to their suitability for some medical devices.

C. Challenges/Problems to Safe and Effective Use in the Home Environment

There are a number of categories of issues that need to be examined with regards the suitability of certain devices for home use, including:

- Age and Disability of the User
- Competency of the User
- Environmental Suitability
- Design Issues
- Architectural Barriers
- Miscellaneous Factors in the Home (e.g., children and pets, that may interfere with the proper functioning of medical devices)

With regards the characteristics of the home user population, it was pointed out that it is essentially unbounded. The age of home device users ranges from newborns to the very aged. Especially with regards the home care of very aged patients, the caregivers are frequently aged themselves. In addition to a range of ages, there is a broad range of capabilities and limitations in the population of potential medical device users. Limitations are both cognitive and physical.

It was readily acknowledged that the type and number of medical devices used in the home is increasing. There is a growing pressure for the use of devices in the home, due to the changes in health care delivery that have occurred in this country as a result of the extraordinary expense of hospital-based care. This causes a strong incentive to move patients out of the hospital as soon as possible, thus necessitating convalescence and recuperation at home or at locations costing less than hospitals, with the help and monitoring of family or of people who are less well trained (and thus less expensive). These patients are now often “sicker” or more medically demanding than in the past, due to their shorter hospital stays. Also, as the American public has become more educated and sophisticated, consumers have demanded having access to certain devices in the home, because they would rather convalesce in their home than stay in the hospital. People are aware that staying in hospitals longer than absolutely necessary puts them at increased risk of infections, they are aware of the inconvenience and discomfort for their families, and they are aware that hospitals are simply not the most comfortable places for their own convalescence. Furthermore, people want to take more responsibility for their own care or for the care of their loved ones out of their own sense of autonomy and responsibility.

However, some participants questioned the current process whereby decisions about releasing patients from hospitals to home care are frequently made without adequate assessment of the capability of the home caregivers or the suitability of the home environment for this purpose. Moreover, the quality and quantity of training and education provided to lay caregivers is highly variable, dependent on the level of reimbursement, and on the capabilities and motivation of the person providing the education (e.g., whether the information is being transmitted by a delivery truck driver or by a registered homecare nurse). One person felt that the cost of needed education needs to be incorporated into the cost of the device.

The changes in healthcare delivery have put increasing pressure on the regulatory agencies to adapt their policies and procedures. For example, the Center for Medicare and Medicaid Services (CMS) impacts the use of medical devices in the home through its reimbursement policies. But this inevitably raises questions about the safety of the use of these devices in new surroundings. This places pressure on the manufacturers of such devices to decide what is needed at home to operate their devices safely. There is increasing pressure on manufacturers to spell out the circumstances for safe use in the home directly on the device labeling. There is also pressure on the manufacturer to design devices to the least common denominator. But the previously mentioned range of cognitive and physical capabilities in the population of patients/lay caregivers makes such strategies extremely difficult and even risky propositions for the

manufacturer.

Manufacturers are ambivalent about the use of their devices in the home. Although presumably the migration of devices into the home increases their markets, it also has significant implications on the safe and effective use of their products. They point to the fact that they are regulated in multiple ways (e.g., by U.S. and foreign regulatory agencies) and they assert that this level of regulatory control provides a large measure of assurance against badly designed devices. But the proper functioning of the device is dependent on the competency of its user. In the past, doctors, nurses, and other highly trained health professionals were the users. Now, the world of users is expanding to include lay people, where there is no real assurance about the competency of the user or the suitability of the home environment for the proper functioning of the device. It is true that some devices are designed by the manufacturer to be used safely by patient or family; such devices, for example, might be designed to have no or few external function buttons, working automatically with little or no human intervention. However, the natural incentive of manufacturers to build in features that differentiate their product from their competition militates against the idea of simplicity or standardization.

But manufacturers are aware that many complicated devices designed for the hospital have been sold into homecare, and they often do not have control over this process of migration out of controlled facilities into uncontrolled facilities. These devices don't meet the manufacturer's requirements for use in the home (e.g., power requirements, alarms, safety mechanisms). At least one manufacturer purchases back its devices intended for the clinical environment that have wended their way into the home. However, this does not appear to be a general practice in the industry.

There was much discussion about ways of addressing the fact that risks of medical device use in the home are greater than those in the clinical environment. Human factors professionals suggest that, as a solution strategy, the first priority ought to be to design out problems in the first place (i.e., obviate the problem from occurring at all). If a potential problem cannot be designed out, then the next priority ought to be to guard against the error (e.g., have an automatic shut off). Only as a last alternative, when the first two priorities cannot be fulfilled, should reliance be placed on warnings about a problem.

One human factors professional objected to the seemingly implicit assumption that manufacturers who design their devices for use in controlled clinical environments, but know that they are being used in the home environment, are nonetheless apparently absolved of the responsibility to make needed design changes to improve use in the home. This person emphasized that the best solutions to user problems are designed into the product. Reliance on instructions, training, and administrative controls are poor substitutes for good design, and are generally not nearly as effective.

There is universal dissatisfaction with the quality of instructional materials accompanying medical devices. And there is also skepticism about how many people actually read instructions. The human factors community does have statistics available on the use and understanding of labeling instructions, and this information might be quite useful in the design of informative materials that the lay public would be more likely to heed. One benefit of equipment designed specifically with lay users and the home environment in mind using human factors principles will be that instructional materials may not need to be complicated, since simpler, more usable systems ought to be easier to explain.

Instructions for how to use devices ought to be clear and easy to understand, and operating the devices themselves ought to be intuitive. In the world of consumer devices, there is general familiarity with the fact that instructional materials are often poor and/or the controls are not intuitive, and these inadequacies consequently limit the ability of consumers to take full advantage of the capabilities of these devices (e.g., the blinking "12:00" on the VCR). Given the fact that the consequences of error with medical devices are much higher than with consumer devices, since errors with some devices might even result in a patient's death, the stakes are much higher for the development of informative materials and human factors designs to help avoid such dire consequences.

Labeling medical devices for consumers presents some very challenging problems. First, people often don't often pay attention to instructions until they are in trouble. Also, the ways people learn are different from individual to individual. Some are visual, some auditory, and some are kinesthetic learners, so a "one size fits all" approach to instructional materials may be unsatisfactory. In addition, some older adults have problems with cognitive processing, and people with certain kinds of disabilities may be unable physically to carry out certain functions. So, if a product is intended for use by older adults or the disabled, then it needs to be tested with these limitations in mind.

From the manufacturer's perspective, writing instructions for device use is extremely difficult, because so many different expectations need to be met. In addition to their own internal requirements, the manufacturer has to meet FDA requirements, end user needs, and the requirements necessitated by the legal tort system. Consequently, it is not unusual for instructional manuals to weigh more than the device. This is hardly conducive for patients or lay caregivers to read and understand them. Furthermore, training materials and instructions prepared to satisfy multiple and sometimes conflicting incentives is not the kind of situation envisioned by human factors professionals when they call for a human factors approach to the development of instructional materials for the health professional as well as for the home lay caregiver. They believe that manufacturers ought to be engaging human factors expertise (e.g., having human factors professionals on staff) in developing instructional materials.

Instructions for home caregivers need to be presented in plain language, with care that jargon is not used, and that the caregiver can understand. Also instructions for home use need to be presented in a sensitive manner that keeps in mind that the caregivers and the patient may be under great stress and may have difficulty in focusing on important device use matters.

There is a company called Simulis (www.simulis.com/home.html) that develops online simulations of medical devices and provides simulation-based device training programs. Presumably this sort of resource might enable manufacturers to perform some kinds of premarket assessments of their devices with suitability for lay users in mind.

Everyone concurs that the competency of the individual using the device is critical to its safe and effective operation. The Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) insists that healthcare organizations must follow guidelines and evaluate the competency of lay caregivers who will be vested with the responsibility of using certain kinds of medical devices. But it is not clear who evaluates the competency of lay caregivers when JCAHO accredited organizations are not involved. Outside of the involvement of JCAHO accredited organizations³, there appears to be no systematized way of enforcing compliance with appropriate standards of competency for lay caregivers. If consumers can obtain medical devices for use in the home, they probably do not have to demonstrate their own competency or the competency of their home environments in order to do so.

There need to be standards for home use, including criteria for prescriptions for home use, that take into account the hazards and unique situations in the home. Home audits may be necessary to evaluate these situations, such as whether there are young children around, whether the caregivers are older adults, whether the electrical power in the home is suitable, etc. Devices for home use need to be designed with these kinds of situations in mind.

³It should be noted that there are some other accrediting bodies for home medical equipment providers, but JCAHO is the largest and most widely recognized.

Some participants advocated the development of an FDA hotline so that home caregivers can get support and unbiased information. Some others felt that a hotline ought to be run by different organizations, rather than FDA, under the presumption that people would not want to talk to a government agency when they are in crisis. One thought that the need for information during a crisis ought to be fulfilled by a process

involving telemedicine. One person pointed out that internal diagnostics in the device itself would be useful in monitoring how the device is being used, and might be helpful in some remote expert in ascertaining the cause and solution of a problem being reported by a home caregiver.

There is no such thing as zero defects. Unintentional situations will always occur, even under the best of circumstances, and with the best processes of design, manufacture, and implementation. Thus, there will always be risks involved with the use of medical devices, whether in the home or in the hospital. The existence of risks should not, by itself, obviate the use of a device in the home.

It is also necessary to take into account the kind of harm that could be done if a particular device was not available for use in the home. There is a need for compassion and creativity as medical devices are evaluated for use in non-clinical environments like the home. There is always a benefit/risk tradeoff that ought to be taken into account. The question needs to be asked, what would be the alternative if a particular device were not allowed to be used in the home. Sometimes the alternative is unacceptable, such that, despite the risk, the device ought to be used in the home.

It is also important to take into account whether the device will be used on a temporary basis in the home, or whether it will be used permanently. A greater risk (i.e. from the seriousness of a potential adverse event, and/or from the likelihood of its occurrence) might be tolerable for a device to be used in the home for a short period of time, as opposed to devices that will be used on a permanent basis.

One participant pointed out that some medical devices are handed down from one lay caregiver to another, without the intervention of some supervising health care assessing organization. And this transfer of devices is accompanied by a transfer of information and experience, but there is no guarantee that the information will be accurate and complete. It is also possible that the transferred device itself may not be appropriate for the intended user.

“Rough Crossing” is a report written by the United Hospital Fund of New York (www.uhgnyc.org) which contains quotes from caregivers regarding equipment. The report emphasizes the problem of lack of coordination in the process of releasing patients to home care.

The National Science Foundation and FDA have a working partnership, developing an undergraduate design program as one means of training the future designers of medical devices.

D. Where Should CDRH Start?

There need to be priorities for action to improve medical devices for home use, as a means of organizing a sensible process to examine and redesign them. One approach is to stratify medical devices by the risk involved in using them, and then proceed to examine those devices presenting the highest risk, rather than considering that all devices for the home reside in one risk category. In this regard, it was suggested to begin a deliberate process of examining devices by focusing on several characteristics, such as prescription devices vs. OTC, Internal vs. external use, and therapeutic vs. diagnostic. One suggestion was for focusing first on prescription devices used for external therapeutic purposes. By suggesting these characteristics to focus on, it was not intended that medical devices with other characteristics (e.g., diagnostic devices) do not present inherent risks. This approach was suggested merely to get a sensible process started.

There was also the suggestion that devices need to be investigated in terms of the level of risk (i.e., the seriousness of the consequences of device malfunction or failure) and the expected frequency of such problems. It is possible to conceive of a risky situation arising from the use of even the most innocuous of devices. But it is apparent that not all devices present the same level of risk nor the same frequency of occurrence of serious problems. There was no disagreement that such a means of stratifying devices by

risk and frequency was necessary in order to have a sensible approach to evaluating devices for home use.

In this regard, it should be noted that the VA National Center for Patient Safety has developed a patient safety matrix in their patient safety handbook. It is available at this website: <http://www.patientsafety.gov/NCPShb.pdf>. The VA National Center for Patient Safety has the same sort of matrix in the Healthcare Failure Modes and Effects Analysis (HFMEA, trademarked), available at this website: <http://www.patientsafety.gov/HFMEAIntro.pdf>. The HFMEA format is applicable for doing proactive risk assessment.

There is a question about what constitutes “safe”? The concept of safety is complex and is relative to the circumstances. This in turn raises the question about the data available alleging risks and problems for particular devices. Assessing risk based on anecdotal information always raises the question about whether this represents the exception or the rule. Is it possible that risks may be anticipated that never really happen?

One way to prioritize medical devices in this respect is to first focus on a category of devices, such as therapeutic, permanent, external devices, and stratify these by risk. It might also be useful to stratify by electrical or mechanical devices, under the presumption that electrically operated devices present greater risk than mechanical devices.

Monitoring needs to be built into devices, so that their operation can be easily monitored and problems diagnosed.

The quality of risk stratification is dependent on acquiring realistic data about the performance of devices in non-clinical environments. There are some sources of information that can be applied. For example, some information might be gathered during the premarket review process. Participants felt that a process for postmarket surveillance in the home environment is needed, in order to ascertain how these devices are used in the home. Data gathered on the rates of success and failure of devices in the home, collected for a suitable period of time, could serve as basis for categorizing devices by risk level. Data on problems might also be obtained from biomedical engineers and technologists working in hospital settings.

It was suggested that two categories of medical device products are responsible for the vast majority of problems in the home environment, and that intensive analysis ought to be focused on these device categories first: 1) Respiratory Therapy, 2) Infusion Therapy. There was a suggestion that a third category, Rehabilitation Therapy, is also responsible for problems in the home. Human factors professionals claim that some device problems can be extrapolated to other similar devices in the same general category, so that it may not be necessary to individually examine every device in the category.

With reference to postmarket surveillance, it was pointed out that CDRH collects adverse event information from manufacturers and from hospitals, clinics, and nursing homes. However, the Center only started capturing the location where an event took place in 1996, so this data is limited. This data is also largely anecdotal, so it suffers from not being able to be statistically compiled. Other agencies have data on device use. For example, the Veterans Administration has a good reporting system regarding adverse events. The JCAHO will check to see what information it collects can be shared with CDRH.

CDRH needs to ascertain what other government agencies are doing. In this respect, these meetings are useful because representatives of other agencies that use medical devices are in attendance, and CDRH staff can make appropriate linkages with other agencies for the purpose of sharing information.

There was a suggestion that there should be a process of assessing patient (or family) capabilities before they should be relied upon to use prescribed medical devices in the home. JCAHO accredits 25% of home

health care agencies and home suppliers, and they do conduct assessments. JCAHO standards require that patients/caregivers are asked to demonstrate their ability to use the equipment. JCAHO has a definition of home use medical devices (not necessarily prescription devices).

Reimbursement policies affect whether patient assessments and reassessments can be or are performed. It is important that manufacturers realize that marketing devices that qualify for reimbursement is not necessarily the same as responding to what the consumer wants.

E. Maintenance and Repair

The performance of routine maintenance and repair of medical devices in the home is acknowledged to be a serious problem affecting the safety and effectiveness of medical devices. Lay caregivers and patients do not necessarily have the knowledge and capability to perform these functions, so the question of who ought to do this is an unresolved issue. There is a sense that durable medical equipment suppliers who install the equipment bear certain responsibilities for maintenance and repair, but it is not clear who would pay for this service. Manufacturers are concerned that, if they were required to perform maintenance and repair of their equipment in the home or other non-clinical locations, this would present them with insurmountable difficulties and expense.

Calibration needs to be included in routine maintenance, and it needs to be part of quality systems. Low maintenance devices would probably gain market favor in the home use environment over devices that require higher levels of maintenance. There is some sentiment that FDA ought to require that devices be either self-calibrating or disposable to be used in the home, thus obviating the need for the home user to perform calibrations.

However, there is also a serious concern that regulations may add hurdles to the development of devices suitable for the home, ultimately acting as a disincentive for manufacturers to design devices specifically for home use.

Finally, the major hurdle regarding maintenance and repair is the issue of reimbursement. Ultimately, any service needs to be paid for, and maintenance and repair are not unique in this regard. Ideally, the design of devices that need no routine maintenance and repair would get around this issue of funding.

F. Future Medical Technologies

There is a general sentiment that robotics and interactive technologies will provide solutions to some of the problems currently plaguing the world of medical devices and also the provision of medical care in the home. Interactive technologies include telemedicine (e.g., teleradiology, teledermatology, etc.). There is also the assumption that "smart house" technologies in the future will help provide capabilities for assisted living. There are also new speech technologies to help those with certain disabilities. Also the growing use of home wireless computing will certainly have applicability.

There is an awareness that markets and manufacturers move faster than the development of regulations, so that regulations might be 3-4 years behind the leading edge of new technologies. Regulatory agencies need to be concerned that, as they try to control certain kinds of problems, they don't act to stifle the development of new technologies, to the net detriment of society.

G. Safe Migration of Devices from Hospitals to Home

There is a general consensus that the use of medical devices in the home ought to be officially recognized, and that it ought not to occur simply by default. Manufacturers ought to acknowledge the

possible or probable use of their devices in the home, and the regulatory process ought to do so as well.

There should be criteria/guidelines about what should and what should not be used in the home, and under what circumstances.. There should also be an effective system of discharge planning, that includes an effective system of patient/caregiver assessment, suitable and effective training, and effective means of assuring equipment maintenance and repair. The discharge process ought to include appropriate consideration for the particular equipment to be used in the home, as well as evaluation of the environment into which it will be placed.

One person suggested that devices ought to be classified by whether they are (or could be): (1) OTC; (2) approved for use by lay persons with suitable assessment; and (3) approved for use only under the direct supervision of a health care professional. Another person thought that there ought to be criteria for the approval of devices that might go into the home, and that assessment of competency ought to be linked to these criteria. Others felt that human factors professionals should play a strong role in the evaluation of devices proposed for home use, as well as in the development of instruments for the assessment of competency. They also felt that there should definitely be involvement of users, especially the aged and the disabled, in the effort to develop criteria and competency assessment instruments. Finally, they felt that potential home use issues should be investigated from three perspectives:

1. User factors – cognitive training and physical capabilities
2. Design factors – Manufacturers responsibilities and compliance with regulations\
3. Documentation and support factors – Use warnings, instructions – need usability testing for the labeling and documentation intended for lay instruction.

Although there was agreement or sympathy over the need for some system of reporting adverse events occurring in the home, there was also some skepticism whether any home reporting system could ever work due to the reluctance of people to admit that they were involved with a problem. It is interesting to note that this reluctance for self-reporting is not unlike the reluctance in the healthcare system in general, where there is concern for the potential legal liability and consequent ramifications from reporting problems. There is also the concern that the decision to gather adverse event data ought to be premised on having a plan for mining the data and for proposing corrective actions.

IV. Final Comments

(Note: Before the close of each meeting, participants were asked to identify their key concerns and questions).

There was a question about how the European Union controls the movement of prescription medical devices in the home. It was acknowledged that the way it happens in the U.S. may not be the norm.

There is concern about how medical devices can be properly maintained in the home.

One participant noted that the issue of children's use of medical devices did not get mentioned, nor the issue of parent/child interaction.

A manufacturer mentioned the concern that ill-considered regulations, however well-intentioned, might serve to stifle progress in the development of new medical devices for the home. The manufacturer also commented that there needs to be a greater participation of manufacturers in this process, in order to ensure that their legitimate concerns as well as their proposals for solution strategies are taken into account. In this regard, he emphasized obtaining input from manufacturers of respiratory therapy and infusion therapy devices⁴. He mentioned that two of the general concerns expressed by CDRH and the

meeting participants, device design and the operating instructions provided to the user, are issues that need to be addressed by manufacturers. Certain manufacturers are already involved in serious efforts to improve the design of their home use devices, provide better training materials to the home patient, monitor patient compliance in the home, and improve the follow-up systems available to DME dealers who deliver the equipment to the home. He also thought that the manufacturers can also provide valuable insight regarding the DME distribution system in the US. He urged CDRH to recall that home use devices are usually delivered to the home by DME dealers, not by an employee of the manufacturer. It is the DME supplier that has direct contact with the patient and their caregivers in the home. He felt that CDRH would be well advised to gain a better understanding of how manufacturers best efforts could be enhanced or thwarted by the DME supplier that delivers the equipment to the home patient.

⁴This manufacturer representative mentioned Respironics, ResMed, AirSep, Puritan-Bennett (Mallinckrodt), Invacare, DeVilbiss, as some of the biggest manufacturers of respiratory and infusion therapy devices

One participant urged a multifaceted approach to the solution of problems affecting the safety and effectiveness of medical devices used in the home, including education programs, focus groups to determine actual failure modes and rates, and the development of standards to deal with problems. Other participants urged that regulation ought not to be the only strategy.

One urged that FDA needs to investigate information and data that already exists in other Federal agencies and private organizations prior to making its own decisions. Its decisions ought to be based on solid data.

JCAHO has already addressed many problems in their healthcare organization accreditation process. It has data that can be used to help quantify the problems. However, this might not yield representative data on home care problems.

Assessing the competency of patients and lay caregivers was acknowledged to be a serious need in the equation about the safety and effectiveness of medical devices used in the home.

Stratification of device risks was acknowledged to be an important strategy in prioritizing the examination of the suitability of devices for home use.

There was a general recognition of the importance of real data needed to make a valid assessment of the kinds of problems that are likely to occur in the home environment, and to quantify their frequency.

There was also general agreement that devices need to be designed better to avoid subsequent problems, including human factors design to help avoid user errors, and that informational materials and educational programs need to be much better than they presently are.

There was the suggestion that potential home use issues should be investigated from three perspectives:

1. User factors – cognitive training and physical capabilities
2. Design factors – Manufacturers responsibilities and compliance with regulations
3. Documentation and support factors – Use warnings, instructions – need usability testing for the labeling and documentation intended for lay instruction.

One participant reminded everyone about the necessity of taking into account the risks of NOT having a medical device in the home, when risks are assessed and solution strategies are devised.

Participants urged that the CDRH operational definition of Home Use Devices be modified to include the

following concepts: broaden “home” to direct or indirect “place of residence”, outside of traditional care settings, recuperation, at risk, robotics, virtual diagnosis and therapy, non-controlled or non-clinical settings.

Updated on August 29, 2002

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Medical Devices in the Home Healthcare Community



Report of a Public Conference Held September 12-13, 2002 at the Natcher Auditorium, National Institutes of Health

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Report Date: November 1, 2002

On Thursday and Friday, September 12-13, 2002, an open public conference was held in the Natcher Auditorium on the campus of the National Institutes of Health, under the aegis of the Center for Devices and Radiological Health (CDRH), which is the Food and Drug Administration's component responsible for assuring the safety and effectiveness of medical devices. Previously announced in the *Federal Register*, the conference was convened for the purpose of discussing the programs, policies, and plans of several government agencies regarding the issue of the safety and effectiveness of medical devices used in the home environment, and for soliciting the comments and opinions of members of the public who attended. This report summarizes the results of that conference.

I. Background

CDRH constituted a Health Care Committee, as a part of CDRH's strategic planning process, to understand the impediments to the safe and effective operation of medical devices used in the home environment and to recommend appropriate Center actions within its legislative mandates and public health responsibility. The committee also wanted to see how the home environment influenced the use, functioning, and safety of devices that were not necessarily intended for use outside of clinical facilities by trained health care practitioners.

As part of its study of how the safety and effectiveness of medical devices used in the home environment can be improved, CDRH asked the Food and Drug Law Institute (FDLI) to convene two meetings earlier this year. On June 6 and 7, two meetings were held by the FDLI at the request of CDRH, involving invited participants from government, academia, manufacturers, health care and patient advocacy organizations, in order to discuss the issue². The report of those two meetings ("Report on Home Use Medical Device Meetings") is available on the CDRH web site at: <http://www.fda.gov/cdrh/cdrhnhc/>. The participants at those two meetings made many important points, especially emphasizing: (1) medical devices and their associated instructional materials need to be designed according to human factors principles, which would greatly improve the likelihood that they can be used effectively and safely not only by non-clinical personnel but also by clinical personnel as well; 2), that the health care reimbursement system needs to provide adequate incentives for the evaluation of the adequacy of the home environment and of lay caregivers for long term care of patients in the home; and (3), that government agencies need to collaborate in order to share information and develop a coordinated strategy to improve the safety and effectiveness of the use of medical devices in the home.

II. Development of the Conference

The September 12-13 conference was convened as an initial response to the strong sentiment expressed at these meetings that the relevant government agencies need to be communicating and collaborating on the home use issue. CDRH planners readily acknowledged that what government agencies do and do not do directly impacts manufacturers, distributors, home health care agencies, health professionals, lay caregivers, and patients, and they intended that those points would be elucidated more fully in a conference in which the policies and programs of relevant government agencies would be highlighted.

Based upon the outcome of the June 6 and 7 meetings, the CDRH Home Care Committee decided to convene an open public conference featuring representatives of government agencies and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to discuss their programs and policies regarding home care. After making preparations to hold the conference at the Natcher Auditorium on the campus of the National Institutes of Health, CDRH published information and an invitation for the public to attend on its website³ (see [Attachment I](#)) and an announcement in the *Federal Register*⁴. Informal invitations were also sent by e-mail and phone to help spread the word about the conference. The Committee contacted a number of Federal agencies about the conference, and many of those agencies agreed to participate as speakers and/or as members of an on-stage panel of experts.

The Conference was organized to consist of a series of formal presentations, each followed by a discussion by the panel and by questions and comments from the audience. The agenda for the meeting, listing sessions and speakers, is attached (see [Attachment II](#)). Also attached is a complete list of all the panelists and speakers with their contact information (see [Attachment III](#)). During the conference, notes were taken by several CDRH staff attending in attendance, and the following summary was prepared based upon those notes.

III. Summary of Conference

Note: Most of the speakers presented projected slides, and the texts of their slides are available for viewing at the CDRH web site <http://www.fda.gov/cdrh/cdrhhhc/>. This report, however, will not summarize individual presentations, but will highlight major points.

The use of sophisticated medical devices in the home environment has evolved as significant changes in medical care delivery have occurred over the past few decades. Prior to World War II, medical care was primarily a home affair, with doctors and nurses visiting the patient in the home, and hospital-based care reserved primarily for the severely ill. However, after World War II, as medical diagnosis and therapy became more sophisticated and intensive, of necessity it was delivered primarily in medical care facilities, such as hospitals, medical offices, and clinics. However, as health care delivery has become more sophisticated, it has also become considerably more expensive, especially since the 1970's. Changes in health care economics, as well as demographic changes, have stimulated a significant evolution of the "hospital" model, with more and more patients being cared for at home or at other non-clinical sites for their convalescence, after the patient's acute medical status has been stabilized. And inevitably, their care has been performed or maintained more and more by patients' parents, spouses, or other non-clinical personnel. As patients have been moved to the home and other non-medical facilities for their recuperation or long term care, the medical devices needed for their care have followed them.

The use of medical devices is an intrinsic part of the delivery of diagnostic and therapeutic medical care. In addition to being used in controlled clinical care environments, such as hospitals, clinics, and the offices of doctors, dentists, and other health care practitioners, medical devices are also widely used in the home, in the workplace, and indeed, in every place where people go. Not only are there a wide variety of medical devices available over the counter, there are increasing numbers available for use by lay people under prescription from health care practitioners. Thus millions of people in the United States now use devices of a bewildering variety. Millions go about their lives with implanted medical devices, including dental

implants, orthopedic implants such as hips and knees, cardiovascular stents, electronic pacemakers, cochlear implants, etc. Many people with impaired mobility use mobility aids, including crutches, braces, walkers, wheelchairs, scooters, etc., and many people use a variety of sensory and cognitive aids. Many people convalescing at home use hospital beds, intravenous fluid delivery devices, inhalation therapy devices, etc. And many people use diagnostic kits and electronic devices, such as pregnancy test kits, occult blood detection kits, glucose monitoring devices, etc.

But many medical devices currently being used by lay people under prescription were originally given CDRH approval for marketing under the expectation that they would be used by trained health care practitioners in controlled health care delivery facilities. Thus sophisticated medical devices are being used under conditions that neither their manufacturers nor the regulatory system had necessarily contemplated or intended. This in turn has had consequences for the safe and effective operation of these medical devices, especially those with sophisticated requirements for proper operation, maintenance, calibration, electrical power, etc.. The benefits of all these kinds of devices to improve diagnosis and treatment of ailments or conditions in the home environment are impressive and necessary to our evolving health care system, but their use comes with a disadvantage--the risk that the diagnostic information may be inaccurate or misinterpreted, or that the therapeutic treatment may be faulty in a number of ways.

Through a variety of information-gathering mechanisms, FDA is aware that deaths and serious injuries are sometimes associated with the use of medical devices, and there are device malfunctions that can and do occur which could lead to death and serious injury if they recur. Despite efforts by manufacturers and FDA to mitigate these problems whenever possible, the risk of unintended side effects from the use of medical devices is an ever-present reality. These sorts of problems occur even with the use of medical devices by trained health practitioners in controlled health care delivery environments, but FDA believes that the use of sophisticated medical devices in the home environment adds an additional level of risk of unintended adverse events. This is not to imply that the use of these devices should be prohibited in the home environment, in order to reduce this additional risk; indeed such a strategy would be practically impossible given the way that health care has evolved. But it is FDA's intention to seek ways of improving the safety and effectiveness of these devices used by patients and lay caregivers.

The safe and effective use of medical devices by lay persons is a multi-faceted issue, involving the design and manufacture of devices; the design and implementation of training users; systems for prescription of suitable devices and for their delivery and setup; the patient's medical condition; the evaluation of patients and lay caregivers for their capability to use the devices properly; the evaluation of the environment in which the devices will be used; systems for maintenance, calibration, repair, and waste disposal; communication between patient/lay caregivers and health professionals; systems for responding to and handling emergencies; and financial considerations. The conference, "Medical Devices in the Home Healthcare Community," September 12-13, 2002, Natcher Auditorium, National Institutes of Health, was convened by FDA's CDRH to explore the involvement in this particular set of issues of several Federal agencies and the JCAHO having various responsibilities in health care. Representatives of these organizations were invited to speak and/or to sit on a panel to discuss the issues presented. The following are issues discussed at the conference.

Scope of the Problem

No one organization is monitoring or tracking the use of many medical devices in the home that were not designed for such use, and that do not have the necessary support system, e.g., installation and set up, training, monitoring, assistance. Nor has any organization obtained a good understanding of the problems occurring with these devices prior to the occurrence of serious adverse events. FDA's CDRH, for example, implements a regulation requiring manufacturers to report deaths, serious injuries, or serious malfunctions in medical devices, but manufacturers can only know about what is reported to them, and the home user is a notoriously poor reporter. And even when these adverse events are reported, the manufacturer has limited ability to recover faulty devices from the home for analysis, and finds it difficult to

ascertain the circumstances surrounding alleged failure from untrained individuals. Regardless what might happen in the home, since the devices are often approved only for use in controlled clinical environments, the manufacturer may disavow responsibility for the home situation. Furthermore, there is no present way of tracking the use of equipment in the home that was not prescribed by health care practitioners and installed by responsible and appropriate third parties, so that outdated or poorly performing or malfunctioning equipment may migrate to the home from somewhere else without any knowledgeable authorities knowing it. Finally, some consumer products (i.e., non-medical) are being used for medical applications (e.g., personal digital assistants used for cognitive assistance). Consequently, the magnitude and scope of the problem of home use equipment remains vague and unclear, with responsible agencies having to rely largely on anecdotal information.

Device Design

One important facet of any device is the interface between equipment and human user. When a device works according to its design, but is applied or controlled improperly by a human user, any adverse outcomes are often referred to as “user error.” This term is inherently misleading. The implication of the term is that the fault for errors lies solely with the user when the device performs predictably according to its design and intended purpose. In fact, many avoidable errors occur because of inadequate or even faulty design that does not accommodate for known human limitations. Many occasions of misuse can be avoided by careful design of the device/user interface. There is growing appreciation of the importance of human factors design principles in the development of equipment that can be used with less risk of error. Broader application of human factors principles in the design of devices is needed to improve the interface between the device, the person, and the environment.

Manufacturers need to be educated and encouraged to consult experts in principles of good device design at an early stage in the product development cycle. The National Center for Patient Safety of the Department of Veterans Affairs has an initiative to actively mentor the manufacturer in developing products. Furthermore, it was emphasized that the use of human factors principles is compatible with the design control requirements in FDA’s Quality Systems Regulation for medical devices.

Furthermore, devices intended for use in the home (i.e., outside of controlled clinical environments) need to be designed with an appreciation that not all that goes on in the home is “medical” in nature. For example, pets and little children running around the house and knocking into devices or pulling cords can have an adverse impact on some devices. Thus there needs to be a greater appreciation for the realities of the environment.

Manufacturers need to be encouraged to understand and take into account the environment in which the devices will be used. One approach involves so-called smart homes. Georgia Tech has sponsored the **Aware Home Research Initiative (AHRI)**⁵, is an interdisciplinary research endeavor at [Georgia Tech](#) aimed at addressing the fundamental technical, design, and social challenges presented by the following questions: Is it possible to create a home environment that is aware of its occupants whereabouts and activities? If we build such a home, how can it provide services to its residents that enhance their quality of life or help them to maintain independence as they age?

A related concern is the location where the devices are intended to be used. We should not restrict our outlook literally to the home, since there are other places besides a person’s home where so-called “home use” devices may be used routinely, such as the workplace, the school, the automobile, and indeed any locale which is part of normal daily life. The Americans with Disabilities Act recognizes that there should be “reasonable accommodation in the workplace.”

Ideas for improving the safety and effectiveness of medical devices used outside of controlled medical environments ought to consider their use in all the locales where the users of these devices normally may go.

There are guidelines available regarding the design of specific device categories. For example, the National Institute on Disability and Rehabilitation Research has information available on the design of products for disabled people. It is important for the manufacturer to meet with patients, lay caregivers, and consumers when designing a device in order to ascertain all the facets and nuances in the needs of these users for achieving a particular medical purpose and for operating the device safely and effectively in the real environment in which the device will be used.

Device Risk Assessment

There is a considerable range in types of medical devices according to the level of risk that they present, especially for patients and lay caregivers. Obviously, the degree of concern for safety and effectiveness depends in large measure on the level of risk that particular devices present, and there is a need for a realistic and sensible approach to rating and categorizing these risks. Much work has been done in developing hazard and risk assessment models, and this work may help facilitate the development of appropriate guidelines and/or requirements. Speakers suggested that a type of stratified approach to risk may be most appropriate for this purpose. In this regard, the Department of Veterans Affairs has developed a comprehensive risk assessment tool (Healthcare FMEA) for determining the severity and probability of each potential cause of risk.

Certification of Home Care Products

Many medical devices, especially FDA Class II and III devices, have not been specifically evaluated for the suitability of their use outside of regulated clinical care environments. The suggestion was made that a process of certifying the suitability of devices for home use would facilitate the effort to improve the safety and effectiveness of patient and lay caregiver use of these devices, and many participants supported the suggestion. Home users or device prescribers could deliberately choose particular models and types of devices certified for home use (this potential benefit would require the availability of some kind of "Consumer Reports" type of database, so that competing products could be evaluated, and manufacturers' claims could be compared). There are many factors that determine the amount of control necessary to ensure safe use of a product in the home. A "one size fits all" approach to the problems is neither possible nor even desirable. Various groups have developed risk models which might be a starting point.

This suggestion immediately calls to mind several key issues among others:

- What Federal or private organization has the capabilities and the stature to perform such an operation? Already existing certifying organizations such as JCAHO and Underwriters Laboratory have expressed a willingness to work with CDRH to develop a certifying program for home use devices. HRSA has developed an Advance Technology Institute which is developing some kind of comparative evaluative tool for devices specifically labeled for home use.
- By what standards would devices be judged for certification? Presumably a certification process would evaluate devices against a "home health standard" that would take into account all the relevant factors in device design and operation related to the capabilities of home users, and would use some standard measures of user capability and performance, including literacy, computer experience, sensory and other physical capabilities.
- What incentives can be put in place to encourage manufacturers to conform their devices

to a “home health standard?”

- What would be the funding mechanism for a certification process?
- How would the effectiveness of such a certification process be evaluated and by whom?
- How would such a process take into account the maintenance of equipment and the environmental factors important for proper device operation?
- Would devices certified by their manufacturers as complying with a “home health standard” be accorded a shortened time of evaluation within CDRH (i.e., an “abbreviated 510(k)”)? If so, this would serve as an incentive for manufacturers to comply with such a standard.

Training and Competency Assessment of Users

Although many medical devices, especially those available over-the-counter, can be used easily and intuitively by many people with little or no difficulty, some devices used in the home are complex and sophisticated, and their proper operation depends on the competency and capabilities of the home user. The needs, capabilities, and competency of the home user and the suitability of the home environment should be assessed with regards the use of more sophisticated devices, such as respiratory therapy and intravenous infusion devices. This is especially true for those devices that require higher levels of cognition, memory, and decision-making and/or physical tasks for their proper operation.

The competency of user should be assessed with regards the unique characteristics of a particular device, with appreciation of the fact that not all users can do all things. For example, not all individuals can operate computers or complicated electronic devices, or can adequately see or hear in order to respond to equipment signals. But not all devices require specialized or sophisticated capabilities on the part of the user, in order for satisfactory results to be achieved. Thus, there needs to be a reasonable relationship between the benefits of projecting the necessity of high levels of user competency for a particular device and the costs and disadvantages of doing so; of course, this raises difficult questions about what is good enough. Many factors need to be considered in the determination. Appropriate outcome studies are needed, but there needs to be agreement by all the stakeholders on what are good indicators to measure.

Among the questions that need to be answered in order to develop a good system for assessing user competency and capabilities are the following:

- Who will do the assessment of user competency and capabilities? Physicians prescribing complicated equipment for the home have a responsibility to take the users competency into account, but frequently they do not have the time and are not given an incentive to do so under current reimbursement policies.
- Who will do any training of family members deemed necessary, and how is the effectiveness of that training monitored and evaluated?
- Who will develop the training protocols that take into account the various factors that affect the ability of lay persons to learn, and how will they be tested for suitability?
- Who will evaluate that the electrical and environmental conditions in the home are acceptable before the equipment is installed.
- Who will follow up to ensure the devices are still working properly, and that they are still being used properly?
- Who will provide help for users when problems occur?
- Who will pay for all this?

It is difficult to write a one size fits all recommendation for training, since users are different and devices are different, and understanding the particular characteristics of the home environment is critical to assessing the needs of individual users.

Accreditation of Home Healthcare Providers

JCAHO accredits over 17,000 healthcare organizations, including writing applicable standards and evaluating adherence to them. The accreditation is voluntary, and the organization seeking accreditation pays for this service. Currently over 4,300 home care agencies are accredited, but this is only 25% of home care providers. JCAHO is currently collecting outcomes data to demonstrate the effects of having or not having accreditation. Allegedly, some organizations are doing quality work without accreditation, but without some other standardized system of evaluating their work, there really is no way to evaluate such organizations unless they seek accreditation. Some have asked if it might be possible for providers to self-certify, but this raises the same question of how would the compliance of such an organization be evaluated and verified.

Costs and resources for accreditation by home healthcare providers are important deterrents to organizations getting accredited. The costs for an accreditation for three years are dependent on size, i.e., the number of patients being cared for by the facility:

- \$3300 if less than 50 patients
- \$4800 for 50-300
- \$6200 for 300-1000
- \$8200 if greater than 1000

JCAHO does not offer limited accreditation, so that an agency seeking accreditation will be evaluated on the basis of all applicable standards. Thus an agency cannot get accredited for just a particular set of devices. The accreditation process involves on-site visits at least once every three years, and JCAHO may put a facility on probation or remove an accreditation for violation of pertinent standards.

In addition to the disincentive of cost, there are few incentives for suppliers to seek accreditation by JCAHO, since accreditation is not made mandatory by the Centers for Medicare and Medicaid Services (CMS) or by third party payers. JCAHO currently does not have agreements with states to supplant state licensing. Additionally, organizations that contract with providers do not all require accreditation.

Telemedicine

Telemedicine offers intriguing new ways of linking home care patients and their professional caregivers in cost effective ways. Various technologies, from simple telephone communications to Internet-based approaches, offer ways that patients can be monitored at a distance, all at considerable savings of professional time and expense. Many of these approaches do not require very specialized or expensive equipment in order to be effective.

The Office for the Advancement of Telehealth in the Health Resources and Services Administration (HRSA) and the Veterans Administration currently fund research projects to demonstrate and evaluate new techniques for linking patients and health professionals using communications technologies. HRSA staff discussed a program they sponsor at the University of Tennessee where a telemedicine program connects cardiac patients with health professionals by means of computers and the Internet. The program demonstrated a significant reduction in healthcare cost in terms of reduction of hospitalizations. The study investigators have estimated that if this technique were used across the United States with all such patients, the savings in health care maintenance of these patients could be as much as \$4 billion a year. The Veteran's Administration's Homebase Primary Care Program has also done a study to demonstrate the positive outcomes and savings from keeping ailing veterans out of the hospital and at home by means of remote monitoring. Hospital admissions, length of stay in the hospital, and clinic visits were reduced. A member of the audience discussed the

success of a telemedicine program at Georgetown University with diabetic patients in improving their care and reducing their overall health care costs. These studies demonstrate that telemedicine could be very important, especially so for patients in rural areas or those at great distances from major medical centers, where they have great difficulty in obtaining routine health care monitoring under any other circumstances.

Unfortunately, telemedicine devices are not reimbursed by CMS, and this serves as a disincentive for manufacturers to investigate and produce new products.

In addition to providing direct communication via remote hookup between patients and healthcare providers, another remote communication tool was mentioned. Monitors on equipment could be programmed to contact service providers and alert them to service needs, equipment performance characteristics, and even inform them if patients are using the equipment as prescribed. In addition to remote communications between equipment and provider, it was pointed out that microprocessor monitors on medical devices could be used to detect certain malfunctions, and either fix them automatically, guide the consumer to fix the problem, or instruct the user to discontinue use.

Speakers offered three suggestions regarding the future development of telemedicine equipment and services:

- There needs to be a deliberate process of determining what works and what doesn't work, and what its significance is in terms of health care delivery, health care maintenance, and health care costs (evidence based medicine). Manufacturers require assistance in designing studies to show the evidence needed.
- Federal support is needed in this area as the research is often too costly for a single manufacturer.
- Reimbursement for telemedicine is needed in order to promote its acceptance and further development. Medicare does not reimburse for telehealth interactions as qualifying visits.

It was noted that patients are influenced indirectly by the Hawthorne effect, i.e., when they know someone is monitoring, their behavior improves. For example, quality of life and improved care were demonstrated when patients needed to appear in front of a TV camera to communicate with their health care provider. The patients typically got up out of bed, got cleaned up, and got dressed, so that the act of communicating itself actually provided them with a strong psychological incentive to lead a more normal life. Caregivers could also see when their patients didn't look quite right, even when a patient was reluctant or unable to articulate a sense of being unwell.

Despite these positive outcomes, telemedicine is not a universal panacea; although telemedicine makes some patients feel empowered, others feel intimidated by homecare technologies and require the kind of hands-on care provided by caregivers in direct physical contact. Nevertheless, telemedicine offers intriguing new ways of delivering communication, a sense of caring, and effective diagnostic and therapeutic care to patients who are at considerable distances from their healthcare providers.

Coordination of Responsibilities Among Government Agencies

It is apparent that there are resources available, including expertise and funding, among several involved Federal agencies which, if coordinated properly, could address many or all of the issues of concern about the use of home care devices. But this raises the question how can they be best coordinated. No single agency is presently addressing all the issues because none has the responsibility, ability, or authority to develop a totally comprehensive program. A broader approach involving multiple agencies is needed to search out and fill the loopholes. In

addition to Federal agencies, there is also the question of whether and how can state and local governments be involved in addressing the problems. And of course, beyond governments, it is apparent that all stakeholders must play a part, including manufacturers and home health agencies, in order to address all aspects of the problems. Speakers suggested that all the problems and issues involved with home care medical devices, and indeed many problems in the world of health care, cannot be solved by one government agency, and that there needs to be a coalition of involved agencies to deal with this issue.

It was suggested that all the relevant Federal Agencies should agree to participate in a Federal Advisory Committee constituted to address all the issues of home care. They should agree to communicate and coordinate their efforts. In addition to Federal agency representatives, advisory participation on the committee should also be offered to representatives of private sector stakeholders. The role of such a committee could be to help determine what training and control (regulation) is needed or appropriate, what research is needed, and what incentives ought to be developed for manufacturers, health care providers, and other private sector stakeholders of this issue.

An alternative approach suggested was to see if the home care initiative could be added to the agenda of the Quality Interagency Coordination Task Force (QuIC)⁶, led by the Agency for Healthcare Research and Quality (AHRQ). This intergovernmental group was established in 1998 in accordance with a Presidential directive. The purpose of the QuIC is to ensure that all Federal agencies involved in purchasing, providing, studying, or regulating health care services are working in a coordinated manner toward the common goal of improving quality care.

Congress has given the Agency for Healthcare Research and Quality (AHRQ) a mandate to report annually to the Nation about health care quality⁷ as part of Public Law 106-129, and this report could include information about home care and medical devices. This National Healthcare Quality Report (NHQR) will include a broad set of performance measures that will be used to monitor the Nation's progress toward improved health care quality. The NHQR is intended to serve a number of purposes, such as:

- Demonstrating the validity (or lack thereof) of concerns about quality.
- Documenting whether health care quality is stable, improving, or declining over time.
- Providing national benchmarks against which specific States, health plans, and providers can compare their performance.

The first report is due to Congress in fiscal year 2003, and subsequent reports will be delivered annually thereafter. The project is being led by AHRQ with collaboration from the National Center for Health Statistics. An interagency work group will develop the final content and design of the report. Other members of the work group include the Office of the Assistant Secretary for Planning and Evaluation, the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration. AHRQ is currently in the design phase of the initiative. CDRH and AHRQ staff have agreed to collaborate about the possibility of incorporating information about home use in the report.

AHRQ is also responsible for the implementation of the Medical Expenditure Panel Survey (MEPS)⁸. The survey provides a new and extensive data set on the use of health services and health care in the United States. Survey data may include information about the use of medical devices in the home, and CDRH and AHRQ staff have agreed to collaborate on this possibility.

MEPS is conducted to provide nationally representative estimates of health care use,

expenditures, sources of payment, and insurance coverage for the U.S. civilian noninstitutionalized population. MEPS also includes a nationally representative survey of nursing homes and their residents. MEPS is cosponsored by the AHRQ and the National Center for Health Statistics (NCHS).

MEPS comprises three component surveys: the Household Component (HC), the Medical Provider Component (MPC), and the Insurance Component (IC). The HC is the core survey, and it forms the basis for the MPC sample and part of the IC sample. The separate NHC sample supplements the other MEPS components. Together these surveys yield comprehensive data that provide national estimates of the level and distribution of health care use and expenditures, support health services research, and can be used to assess health care policy implications.

Reimbursement

Ultimately, discussion of any home use issue brings up the question of reimbursement. Reimbursement or the lack of it drives development and availability of home use devices and drives the direction in which implementation systems go. It was recognized that outdated or unreasonable CMS reimbursement regulations need to be changed, but there was considerable confusion about how appropriate regulatory change at CMS can be achieved. CMS needs to be more instructive on how that can be done. Current reimbursement regulations under Title 18 of the Social Security Act consider only whether a given healthcare treatment modality meets a benefit category and whether it is medically necessary. Equipment can be reimbursed only if it is considered durable; expendable items are not covered for reimbursement. Furthermore, devices must be used primarily for medical purposes, and cannot be used in the absence of injury in order to qualify for reimbursement. If there are alternatives to traditional reimbursement schemes for both products and services, the case needs to be demonstrated to CMS with positive outcomes data. It will be challenging to develop policies that will keep pace with fast changing technology, but there are a number of Agencies that can assist in the development of outcomes study designs. It was noted that there is a Memorandum of Understanding between FDA and CMS regarding the reimbursable use of so-called investigational devices that are not experimental. Finally, it was suggested that other third party payers need to be involved in any attempts to change the reimbursement policies.

Privacy

All homecare performed with the involvement of those outside the family bring up issues of privacy and how is patient's information is handled? Whose responsibility is it to ensure privacy is maintained? What is the role of HIPAA in this respect?

Telemedicine brings up special issues that need to be considered, such as the privacy concerns occasioned by the storage of data bases, and the quality and the integrity of the data. Speakers mentioned that firewalls are needed to protect information that goes through the internet.

Orphan products

Orphan devices for use in the home need special attention. There is not enough incentive for manufacturers to develop products for use by smaller disabled populations.

Public Awareness

The public needs to be educated concerning the most common problems with or misuse of medical equipment. It was suggested that public awareness of these issues might be heightened if a "Home Medical Device Safety" week was recognized and promoted. For example, disposing of sharps is an area of public interest. Funding for public education

projects is a need, but grantors may not themselves be aware of home health issues. In addition to the general public, speakers felt that manufacturers need to be informed about the needs in this area.

IV. NEXT STEPS

At the conclusion of the conference, CDRH staff made some concluding remarks concerning current activities and the possibility of future actions. CDRH is in the process of conducting focus group meetings with consumers regarding the use of medical devices in the home, and will make that information available. CDRH recognizes the importance of partnering and collaborating with other governmental agencies to deal with the full scope of medical devices in the home, a problem well beyond the authority and resources of CDRH alone. In this regard, CDRH is considering developing an independent advisory committee composed of representatives of the government agencies relevant to the issue of home use medical devices, as a means of developing a long term strategic plan for improving the safety and effectiveness of the use of home use devices.

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2. The meetings were facilitated by Mr. Joseph S. Arcarese, under an agreement with FDLI. Mr. Arcarese, FDLI's former Executive Vice President, currently is a private consultant. Prior to his seven years employment with FDLI, Mr. Arcarese worked for 26 years with CDRH and its progenitor organizations.
3. The website with information about the Conference appeared at <http://www.fda.gov/cdrh/meetings/meddevhome.html>. A copy of the announcement is included in this document as [Attachment I](#).
4. "Notice of Public Meeting", Federal Register, Volume 67, Number 161, August 20, 2002, pp. 53954-53955.
5. Information about the Aware Home Research Initiative is available on the web at <http://www.cc.gatech.edu/fce/ahri/>
6. Information about QuIC is available on the web at <http://www.quic.gov/>
7. Information about National Healthcare Quality Report is available on the web at <http://www.ahcpr.gov/qual/nhqrfact.htm>
8. Information about MEPS is available on the web at <http://www.meps.ahcpr.gov/Pubdoc/HC026H/H26HDoc.htm>

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