Review Article

HANDLING OF MEDICAL DEVICES: REFORMS AND REGULATIONS

ABSTRACT

With the evolving technology and changing regulations, the medical device sector is set to grow quickly soon. Even though they are an integral part of patient care they present several unique problems which are not sufficiently addressed by the device manufacturer or the medical community in general. Medical device is widely used by professionals in a clinical setup, by patients, family members at home. As step towards better understanding the rules, regulations, and the required reforms for the safe use of medical devices various measures taken by different regulatory authorities to ensure the minimization of use error are discussed. Human factor engineering and ergonomics are considered while designing a medical device. It is evident that all the stakeholders involved contribute to the safety of the medical device keeping in mind the welfare of the patient but is that enough and what can be done is discussed in this review work.

Keywords: Human Factor, Use error, ISO 623366, Medical instrumentation, home healthcare medical devices, Healthcare technology management.

Introduction:

Is it guaranteed that the practice is safe just because it is in a clinical setup or is the home healthcare getting enough information to ensure that the equipment is handled properly? Usage of a medical device dates to the 1780s with hand-made stethoscopes to better understand the inner workings of the human body without operating or cutting the person open. So, medical device usage was born out of the need for a safe and effective tool to improve practice and work in ways that seemed impossible for bare hands.

The use of medical devices and the impact it has over the healthcare system has multiplied many folds as its applications are limitless. [1] The medical device industry makes an enormous number of products ranging from optical glasses to scalpels to artificial joints to imaging equipment, it just goes to prove that in every step of treatment medical technology is involved one way or another in form of diagnosis, treatment, or to prevent an ailment.

Medical technology accounts for many advancements in drug delivery, rehabilitation, restoration, monitoring, screening devices, allows keeping a close track of major health indicators.

With the evolving technology and changing regulations, the medical device sector is set to grow in the future. Even though they are an integral part of patient care they present several unique problems which are not sufficiently addressed by the device manufacturer or the medical community in general. Are human error and environmental factors being taken considered while designing and manufacturing a medical device.

The way a medical device is used dictates the patient's safety. But there is ample evidence that errors in the understanding and use of medical devices are responsible for considerable morbidity and mortality. [2]

Discussion:

Who uses medical devices? Professionals in a clinical setup, patients, and family practice the usage at home. Is it guaranteed that the practice is safe just because it is in a clinical setup or is the home healthcare getting enough information to ensure that the equipment is handled properly? Are human error and environmental factors being considered while designing and manufacturing a medical device. What are the regulatory body and the manufactures contributing towards the safety of the patient, and is that enough?

As a step towards better understanding the rules, regulations, and the required reforms for the safe use of medical devices we discuss various measures taken by different regulatory authorities to ensure the minimization of use error. After a clear knowledge let's put forth our ideas on how else this can be managed better. [3]

Human Factors in Medical Device

Denise Melanson – a Canadian who died when infusion pump was programmed by a nurse to deliver a medication over 4 hours rather than 4 days. [4]

This represents the dire situation that might happen to anybody anywhere anytime even if the whole process is double-checked or if the user is overly familiar with the workings of the equipment. So, who is to be blamed in cases as these? Normally the user is always the first to take the blame. [5] This might be true if the accused lacks training, or is being inattentive, or is in component. But that's not always the case and increased awareness of the fact that the extent of the human errors beyond the work system has become abundantly clear. This has bought about the change in viewing user errors as use errors by considering various aspects such as environmental issues, design of the device, and user ability rather than attributing the failures on a whole to the individual.

To understand the most complex part of any medical device the user, human factors are employed. Human factors (HF) in medical device refers to all the circumstances that influence or might alter the cognitive skills of the user. HF determines scientifically how humans would react, respond, think, take decisions, their adaptivity to new environments, how they handle stress etc. By understanding all these factors and effectively employing them into the design of any medical device would make possible of manufacturing a device that can be safely and effectively by the user. [6]

Though human beings are forever evolving, complex and versatile. Focus is given to the basic elements such as human behaviours, competence, limitations, and practices. If implemented properly this would guaranty improvement in performance for the user and minimizes usage errors ensuring patient safety.

An initial knowledge about the terms associated with the human factor is essential for a better understanding of the guidelines, standards, and their applicability in designing a medical device. [7]

Ergonomics: "The understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimise human well-being and overall system performance."

Usability: Term often used as a synonym to human factor. "a qualitative measure of how easy user interfaces are to use.

User Interface: "the hardware and software features that defines the interaction between user and equipment". [8]

Importance of Human Factor Engineering in Medical Device

The user's physical, sensory and mental abilities are unique and vary very drastically. Even amongst clinical staffs with prior training and similar education there is a huge difference in their practice. Now imagine a lay person using a medical device at home with no medical supervision, only with the knowledge available in form of instructions. The uncertainty and the unpredictability are huge. Contributing to this is the environment in which a medical device is used since devices are used in Intensive care units, Emergency rooms, laboratories, clinics and home. Factors like stress, workload, anxiety, fatigue also contributes to a degrading performance. Lack of human factor implication in design of medical device results in design induced errors, user interfaces that are misleading and illogical. Instructions that might not be comprehensible even for a skilled practitioner. [9]

Table 1: Chronology of Human Factor guidelines evolution in FDA. [10]

1993	AAMI-HE 48: 1993 Human Factor Guidelines and preferred practices for the Design of Medical device.
2000	Medical Device Use Safety: Incorporating Human Factors Engineering into Risk Management (FDA).
2001	**ANSI/AAMI HE 74: 2001** Factor design process for medical device.
2009	**ANSI/AAMI HE 75: 2009** Human Factors engineering – Design of medical device. **ANSI/AAMI HE 74: 2001** (R2009) Factor design process for medical device.
2011	Applying Human Factor and Usability Engineering to Medical Device – Guidance for Industry and FDA.
2016	Applying Human Factor and Usability Engineering to Medical Device – Guidance for Industry and FDA.
2018	**ANSI/AAMI HE 75: 2009** (R2018) Human Factors engineering – Design of medical device.

ASSOCIATION OF THE ADVANCEMENT OF MEDICAL INSTRUMENTATION (AAMI)

AAMI has been functioning since 1965. The purpose of its creation is to serve as a vehicle to help clients in introduction of their innovative medical devices in the market and to establish guidelines and safety standards for design and usage of medical device.

AAMI is a non-profit and a voluntary organization, so compliance with the standards is not mandatory while inspection or submission of application. AAMI mainly focuses on providing guidelines for the end user, regarding use, care, maintenance, and processing of medical device to ensure it is put to best use.

AAMI develops standards, Technical Information Reports (TIR) and Consensus reports on high priority topics related to health care. Also offers training and certification for use of medical device along with private customized training as per necessity. All documents published by AAMI are in consonance with the American National Standards Institute (ANSI). All documents are reviewed and if essential updated every five years. The committee has also established a harmonization with international communities such as International Organization for Standardization.

The Human Engineering Committee of AAMI consists a balanced mix of medical device manufacturer, HF professionals, clinicians (primarily anaesthesiologists), and regulators. As of now, more than 7000 individuals including healthcare organization and device manufacturers are members of AAMI. [11]

Training offered by AAMI includes:

- Quality Systems
- Human Factors (HF)
- Sterilization
- Software and Cyber Security
- Healthcare Technology management

Human Factor for Medical Device

The training program provides best means to evaluate and test human factors, details on expectations of CDRH and CDER on device usability, pre-market review process and all the parts of design of medical devices that focuses on human factor.

Regulatory Basis for HF at FDA

CDRH recommends manufacturers to submit human factor data during premarket submission.

21 CFR 820.30

(c) Design Input "address the intended use of the device, including the needs of the user and patient"

(f) Design Verification "confirm that the design output meets the design input requirements"

(g) Design Validation "ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate."

(i)72 "when designing a device, the manufacturer should conduct appropriate human factors studies, analyses, and tests from the early stages of the design process until that point in development at which the interfaces with the medical professional and the patient are fixed."

(i)159 "FDA emphasizes that any death, even if the manufacturer attributes it to user error, will be considered relevant by FDA and will have a high risk potentially associated with it. User error is still considered to be a nonconformity because human factors and other similar tools should have been considered during the design phase of the device." [12]

Applying Human Factors and usability engineering to medical device – Guidance for Industry and FDA. [10]

The contents of the documents include,

- Preliminary Analyses and Evaluations
- Elimination or Reduction of Use Related Hazards
- Tasks and Use Scenarios
- Participant Training
- Data Collection
- Analysis of Human Factors Validation Test Results
- Actual Use Testing
- Human Factors Recommended Report
- List of Highest Priority Devices for Human Factors Review

Medical Device Home Initiative (FDA 2010)

FDA defines a home use medical device as "a device intended for users in a non-clinical or transitory environment, which is managed partly or wholly by the user, requires adequate labelling for the user, and may require training for the user by a healthcare professional in order to be used safely and effectively."

*This included implants and any type of equipment that is required for recovery and rehabilitation.[11] And the term "home use" extends beyond the home, to encompass all environment in which the care recipient plans to use the device in day-to-day life.

The programme focuses on ensuring the safety and proper use of medical devices at home, as home healthcare has become more prevalent in the United States as a result of an ageing population and shorter hospital stays. As a result of these changes, more medical devices such as infusion pumps, ventilators, and wound care therapies have made their way into people's homes. Healthcare offers a variety of advantages in terms of both qualities of life and cost.

There are about 7.6 million induvial in-home care. And the market accounts for $56.6 billion dollars every year. It is also reported that it is growing 20% every year. It is estimated that by 2030, over 71.5 million induvial would age over 65 and every one out five are reported to have a disability that might require home care. [12]

The unique challenges faced are addressed by the regulatory body through the following measures: Establishing guidelines for manufactures of home use devices, develop a proper home use labelling process, enhance post market oversight, and increase public awareness and education.

Measures taken under this initiative:

Guidance for Industry and Food and Drug Administration Staff: Design Considerations for Devices Intended for Home Use

The guidance supports the manufacturer in the areas of designing, testing, and labelling of home use device by covering grounds such as environmental considerations, user consideration, design considerations such as lock-out mechanisms, maintenance, calibration, mechanical, electrical issues, human factor (User training and certification), labelling, post market consideration and medical device reporting. [13]

Electronic submission for home use device labelling

Since home care recipients, consumers and caregivers require immediate and easy access to information this submission pathway was initiated in 2011. As an add on, CDRH surveyed caregivers and healthcare professional in respective research studies to understand the requirement of information in these labels, its use and access. This program was made available from April 17, 2015. This ensured that all information required by the user was easily accessible and available online.

Increasing Public Awareness

To assure safe practice of medical devices at home and to tackle the unique problems that arise in a non-clinical environment. The FDA partnered with various organisations to ensure that adequate thought is given to the device design during manufacturing, constant training for the user whenever required and to aid the challenges faced by the family in any way necessary.

- Kwik point, a cooperative research and development agreement to design visual aids for home users, these guides are signs meant to provide information to the user without language or literary barriers.
- American Association for homecare, educate all the stakeholder with respect to home use devices regarding the medical device safety and the role of FDA in regards to these medical devices.
- The Caregiver Action Network, to understand, analyse and evaluate the problems faced by the caregivers and this network provider's communities and forums to share experience to share experience and instructions for better care. [14]

Brochure - Home Healthcare Medical Devices: A Checklist

This checklist is put together by FDA to aid the usage and maintenance of medical device effectively at home. This lists out all the information, precautions and measures the user must take during the use of medical device. [15]

Specific Devices for Home Use

This contains product related information and instructions to the most common home use devices like infusion pumps, blood glucose meters, infusion therapy, hearing aids, contact lenses, home use tests and other OTC medical devices.

Med Sun: Medical Product Safety Network

An adverse event reporting program under FDA's CDRH launched in the year of 2002. Med Sun was initiated to assess and sort out problems associated with the use of medical device by collaborating with clinical communities.

Med Sun exists as a bridge between clinical sites and CDRH. How med sun functions is by obtaining all available issues reported to the clinical sites. And respective researchers work on identifying the case of the event and try to understand it.

The analysis obtained are then shared to the public after retracing the patient's personal details.

Med Sun is an internet-based system structured in a way that ensures easy and safe way of adverse event reporting for medical device.

The clinical community have complete access to the files that are submitted and the files can be accessed, tracked any time and also receive device-related feedback.

Med Sun has over 350 facilities nationally which includes hospitals, nursing homes, outpatient clinics and health agencies. [16]

SUMMARY AND CONCLUSION

Medical technology has advanced so much that the complexity in correspondence to it has also had an upsurge, but this can't dispute the fact that medical device and its aid to the healthcare has been humongous. Let's look at the facts since the 1800's medical device big or small has been constantly used in drug delivery, monitoring, screening, rehabilitation, and now we have advanced as far as completely replacing body parts and organs with it.

Regulations in place to ensure and monitor the safe use of medical devices pales in comparison with the regulation for the prescription drug. The use of the medical device in clinical as well as non-clinical setup continues to expand. Which results in numerous complicated devices that might pose difficulties even for highly experienced practitioners. This is to be expected with the steep growth in technology. It must dawn on people the necessity of proper product-specific training for both the clinical and technical staff before embracing any new technology since it is very important that the equipment is put to best use. The people who handle medical device (physicians, nurses and other care providers) must be asked these questions how often do they need to train? Who assess the quality of training and in what they need to be trained? These questions need to be answered to ascertain that they have clinical knowledge, clinical judgement and the technical skills needed for the safe and effective use of medical device.

So how are the stakeholders accounting for its safety? It is evident from the discussion that right from designing a medical device its safety, usability, and effectiveness are prioritized. Followed by which during procurement healthcare professionals are receiving appropriate training. This training and knowledge are constantly updated and kept in pace with the fast-paced growth in technology. Followed by which in the post-market phase, the medical device is under surveillance until the product's lifecycle.

Medical device in home healthcare receives the same amount of scrutiny which is more focused on the unpredictability of the environment with specific labelling, training programs structured for addressing a selective population followed by helplines by the regulatory body.

All the regulations and reforms around the usability of the medical device look good on paper, but how far the results have reached the intended population is the actual question as despite all these measures use error still accounts for a portion of accidents.

It is always easy to criticize, but what is required here is to implementation of the regulations in a way that is acceptable by all the stakeholders alike. If all these standards are carefully carried out it will significantly enhance the quality of medical device interface design which can lead to a safer medical device practice.

Priority status for practising of medical device based on their risk classification, that is people can be specifically qualified (training and knowledge) for handling of certain medical device based on the risk associated with it. This ensures that people get enough training in that solitary field and that they don't rely primarily on experience. This allows them to broaden their perspective by including various models, and familiarise them across varied technology.

Implementation of a real-world performing monitoring would be more helpful rather than focusing on post marketing surveillance alone. With this broaden approach error at any stage of the products lifecycle management can be identified and corrective measures can be employed.

A shift in perspective is necessary for the manufactures to understand that applying human factors while designing a medical device extends the lifecycle of the device in the market and is beneficial for the user too by improving its acceptance with reduced training and greater safety. Healthcare professionals must not neglect training and knowledge by saying that they are experienced, since no matter how experienced training is vital with the advancing technology. Home healthcare users must utilize all the resources available for them to ensure that they are fully aware of how to use the device before practicing it and stay vigilant.

When all the stakeholders hold up their end it can be guaranteed that the accidents associated with user error can be minimized significantly.

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