Technical Information Report

AAMI TIR49: 2013/(R)2020

Design of training and instructional materials for medical devices used in non-clinical environments

AAMI
Advancing Safety in Health Technology

Design of training and instructional materials for medical devices used in non-clinical environments

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Association for the Advancement of Medical Instrumentation

Abstract: The purpose of this document is to support safe, accurate, and efficient user performance by providing guidance on the design of user instructions and training

Keywords: usability; human factors; home care

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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Committee representation

Association for the Advancement of Medical Instrumentation

Medical Devices and Systems in Home Care Applications Committee

This AAMI Technical Information Report was developed by the AAMI Medical Devices and Systems in Home Care Applications Committee. Approval of the Technical Information Report does not necessarily mean that all members voted for its approval.

At the time this document was published, the **AAMI Medical Devices and Systems in Home Care Applications Committee** had the following members:

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NOTE—Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.

Foreword

This technical information report (TIR) was developed by the Medical Devices and Systems in Home Care Applications Committee.

It is widely recognized that medical devices are increasingly being used outside of a traditional healthcare setting and by individuals with little, or no, prior training on the use of these devices.

The objective of this TIR is to provide guidance on the design of user instructions and training to support safe, accurate, and efficient user performance of healthcare devices in the home and public places.

As used within the context of this document, "should" indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. "May" is used to indicate that a course of action is permissible within the limits of the recommended practice. "Can" is used as a statement of possibility and capability. Finally, "must" is used only to describe "unavoidable" situations, including those mandated by government regulation.

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE—This foreword does not contain provisions of the AAMI Technical Information Report, *Design of training and instructional materials for medical devices used in non-clinical environments* (AAMI TIR49:2013), but it does provide important information about the development and intended use of the document.

Introduction

Advances in healthcare technology and practice have led to a transition from clinical-based healthcare to healthcare that is practiced in non-clinical environments, such as the home or even public places: consider the use of automated external defibrillators (AEDs) in stadiums and other venues by lay people in life-saving endeavors. As medical devices make this transition, manufacturers must carefully consider the design of the training and instructional materials that will accompany these medical devices.

ANSI/AAMI HE75:2009, *Human factors engineering—Design of medical devices* describes human factors engineering (HFE) as "the application of knowledge about human capabilities (physical, sensory, emotional, and intellectual) and limitations to the design and development of tools, devices, systems, environments, and organizations." Training and instructional materials are tools that support the user in the safe, accurate, and efficient use of medical devices. As such, training materials and instructions are as much an integral part of the user interaction as the industrial design and the user interface, and therefore should be crafted as carefully and with as diligent attention to design as these other facets of a medical device.

When a medical device's use moves outside clinical environments, manufacturers cannot automatically assume that the user of a medical device will achieve the same level of expertise expected of medical professionals in the use of that medical device or in knowledge of the condition that it treats. Users in these non-clinical settings are likely to be less familiar with medical technology and terminology, both in general and with respect to the medical device in question. They can also be expected to be less comfortable with the operation of these medical devices.

Instructional and training materials for medical devices intended for use outside of clinical settings must successfully guide user performance under normal conditions, off-normal conditions (i.e., situations that will likely occur but cannot be predicted, such as medical device malfunctions), and in emergency situations, where seconds count.

The application of HFE principles and processes throughout the design and development of training and instructional materials for medical devices, in addition to the medical device itself, will enhance the user's and the patient's safety, reduce errors of omission and commission, and improve the efficiency of the medical device's user in completing tasks with that medical device. It will also ensure that user populations and environments of use, which will be quite different from those of medical devices within clinical environments, are carefully considered within the design process.

Ideally, the design and development of the training and instructional materials for a medical device should occur in conjunction with the design and development of the medical device itself. The designers of the training and instructional materials should be involved in the design process of the medical device itself to ensure a comprehensive understanding of the medical device. Moreover, it is often the case that early in the design process of the medical device, the designers of the training and instructional materials might identify potential issues that could result in changes to the design of the medical device. Because of the nature of medical devices, the development of the training and instructional materials should not be a task assigned to technical writers unassociated with the development of the medical device, after the medical device has been designed.

One emphatic note of caution: training should never be used as an alternative to a well-designed medical device. Although good design can reduce the amount of end-user training required, statements that something "will be addressed in training" are indicative of a poorly-designed medical device that must be redesigned to ensure the safety and efficiency of the user. Annex D of ANSI/AAMI/IEC 62366, *Medical devices—Application of usability engineering to medical devices,* details the user-centered design process that must be conducted so that medical devices are designed to ensure maximum usability and safety. The information provided in this technical information report (TIR) focuses on enhancing the performance of the user by means of well-designed training and instructional materials and training processes.

Design of training and instructional materials for medical devices used in non-clinical environments

1 Scope

The purpose of this technical information report (TIR) is to provide a relevant source of information, design criteria, and guidelines for the instructional and training materials and processes intended to accompany medical devices used in a non-clinical environment, which for the purpose of this document, is defined as an environment other than a facility where a health professional is continually present whenever a patient is present.

However, much of the information presented in this document can be applied, as well, to the design of instructions and training for the use of medical devices that will be used within clinical environments or in both clinical and non-clinical environments. The information in this document also applies to training and instructions for the use of combination products (e.g., transdermal drug delivery patches), which manufacturers sometimes do not consider to be medical devices.

These guidelines are meant to supplement Annex D of ANSI/AAMI/IEC 62366:2007, ANSI/AAMI HE75:2009, and the numerous references available on the topic of human factor engineering, with a focus on the training and instructional materials that accompany medical devices used outside of clinical environments.

This document will help medical device manufacturers to

a) understand how the design of instructions and training, including the development and validation of labeling and training materials, fits into the user-centered design process;

b) recognize the importance of utilizing a systematic process in the design of these materials;

c) develop an understanding of models of human learning, retention, and transfer of learning and how these models can be applied to the design of training and instructions;

d) recognize the unique advantages and disadvantages of various media available for training and instructions;

e) select appropriate media for training and instructions; and

f) identify specific design guidance applicable to training employing the selected media.

It should be noted that this TIR does not address regulatory requirements that the FDA or other organizations might impose with regard to training and instructions for use for medical devices.

2 Using this document

This section provides an overview of the subsequent major sections of this TIR.

Section 3, "Definitions," defines various terms used in this document, in some cases somewhat differently than in published standards and regulations used in the field.

Section 4, "The human performance goal of training and instruction," describes the factors that influence performance and how learning and instruction relate to these factors. In addition, this section describes the three learning steps involved in training—acquisition, retention, and transfer—and how designers can facilitate these steps through the design of training programs.

Section 5, "A systematic approach to designing instructions and training," first discusses integrating the design process for instructions and training materials within a user-centered design process. Some of the material in this section is taken from Annex D of ANSI/AAMI/IEC 62366:2007, which provides an overview of human factors engineering and a user-centered design process. The goal is not to describe the user-centered design process in detail, but to discuss how this process can be used to design effective training and instructional materials. The