Technical Information Report

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Post-market surveillance of use error management

AAMI
Advancing Safety in Healthcare Technology

Post-market surveillance of use error management

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AAMI

Abstract This document will address the issue of use error detection for medical devices from clinical, manufacturer, and regulatory perspective regarding human factors assessment. The goal is to provide guidance on how clinicians and manufacturers can best collect and leverage post-market use error data to improve product safety and usability.

Keywords: human factors, usability, hospital, clinical

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www.aami.org/standards/glossary.pdf

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Association for the Advancement of Medical Instrumentation

Human Factors Engineering Committee

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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 Human Factors Engineering Committee.

It is widely recognized that there is little existing guidance for conducting post-market surveillance.

The objective of this TIR is to provide guidance on how people in various areas can collect, assess, and leverage post-market use error data to mitigate medical device product risk, and to improve product safety and usability.

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

NOTE—This foreword does not contain provisions of the AAMI TIR50, *Post-market surveillance of use error management* (AAMI TIR52:2014), but it does provide important information about the development and intended use of the document.

Post-market surveillance of use error management

1 Purpose

This document addresses the issue of use error detection for medical devices from the clinical, manufacturer, patient, user and regulatory perspective. The goal is to provide guidance on how these individuals can best collect, assess, and leverage post-market use error data to mitigate product risk, and to improve product safety and usability.

2 Scope

The guidelines described in this technical information report (TIR) are not separate from or in opposition to the existing U.S. Food and Drug Administration's (FDA's) and other regulatory bodies' reporting protocols for product failure or adverse events (concerning morbidities or mortalities), which already have standardized protocols. This TIR focuses instead on a process for handling complaints associated with use errors occurring from medical devices, drug delivery systems and combination medical products. These use errors could be from close calls, user dissatisfaction and/or quality complaints as they relate to use error events and therefore would not normally be reported and evaluated. User dissatisfaction is important, as it can be the source of complaints regarding how devices interfere with the normal workflow and require inappropriate levels of attention. This document recognizes the significant efforts during the pre-market phase to evaluate and improve usability. However, products used in the post-market environment can provide the largest usability study data set available. This document seeks to enhance the opportunity to have access to such information.

The process described in this TIR is not intended to be prescriptive but instead to provide a framework of guidelines for developing protocols and systems for capturing use errors in order to assure they are available to the appropriate stakeholders. This high-level guidance describes process flow, training and scalability and includes sample questions for data collection. The intended audience of this TIR not only includes manufacturers and clinicians, but also patients, caregivers and other laypersons who would be reporting the events.

2.1 Stakeholder entities (not all inclusive)

- Clinicians
- Human Factors and Usability Specialists
- Clinical Human Factors Professionals
- Safety Officers
- Complaint Handlers
- Technical Support
- Customer Facing Personnel (Marketing, Sales, Field Service, Customer Service)
- Product Quality Management (Risk Managers, Quality Engineers)
- Post-market Quality Organizations
- Pharmacovigilance Groups
- Patient Safety Organizations
- Medical Affairs
- Service Organizations (internal and subcontractors)
- Product Development Support/Maintenance Teams
- All Manufacturer Employees (if receiving complaints from customers)
- Manufacturer Usability Practitioner

2.2 Reporting entities (not all inclusive)

- Technicians (Biomedical Engineer, Scrub Tech, etc.)
- Laypersons (Patients, Family Members, Caregivers, etc.)

- Clinicians (Nurse, Physician, Therapist, etc.)
- Manufacturer's Customer Facing Functions

3 Terms and definitions

For the purposes of this TIR, the following definitions apply.

3.1 abnormal use: Intentional act or intentional omission of an act by the responsible organization or user of a medical device as a result of conduct that is beyond any further reasonable means of risk control by the manufacturer.

[ANSI/AAMI/IEC 62366:2007, 3.1]

3.2 customer: Purchaser or contributor to the purchase with significant influence on the decision.

3.3 close call: Instance in which a user experiences confusion, misinterpretation, or difficulty in which they almost commit a use error while performing a task, but "catches" himself or herself in time to avoid making the use error.

3.4 cognitive walk-through: A structured review of user requirements for the performance of a sequence of predefined tasks[1].

NOTE—A cognitive walkthrough early in the design process permits evaluation of different preliminary design concepts. Later in the design process, when designs have become better defined, a cognitive walkthrough may still be productive.

3.5 contextual inquiry: Process of observing and working with users in their normal environment to better understand the tasks they do and their workflow (Helander, Landauer, and Prabhu, 1997, p. 350[2]).

NOTE—The output of a contextual inquiry study is a detailed task list, user profiles and a use environment description.

3.6 expert review: Review that depends on the knowledge and experience of human factors (HF) specialists to identify design strengths and weaknesses and to recommend opportunities for improvement.

[adapted from D.5.6 of ANSI/AAMI/IEC 62366:2007]

3.7 harm: Physical injury or damage to the health of people or damage to property or the environment.

[ANSI/AAMI ES60601-1:2005, 3.38]

3.8 heuristic analysis: Evaluation by clinical or human factors experts of a device or system through the assessment of how it conforms to well-established user interface design rules (Nielson, 1993[1]).

3.9 human factors (HF): Scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data, and other methods to design in order to optimize human well-being and overall system performance.

NOTE—The HF discipline includes cognitive and physical ergonomics, anthropometry and biomechanics.

3.10 lay users: Any user of a medical device who does not have clinical training or experience.

[ANSI/AAMI HE75:2009, 3.53]

3.11 post-market surveillance: Practice of monitoring the safety of a pharmaceutical drug or device after it has been released on the market.

3.12 usability: characteristic of the user interface that establishes effectiveness, efficiency, ease of user learning and user satisfaction

[ANSI/AAMI/IEC 62366:2007, 3.17]

3.13 usability testing: A systematic evaluation that characterizes and validates design mitigation of potential use-related hazards. Procedures typically involve users engaging in simulated use or interacting with a device or subcomponent of a device while user performance and subjective assessments are systematically collected. Usability tests can be performed in a laboratory setting, in a simulated environment, or in the actual environment of intended use. Usability testing processes are necessary for formative and summative testing, with the methods being informal and exploratory in nature in the former and sufficiently formal to support human factors validation in the latter.

3.14 use error: An act or omission that results in a medical device response that is either not expected by the user or unintended by the manufacturer.