Technical Information Report

AAMI TIR50: 2014/(R)2017

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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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

Human Factors Engineering Committee

This AAMI technical information report was developed and approved by the AAMI Human Factors Engineering Committee.

At the time this document was published, the **AAMI Human Factors Engineering Committee** had the following members:

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Robert G. Radwin, PhD, University of Wisconsin
Tim Reeves, PhD CHFP, Human Factors MD Inc.

Arathi Sethumadhavan, PhD, Medtronic Inc. WHQ Campus
Adam R. Shames, Core Human Factors Inc.
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Vijender Singh, Intertek
Debora Stapleton, Covidien
Robert C. Sugarman, PhD, RCS Performance Systems Inc.
Tom Varricchione, Ximedica
Matt B. Weinger, MS MD, Vanderbilt University Medical Center
Tracy Weldon, Kimberly-Clark Corporation
Michael E. Wiklund, PE CHFP, UL LLC
Stephen Wilcox, PhD, Design Science Consulting
Lee Wood, F Hoffman-La Roche Ltd

Alternates:

Paul A. Blowers, Abbvie
Joe Cesa, BA, Kimberly-Clark Corporation
Shannon Clark, Intuitive Surgical Inc.
Wende Dewing, Medtronic Inc WHQ Campus
Elise Edson, Covidien
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Patricia Ryder, Fresenius Medical Care Renal Therapies Group
Joan M. Spear, MBA RM CMPR, B Braun of America Inc.
Svetlena Taneva, Healthcare Human Factors

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.)

