
Working with Non-governmental organizations: The Perspective of the World Health Organization

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Abstract

The World Health Organization (WHO) is involved in health-related decisions affecting people all over the world. To gather knowledge and experience, collaboration with partners is an essential part of the process to create guidelines and policies for the WHO Member States. This paper describes our experiences as HCI researchers in a collaboration with the WHO on a project to establish a global classification system for medical devices.

Author Keywords

Non-governmental organization; World Health Organization; Medical Devices

ACM Classification Keywords

- Information systems: Digital libraries and archives.

Introduction & Background

The goal of the WHO is “to build a better, healthier future for people all over the world” [1]. To achieve this WHO “engages actively with a broad range of non-State actors” [2]. The WHO was founded in 1948 as a specialized agency of the United Nations (UN). It has close partnerships with other UN agencies, donors and non-State actors. WHO recognizes four groups of non-State actors:

- Non-governmental organizations,
- Private sector entities,
- Philanthropic foundations,
- Academic institutions.

Collaboration is important because WHO acknowledges the significant contribution of non-State actors to global health and their activities to protect and promote public health. At the same time there is a framework in place to protect the work of WHO from potential risks such as conflict of interest, reputational risks, and undue influence [3]. The terms of reference for the collaboration of NGOs with WHO is defined in the Framework of Engagement with Non-State Actors (FENSA) [4]. For NGOs in official relations with the WHO, there is a Register of non-State actors [5]. Here, the legal status, governance structure, finances and activities can be found. Additionally, information about the collaboration, including objectives and activities are listed. As of January 2018, there are 214 non-State actors in official relations with WHO [6].

In 2015, the UN General Assembly published their development agenda "Transforming our world: the 2030 agenda for sustainable development" which includes 17 goals (Sustainable Development Goals, SDGs) in the three dimensions economic, social and environmental topics. The SDGs address the fight against poverty and hunger, but also include human rights for all. WHO puts its focus on third SDG to "ensure healthy lives and promote well-being for all at all ages". One of the specific targets of this goal is Universal Health Coverage (UHC) which aims at providing access to quality essential medicines and health-care services [4]. To provide access to health-care services, such as blood tests, the availability of

appropriate medical devices has to be ensured. A key to this problem is a global classification system for medical devices, because co-existence of many different systems to classify, name and code medical devices causes problems in the collaboration between manufacturers, regulators, hospitals and other institutions. Additionally, the resources for development, training, implementation and maintenance of these concurrent systems could be significantly reduced by using a global system.

Currently, 84 out of the 194 Member States of the WHO do not have an official nomenclature system (for simplification reasons the term nomenclature system will be used to represent classification, coding and nomenclature systems in this paper). Out of the 90 countries which have a nomenclature system, 26% have developed their own national system and 22% use different existing international systems [5]. Some of the issues of these systems are high licensing fees and a lack of transparency, e.g. in the creation of new categories of devices.

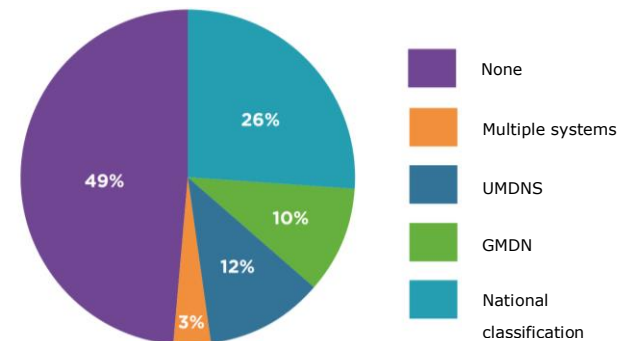


Figure 1. Distribution of nomenclature systems for medical devices in WHO Member States. Adapted from [8].

Example of Classification, Coding and Nomenclature

The following example is taken from the Italian Classificazione Nazionale Dispositivi Medici (CND).

The code in bold (e.g. **A01**) refers to the code of the medical device class, the term in italic (e.g. *NEEDLES*) refers to the nomenclature of this class of medical devices and the tree structure (A – A01 – A0101) describes the classification.

A
*DEVICES FOR
ADMINISTRATION,
COLLECTING AND
PICKING*

A01
NEEDLES

A0101
*INFUSION AND
COLLECTING
NEEDLES*

Those problems make it difficult for authorities, especially in less developed countries, to procure and maintain medical devices. To overcome this problem, we are currently in the process to establish a global nomenclature system with the WHO.

Currently, there are lots of concurrent systems to classify, code and name medical devices. The co-existence of many different systems causes problems in the collaboration between organizations in trade, customs, maintenance and management of medical devices. Also, the existence of different classifications slows down the communication between the stakeholders in the life cycle of a medical device from manufacturing, approval through regulators, shipment and post-market surveillance (e.g. recall after device malfunction). The consequences range from high costs to a lack of access to medical devices.

Therefore the World Health Organization (WHO) works on defining specifications for a global classification system. There are two options on how these specifications can be implemented:

1. A new classification system is developed by WHO
2. An existing classification is adopted to comply with the specifications of WHO

The goal of this project was to support the development of specifications for a global medical devices classification and nomenclature. Nomenclature is defined as assigning names or terms, in this context to medical devices; classification refers to categories or characteristics of devices, often used in hierarchies.

A Global Classification, Coding and Nomenclature System for Medical Devices

Therefore, the WHO proposes a single, global nomenclature of medical devices that is available throughout the life cycle of a medical device. The benefits can be an accelerated regulation process, better allocation of resources, improved supply and higher availability of medical devices to increase overall patient safety. From a HCI point of view, the main challenge is deriving use-cases for stakeholders with a variety of different roles. Therefore it is essential to get a thorough understanding of the stakeholders' needs and goals.

Procedure

To assess the needs of the different stakeholders, a survey was rolled out in January 2018. It was disseminated to professional societies, NGOs, manufacturers, regulators, hospitals and other agencies and organizations. The survey contains questions on what nomenclature systems are currently used, what the specific usage scenarios are and how they can be improved. As of February 2018, more than 100 participants from 41 countries have submitted to the survey. The participants are regulators, manufacturers, vendors, academia, UN-organizations, NGOs, government organizations, ministries of health, hospitals and independent consultants.

As the next step we have planned to conduct approximately 10 phone interviews with a representative sample of the survey participants to learn more about their specific tasks when working with nomenclature systems, as well as how the nomenclature integrates into the rest of their work.

In March 2018 the collected data will be compiled to a document with technical specifications for the nomenclature system. This document will be published for global consultation.

This work is done in collaboration with many organizations, including United Nations Organizations (UNICEF, UNDP), NGOs (Red Cross, Doctors without Borders, International Federation for Medical and Biological Engineering) and the European Union. Some of these organizations are responsible for the supply of medical devices in many countries and therefore know about the issues caused by the different nomenclature systems. In the context of WHO's work on medical devices, NGOs provide input from "the field", meaning that they are involved in activities that take place in countries, whereas WHO is responsible for international policies. WHO therefore uses the experience of NGOs to develop policies and guidelines. It is also part of the work of NGOs to disseminate the information published by WHO to the Member States.

Conclusion

The methods for data collection (survey and interviews) were appropriate to get a high amount and a broad spectrum of participants in a short amount of time. However, due to the less scientific nature of the project, a statistical evaluation of the data was not conducted. This limits the value of the data for future work.

Additionally, even though actual users were visited at an early stage of the project to get a general understanding of their work, it would have been helpful to do additional inspections in the field to gain more

insight into issues that might not be easy to communicate for the users.

We as HCI researchers can play a role in WHO's goal to improve access to medical devices. This can be achieved, for example, by applying data collection methods, such as semi-structured interviews, to define use-cases for the different stakeholders. The detailed selection and implementation of HCI methods will be defined at later stages of this project.

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Author biography

Daniel Diethei is a PhD candidate in the field of human-computer interaction at the University of Bremen, Germany. Previously, he studied human-computer interaction at the University of Würzburg, Germany. His research focus is on human factors. For his master's thesis he designed a power plant control room in virtual reality. Besides that, he worked on usability tests for infusion pumps in the intensive-care unit at Toronto General Hospital. He wrote his bachelor's thesis on radar displays for air traffic controllers at the German Aerospace Center. He also worked for the Siemens Healthineers, improving user interfaces for X-ray systems.