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Safety and Usability of Medical Devices

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In the field of medical devices, innovation and safety are key drivers for product suppliers. Standards provide an essential route for suppliers to demonstrate quality and consistency and provide vital specifications for comparability and testing. There are multiple approaches to standardisation, for example, specification of a product, implementation of management systems (process) or establishment of common values or principles to maximise business potential. The paper will outline the use of product standards (technical specifications) during medical device development, and examine the inherent benefit.

Introduction

Standards provide for the growth of markets. Across a market as a whole, standardisation offers efficiencies in terms of maintenance, compatibility and elimination of wasteful duplication or unproductive labour (DTI 2005). Standards also underpin the regulation of products. For example, in the European Union, the “placing onto market” of medical devices is governed by a number of European Council directives that are implemented through national law. The directives specify essential regulatory requirements, corresponding to the quality, safety and performance of medical devices. Modular, open, voluntary and harmonised standards support compliance with the regulatory requirements. Within the EU, this exemplifies a class of “new approach” directive. Contrasting “old approach” directives contain a large amount of technical detail, which adds to the challenge associated with approval and revision. For new approach directives, bodies such as CEN and CENELEC prepare consensus standards to support compliance. National Standards Bodies (NSB) are involved in the generation of consensus standards and private, independent, certification authorities or “Notified Bodies” assess conformity. This means that new
approach directives need only contain essential requirements. For medical devices, the adoption of harmonised consensus standards provides benefit as a single European standard replaces numerous national standards. Harmonised standards therefore cut the cost of compliance, provide a single point of access to the market and support free trade. As the adoption of standards is voluntary, organisations are free to innovate, although in many cases, incorporation of tried and tested solutions is appropriate. In these cases, product standards provide a basis for quality, consistency, comparability and testing. For consumers, standards communicate an attribution of quality and safety that would otherwise remain hidden (e.g. use of the CE mark).

**Product standards and medical devices**

There are approximately 300 standards that are current, UK-specific and applicable to general medical devices. Examples include the use of standard scalpels (BS EN 27740:1992), surgical gloves (the BS EN 455 series) and standardised connector types such as the Luer conical fitting (BS EN 20594-1:1994). The final case is interesting, because the Luer fitting was originally developed in a proprietary setting by Karl Schneider, for Wülffing Luer, in 1896. It was then made available to the wider industry to promote interoperability. Without standardisation, health services fail to work together in an effective way. For example, in 1988, following the Ramstein air-show disaster, incompatibilities between the connector types used on IV catheters impeded the emergency response (Brown 2012). The Luer fitting has since become a global standard. Conversely, although the Luer connector has proved successful in allowing interconnection between multiple equipment types, it has also been implicated in several wrong-route administration errors. These are where mistaken connection of the wrong device or substance results in delivery to an unintended part of the body. A study commissioned by CEN showed that when the potential for misconnection was considered across multiple medical connector types (including the Luer), 27% could be fatal (PD CR 13825:2000).

There is therefore an inherent complexity in product standardisation, with a balance to be achieved between flexibility and control. It can be challenging to future-proof a solution and consider system-wide factors. But by incorporating sufficient flexibility, product standards can provide a force for good. For example, within England, over 15m people have Long Term Conditions (LTCs), accounting for 70% of the health and social care budget. Standards enable assisted living technologies to be deployed, to address this societal challenge. Standards can be used to incorporate the needs of the mildly to moderately impaired, design products for home use (e.g. BS EN 60601-1-11:2010) and, in combination with ergonomic data, take into account cultural, social and individual differences (e.g. ANSI/AAMI HE75:2009). Product standards can be applied to optimise user interaction and facilitate commonality in the principles of operation or the properties of the user interface (e.g. PD IEC TR 60878:2003; BS EN 60601-1-8:2007). They also allow developers to incorporate tried-and-tested electro-mechanical solutions therefore saving on development resource.
Product standards therefore generate a level playing field across the market as a whole. This is because organisations avoid the need to develop their own solutions. In this way, standards benefit Small and Medium sized Enterprises (SMEs), through a reduction in development cost. Within the EU, 80% of medical device companies are SMEs (Eucomed 2012). If a standard is unnecessarily complicated, difficult to implement or inaccessible, benefits may be outweighed by difficulties experienced during implementation. For medical devices, this may act as a barrier to safety and usability. Safety has become a recent concern within the EU and USA, due to a number of high profile device recalls (FDA 2011, EU 2012).

**Mechanisms of standardisation and the safety and usability of medical devices**

Research has examined the extent to which those involved in the design, development and deployment of medical devices find harmonised standards of benefit. An aspect of safety relates to the interaction between the user and the device interface. Here, the design of equipment can reduce the likelihood of errors occurring and ease of error recovery. A qualitative interview study, focussing upon the interactive properties of devices, examined the challenges associated with the adoption of standards in this area. Practitioners expressed a need for clear, concise, graphically illustrated material. They suggested that interpretation is currently constrained by lengthy annexes and complicated interdependencies (Vincent and Blandford 2011a).

In another case, relating to medical device connector types, there were delays incorporating a proposed solution into a network of products. These were partly due to concerns regarding competing or superseding standards. There was a fear that standards could be usurped at an international level (Vincent and Blandford 2011b). For example, if a standard is revised shortly after an organisation has adopted it, or a different standard comes into widespread use, there may be a significant cost associated with change. In many cases, the willingness of a manufacturer to adopt a given standard was dependent upon the extent to which customers perceived it to be beneficial.

For global markets, studies have shown that in some cases, standards fail to realise their purpose. For example, graphical symbols designed for medical contexts are sometimes supplemented with regional specific textual labels (IEC 60878:2003). This is because comprehensibility varies across symbol type and country. For example, the “bell cancel” symbol (IEC number 5576) was reported comprehensible by 100% of German users, but only 65.4% of Chinese users. The “do not reuse” symbol (IEC number 1051) was reported comprehensible by 32.5% of German users and 46.2% of Chinese users (Liu and Hoelscher 2005). In this case, manufacturers may question the benefit provided by standardisation.
Conclusions

Understanding when and why organisations do, or do not employ standards is important. This is because insight can be used to help inform future standards, confirm the suitability of current standards and guide the approach to standardisation. From the perspective of those implementing standards, there are many questions that need to be considered when deciding on an approach. For example: To what extent is the information contained within a standard accessible and how easy will it be to apply it efficiently? Is the standard adequately specified? How current is the standard and for how long is it likely to remain current? How widely adopted and recognised is a standard? Is there a need for recognition beyond a given market? In the future EU medical device regulations are likely to continue to recognise the role of harmonised standards (EU 2012). Optimising their utility will be of benefit.

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References