Cultural Diversity - New Challenge to Medical Device Use Safety for International Markets

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Abstract. Medical device nowadays may be used by user groups with quite different cultural backgrounds. Cultural diversity may influence normal medical device use or even induce risks and hazards. Manufacturers are facing up to a new challenge to consider cultural diversities in design. This paper aims to formulate a systematic framework to handle medical device design for international markets. The standardized requirement specified in risk management standard of ISO 14971 is adopted as a basis. The cultural diversities that may induce risks and hazards are summarized. Medical device design issues that should be adapted are discussed. Many examples on these issues are presented.

Keywords: Cultural diversity, Medical device design, Use safety.

1 Introduction

Ongoing economic globalization has fostered increasing exchange of technical products worldwide. Statistics show that many medical products are aiming at global markets instead of national markets. Reports on medical device market in 2009 showed that the world's total exports in this area valued at a high level of 170.487 billion dollars, which was almost half of the total production. The biggest exporting countries are USA, Swiss, China and Japan. The important target importing countries are USA, Mexico, Ireland, Germany, China and Japan etc. These countries imported about 60% of the total medical device traded worldwide.

As the medical device market becomes more global and the user groups become more varied, design of medical device has evolved some new characteristics. Manufacturers nowadays should face up to additional design considerations posed in designing products for multiple cultures, user groups or markets. Cultural diversity – not only the thinking patterns, values, habits, beliefs of the target users, but also the level of economic development, political system, physical environment, etc. has

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become a new influencing factor to medical device design. It is clear that under global circumstance, a well usable medical device in one culture might meet with serious problems in another culture. Cultural differences will influence effectiveness of medical device use, or even induce risks and hazards.

2 Cultural Diversity as New Factor to Hazards and Risks

According to the definition in the ISO 14971, hazard is the potential source of harm, and risk is the combination of the probability of occurrence of harm and the severity of that harm. Fig 1 shows the occurrence of the harm. If a person is exposed to a hazard, the harm may occur. In the medical device use, there are different kinds of hazards, such as the biological hazards, radiation hazards, and chemical hazards, etc. In order to avoid the occurrence of harm, the causes of (or contributing factors to) the hazards should be effectively identified, analyzed, and controlled.

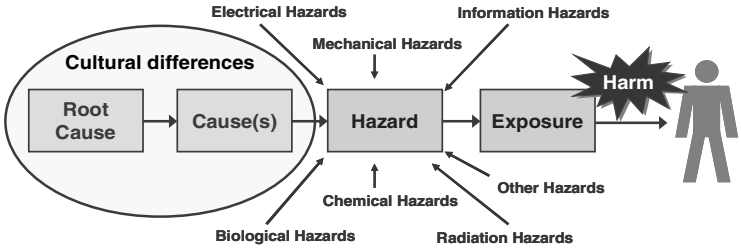

Fig. 1. Cultural differences as new contributing factors to hazards and risks

For medical device intended to be used in international markets, the cultural diversity has become an additional root cause for the hazards (see Fig. 1). As user groups or use context are changed, the existent operation attributes that certainly impact efficiency and safe use of medical devices have changed. Consequently, measures should be taken to analyze new influencing factors and adapt medical device design to the changed use conditions. However, at present, although there are many researches or even applicable results in the area of culture-/nation-specific design, most of them focus on the computer industry. There is not enough concern in the medical device design area. Many particularities in this area are still unknown both for the researchers and the manufacturers. Furthermore, previous experience gained from other application areas may not be suitable for design of medical device due to some particularities of medical device use

It is therefore necessary to consider the medical device design for international markets in a different way. New framework should be developed to define cultural influences and to incorporate these influences in design solutions.

This paper adopts a meta-culture model developed by Stewart and Bennett (1991) as a basis to formulate categories of cultural diversities to be considered in medical device design. The meta-cultural model classifies culture into two layers: *objective culture* and *subjective culture*. Objective culture comprises the institutions and

artifacts of a culture, such as its economic system, political structures and processes, social customs, arts, crafts and literature. Subjective culture comprises the psychological features of a culture, including assumptions, values, and patterns of thinking. In consideration of the requirements in EN 62366, which indicates that the user profiles, task profiles, context of use (organization, environment, technical, social, hygienic, etc.) should be addressed in medical device design, the cultural diversities that should be considered could be classified into three categories:

- National issues: language, unit system and format, regulatory issues;
- Culture-specific use context: use environment, professional traditions and work organization, technological environment, social context;
- Culture-specific operator profile: demographics, anthropometric characteristics, interpretation of colors and symbols, preference and expectation, attention, knowledge and experience.

These cultural diversities may probably induce hazards and risks for medical device use in international markets. They are similar to the other lists of cultural diversities of some researchers (such as Del Galdo EM) but are different to those in detail. The way of this classification also well reflects the understanding of the practitioners in medical arena. In the following sections, some examples on the detailed information of these diversities will be presented.

3 Framework of Factors for Safe Medical Device Design

As the risk management standard ISO 14971 is one of the most important standards for medical device design, it is rational to adopt its requirements as a basis to formulate the framework of factors concerned in medical device design for international markets. Fig 2 shows the risk management process specified in the ISO 14971. There are 4 steps for the risk management: risk analysis, risk evaluate, risk control, and post-production information.

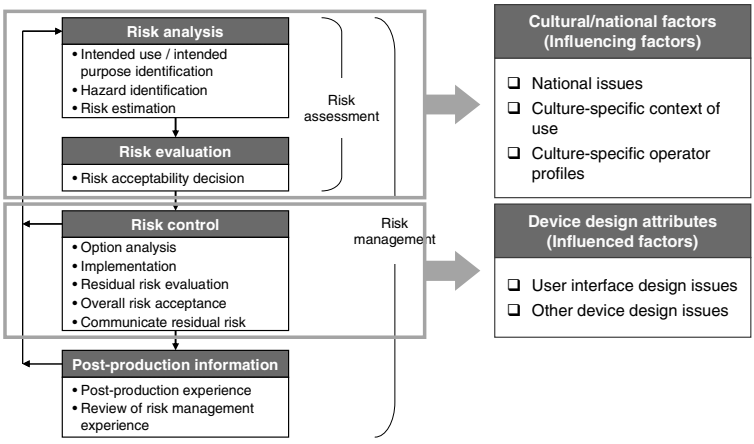

Fig. 2. Risk management and factors for cross-cultural design of medical device

If any cultural influencing factors may induce unacceptable risks for medical device use, in the risk control phase, corresponding design adaptations should be formulated as control measures. These issues can be referred to as the device design attributes (see Fig 2). The following two groups of factors should be addressed in the medical device design for international markets:

- Influencing factors: cultural factors.
- Influenced factors: device design attributes.

The relationship of these two groups of factors is shown in Fig 3. More detailed description of these factors is presented in the next sections.

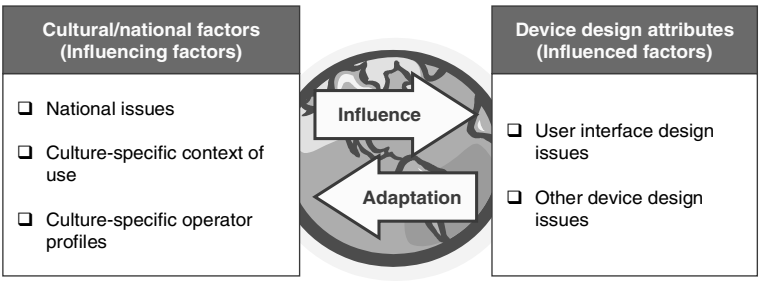

Fig. 3. Relationship between the two groups of factors

3.1 Influencing Factors

National Languages

Language is a key challenge for designers of products for international markets. Although many non-English speaking operator groups read and understand English well, a critical situation may result in high stress on the device operator. When required to use a non-native language, use errors could occur that are directly attributable to the requirement that the operator interacts with the device in a foreign language. So, the subset of preferred languages that manufacturers support should be chosen carefully otherwise it will become a potential source of harm.

Language issues which should be considered for the design of medical devices include: script, length of words, grammar, spelling differences, alphabetical order, reading/writing direction, different meaning of same words, homonyms, idioms, etc.

Unit System and Format

Units used in different countries are various. The use of the imperial units system in the UK and USA and the SI system used in many other countries is well known. Additionally, some countries continue to use unique traditional unit systems in some product areas (e.g., “Gauge”, “French” and “Charrière” as the diameter of needles or catheters …).

Other national differences relate to the use of different formats for date, time, number, address, etc. that can confound the use of medical devices. For example the date format of 05/09/02 is unclear without any cultural context. Designers should be aware of these diversities and prevent them from inducing new risks.

Professional Traditions and Work Organization

The traditions for medical treatment and its workflow vary among different countries. The work organization (division of labor, responsibility, hierarchy, etc.) of health care practice also differs from country to country. This may result in differences in operators of medical devices in the same type of care area in different parts of the world. For example:

- In operating rooms throughout the world, patient monitors and anesthesia delivery systems are primarily operated by anesthetists;
- Outside of operating rooms, patient monitors are primarily operated by nurses or technicians in the United States and Canada, but by physicians in Europe;
- Intensive care ventilators are mainly operated by physicians in Europe, but by respiratory therapists in the United States.

Technical Environment

The general level of acceptance of technical devices in a target market influences that market's ability to support new technology and its acceptance of different technologies (e.g., new or obsolete technologies). For example, Korea tends to adopt new technologies more quickly than Ireland. The technological traditions of the target market include specific technical standards for mandatory design requirements (e.g. different "safe" levels of radiofrequency exposure for different countries). The existence of other devices already in use can influence the use of the medical device in question. Differences in the characteristics of the area's power system, as well as its quality (e.g., stability of power supply), should also be considered.

Social Context

Use of medical devices may involve more than just medically trained caregivers, possibly including the patient and their family members. The social context of the target culture (e.g., the relationship of different family members) can be quite different, exerting direct influences on the use of medical devices in that locale.

Anthropometric Characteristics

Body size and physical performance characteristics (e.g., strength) differ among different populations. On average, Asian people are smaller than Westerners. So anesthesia workstations designed for people who work in US hospitals may be too large for smaller operators in Japan, leading to reach and vision envelope-related problems. The design of the workplace, control elements and other components directly interfacing with people (both caregivers and patients) should consider differences in the anthropometric characteristics of target operators.

Interpretation of Colors and Symbols

In respect of color application, manufacturers should be aware of the possibility that a color will be interpreted differently, impacting the way people use a given medical device. An example is on the interpretation of colors red and green among different cultures. In Europe and the USA, people associate the color red with danger or stop and the color green with start (primarily because of how those colors are used on traffic lights). While in China and Japan, the color red is associated with prosperity and happiness. In a Japanese infusion pump, a red button is used for start and a green button is used for altering the settings. If such a pump would be used by users in Western cultures, it is foreseeable that use errors may be easily provoked under emergency (Fig. 4).

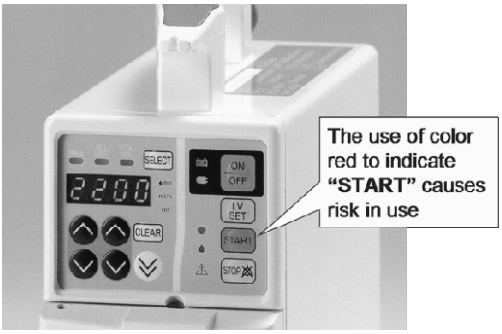

Fig. 4. Example on different design that may induce risks

Preference, Expectation and Attention

Operators in different cultures have different preferences and expectations, which can significantly influence medical device use. For example, in central Europe, the rotation directions for mechanical and electronic devices are typically different. Turning a knob clockwise reduces a setting by closing a pneumatic or hydraulic valve, but increases a setting on an electronic device e.g. the volume control. In contrast, in the United States, the rotation directions of hydraulic valves (e.g., water valves) may be different. Turning a knob clockwise might close a hot water valve, but open a cold water valve. These differences should be carefully addressed in device design, because in the presence of stress or lack of attention a user easily falls back into stereotypical behavior even though the task may require the opposite behavior.

3.2 Influenced Factors

A variety of medical device design issues are influenced by the cultural-/national-factors described above. According to ISO 14971, these design issues are taken as the control measures for risk control in international markets. Two groups of design issues could be classified:

- User interface design issues: hardware design issues, interface structure, navigation, dialogue system, information presentation, help information, warnings, etc.;
- Other device design issues: functional and technological features, technical documentation, operator support, training, etc.

Hardware Design Issues

One of the first points to consider in designing the hardware aspects is to adapt the workspace, size of control elements and other components to the anthropometric features of the target operators. Input and output (display and printing) should be considered to facilitate the operator's interaction with the medical device. This is especially important for languages (such as Greek, Russian, Chinese, Japanese, etc.) with many ideographical characters (e.g., a Chinese operator may prefer a writing pad to input the Chinese characters rather than a keyboard). The memory size required for the device's character set should also be considered.

Interface Structure

For a medical device, more than one operator is usually involved. If possible, the interface structure should be based on each operator's tasks, work organization and responsibilities. An operator usually only interacts with operating functions related to his/her area of responsibility. If the work flow, task completion and responsibility vary, the operator-device interface structure should be optimized to support all important operator needs to the greatest extent possible.

For example, the responsible operator for the intensive care unit ventilator is the respiratory therapist in the USA, but is a physician or nurse in Europe. If an ICU work station, being designed for use in the USA and Europe, incorporates both patient physiological monitoring and ventilation, then the structure of the user interface should take the responsible operator into account. It should also consider that in the USA different people may work with the integrated work station at the same time.

More significantly, the operation sequence is largely determined by the operator's work habits too. For example, the operation sequence for setting the infusion rate of a large volume infusion pump is quite different for nurses in Germany, Spain, Switzerland and UK, because the VTBI (volume to be infused) function is rarely used in Germany.

Language Issues

Translation of a device's user interface into the operator's native language is the most basic adaptation of a medical device to a particular country or region. The translation should be done by persons with experience using these medical devices; however, target operators may still have problems understanding the translated user interface. Several details have to be considered with respect to this issue:

- Display resolution: for example a higher display resolution is needed to display a Chinese character than is needed to display a Roman character.
- Text field (Character) widths: a paragraph of German text usually occupies more space than a paragraph of English text (general rule of thumb is 25-30% more space for German).
- Prioritized translation: if a complete translation of the user interface is unrealistic considering time and cost, at least the most critical labeling and indications should be translated. The hazard/risk analysis must be updated to address the non-translated parts, however.
- Country requirements: some countries require specific languages for device and their accompanying documents, other countries allow device to be in a foreign language, but require the accompanying documents to be in a specific native language. Manufacturers should also check with sales agents within the country because specific language requirements may exist in tender documents.

Technological Features

Foremost, the technical specifications of a medical device should meet the relevant regulatory requirements of the target market for the specific device. These can differ from country to country. For example, the US National and IEC standards have different requirements for chassis/enclosure and earth/ground risk currents, which should be addressed by the manufacturers.

Other differences in local power supply, radio frequency allocation, and electromagnetic interference and compliance (EMI/EMC), etc. should also be considered.

To ensure that medical devices function reliably wherever they are used, device design should incorporate special technical measures intended to mitigate the effects of possible environmental factors such as high humidity, high concentrations of acidic substances, fluctuations of temperature, electricity supply, etc. Changes to address these issues in the device's technological features may also affect the overall design of the user interface.

Operator Support

A device's working life may vary by country as well. For example, some countries replace anesthesia machines regularly while others continue using them for 20 or more years. Due to geographical restraints and possible shortages of qualified service personnel available in a specific area, support services such as maintenance and repair, spare part supply and operator training pose problems. Special measures such as using spare parts that are readily available on the local market should be considered to minimize dependence on manufacturer-provided support.

Not many design adaptation measures could be presented here, however, according to the ISO 14971, the design measures could be generalized into the following order with decreasing priority:

- Device design adaptations to avoid potential hazards (inherent safety by design);
- Protective design measures, such as alarms etc.;
- Information for safety, such as those described in user manual.

4 Guide to Cross-Cultural/-National Design of Medical Device

Once a manufacturer decides to enter a new market, they must decide how to adapt their product to the new market's requirements. Their decision making on cross-cultural/-national design is largely influenced by the following factors:

- How large is the expected market volume for the device?
- What is the scope of the changes required to modify the design for the new market?
- How complex is the work to implement the design adaptation?
- If design adaptations are infeasible, what is the risk for safe use of the device in target culture?

The decision on when and how to start a cross-cultural/-national design process can be based on a cost-benefit analysis. Manufacturers must consider their own design resources, experience, and the potential benefits gained through the design adaptation. The manufacturer's representatives in the target markets should provide adequate information. The final decision, however, will be based on the manufacturer's own circumstances.

The general development process of medical device considering cultural and national differences in the different markets is essentially the same as the HFE process defined in EN 62366 and ANSI/AAMI HE74. Recognition of cultural differences may, however, affect the specific characteristics of the analysis and specification (operator investigation), design and realization, and design evaluation.

5 Conclusions

As business is becoming more global and medical products are more globally accessible, the importance of the cross-cultural/-national design should be better recognized by the manufacturers. Looking into the future, it is clear that only manufacturers who are good at analyzing culture-/nation-specific requirements of each market's target operator groups and integrating these requirements into device design will be successful. At present, there is controversy with respect to affordability and safety, how far operators must adapt to technology and how far technology can adapt to operators. Manufacturers must assess the resulting risks and mitigate or control them as necessary. Unfortunately, some markets are not large enough to be treated independently, so their unique requirements may not be considered explicitly. Not selling medical device into those markets could put patients at risk by withholding necessary treatment. It is the manufacturer's obligation, via its risk management process, to make decisions on the acceptability of the remaining risks

and to establish methods to collect post-market data for feedback into the risk management process.

Globalisation may replace many local habits and values with internationally uniform habits and values. The internet, TV, news and literature together certainly have a strong influence on some operator groups. The result may be that the need for specific cross-cultural/-national designs of a human-machine-interface may gradually become less critical over time.

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