Evaluation of Graphical Symbols Used in Intensive Care Units (ICU): Comprehension among Users in Different Countries

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Introduction:

Modern medical devices and their user interfaces apply increasingly more graphical symbols to convey information. Previous researches have indicated some advantages of graphical symbols in conveying information: a) high visual impact to transmit information effectively; b) compact information which occupies less space on products; c) information independent of national languages, etc [1] [2] [3].

The advantages of symbols are becoming more important for global marketing of complex medical devices. However, researches showed that symbols can be differently comprehended among users in different countries [4] [5]. Although standards and technical reports have been issued regarding the application of graphical symbols for use on medical devices (e.g. EN 980:2003 *Graphical symbols for use in the labelling of medical devices*; IEC 60878:2003 (draft) *Graphical symbols for electrical equipment in medical practice*; ISO 15223:*2000 Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied*), few studies have been published regarding evaluating the effectiveness of symbol in different countries. If safety relevant symbols are not correctly understood, use-related risks for the operator or patient may be provoked. These risks should be analysed and controlled according to the requirements of ISO 14971 and EN IEC60601-1-6, [6] [7].

Purpose:

To evaluate the comprehension of symbols used in the intensive care units (ICU) among users in different countries and to identify potential problems with their application.

Method:

Different criteria can be used to evaluate graphical symbols: noticeability, legibility, comprehensibility and suitability for learning [8]. For symbols used in medical areas, the comprehensibility should be the most important one.

The comprehension test method recommended by ISO 9186: 2001 was applied in the study [10], with the open-ended “free definition” task in the test. The participants were presented with the symbols and were instructed to write down their own opinion on the meaning (the response) of the symbols freely. Two rounds of the test were separated: the first round was the comprehension with a *global* context which showed the general product type or the general use environment; the second round was conducted with a *fine* context presented additionally which showed the direct application environment (e.g. with other possible symbols together). Totally 16 symbols used in the intensive care areas and in the operation theatre were tested. 13 of these symbols were chosen from the draft of the IEC 60878 TR Ed. 2.0: 2003 [8]. The other 3 were taken from products of different manufacturers.

Two groups of participants participated in the test: 20 volunteer German nurses and doctors and 13 volunteer Chinese nurses and doctors working in the intensive care units. The responses of all participants were independently assigned by 3 judges into 7 categories according to the criteria specified in ISO 9186. The final score of a symbol is also obtained by summing and weighting the percentages of responses in the different categories, according to the formula recommended in ISO 9186. It reflects the comprehension of the symbol.

Results:

The comprehension scores are generally low in both countries: In China, the average comprehension score is 32.2 (SD = 30.3) for global contexts and 48.2 (SD = 28.9) for fine contexts; In Germany, the average comprehension score is 42.7 (SD = 36.3) for global contexts and 52.3 (SD = 27.7) for fine contexts. Half of the symbols reached a comprehension score higher than 67% (the acceptance criterion specified by ISO 3864 [11] for safety-relevant symbols) in Germany but only 4 symbols reached this level in China. If the criterion of 85% specified by ANSI Z535.3 [12] was considered, only three symbols (both in China and in Germany) would be accepted. Some safety-relevant symbols, for example, the symbols for "Date of manufacturing" and "Don't reuse" reached a very low comprehension score in both countries, which suggested potential problems with application of these symbols in practice.

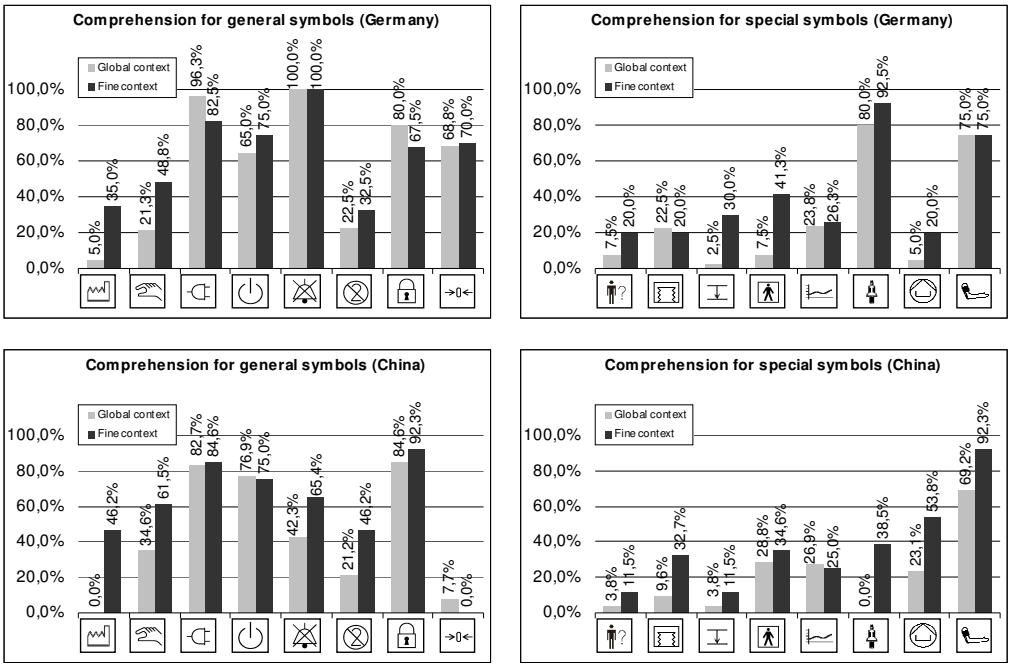

Figure 1 Symbol comprehension among users in Germany and in China

Further analysis was conducted to reveal differences in symbol comprehension between the two countries. The ANOVA analysis showed, neither with global context nor with fine context, the comprehension scores were significantly different for participants in China and Germany [$F(1,28)=0.878$, $p=0.357$ for global context, $F(1,28)=0.186$, $p=0.669$ for fine context]. The result implies that the cultural differences of participants in these two countries have no significant influence on the comprehension of the graphical symbols used on medical devices in ICU area.

It is deduced that the experience with graphical symbols would significantly influence their comprehension. Further ANOVA analysis revealed the influence of this factor. In test, we used two types of symbols: The *general* symbols are those widely used in different medical products (not only in ICU); The *special* symbols are those dominantly used in ICU area. The general symbols can be more frequently experienced by users when they work. The ANOVA analysis showed that either

with global contexts or with fine context the comprehension scores of general symbols were significantly better than those of special symbols [$F(1,28)=5.519$, $p=0.026$ for global context, $F(1,28)=5.585$, $p=0.025$ for fine context]. The result implies that the experience with the symbol use may have significant influence on the comprehension of the graphical symbols used on medical devices in ICU area.

The study results implied that not the cultural background of the users but their actual experience with the use of the symbols significantly influenced their comprehension. For effective symbol application, beside the well design and selection of relevant symbols to convey specific information, training should be a very effective way. This would be a situation for symbol application in medical area in general.

Conclusions:

Summarizing the results the following conclusions can be reached:

- The comprehension of the graphical symbols tested in both countries is very poor. Half of the symbols (in Germany) or 4 symbols (in China) reached the acceptance criterion of 67% specified by ISO 3864. But only three symbols reached the acceptance criterion of 85% of ANSI Z535.3 in both countries;
- Statistical analysis did not show significant difference in symbol comprehension between participants in the two countries. The test results imply that cultural difference of the users have no significant influence on the symbol comprehension;
- Other factors, especially the experience with using of specific symbols significantly influence their comprehension among target users. This means that training would be an effective way to compensate the weakness of symbol comprehension in practice. Symbols should be learned by target users to ensure their application effectiveness.

Based on these conclusions, it is suggested that medical device manufacturers should be careful in applying symbols to convey safety-relevant information on their devices. Special measures should be incorporated in medical device user interface design, such as online prompts to indicate the meaning of the symbols, to reduce the risk of misunderstanding, as well as to encourage user's learning in the use process;

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