Ergonomics as a source of errors

Two thirds of adverse events with medical products derive from errors of usage and only one third from product errors. The number of errors of usage could be reduced by making products more usable and ergonomical in design.

Ergonomics not only refers to user satisfaction but also safety of use. The risk of unintended use is why usability legislation is required. The usability of medical products can be examined and specified by testing products in a "Big Brother OP" as provided by Use-Lab GmbH. A clear distinction is drawn between user errors and errors of usage. While with user errors the cause is primarily sought in those who use the product, in the case of usage errors it is more of a mixture of product design being conducive to error, the circumstances in which a product is used and factors relating to the user (such as training, concentration, fatigue etc.). It has emerged that errors are not usually solely down to the user but generally lie in the usage of the product - which means that the adverse event is polycausal. This perspective on errors of usage is important because people are understandably less willing to report errors which would attribute blame to themselves. However, the systematic registration and investigation of such errors is crucial so as to be able to avoid repetition.

Companies do attempt to incorporate the perspective of users in product development, but this is often difficult as in practice there is no such thing as "the user". Most medical products are used by different groups of individuals with different levels of training, even including non-experts caring for sick relatives, for example. This broad range really requires product design to be adapted accordingly so as to take account of the needs and skill level of users.

What is more, in an internationalized market such as medical technology virtually all products are marketed beyond national borders. "Some manufacturers are starting to accept that there are cultural differences here and that this has consequences in terms of product design," says Torsten Gruchmann, Managing Director of Use-Lab. "There can even be problems within Europe." The distribution of skills can vary considerably even in neighbouring countries. For example, in Switzerland a nurse or radiological assistant will carry out tasks which in Germany only a doctor would perform. In some cases there are special qualifications, such as the respiratory

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Picture: Use-Lab

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2) "A high level of patient and user reliability can be assumed at the market launch of the medical product, while the complaint rate is significantly reduced," says Barbara Breuer-Thal, Director Innovation & Technical Marketing Medical Devices with Fesenius Kabi Deutschland GmbH

German Summary

Zwei Drittel der unerwünschten Ereignisse mit Medizinprodukten entstehen durch Anwendungsfehler, nur ein Drittel durch Produktfehler. Die Zahl dieser Anwendungsfehler könnte durch eine gebrauchstauglich und ergonomisch orientierte Gestaltung reduziert werden. Der deutschsprachige Beitrag ist nachzulesen auf www.meditec.mi-verlag.de/medi0411ergof

therapist in the USA who is responsible for the entire area of respiration.

The discipline "Intercultural Usability Engineering" deals with precisely these issues, but does not focus on setting standards. The aim here is to find out where there are differences and to discover whether these differences involve any unidentified risks. After all, a product which might work perfectly well with one group of users may cause unforeseen problems with another. Tests carried out at the Use-Lab's Big Brother OP focus on all user groups potentially targeted by the manufacturer's product. This may means entire OP teams flying in from Spain, Sweden or the USA. Observations are then made as to whether dangerous situations can arise with the product in question deriving from the design, differences in customers, processes, degrees of training or cultural specifics. The idea is that products tested by Use-Lab only carry justifiable risks. Calculable misuse can occur, but must be registered as an acceptable risk within the risk management system. Here, a note might be included in the operating instructions, for example.

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Essentially, this type of test preempts some of post-market surveillance work. The product is not first put into circulation and then exposed to criticism, but tested and improved in advance. "A high level of patient and user reliability can be assumed at the market launch of the medical product, while the complaint rate is significantly reduced," says Barbara Breuer-Thal, Director Innovation & Technical Marketing Medical Devices with Fesenius Kabi Deutschland GmbH, summarizing the benefits gained from the Use-Lab tests. "If we convey to people outside the company what the product is supposed to do, we are confronted with user questions which we would not have posed internally: there is a more objective view of things." The costs are low as compared to what a company can potentially lose if a product is designed in a way which is conducive to error, leaving a trail of adverse events behind it and possibly having to be taken off the market. Torsten Gruchmann estimates the cost-benefit at about 1 to 10, with savings deriving from shorter training times for manufacturers and users, thinner manuals, shorter development periods, longer market durability and avoidance of damage claims.

Ramona Riesterer ←

Patient safety – Denmark as a role model

Professor Uvo Hölscher, Head of the Center for Medical Technology and Ergonomics at Münster University of Applied Sciences, calls for an amendment of German patient rights legislation:

The healthcare system applies various measures to counter risks: legislation, management, process organization, environment, ergonomics, technology, training etc. No single protective measure is perfect and each can only prevent adverse events in combination with the others.

Research funding provides generous support for the development of new diagnosis and therapy techniques and large amounts are paid for the avoidance of deaths in road traffic (3,651) and from HIV (431). However, the area of patient safety (approx. 17,000 avoidable deaths per year) has attracted hardly any funding at all to date. In some cases the argument is that patient safety and its research is solely the responsibility of hospitals. However, the structures of the public utilities sector are so complex that individual initiatives can barely cover causal research, mutual cross-networking and the necessary improvements across the board.

Risk management includes observation, recording and analysis of adverse events as well as the planning and implementation of measures. This medical improvement process is based on trust of those involved in the processes and the legally controlled vigilance system for medical products (BfAM) as well as the voluntary Critical Incident Reporting Systems (CIRS). In Denmark, informants are protected by Danish patient safety legislation from the use of their information in forensic medicine or labor law. This is why risk management works much better there than it does here. The draft of the German patient rights law must be amended so as to generate trust in risk management!

Prof. Uvo Hölscher is head of the Center for Medical Technology and Ergonomics, comprising six scientists and focusing on ergonomics and patient safety. (www.fh-muenster.de/medizintechnik/forschung/referenzprojekte.php?p=3,0)