Human Factors Engineering Can Improve Patient Safety
By Kim Vincent

Adverse drug events (ADEs) are the leading threat to patient safety, and have been estimated to cost $2 billion annually in the U.S., not including costs of injuries to patients or malpractice costs. Analgesics (e.g., morphine, meperidine) are the most likely drugs to be associated with preventable medical injury. Furthermore, 45 per cent of the adverse drug events associated with analgesics involved misuse or malfunction of drug infusion devices of various types (e.g., patient-controlled analgesia). Thus, sizable improvements in patient safety could be achieved by improving the safety of drug infusion pumps.

Other safety-critical industries, such as nuclear power and aviation, have reduced human error by applying techniques from human factors engineering. This discipline focuses on the interaction between technology, people, and their work context. Leading experts have stated that the key to improving patient safety is to apply human factors engineering techniques to health care so that the incidence of medical error can be reduced.

To test the value of this design approach, my colleagues and I selected a commercially available patient-controlled analgesia (PCA) pump--the Abbott Lifecare 4100 PCA Plus II infusion pump (Abbott Laboratories, North Chicago, IL, USA). This particular pump is the market leader, is used regularly in thousands of hospitals around the world (including Canada), and represents approximately 75 per cent of all PCA use in the U.S. alone. While the Lifecare 4100 has been used safely many times, several patients have reportedly died while connected to it after concentration programming errors were made. Because the pump is so widely and frequently used, even a small improvement in its design could lead to significant gains in patient safety.

In an effort to reduce programming errors, we used human factors design principles to develop a new prototype design for this pump. Whereas the commercially available design requires users to look at a maximum of 27 screens, the new prototype design requires only 12 screens, a reduction of 56 per cent. To see if this reduction in complexity could improve programming performance, an experiment was conducted to compare the new design with a simulation of the existing design. The experimental subjects were professional nurses averaging over five years of experience with the existing design and only half an hour with the new design. Even though nurses had minimal experience with the new design, it completely eliminated safety-critical concentration programming errors, whereas the old design did not.

These results show that the cause of errors is not negligence or incompetence; if people were to blame, then changing the design of the device should not make any difference. But it did. Safety-critical errors were eliminated, suggesting that making infusion pumps easier for health care providers to use may reduce potential ADEs, thereby improving patient safety.

Nevertheless, the application of human factors engineering to medical devices is still in its infancy. Under-reporting of ADEs is one of the most significant obstacles to change. Epidemiological studies revealed that for every ADE that is reported, there are an additional 12 to 82 that go unreported. Therefore, the true magnitude of difficulties that health-care practitioners experience with infusion pumps and other medical devices is largely unknown.

And because the number of reported incidents reported is often low, it may be difficult for medical device manufacturers and government regulators to justify changing the design of devices. Nevertheless, the under-reporting rates cited above suggest that the number of incident reports that are currently received are just the type of the iceberg—preventable errors and ADEs are likely far more numerous than these data indicate.

What can you do to help? Each time you experience a near miss or an ADE or have a concern about a medical device that is difficult to use, you can make a report to the Institute for Safe Medication Practices Canada (ISMP Canada), an independent and non-profit organization established to promote medication use safety. Reports made to ISMP Canada are treated with strict confidence. (Reports can be submitted via www.ismp-canada.org web site) You could also fill out and send a voluntary problem report to Health Canada. The form is easy to fill out and can be found on the internet.[1] If every incident was reported, then the true magnitude of the problem would come to light and the adoption of human factors engineering design principles to improve patient safety would be far more likely to occur.

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[1] (www.hc-sc.gc.ca/hpfb/inspectorate/md_pro_rep_form_tc_e.html) June 17, 2002.

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