

Risk and the sense of safety

The concept of risk is not complex in itself. It can even be expressed in an arithmetical formula as the product of a usually negative outcome and probability. This enables one to balance bad but unlikely outcomes with less bad but more frequent ones. This knowledge may be used in risk calculations and risk assessments, but how probabilities can be assessed in an objective, unbiased, and thus correct, manner can pose a problem.

People find it difficult to estimate the actual chance of becoming a victim, especially when the outcome is extremely negative, e.g., death, and they are inclined to take no chances in such situations. However, their judgement is highly dependent on factors such as habit, experience, knowledge, and their personal situation. All these factors are not included in the arithmetical formula for calculating risks but apparently influence our sense of safety.

When war broke out in Iraq, people were hesitant to travel by air, or to the USA, fearing they would become victims of terrorist attacks. With the growing incidence of infection and death from severe acute respiratory syndrome (SARS), people feel anxious about travelling to Canada, or the United States, although, at that time, only the city of Toronto, with a small number of patients affected, was involved. At the same time, these people take risks in everyday situations, like traffic, with a chance of harm that is probably much higher and comparable in outcome. These examples indicate that individuals find it very difficult to make proper and objective estimations of risks.

In clinical pharmacy, one way of improving the system is to analytically describe the entire process and obtain quantitative data on the failure rates of every step in the process. This might enable us to identify the most critical parts of the chain and, by securing these steps, to improve the entire process more effectively. However, when, for instance, reported medication errors from Faults Or Near Accident (FONA) committees are classified according to such an analytical model, it appears that a majority of reported (near) misses cannot be classified. In fact, in a highly complex socio-technical system like drug distribution, there are so many chances of a disastrous outcome that the analysis of possible causes probably reflects the imagination of the analyst rather than reality. In other words, it is hard to imagine where things can go wrong.

Nevertheless, risk assessment in clinical pharmacy is a powerful tool to improve safety in a proactive manner. Currently, in hospitals, it is more common to study faults by means of a spontaneously reporting system than by studying incidents in a reactive manner by a FONA committee. Such an approach needs systematic trend analysis and a good understanding of the drug distribution process in order to yield useful information for improvement.

In recent years, in the scientific literature as well as in clinical practice, a lot of attention has been paid to medication safety. A decision has been made to change the system and to introduce modern technol-

ogy, such as computerised physician order entry systems, drug distribution robots, or barcode-assisted drug dispensing and administration, or to explore satellite pharmacies. All these changes are aimed at improving the drug distribution process and securing the patient's safety. Indeed, many patients will benefit from these improvements, but the change in methods, techniques and systems often lead to unstable, untried and risky situations.

Atul Gawande, a surgeon in a Boston hospital, describes this learning curve of improvements in an excellent manner in his book 'Complications'¹. He reports on the results of a novel surgical technique by a group of surgeons from a famous paediatric surgical clinic in London. The surgeons, who originally published their results in the *British Medical Journal* in 2001, performed surgery in the period 1978–1998 on 325 children with a severe cardiac defect called 'transposition of the main arteries'. Without surgery, babies would die at an early age from insufficient oxygen saturation. The conventional surgical method, the so-called Senning procedure, was successful. Children could grow up to adult age but still had a much lower life expectancy. Technical developments made it possible to correct the transposition of arteries at a young age, and this novel surgical technique was introduced in the London clinic in 1986. For the entire cohort of patients, the novel technique was a success: the number of patients dying per year had decreased by more than 75% and the life expectancy of the patients had increased from 47 years with the Senning procedure to 63 years with the new technique. However, it appeared that the price for introducing this new technique was extremely high. For the first 70 surgeries involving the novel technique, a death rate of 25% was found, as opposed to only 6% involving the Senning procedure, and with the introduction of the technique, 18 babies died, twice as many as during the entire Senning period. With the gaining of experience, the number of deaths decreased dramatically: 5 babies died during the next 100 operations. This case illustrates that 'doing no harm' is not an absolute ideology. Moreover, it makes us realise that the introduction of a change is itself a risky operation.

This special issue of *Pharmacy World & Science* is dedicated to medication safety and medication errors. It not only reflects and reports on initiatives to make a safer drug distribution system for our patients, it also illustrates the complexity of the apparently simple concept of risk.

Reference

1. Atul Gawande. *Complications*. New York: Metropolitan Books, Henry Holt and Company, 2002.

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