Evidence-Based Medicine Doesn’t Preclude Common Sense

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If you went skydiving, would you first ask for scientific evidence from a randomized trial that a properly functioning parachute prevents injury before you’d consider using one during your freefall?

Probably not.

In fact, no such study exists. Of course, some people without a parachute have survived a freefall from extraordinary heights without injury, and others have sustained injuries even when using a parachute. But it’s clear that you’d use a parachute when skydiving, even without a single randomized trial to prove its effectiveness. Yet, when it comes to medicine, clinicians may be reluctant to employ any intervention without rigorous scientific evidence for its efficacy.

The need for sound evidence evolved from a history of medicine that’s littered with practices that were later abandoned from a history of medicine that’s littered with practices that were later abandoned. After all, who would allow themselves or their family member to be randomly assigned to a control group—be it freefalling without a parachute or being the recipient of a prescription using an abbreviation like “U” for units, each with anecdotal evidence of causing harm. Moreover, an institutional review board would never approve either study.

The incredibly large scope of a study that could prove efficacy might also be a limiting factor. For example, let’s consider the practice of requiring a leading zero for doses of less than one (e.g., 0.10). Perhaps only one in 100 clinicians would misread the dose as a whole number (10) if the leading zero were omitted. Maybe one in five such errors (20%) would affect the patient and 1 in 10 errors (10%) would cause significant harm. It would be incredibly difficult to carry out a controlled study of sufficient size to prove that patient harm is reduced when leading zeros are used. More to the point, is such a large and costly study needed if experience tells us that leading zeros reduce the risk of errors, some of which have caused significant patient harm?

A MORE BALANCED APPROACH

In the end, a traditional evidence-based approach cannot be our only source of promoting patient safety. The safe administration of anesthesia is a good example.

Although mortality rates during elective anesthesia have declined by 10-fold in the past few decades, this achievement was not driven by meticulous scientific evidence that certain practices reduced mortality. The reduction was not attributable to any single practice, new drug, or technology. Instead, a broad array of changes were required in processes, equipment, organizational leadership, education, and teamwork—not one of which has had a clear-cut impact on mortality. Rather, safety was achieved by applying a host of changes that (1) were based on an understanding of principles involving human factors as well as on a clear link between certain processes and observed adverse events (e.g., an anesthesiologist giving medications), (2) were learned from safety practices in other industries, and (3) made sense, considering the potential risks and benefits of the interventions.

These criteria, then—common sense, principles involving human factors, a linkage between processes and adverse events, and lessons learned from safety practices in other industries—should not be given short shrift in favor of evidence-based interventions alone. In fact, it would be tragic to abandon safety initiatives such as pharmacy intravenous admixture systems and computer-generated medication administration records (MARs) simply because they are not backed by scientific evidence. And to await irrefutable proof of effectiveness is simply not an option. We must make informed decisions based on the best available information and common sense.

REFERENCES