Facing the Challenge of Modern Anesthesia Technology: Alarms, Ergonomics, Software and Cognitive Burden

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Who among us has not encountered frustration getting his or her computerized anesthesia machine to check out properly or spent many an anxious minute (anxious to the patient, anyway) trying to troubleshoot the electrocardiogram, the pulse oximeter or some other item prior to inducing anesthesia? Similarly, who has not expressed annoyance when the source of an alarm is completely unapparent or when an ASYSTOLE alarm occurs despite the presence of both a good arterial blood pressure waveform and a high-quality pulse oximeter tracing? These are examples of the difficulties anesthesiologists frequently face in dealing with modern anesthesia technology. Some of these challenges divert vigilance away from direct patient monitoring as attention is focused on addressing some technical problem. (In aviation a similar problem exists; in one famous case, both the pilot and copilot focused their attention on troubleshooting a faulty landing gear indicator, only to subsequently crash into a mountain.)

Problems related to poor software design or careless user interface design have also led to patient harm. In this presentation, I discus some approaches clinicians and engineers are employing in dealing with the above challenges.

Ergonomics

Ergonomics is the art and science of matching equipment design and job procedures to the worker, usually with a view to reducing error and improving productivity. Also known as "human factors engineering," ergonomics is a relatively new discipline, but one which has already led to enormous improvements in design. As a result, equipment ranging from photocopiers to nuclear power plants have all seen improvements from the application of ergonomic principles. Still, examples of confusing, baffling and even dangerous designs produced in violation of ergonomic principles are not hard to find; Michael J. Darnell's website **www.baddesigns.com** offers a collection of frequently amusing examples. But when bad designs lead to injury or death, the situation is far from entertaining. This is sometimes the case for anesthesia equipment. For instance, ergonomic flaws in the Abbott Lifecare 4100 PCA Plus II machine have been held to be responsible for a number of opiate overdose deaths.[1]

The FDA website offers a valuable ergonomic resource titled "Do it by Design" that is full of design hints and cautionary tales.[2] One relatively new design approach, known as "ecological interface design,"[3] has much to offer designers, but has not been universally embraced, likely due to the time, effort and money needed for its implementation, as well as the fact that many designers are simply unfamiliar with the concept.

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Software

Computers are now being increasingly introduced into safety-critical systems such as aircraft and medical equipment and, as a consequence, have been involved in a number of deadly mishaps. A noteworthy example was the Therac-25 radiation therapy machine. In 1986, two cancer patients died when they received lethal doses of radiation. An investigation revealed that one factor was failure of the software team to recognize a "race condition," a miscoordination between concurrent tasks. This oversight resulted in a number of individuals being overradiated.

As a result of patients harmed from software defects, the FDA has taken a special interest in the issue.[4] In particular, the 1990 Medical Device Amendments to the Food and Drug Act have led to changes in the regulation of medical software. Regulations now place special emphasis on "quality" issues and the need to incorporate validation criteria in the design from the very beginning. It also replaces prior emphasis on a premarket approval process with an emphasis on postmarket surveillance, while users are now required to report

to the FDA and the manufacturer any defects that cause harm. Of course, while such regulatory oversight improves safety, it also increases development costs and delays the introduction of new innovations to the marketplace.

Alarms

Alarms are important in alerting anesthesiologists to adverse conditions, but they are possibly even more important in clinical environments such as the ICU, where extreme multitasking sometimes occurs. Clinicians frequently lament that the rate of false alarms in the O.R. and ICU can be so high that alarms are effectively useless; some even (unwisely) globally disable all alarms in response. This is not to suggest that academics and manufacturers have not made significant advances in this area; they truly have. But these advances have been regrettably slow to reach the clinical arena, in part because of a complex and daunting regulatory framework.

For example, the false ASYSTOLE alarm mentioned above, which I still frequently encounter, is usually triggered by ECG signal problems. Although this error would appear to be easy to prevent via software when a concurrent, high-quality photoplethysmograph signal is present (in which case the alarm might instead read ECG PROBLEM), such an application of sensor fusion technology[5] continues to be more theoretical than real. Other developments in the alarm arena that are slowly emerging are in the field of "knowledge-based" alarms.[6] For instance, a future patient monitor encountering a combination of hypotension and bradycardia might produce a pop-up window asking the clinician to consider diagnostic possibilities such as high-spinal anesthesia, excessive inhalational anesthesia or excessive beta blockade. Furthermore, one can imagine future systems automatically discontinuing an existing remifentanil infusion in such a setting, or even automatically administering a dose of ephedrine.

The difficulties identified above can take their toll on the clinician in a number of ways, but one important psychological process that persists throughout is the cognitive burden anesthesiologists face as a result of operating in a complex environment whose properties can vary rapidly as clinical circumstances change. This burden can be worsened when the environmental conditions are exacerbated by false alarms, hostile user interfaces and the like. It is time for anesthesia equipment designers and regulatory authorities to renew their commitment to this challenge.

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