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EDITORIAL

Closed-loop systems and automation in the era of patients safety and perioperative medicine

Maxime Cannesson · Joseph Rinehart

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In 2013, General Motors, BMW, Mercedes-Benz, and Tesla all announced that they would bring self-driving cars to market for the general population before 2020 [1]. Some expectations suggest that by 2040, 75 % of all cars will be autonomous [2] and that this may reduce traffic accidents by a factor 10 [3]. In looking ahead at this possibility, three US states have already enacted laws addressing autonomous vehicles (California, Florida, and Nevada). We've come a long way since the model T first rolled off the assembly line.

A moment's reflection will show that automation has flourished in nearly every part of our daily lives. It has made aviation safer and more fuel efficient, modern life more comfortable with the widespread adoption of air conditioning, and has transformed the food industry with the invention of the refrigerator. The whole concept of life and *homeostasis*, described by Claude Bernard decades ago, relies essentially on feedback control; mammalian physiology may be the most sophisticated series of closed loop systems to ever exist.

In looking at our specialty, it is likely that forms of automated anesthesia are the next major disruptive technological innovation we should expect. However, as with most major innovations in healthcare, it may take longer than expected before it becomes a reality. Given the otherwise wide-spread success of these systems, one may rightfully ask why has it taken so long for automated systems to come to fruition and help improve patient safety and outcomes in the perioperative environment. There are several probable causes, but the main hurdles have and will remain regulatory approval, acceptance by clinicians, and misassumptions by the community of clinical scientists on the development pathways that should be taken to bring this concept to the bedside.

Regulatory pathways for developing new technologies have become more difficult during the past 20 years. Some technologies used on a daily basis that were approved 20 years ago would probably not pass the bar of the regulatory agencies today. The European regulatory process has been considered "easier" than the FDA process and this has helped to bring new technologies to the bedside faster in Europe than in the US. However, CE regulations are going to be modified in the next 2 years and it is expected that the new process will be as expensive and as detailed as the FDA process is now. This is good news in some ways, but this is concerning in other ways. For the pessimist, who sees risks and danger in any novel technology, this is good news because it guarantees that new technologies will have to be extensively tested and their benefit will have to be demonstrated before commercial sales begin. For the optimist, who sees the benefits new technologies will ultimately bring, this is bad news because it may delay the implementation of new solutions to old problems [4].

The second significant hurdle to automation is going to be acceptance by clinicians. *A priori*, when the concept of closed loop is presented to anesthesiologists, the first reaction is to say: "Wow, you are trying to replace us and to take over our jobs!" If we, as anesthesiologists, truly believe that the entirety of our job is to push the plunger on a propofol syringe, turn the sevorflurane canister on and off, or adjust the flow rate of the crystalloid bag during surgery then, yes, closed-loop systems are a threat to our profession. On the other hand, if we believe that our job is

M. Cannesson (✉) · J. Rinehart
Department of Anesthesiology and Perioperative Care, School of Medicine, University of California, Irvine, 101 S City Drive, Orange, CA 92868, USA
e-mail: mcanness@uci.edu

to optimize our patients in the preoperative period, to set medical strategies and resuscitation endpoints during surgery and manage complex physiology in the face of ongoing stress, and to conduct postoperative medical management in the recovery rooms and in the ICUs, then closed-loop systems are no more a threat to our profession than autopilot has been to airline pilots. These systems are an opportunity to guarantee that our chosen strategies are consistently applied and that our physiological goals are met; they are tireless servants that take our direction and make us more efficient and more effective. In our own personal experience, closed-loop systems, once actually used by care providers, are quickly seen not as a threat but as valuable and desirable tool like any of the other familiar devices in the operating room. On the other hand, if "expert system" and "decision support" may a priori be perceived as more acceptable, these systems dictate the strategy and clinicians then just apply the treatment… The question is then: What role do clinicians want to play in the delivery of care? Do we want to be the brain or do we want to be the hand? Our guess is that we would rather be the brain…

The last hurdle to automation may be how these technologies are developed and brought to the market. Recently, the Sedasys® (Ethicon®, Somerville, NJ, USA) has become commercially available. The purpose of this system is to allow safe administration of propofol during colonoscopy, but the intended users for this system are not anesthesiologists, they are gastroenterologists. For decades, anesthesiologists have worked on making anesthesia and sedation safer and we have been tremendously successful in this goal. While a closed-loop system may be able to accurately administer propofol, neither the Sedasys nor our gastroenterology colleagues are as qualified to perform airway management, resuscitation, or hemodynamic management appropriate for the wide range of clinical effects propofol may have as an anesthesiologist would be. This system, therefore, while standardizing propofol administration during colonoscopy and providing a level of safety assurance, may nevertheless have created a new set of risks to patient safety related to sedation by replacing the best-trained rescue providers. The FDA recognized this fact and required, as a condition of use, that the Sedasys "will only be offered to facilities where an anesthesia professional is immediately available to the user for assistance or consultation as needed" [5]. We strongly believe that the goal of automation is not to *replace* a qualified care provider normally required for a particular task or intervention, but rather to *assist* a standard provider in application of an intervention. The goal of perioperative automation, therefore, should be to make patient safety stronger by supporting anesthesiologists in the way they deliver care to their patients while at the same time increasing compliance to clinical protocols that have been shown to improve outcome [6]. In the present era of bundle of care, systematic application of best evidence/best practices, coordination of care, enhanced recovery after surgery programs, and perioperative surgical home, we believe that such systems will be of tremendous help to the community.

In this special issue of the Journal of Clinical Monitoring and Computing, we are pleased to present six excellent papers on the concept of closed loop in the perioperative period. Dumont et al. [7] present a very synthetic overview of feedback control for clinicians in order to demystify the concept. Wang et al. present a simulated environment for the evaluation of closed-loop systems [8]. This is of major importance because controllers must be tested in a very specific way before use on patients is justified. It would not be acceptable to start a clinical trial with a new drug before extensive laboratory testing would be performed; why would we accept any less with a closed loop system? *Thomas Hemmerling's* group in Montreal, Canada, present two manuscripts: one on a novel pharmacological anesthesia robot [9] and one on decision support for anesthesia which improves clinical management during orthopedic surgery [10]. Dussaussoy et al. [11] describe the impact of closed loop on workload during vascular surgery. Finally, Wysocki et al. [12] present an exhaustive review on closed loop mechanical ventilation.

All of these papers present closed-loop systems as an aid to the clinicians. The authors and developers of these systems strive to provide solutions to make the perioperative setting ever safer and more consistent for our patients. At the end of the day, the more technology can handle the mundane tasks we have to accomplish during patient management, the more we will be able to focus on what once made us become physicians: the art of medicine and the ethical and compassionate care of our patients.

Conflict of interests Maxime Cannesson and Joseph Rinehart are the inventors on several US and International patent applications related to closed-loop fluid administration and hold equity positions in Sironis, a company developing closed-loop medical devices.

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