03RC1

Automation and computerisation – how much is enough?

C. J. Kalkman

Perioperative & Emergency Medicine, University Medical Centre Utrecht, Utrecht, The Netherlands

Saturday, June 6, 2009 14:00 - 14:45 Room: Yellow 3

Computing in anaesthesia: a little bit of history

The 1980s saw the rapid development of personal computing. Affordable personal computers such as the Atari, Apple II, BBC Micro and the first IBM PC suddenly made computing available to the masses. In September 1983 an international group of anaesthesiologists eager to explore computing applications for patient care and research attended the '*First Symposium on Computing in Anaesthesia and Intensive Care'* in Rotterdam, the Netherlands. Twenty-five years later almost every electronic device has a built-in microcomputer and computerisation of medical devices is absolute. Many of the early promises of computerisation have become a reality. For example, the large amounts of computing power needed for advanced monitoring modalities such as echocardiography, EEG or evoked potentials were previously only available in bulky and expensive devices. The telecommunication revolution made it possible that EEG monitors and powerful computers can be built into extremely small packages and manufactured at very low cost (Figure 1). Other technologies are emerging, such as the combination of advanced optics and computing power for non-invasive continuous monitoring of tissue oxygen, haemoglobin or even glucose. In contrast, other promises such as closed-loop control of anaesthetics [1-3] or even vaso-active drugs [4] have mainly remained in the realm of the laboratory and the hands of dedicated clinical researchers.

Figure 1

The evolution of EEG monitors and personal computers 1977-2009

To what extent are developments with computerized drug delivery and closed-loop control solutions for real clinical problems or ‘gadgets’ for technically talented anaesthesiologists? Closed-loop control of neuromuscular blockade is certainly feasible [5, 6] and relatively safe; overdosing will necessitate postoperative mechanical ventilation. In contrast, errors with closed-loop administration of vaso-active drugs could kill a patient. Potential sources of error are unreliable blood pressure data or undetected software errors. Interestingly, even the model-based ‘target- controlled’ infusion of hypnotics that has long been available to anaesthesiologists in Europe is still not approved in the US by the Food and Drug Administration. Much to the chagrin of TCI enthusiasts, FDA employees have expressed vaguely defined fears such as ‘important health implications’, ‘significant incremental risk’ of anaesthetic controllers, ‘combining high level languages, general purpose computers, and complex operating systems that might result in products that are too elaborate for the developer to verify entirely’ [7]. The logical result is that manufacturers have been discouraged from developing improved systems and entering this market.

Automation vs the experienced human operator: who is in charge?

There seems to be a dividing line between Europe and the US regarding the amount of control we are willing to hand over to automation. The Americans seem to be more distrustful of computers taking control than Europeans. Nonetheless, it is impossible today to make any scheduled flight in a modern jet aircraft without entrusting one’s life to the proper functioning of a large amount of computer systems, both in the plane and on the ground. The two major aircraft manufacturers, Boeing and Airbus, have opposing views as to the degree to which the flight data management computers should be able to overrule a pilot when he is about to subject the aircraft to dangerous extreme attitudes and control movements. While each aircraft will generate alerts and voice alarms (“pull up!”, “too low, terrain!”), the automation of a Boeing will never take control away from the pilot and will grant him the power to decide how to steer the plane. In contrast, Airbus has decided that the safety of the flight is best guaranteed if the automation can overrule a pilot who is about to perform a very dangerous manoeuvre. These differences in ‘control philosophy’ will soon become important in health care. Designers of anaesthesia machines and delivery systems are already confronted with such decisions. Similar design issues also confront software developers who build hospital-wide electronic patient record systems. Should a doctor be blocked from prescribing penicillin to a patient when the ‘allergy’ data field contains: ‘allergic to penicillin’, or should she only be warned and required to electronically sign a motivated waiver?

Taken together these issues constitute the field of *human factors*. It is remarkable how many industries have embraced the science of human factors to help them improve man-machine interaction, the design of user interfaces and team interaction. Healthcare has been slow in adopting human factors knowledge into the design of its processes and equipment. The rapid rise in complexity of care, new technology and increasing pressures to produce both efficient and safe care, make it necessary to better reflect on the design of interfaces to IT systems and medical devices.

Anaesthesia Information Management Systems (AIMS)

With the advent of personal computers, automated anaesthesia record keeping systems in the operating room became a realistic option. Early systems were often created locally by engineers and anaesthesiologists. There are now worldwide about a dozen manufacturers of anaesthesia record keeping systems. A computerised anaesthesia record is always legible, consistent in its organisation and more complete when compared with handwritten records. Manually entered blood pressures and heart rates are typically ‘smoothed’ by the anaesthesia provider, meaning that extreme values are altered slightly up or downwards towards the average [8]. Reich et al compared handwritten and computerised records and concluded that there are sufficient discrepancies to suggest that some data in handwritten records are inaccurate [9]. Peaks in systolic blood pressure were higher and troughs were lower in the computerised records. This potential inaccuracy should always be considered whenever handwritten records are used as material for research, quality assurance, or legal purposes.

An important legal issue is automatically recorded *invalid* physiological values. For example, heart rate is unreliable when the ECG cannot consistently detect a QRS complex, blood pressure artefacts occur when a surgeon is pressing his abdomen against a blood pressure cuff during measurement, or erroneously low end-tidal CO_2 values may result from leaks in the breathing circuit. It is, therefore, important that the anaesthesiologist ‘annotates’ the computerised anaesthesia record whenever there is a suspicion that the automatically recorded physiological values are inaccurate. Wax et al recently studied the frequency of such corrections in almost 30,000 cases and found that 19% of records had one or more data points manually invalidated by the anaesthesiologist [10].

Factors determining the acceptability of AIMS

Changing from paper-based record keeping to computerised anaesthesia records is a considerable project for any anaesthesia department; it can result in stress and even outright opposition from staff and nurses. Several factors will influence the acceptability of AIMS. Ease of data entry is extremely important. Does the system have an intuitive user interface that mimics the old way of working, or is the screen confusing and cluttered with icons? Is it overly configurable, so that it never looks the same in different operating rooms? How much time is spent entering a bolus dose of 5 µg sufentanil, or is it just as easy as before? Can you position new data exactly at the correct time point when data are entered some time after the event (for example, after a difficult intubation or after an intra-operative crisis)? These issues, collectively grouped under usability, have been surprisingly little studied. Figure 2 shows examples of some anaesthesia record keeping screens. Unfortunately, many systems were designed by engineers and programmers with little understanding of ergonomics and the intricacies of the anaesthesia workflow, which increased resistance from those who were already biased against the use of an AIMS.

Figure 2

Examples of Anesthesia Record Keeper main screens

Fear of litigation

This remains a major obstacle to acceptance of AIMS in some departments. Some colleagues fear that the ‘unfiltered’ physiological data will help lawyers to paint a picture of complacency and malpractice after a serious adverse event. Is there evidence that this fear is justified? Could the use of AIMS facilitate litigation after an incident that resulted in patient harm? Or is the reverse the case and will the AIMS protect anaesthesiologists against unjust accusations and thus reduce the risk of being convicted for malpractice/negligence? Obviously, AIMS will make all our actions and their immediate consequences for the patient transparent. In a survey among anaesthesia departments that had used AIMS for at least 5 years, 41 malpractice cases had been filed since adopting the technology. Only 11 of the cases went on to settlement or litigation. There were no reported cases in which the automated record hindered the defence process. Many respondents viewed AIMS as valuable for risk management [11].

Audit trails and prospective data entry

Anaesthesiologists may be tempted to improve workflow by documenting events that have not yet taken place, for example entering the time of emergence prospectively in order to have one's hands free during the actual event. Although tempting, this practice will undermine the integrity of the anaesthesia record after an adverse event, because all modern AIMS will attach a time stamp (date and time) to every item entered, thus creating a recoverable 'audit-trail'. Lawyers who are aware of this feature may ask to see this audit-trail, and can accuse the clinician of lying if evidence of prospective data entry is found [12].

Recording of anaesthesia complications

Many modern AIMS have incorporated a facility to record anaesthesia complications, using a structured format with additional free-text fields for commentary. Such systems can greatly facilitate the organisation of morbidity/mortality conferences and track changing patterns of anaesthesia complications. Regulatory bodies in several European countries have started to demand that practitioners implement local systems to record and discuss complications.

Extending the AIMS: pre-operative and postoperative care

Most AIMS systems started as intra-operative anaesthesia record keepers, using local standalone computers that communicated only with the anaesthesia machine and patient monitors. Today most AIMS are networked and part of the hospital IT infrastructure. This creates the opportunity to integrate pre-operative, intra-operative and postoperative data, including laboratory data and imaging, which greatly enhances their clinical utility. For example, pre-operative instructions, risk scores and warnings can be transferred to the operating room display and made available to the anaesthesiologist who will perform anaesthesia, even without the need for the clinician to actively log into the system and select the patient's pre-operative data record. By installing AIMS workstations in the recovery room and ICUs, continuity of physiological data recording is guaranteed. In addition, capture of adverse events occurring in the immediate postoperative period now becomes feasible. Documenting postoperative pain scores and postoperative nausea and vomiting (PONV) can help to fine tune departmental protocols for pain and PONV.

Decision support

There is increasing interest in using AIMS to help remind clinicians of tasks and actions that can be easily forgotten in case of distractions. 'Friendly reminders' have been designed to alert the anaesthesiologist to administer prophylactic antibiotics within a predefined optimal time window, for example between 60 and 15 min before skin incision. After the start of a new case the system continuously checks if induction of anaesthesia already has taken place and then triggers the alert if the anaesthesiologist has not entered a dose of antibiotics within 15 min after induction. Alerts can be visual ('antibiotics?'), auditory ('beeps' or spoken messages) or a combination of both, depending on the preferences of the department. Studies showed that such automated alerts increase the proportion of patients who receive the required antibiotics with the correct time frame [13, 14].

Other potential uses of automated reminders are to alert the clinician to an increased PONV risk, prompting administration of prophylactic anti-emetics [15] and reminders to record the presence of anaesthetic complications ("please fill in the anaesthesia complication record"). The latter kind of reminders can also be sent out at a later time in an email message to the anaesthesiologist, asking to complete the anaesthesia record. A hyperlink can be added in the email that will take the provider immediately to the correct location in the database [16].

Unintended consequences of technology: problems and pitfalls of automation

We have already discussed the potential issues of handing over control to automation and the fundamental design dilemmas they pose. As we rapidly move towards hospital wide electronic patient records (EPR) and computerized physician order entry (CPOE), new types of errors can occur. Several studies have shown that CPOE reduces the number of medication error, but it is unclear to what extent serious new errors resulting from working with a computer interface might counterbalance the benefits of CPOE. To select a drug, so-called 'pick lists' are used in pull-down menus. It is relatively easy to accidentally select the item below or above the correct item in an alphabetic pick list. A similar problem might occur with preformatted order sets.

Will automation promote complacency? When automated blood pressure monitors appeared, taking a blood pressure was no longer an act that involved feeling the patient's pulse. Some experienced anaesthesiologists expressed fear that automated blood pressure monitoring would reduce vigilance and lead to anaesthesia practice that is less 'hands-on'. Similar objections have been voiced against automated anaesthesia record keeping systems: they might discourage systematic scanning of the monitors and promote complacency. Few studies have addressed this issue. Loeb et al found no evidence for reduced vigilance when anaesthesia residents were relieved of the task of charting the anaesthesia record [17]. Weinger et al also were unable to document a reduction in vigilance when an anaesthesia record keeper was used during anaesthesia for cardiac surgery [18].

What if the system fails: are we ready?

The more hospitals start to rely on IT solutions for their clinical processes, the more critical such systems become for safe patient care. Beth Israel Hospital in Boston, USA was a pioneer with EPR and its residents had never used paper-based records or ordering. In November 2002 the network was down for 4 days, forcing doctors and nurses to revert back to pen and paper. The cause of the problem was later discovered. A researcher had started to upload several gigabytes of data and the process was stuck in an endless loop blocking the network. Separating databases for research and clinical use clearly is mandatory, using 'mirror' databases for all clinical research queries.

The issue of how to balance the need for redundancy with the additional costs is also unresolved. Pagers and analogue telephones are on the brink becoming extinct and new technologies such as voice over IP (VoIP) are ready to take over. The risks of entrusting all communications (data and voice) to a single hospital network are immense. If today a part of the hospital information system fails, doctors and nurses can still use the telephone to communicate with colleagues, the emergency room, ICU or the laboratory. If the network is also used for voice communication and the network is down, all communication except talking face to face becomes impossible.

The business case for AIMS: finance, logistics, quality control and research

Billing

Obviously, an AIMS can capture all data items necessary for correct and complete billing, such as the duration of the case, the type and amount of disposables and drugs used, special monitoring or anaesthesia procedures and names of personnel present in the operating room. Again, (email) reminders can be used to prompt staff to complete the anaesthesia record, thus ensuring accurate, complete and timely collection of revenues for the department [19]. In some cases - dependent on the financial aspects of the national health care system - this capability by itself could be sufficient to produce return on investment for an AIMS system.

Scheduling

As many European countries experience shortages of qualified personnel to staff the operating rooms, optimal use of limited available OR capacity becomes extremely important. Optimising operating room scheduling, various types of block allocation and monitoring of utilisation require a mature IT infrastructure. Operating room managers can rely on dedicated software for scheduling or the software can be incorporated into the AIMS. In either case, there needs to be a tight integration between the anaesthesia and scheduling modules.

Quality control

Increasingly, regulators require that hospitals monitor their quality of care both at the level of 'structure' (for example, 'does this hospital have a 24 hour recovery facility?'), 'process' (for example, does every team perform a 'time-out' before surgery?) and outcome (for example, percentage of postoperative wound infections by type of surgery). In addition, it has become accepted among surgeons that for complex surgical procedures a minimum number need to be performed each year to guarantee good outcomes. For anaesthesiologists, the AIMS can track the total number of procedures performed, proportion of regional anaesthesia and a subdivision in the various types of regional blocks, number and nature of anaesthesia complications (derived from voluntary reported complications in the AIMS). In addition, the AIMS can also be used to systematically study process deviations such as hypotension, tachycardia or hypoxaemia.

Research

For research-oriented anaesthesia departments the AIMS can be a rich source of clinical data that can help answer such questions as: what is the relationship between intra-operative events and postoperative outcomes; can we predict the occurrence of intra-operative events (for example, hypotension on induction of anaesthesia); and, can we prevent certain intra-operative incidents and postoperative complications as PONV using a risk-tailored approach based on pre-operative quantitative risk-assessment [20]?

Conclusions

Computers and automation have arrived and will remain an integral part of anaesthetic practice. Computer control is already built into many new anaesthesia devices, but closed-loop control of critical anaesthesia processes such infusion of vaso-active drugs or hypnotics remains in the experimental domain. Installing an AIMS and parting with the paper-based anaesthesia record can bring several advantages to an anaesthesia department. The fear for increased legal risk is not supported by the literature. In contrast, lawyers are more likely to build a successful case of complacency with a half-empty handwritten anaesthesia record. This wave of IT also creates new challenges, as we slowly discover the unintended consequences of this technology. Unique new types of error such as selecting the wrong drug from an alphabetic pick list require new solutions. Considerable clinical benefits may come from decision support in the form of computerised reminders and alerts, but we do not know the risk-benefit ratio of allowing IT to overrule the doctor. Finally, as hospitals become dependent on the correct functioning of their network and tightly coupled IT subsystems, sufficient redundancy needs to be built into the system.

Key Learning Points

- Despite tremendous advances in computing power and software tools, the closed-loop control of anaesthetic drug delivery has remained experimental.
- Anaesthesia Information Management Systems (AIMS) will proliferate in the next decade.
  They provide a far more accurate representation of the physiological variables in the peri-operative period. Fear for increased litigation risk with AIMS is probably unjustified.
- AIMS can contribute to safer care by generating automated alerts and reminders, for example, a reminder to administer prophylactic antibiotics within the optimal time window.
- The more systems replace paper-based documentation, the more we become dependent on the correct functioning of software, servers and the network; it is crucial that sufficient redundancy is built into these systems.
- In the near future we will need to make conscious decisions regarding the desired ‘control philosophy’:
  will we allow software to generate reminders and alerts only, or will we allow algorithms to overrule our decisions?

References

1. Absalom AR, Kenny GN. Closed-loop control of propofol anaesthesia using bispectral index: performance assessment in patients receiving computer-controlled propofol and manually controlled remifentanil infusions for minor surgery. Br J Anaesth 2003; 90: 737-41.
2. Liu N, Chazot T, Trillat B, et al. Feasibility of closed-loop titration of propofol guided by the Bispectral Index for general anaesthesia induction: a prospective randomized study. Eur J Anaesthesiol 2006; 23: 465-9.
3. De Smet T, Struys MM, Greenwald S, Mortier EP, Shafer SL. Estimation of optimal modeling weights for a Bayesian-based closed-loop system for propofol administration using the bispectral index as a controlled variable: a simulation study. Anesth Analg 2007; 105: 1629-38.
4. McKinley S, Cade JF, Siganporia R, et al. Clinical evaluation of closed-loop control of blood pressure in seriously ill patients. Crit Care Med 1991; 19: 166-70.
5. Ebeling BJ, Muller W, Tonner P, Olkkola KT, Stoeckel H. Adaptive feedback-controlled infusion versus repetitive injections of vecuronium in patients during isoflurane anesthesia. J Clin Anesth 1991; 3: 181-5.
6. Lendl M, Schwarz UH, Romeiser HJ, et al. Nonlinear model-based predictive control of non-depolarizing muscle relaxants using neural networks. J Clin Monit Comput 1999; 15: 271-8.
7. Egan TD, Shafer SL. Target-controlled infusions for intravenous anesthetics: surfing USA not! Anesthesiology 2003; 99:1039-41.
8. Block FE, Normal fluctuation of physiologic cardiovascular variables during anesthesia and the phenomenon of “smoothing”. J Clin Monit 1991; 7: 141-5.
9. Reich DL, Wood RK, Mattar R, et al. Arterial blood pressure and heart rate discrepancies between handwritten and computerized anesthesia records. Anesth Analg 2000; 91: 612-6.
10. Wax DB, Beilin Y, Hossain S, Lin HM, Reich DL. Manual editing of automatically recorded data in an anesthesia information management system. Anesthesiology 2008; 109: 811-5.
11. Feldman JM. Do anesthesia information systems increase malpractice exposure? Results of a survey. Anesth Analg 2004; 99: 840-3.
12. Vigoda MM, Lubarsky DA. The medicolegal importance of enhancing timeliness of documentation when using an anesthesia information system and the response to automated feedback in an academic practice. Anesth Analg 2006; 103: 131-6.
13. O’Reilly M, Talsma A, VanRiper S, Kheterpal S, Burney R. An anesthesia information system designed to provide
14. physician-specific feedback improves timely administration of prophylactic antibiotics. Anesth Analg 2006; 103: 908-12.
15. Wax DB, Beilin Y, Levin M, et al. The effect of an interactive visual reminder in an anesthesia information management system on timeliness of prophylactic antibiotic administration. Anesth Analg 2007; 104: 1462-6.
16. Kooij FO, Klok T, Hollmann MW, Kal JE. Decision support increases guideline adherence for prescribing postoperative
17. nausea and vomiting prophylaxis. Anesth Analg 2008; 106: 893-8.
18. van Wolfswinkel L, Kalkman CJ. Improved compliance with voluntary reporting of anesthetic complications using unobtrusive intraoperative probing and postoperative email reminder. ASA Annual Meeting, 2005: Abstract A1298.
19. Loeb RG. A measure of intraoperative attention to monitor displays. Anesth Analg 1993; 76: 337-41.
20. Weinger MB, Herndon OW, Gaba DM. The effect of electronic record keeping and transesophageal echocardiography on task distribution, workload, and vigilance during cardiac anesthesia. Anesthesiology 1997; 87: 144-55.
21. Reich DL, Kahn RA, Wax D, et al. Development of a module for point-of-care charge capture and submission using an anesthesia information management system. Anesthesiology 2006; 105: 179-86.
22. Apfel CC, Laara E, Koivuranta M, Greim CA, Roewer N. A simplified risk score for predicting postoperative nausea and vomiting: conclusions from cross-validations between two centers. Anesthesiology 1999; 91: 693-700.