

Using portable digital technology for clinical care and critical incidents: a new model

Stephen N Bolsin, Tom Faunce and Mark Colson

Abstract

The number of patients suffering adverse incidents during treatment in hospitals is not declining. The cost of this poor safety record in Australia is \$1 billion to \$4.7 billion each year. Quality and safety initiatives focus on promoting adverse event reporting. Major problems include poor reporting of adverse events and lack of clinician involvement.

We propose a model for clinician-led reporting based on secure transmission of encrypted data from a programmed personal digital assistant (PDA) to a secure database, leading to automated analysis of clinician-performance data. The programmed PDA also facilitates the reporting of critical incidents. All critical incidents are automatically fed back by email to the organisational quality managers.

Aust Health Rev 2005; 29(3): 297–305

What is known about the topic?

New information technologies promise to make meaningful, accurate data about patient care broadly available, and the potential advantages for quality and safety have long been anticipated. Realising those benefits has been a difficult and slow process.

What does this paper add?

A system which enables anaesthetists to record routine clinical data, and critical incidents, by means of hand-held computers has been successfully introduced in three major hospitals, with good results. Careful attention to the ownership and security of data, and the questions of cost and indemnity have been critical to the success of this model.

What are the implications?

Direct input of clinical data by clinicians at the point of care is practically and financially feasible, and professionally acceptable, in at least some settings, and offers significant potential benefits for the safety and quality of patient care.

The problem in health care

The available evidence suggests that the percentage of hospitalised patients suffering an adverse incident during admission is not declining.¹⁻⁵ Major inquiries into publicised revelations of substandard health care performance continue to find one of the major contributing factors is an

institutional and professional culture opposed to self-reporting and open disclosure.⁶⁻¹⁰ The costs of this continuing poor safety record run to billions of dollars in most developed societies.^{1,5,11} Current quality and safety initiatives focus on promoting adverse or sentinel incident reporting to institutional committees seeking to discover contributory causes and implement corrective strategies.^{1,12,13} Unfortunately, poor individual reporting rates for adverse events in health care and inadequate clinician involvement in the related processes continue.^{1,14-18} This is despite other industries, such as aviation and environmental resource management, making considerable progress in this area.^{19,20}

The adoption of sustained health care quality improvement programs is similarly poor despite the fact that numerous authors have documented the benefits of such programmes to improved

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patient outcomes.²¹⁻²³ There is a clear need for routine performance monitoring by all clinicians. This will involve clinicians, or their specialist associations or Colleges, in approving and sanctioning the collection and analysis of routine performance data.²³⁻²⁵ The available evidence seems to suggest patchy commitment to such data collection on individual clinical performance, and also to incident reporting, for a variety of reasons.^{23,26-28}

Medical practitioners in all practice areas are currently accorded professional status from society and government, with the attendant privileges, in return for ensuring consistently high standards of practice.^{29,30} When self-regulation fails, as it did in the Bristol Royal Infirmary, The Winnipeg, The Canberra, and the King Edward Memorial hospitals, or the Harold Shipman case, then many in society tend to lose trust in the profession and government is pressured to increase external regulation or ensure adequate self-regulation.^{9,29-36} Exposure of high levels of safety breaches and poor quality in health care, though a necessary antidote to inefficient quality and safety processes, raises the public anxiety about medical self-regulation.⁶ If self-regulation is to be preserved, the profession and government must act to ensure an effective commitment to high quality and safe health care provision.²⁹

Such considerations also arise from the current significant and increasing costs of medical indemnity in Australia, which has some parallels in the United Kingdom.^{4,37,38} These increased indemnity costs may in part be related to an unsustainable level of adverse events in Australian health care,² of which more than one third were attributable to a failure or complication of a technical procedure.³

Some UK studies suggest that failure to report adverse events arises at least partly from a culture in the medical profession that does not support the open or confidential disclosure of poor safety or performance.^{16,17,26} Evidence from medical educators suggests that medical students become worse at reporting incidents of unethical behaviour during their training.^{39,40} A "hidden" or informal curriculum of medical education has

been identified and blamed for this decline in medical students' ethical standards, related to adverse event reporting, during training.⁴¹⁻⁴³

In this context, any proposed model for performance monitoring and incident reporting needs to be able to demonstrate that it can effectively deal with these aspects of the medical profession and its culture, if it is to be of long-term value in improving health care quality and safety.

Regulatory theory tells us that communication among peers, and between regulators and those they are regulating, contributes significantly to the success of most regulatory systems.⁴⁴ Furthermore, ignoring the qualitative and emotional content of these conversations may inhibit our understanding of the nature of the problem and, consequently, the most appropriate regulatory response.⁴⁵ Numerous health care quality and safety inquiries have concluded that secrecy inhibits and obstructs the creation of a culture of open disclosure, incident reporting and personal performance monitoring.^{6,10} These findings imply that transformational change of the institutional and professional cultures of secrecy is required. Regrettably, the means by which to bring about such a change efficiently is rarely discussed in the health care literature. However, emerging evidence suggests that precisely this type of cultural change is being achieved in ANZCA-accredited trainees (Australian and New Zealand College of Anaesthetists) in Australia using portable digital technology.^{41,46-48} The key elements, costs and benefits of this model are outlined below. Requirements for broader implementation are also considered.

A potential solution: self-reporting and personal digital technology

This article proposes a practical model for changes in approach that may have broad application to health care quality and safety in Australia. The model has been developed and accepted within anaesthesiology, with greater than 26 000 cases already reported from 100 Australian hospitals (Sync International, unpublished data). We contend that the model could be

implemented across all specialities with significant benefits. The most interesting feature of the model is the linkage of conscience and professional virtue, and the desire for personal and professional development, with modern portable digital technology embedded in existing clinical governance structures.

The new model for health care quality and safety we are proposing employs a programmed personal digital assistant (PDA) to collect three types of clinical data.

- *Case exposure or "logbook" data.* The PDA programme generates a detailed logbook of all cases undertaken by the clinician. The programme records important information such as level of supervision (for trainees), in-hours or out-of-hours work, type of anaesthesia employed, type of surgery undertaken and location of the case.
- *Personal performance data.* The clinicians themselves undertake the collection of personal performance data at the point of care. Thus the data entered is trusted, reliable and relevant from the clinicians' viewpoint. These features are more likely to encourage clinicians in ongoing collection of performance information. The data collected includes success or failure at procedures such as arterial line insertion, central venous catheter (CVC) insertion, spinal and epidural completion.
- *Incident reporting.* The programmed PDA also facilitates the reporting of critical incidents in the practice of the clinician at the place and time that the incident occurs.⁴⁶ This has led to a documented 98% incident reporting rate in ANZCA trainees.⁴⁸ The incidents are reported by single screen touches to a drop down menu of 8 possible categories of incident with sub-classification of each major incident reporting type. The classification is currently derived from literature reviews of best practice but is being developed to fit into proprietary risk management software such as "Riskman" (Sync International, unpublished data). The system allows the entry of free-text descriptions of all incidents.

Furthermore, the registrars have reported inci-

dents when "minor" or "no" patient harm has occurred.⁴⁸ This is the "near miss" incident data, which has been the "holy grail" of health care safety experts, and was said to be the most important safety information in transforming civilian aircraft safety in the 1970s.¹³ In the proposed model, all critical incidents are automatically and electronically fed back by email to the departmental morbidity and mortality coordinators. Incidents with "major" adverse patient outcomes or "death" are automatically emailed to the hospital quality manager. This provides a robust technical solution for recording, reporting, analysing and correcting both substantial and near miss incidents in health care organisations.⁴⁹

Incidents are currently classified according to type (eg, airway, cardiovascular, pharmacological, etc.), but could be classified in any way that provides convenient drop down menus on a screen. The ease of incident reporting has been a positive feature of the data collection and is seen as a contributory factor in successful incident reporting.⁵⁰ Further classification of the incidents according to accepted criteria would be an enhancement, but there is not as yet a nationally accepted standard.

Secure electronic transmission of the encrypted data from the PDA to a secure database leads to automated analysis of the performance data in the secure database before secure return of the encrypted analysed data back to the clinician. The data analysis proposed is an industrial quality assurance methodology of the continuous process control type, such as Cusum analysis.^{51,52} This produces an easily interpreted performance chart with acceptable and unacceptable performance boundaries.^{24,53,54}

This is already an accepted standard for registrars accredited by ANZCA in the Geelong, Alfred and Princess Alexandra hospitals, and for other subscribing specialist anaesthetists.⁴⁶ The data collection is linked to ANZCA approval for logbook and procedural performance documentation for accredited trainees. Specialist anaesthetists obtain the full 25 annual quality assurance (QA)-maintenance of professional standards (MOPS) points for

each year of data collection. For comparison, QA-MOPS points can be obtained by attending QA committees (1 point per hour to a maximum of 10); local QA meetings (3 points per hour); or 25–30 points for involvement in a clinical project on a QA subject or audit.⁵⁵

Another advantage of this type of continuous process control methodology is that the “acceptable” and “unacceptable” performance boundaries can be modified and changed in the light of information about the clinician or the patient. Thus, the boundaries for a first-year trainee may be set differently to those for a senior specialist. Similarly, the performance boundaries for more complex cases or those with known comorbidities can also be set appropriately to ensure the confidence of the profession in the analysis.

Security

While unauthorised access to the data is a theoretical possibility, the likelihood is extremely remote. The use of personal identifiers for patients has been eliminated by the PDA programme in order to comply with privacy regulations. Thus patient names, dates of birth and unique identifiers are not included in the data logged to the central database. Patient tracking for critical incident analysis is done through the reporting practitioner using the location, time and type of incident reported. With an incident reporting frequency of 3% (of which 50% do not have an adverse outcome for the patient) the practitioner is able to link the incident to a patient and the programme will automatically link the incident to a time of day, location (hospital), anaesthetic and operation type.

- *Password and username access codes.* The PDA-based programme requires password and username access, which is unique to the user and decided by them.
- *Encryption of data before transmission.* The data collected in the PDA is encrypted using SSL (Secure Sockets Layer) encryption before it is transferred to the central database. The level of encryption is 124 bit, which ensures a commercial and military level of encryption, preventing unauthorised access. The data is

currently synchronised to the database through a modem or telephone line. During synchronisation of the PDA over the Internet, the data is encrypted and de-encrypted at both ends (on the hand-held device and on the server) before transmission. This means that in the unlikely event that the data was recorded during the transmission, the data would be in an encrypted form.

- *Database security.* The database is currently in a secure data farm in Victoria, Australia. The database has secure back-up in a separate building and is protected by commercial level security with swipe-card access to the building and password and username access to the database by employees who have been security screened.
- *Web-based analysis of analysed data.* The encrypted data sent to the database is automatically analysed and presented for review via a secure web page. Users with username and password identifiers can only access the individual data. This ensures the appropriate levels of security for the analysed data of individual contributors.

Data ownership and disclosure

A further issue that needs to be clarified is related to the ownership of the data. This is a contentious subject but is governed by simple legal principles, related to the question of who pays and the laws regulating access to the data. Thus, if an individual practitioner pays a subscription to participate in the data collection they have control over access to their data. Similarly, if an organisation has paid for the data collection they have control over the access to the data. However, this control can be a two-edged sword. For example, a survey in the UK National Health Service found that if trainees do not trust the body attempting to collect data they might not cooperate with incident reporting.⁵⁶ Thus control of the database must be coupled with sensitivity to the needs and perceptions of the users in order to gain maximum benefit from the data collection.

A patient has the right to see any data collected about their management during a health care

encounter and could therefore potentially successfully request that their information, but only their information, be disclosed to them. Thus a patient might successfully obtain information confirming that the procedure undertaken on them was unsuccessful but could not obtain information from the database about the outcome of previous similar procedures by the same practitioner.

In our presentations of this topic to medical audiences, one of the early inquiries always relates to the reliability of the data entered through the programme. The question is "How do you know that the practitioner is telling the truth when they say a procedure was successful?" The honest answer to this question is that it is not possible for the programme to detect or prevent dishonest entries on the PDA. The programme as outlined provides clinicians with the ability to record accurate performance data and receive feedback.⁴⁶ We must rely on the honesty of the medical practitioner if the programme is to be of value to health care. If we cannot rely on the honesty of the medical practitioner we must be training doctors incorrectly, and there is some evidence to suggest this.^{39,41-43} We have observed that the use of programmed PDAs seems to reverse the acquired "hidden curriculum" in anaesthetic trainees and may be of value in medical student education.⁴¹

Funding: who pays for what?

The costs of introducing the programme and implementing the data collection would be borne by different parties within the health care system, who would each receive discrete returns for their financial contribution.

The specialist

The specialist pays for subscription to the programme to install on the PDA. For this subscription and participation the specialist may obtain a reduction in medical indemnity premiums, which may be sufficient to cover the cost of the subscription in such specialties as obstetrics or neurosurgery (personal communication, Laurie Williams, Specialist Obstetrician, Melbourne, Victoria).

The hospitals and health care institutions

The hospitals, health care institutions, and possibly the medical indemnity organisations, may pay the subscriptions of their trainees, knowing that the use of the programmed PDA is likely to reduce the potential cost of litigation against trainee anaesthetists.⁴⁷

Indemnity organisations

Indemnity organisations have contributed to the development of the programmed PDA and its implementation with encouraging results.⁵⁷ They may choose to continue their financial support, because of the risk-reduction benefits. If indemnity organisations contribute to the funding of the programme it is possible that they could access the data collected with the programme. As a trusted partner in the indemnity and reporting loop, this access should not be threatening to clinicians.

Colleges and specialist associations

The Colleges and specialist associations may also choose to purchase access to data at an appropriate level of aggregation. The Colleges could fund data analyses demonstrating the level of success of accredited trainees at different levels of training in different procedures. For example, the Colleges might want to quote the success rate for first, second or third-year trainees at CVC insertion, epidural or spinal completion, etc.

One of the major objections cited by health care administrators and clinicians is the cost of introducing the programme at a state or federal level, based on their perceptions of the cost of PDAs and the cost of subscribing to the programme. Although there is a cost for annual subscription, we conclude that the benefits outlined above outweigh the costs.⁴⁷

The Federal Department of Trade and Industry has expressed confidence in the sustainability of the model through their recent decision to award a \$0.53 million grant to the software authors of the PDA programme (DTI Grant Reference Number GRA03204; Project Name: Medical Incident Management and Procedure Collaboration). This funding is to develop the rest of the medical

speciality programmes for the PDA to allow data collection in all areas of medical practice.

Benefits of the model

There are major benefits of the model arising from its potential to improve health care quality and safety in Australia.

To patients

Improved patient outcomes from the monitoring of performance by professionals have occurred in many of the examples now cited in the medical literature, and this is an axiom of health care quality improvement.^{21-23,27} Additionally, patients will be in a position to request information on the outcomes of particular courses of treatment achieved by their treating clinicians. This has been recently proposed as a new ethical standard for surgeons and, by implication, other health care professionals.⁵⁸

To the medical profession and the Colleges

The proposed model will provide clinicians with the ability to improve their practice, and reduce their medico-legal risk, through routine, secure, authorised and personal data collection. There need not be a requirement for publication or sharing of individual performance data, although one specialist using the programme has chosen to print his performance charts to demonstrate the likely risks of complications to patients, in his hands, at a preoperative assessment (personal communication, J Barson, Visiting Specialist Anaesthetist, The Geelong Hospital, Geelong, Victoria).

Participation will fulfil the requirement for clinician involvement in their QA activities,²⁷ and the professionals may also gain other credentialling benefits from public or private employing authorities. They will also have gained transferable skills in the use of information technology.

The Colleges benefit from improved standards of clinical practice and quality assurance⁴⁶ by their participating members. The Colleges may also gain access to better performance information of value for the accreditation of training programmes.

To hospitals

The provision to registrars of programmed PDAs has been demonstrated to be cost effective and allows hospitals to be confident in monitoring the performance of trainees in their organisation.⁴⁷ The model has been described as conforming to the highest standards of clinical governance, which would provide hospital board-level reassurance around clinical governance structures.⁴⁷ There is also evidence that use of the proposed model at the trainee level helps to produce long-term beneficial, transformational, cultural change that leads to continued use of performance-monitoring tools.⁴¹

To credentialling organisations

The proposed model could be used as part of Australian Council on Healthcare Standards (ACHS) credentialling activities, particularly the professional credentialling component, with the advantage of relying on routinely collected data. The standard may be as simple as the proportion of specialists or trainees collecting the College-approved data. We suggest that this would still be more robust than the current ACHS professional credentialling process for health care institutions.

To indemnity organisations

The benefits for indemnity organisations are improved clinical risk management, potentially by all clinicians, and reduced future costs. This could allow the medical indemnity organisations to reduce the cost of medical indemnity premiums to the profession and support the future viability of the current arrangements.

To regulatory bodies

Current international regulatory theory supports and encourages self-regulation. Within this framework, punitive sanctions are introduced only when self-regulation fails and patient safety is compromised.^{36,59} The promotion of professionalism and the reporting of their individual performance by practitioners in the proposed model are entirely consistent with this regulatory theory.

Broader implementation of the model

The data collected by the medical practitioner could be used for different purposes, by different organisations at different levels within the health care system. Thus a College supervisor of training, at a local level, could use logbook and performance data to monitor and modify training and exposure of trainees in an organisation. However, the same information could be used centrally by the College to credential trainees and accredit health care organisations. Similarly, the use of critical incident reports by the local morbidity and mortality coordinator would supplement current reporting but could also be used by the organisation's quality manager to initiate root cause analyses, collate related incident reports and define improvements in organisational safety over time. These applications would support other initiatives of both individual and organisational insurers at both levels. The hospital/network could use the information to monitor aspects of clinical governance and support applications for credentialling to the ACHS as well as state and federal departments.

The ability to "electronically hand over" patient care by beaming details from the PDA of the doctor ending their shift to the PDA of the doctor commencing care of the patients is another important potential benefit. Further benefits for hospitals arise from complying with high standards of clinical governance, enhanced reputation, and the capacity to continue to drive down the costs of poor safety and quality in health care.

The model will require the collaboration of the specialist associations, Colleges, medical schools, medical indemnity organisations, hospital or network boards, health care organisation quality managers, the ACHS, the Department of Health and Ageing and the state Health Departments through their insurers.

Conclusion

We propose a model in which secure electronic transmission of encrypted data from a PDA to a secure database leads to automated (and then

supervisor-directed) analysis of performance data.⁴⁶ This has been successfully introduced for ANZCA-accredited trainees in The Geelong and Alfred Hospitals in Victoria, Princess Alexandra Hospital in Queensland, and Royal Darwin Hospital in the Northern Territory, and is being trialled for obstetrics and gynaecology trainees in the Geelong hospital.

The programmed PDA will also facilitate the reporting of critical incidents in the practice of the clinician at the place and time that the incident occurs. This has led to a documented 98% incident reporting rate in ANZCA trainees in the Geelong hospital.⁴⁸ Registrars have reported incidents with "minor" or "no" adverse outcome for the patient. It is possible that this is likely to be the "near miss" data, which has been difficult to obtain in the health care industry.⁴⁸ All critical incidents are automatically fed back by email to the departmental morbidity and mortality coordinators.⁴⁹ Serious incidents are automatically emailed to the hospital safety manager.⁴⁹

One intriguing aspect of our proposal in relation to medical education is that it firmly links the tradition of virtue ethics, with its emphasis on professional conscience, to state of the art portable digital technology embedded in existing clinical governance structure.⁶⁰ We see this model for health care quality and safety as an imaginative, realistic, practical and achievable goal for Australian health care in the next 5 years. We hope that widespread implementation of an affordable model, which has already achieved documented benefits for users and providers of health care in Australia, can be rapidly adopted, adapted and extended into most health care settings in Australia.⁴⁶⁻⁴⁸

Competing interests

Steve Bolsin and Mark Colson are directors in the company Personal Professional Monitoring Pty Ltd, which was formed in order to enable the development of the PDA programme with a commercial partner. The company has never actually made a profit. The authors will not benefit from any sales of the programme and hope that the programme will make Australian health care safer and more effective.

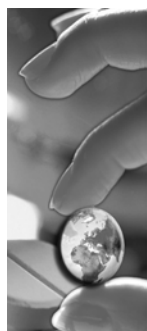
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(Received 10 Nov 2004, accepted 5 Jun 2005)

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