5. Macri FJ, Grimes PA. The effects of succinylcholine on the extraocular striate muscles and on the intraocular pressure. *Am J Ophthalmol* 1957; **44**: 221–30
6. Martyn JA, Richtsfeld M. Succinylcholine-induced hyperkalemia in acquired pathologic states: etiologic factors and molecular mechanisms. *Anesthesiology* 2006; **104**: 158–69
7. Laxenaire MC, Moneret-Vautrin DA, Widmer S, et al. [Anesthetics responsible for anaphylactic shock. A French multicenter study]. *Ann Fr Anesth Reanim* 1990; **9**: 501–6
8. Bresland MK, Bodenham AR. Hyperkalaemic cardiac arrest. Use of suxamethonium should be avoided. *BMJ* 1996; **313**: 692
9. Tran DTT, Newton EK, Mount VAH, et al. Rocuronium vs. succinylcholine for rapid sequence intubation: a Cochrane systematic review. *Anaesthesia* 2017; **72**: 765–77
10. Hunter JM, Jones RS, Utting JE. Use of atracurium during general surgery monitored by the train-of-four stimuli. *Br J Anaesth* 1982; **54**: 1243–50
11. Apfelbaum JL, Hagberg CA, Caplan RA, et al. Practice guidelines for management of the difficult airway: an updated report by the American society of anesthesiologists task force on management of the difficult airway. *Anesthesiology* 2013; **118**: 251–70
12. Sorensen MK, Bretlau C, Gatke MR, Sorensen AM, Rasmussen LS. Rapid sequence induction and intubation with rocuronium-sugammadex compared with succinylcholine: a randomized trial. *Br J Anaesth* 2012; **108**: 682–9
13. Bisschops MM, Holleman C, Huitink JM. Can sugammadex save a patient in a simulated 'cannot intubate, cannot ventilate' situation? *Anaesthesia* 2010; **65**: 936–41
14. Guihard B, Chollet-Xemard C, Lakhnati P, et al. Effect of rocuronium vs succinylcholine on endotracheal intubation success rate among patients undergoing out-of-hospital rapid sequence intubation: a randomized clinical trial. *JAMA* 2019; **322**: 2303–12
15. Schäfer MS, Hammer M, Santer P, et al. Succinylcholine and postoperative pulmonary complications: a retrospective cohort study utilizing registry data from two hospital networks. *Br J Anaesth* 2020; **124**: 91
16. Kirmeier E, Eriksson LI, Lewald H, et al. Post-anaesthesia pulmonary complications after use of muscle relaxants (POPULAR): a multicentre, prospective observational study. *Lancet Respir Med* 2019; **7**: 129–40
17. Savarese JJ, Kitz RJ. Does clinical anesthesia need new neuromuscular blocking agents? *Anesthesiology* 1975; **42**: 236–9
18. Thevathasan T, Shih SL, Safavi KC, et al. Association between intraoperative non-depolarising neuromuscular blocking agent dose and 30-day readmission after abdominal surgery. *Br J Anaesth* 2017; **119**: 595–605
19. Grosse-Sundrup M, Henneman JP, Sandberg WS, et al. Intermediate acting non-depolarizing neuromuscular blocking agents and risk of postoperative respiratory complications: prospective propensity score matched cohort study. *BMJ* 2012; **345**: e6329
20. Zaimis EJ. Motor end-plate differences as a determining factor in the mode of action of neuro-muscular blocking substances. *Nature* 1952; **170**: 617–8
21. Walts LF, Dillon JB. Clinical studies of the interaction between d-tubocurarine and succinylcholine. *Anesthesiology* 1969; **31**: 39–44
22. Lee C. Train-of-four fade and edrophonium antagonism of neuromuscular block by succinylcholine in man. *Anesth Analg* 1976; **55**: 663–7
23. Bartels K, Hunter JM. Neostigmine versus sugammadex: the tide may be turning, but we still need to navigate the winds. *Br J Anaesth* 2020; **124**: 504–7
24. Schmartz D, Chenard L, Baumann C, Meistelman C, Fuchs-Buder T. Measurement of recovery from succinylcholine-induced neuromuscular block using an improved train-of-four ratio (TOF). *Eur J Anaesth* 2018; **35**. e-supplement 56: 01AP4-4
25. Blobner M, Hunter JM, Meistelman C, et al. Use of a train-of-four ratio of 0.95 versus 0.9 for tracheal extubation: an exploratory analysis of POPULAR data. *Br J Anaesth* 2020; **124**: 63–72

British Journal of Anaesthesia, 125 (4): 425–429 (2020)
doi: 10.1016/j.bja.2020.06.045
Advance Access Publication Date: 15 July 2020

Sustainable quality and safety improvement in healthcare: further lessons from the aviation industry

Craig S. Webster[1,2,*], Robert Henderson[3,†] and Alan F. Merry[1,4]

[1]Department of Anaesthesiology, School of Medicine, University of Auckland, Auckland, New Zealand, [2]Centre for Medical and Health Sciences Education, University of Auckland, Auckland, New Zealand, [3]Henderson White Associates Ltd, Thames, New Zealand and [4]Department of Anaesthesia, Auckland City Hospital, Auckland, New Zealand

*Corresponding author. E-mail: c.webster@auckland.ac.nz

[†]Formerly of Human Factors Group, Airline Training, Air New Zealand, Auckland, New Zealand.

DOI of original article: 10.1016/j.bja.2020.07.002.

This editorial accompanies: What can we learn from smart-pump infusion data analysis? by Litman et al., *Br J Anaesth* 2020:125: 430–432, doi: 10.1016/j.bja.2020.07.002

Keywords: aviation; big data; cognition; decision support systems; human error; medication error; patient safety; system redesign

In recent years, there have been repeated calls for new approaches to solving the persistent and concerning problem of medication administration errors in anaesthesia.[1–5] It was suggested recently in the *British Journal of Anaesthesia* that independent observation combined with patient chart review constituted a new paradigm for medication error research.[6] While the sentiment behind these calls to arms is admirable, and new approaches should indeed be pursued, practical considerations cannot be ignored. Chart review and independent observation are not new approaches, and are two of the most expensive forms of data collection available when it comes to determining the efficacy of new safety interventions.[7,8] Both approaches have been used previously in short-term research projects, but their routine use is heavily constrained by the overheads of the cost of additional personnel and training associated with these methods. Furthermore, while these methods detect higher rates of medication errors than other techniques, including self-reported incident studies, this, in itself, does not guarantee establishment of the absolute rate of medication error in any particular context.[9] Neither is establishment of the absolute rate necessary for detection of improvements in processes and outcomes associated with safety gains. Pragmatically, a good evaluation of change over time can be achieved by continued collection of data under constant conditions with access to a reliable denominator in order to calculate error rates.[10,11]

Many commercial airlines throughout the world use an alternative approach to continuous quality and safety improvement that could be practically applied to the complexities of healthcare, including the medication error problem. This is a system of activity monitoring called Flight Operational Quality Assurance (FOQA). FOQA involves a process in which data from on-board aircraft systems are collected during flight, and then downloaded from the aircraft and automatically analysed.[12] Analyses can identify events of concern of various severities which fall outside the predetermined operating parameters of the aircraft, thus highlighting opportunities to improve in-flight safety and operational efficiency. An important aspect of FOQA is that the automatically analysed data are combined with other forms of data collection, including incident reports completed by pilots for anything they consider to be of concern. In approximately 50% of cases, events of concern reported by pilots are also detected by the automated system (we call this Tier 1 and Tier 2 data, respectively, in Fig. 1). The advantage of this dual approach to data collection is that pilot incident reports (Tier 1) can capture meaningful contextual information, including the intentions of the pilots during such events, which can supplement the automated data (Tier 2) and substantially aid in understanding why the event of concern occurred, and thus lead to better strategies to improve safety and efficiency.

Observation clearly has a place in patient safety research, whether this is done by traditional methods, or by making use of video recordings. A recent technique, also aligned with the aviation safety analogy, called the Operating Room Black Box, allows continuous video and audio recordings to be made of events in the Operating Room for the purposes of research and quality improvement, and has been suggested as a possible low-cost alternative to an observer.[13] Both the Black Box and FOQA techniques are used in aviation safety programmes, hence these are not rival safety technologies but are in fact complementary, and yield different kinds of evidence for safety studies, and for the analysis of accidents. However, it is also important to be aware of the limitations of observational methods in determining why things go wrong, particularly in the healthcare context.[14]

In the field of physics, independent observations are typically presumed to yield objective measurements of physical properties (e.g. mass, density, charge, etc.). However, observations of the behaviour involved in medication administration constitute something much more akin to social science than physical science: the measurements being made are of aspects of complex clinical actions in the context of multidisciplinary teamwork. Even with the use of structured observation tools, some degree of interpretation of the events under study is typically needed. Events of interest can be highly context dependent, and this often requires substantial clinical knowledge on the part of the observer (or coder in the case of a video recording) in order to interpret events and to collect data in a meaningful way. This unavoidable element of interpretation may bias the measurements being made or contribute to poor inter-rater reliability between observers or coders. In addition, the observers typically cannot be blinded to study conditions, as it is usually obvious to a trained observer or coder whether things are being done in the conventional way, or with a new purportedly safer technique.[15]

Finally and most importantly, observation alone cannot distinguish errors from violations, since the key difference between the two lies in the intention in the mind of the individual being observed, something which, in itself, is not observable. An error has been defined as 'unintentional; it involves the use of a flawed decision or plan to achieve an aim, or the failure to carry out a planned action as intended'.[16] In contrast, 'a violation is an intentional—but not malevolent and not necessarily reprehensible—deviation from those practices deemed necessary (by designers, managers, or regulatory agencies) or appreciated by the individual as advisable

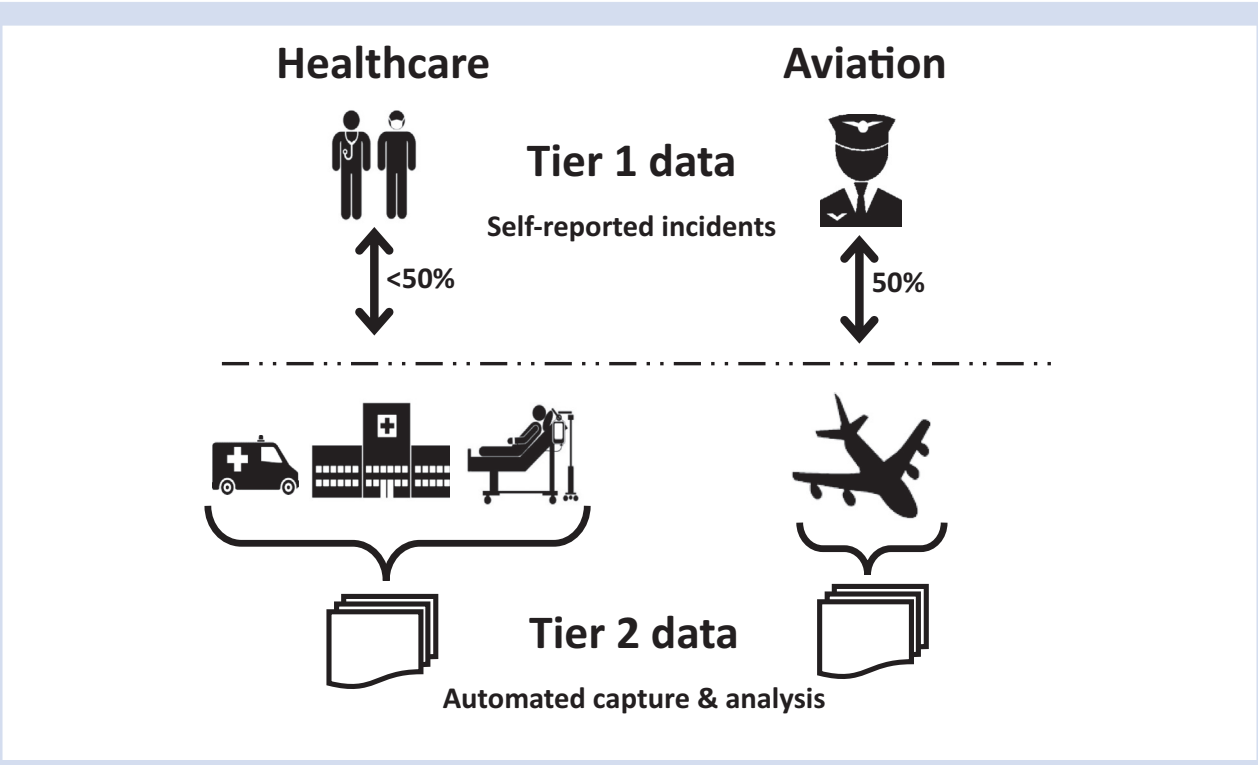

Fig 1. A dual data collection approach in healthcare and aviation, combining self-reported incident data, containing contextual and intentional information, with automated data collection and analysis.

to maintain the safe operation of a potentially hazardous system.'[16] Errors involve no intention to depart from an accepted standard, but violations, often made for a variety of reasons in healthcare, do involve a deliberate departure from an accepted standard.[17] Hence, errors and violations are causally different phenomena. Yet this critical distinction is seldom made in safety studies in healthcare, despite the fact that it has real implications when attempting to design strategies to improve safety by preventing errors and violations. Effective strategies intended to prevent errors are very likely to be different to those strategies able to prevent violations. Distinguishing the two requires the use of some method to establish the mental model or intentions underlying particular actions.[17 18] While observation alone cannot distinguish errors from violations, an FOQA-type approach does allow such insight, because it combines a large amount of automatically collected data (Tier 2, Fig. 1) with a smaller amount of incident data for the same events reported by those involved, which contains contextual and intentional information (Tier 1, Fig. 1).

How do we practically apply an FOQA-type approach in healthcare? Unlike in aviation, data associated with the care of patients tend to be fragmented. Currently, only some patient data sources are integrated and stored centrally, while other data are stored temporarily in isolated devices and then discarded, and still other data may not be captured at all. However, an FOQA-type analysis can nevertheless proceed with existing data sources. Centrally stored data currently comprise electronic anaesthetic records and electronic patient records, containing numerous traces of physiologic measures, timed records of medications given, allergy information, laboratory results, days in hospital, procedures conducted, and sequelae experienced. Such data can be analysed automatically using big-data or trigger-tool approaches to identify signs of potential medication errors during anaesthesia.[19 20] Trigger tools are an established and well-described technique to detect signs of adverse events in patient information, and formal frameworks and sets of triggers have been developed, including for medication error.[19] Examples of such triggers might include the atypical use of an opioid reversal agent, suggesting opioid overdose, or the improper timing of prophylactic antibiotics, suggesting increased risk of postoperative infection. However, triggers may constitute a host of other detectable events, including exceeding threshold values for key physiological variables (such as oxygen saturation, HR, or BP), prolonged stays in the PACU, or even particular patterns of medication administration and BP change.

An FOQA-type analysis using trigger tools would take the following steps: 1) identify data sources in a known risk area; 2) perform an automated Tier 2 analysis to identify cases containing triggers associated with events of concern (e.g. a class of medication error); 3) conduct an in-depth analysis combining the results of the automated Tier 2 analysis with Tier 1 data; and 4) report results and recommendations to the hospital quality assurance committee. Combining Tier 1 and Tier 2 data during the in-depth analysis allows an estimate of the extent of the problem and an understanding of the

intentions of the clinicians involved (hence both the 'what' and the 'why' aspects of the problem). This is important because the mental models of members of experienced clinical teams who work regularly together can be surprisingly diverse in terms of the beliefs of who should do what, and when it should happen, even during routine procedures.[18] Remedial measures thus developed will be more complete, and may involve anything from procedural change to system redesign.

Other devices involved in medication administration also collect operational data on their usage: these data are not typically integrated or stored centrally, but nevertheless can be used in an automated Tier 2 analysis.[21] For example, modern medication infusion pumps collect information on many variables during use, including events where 'soft' and 'hard' limits on dosing algorithms have been exceeded or overridden. Safety studies using such data have been published and companies now exist to provide analytics for infusion pumps. However, these studies have yet to include Tier 1 data, hence have not included contextual or intentional information in analyses.[22–24]

An FOQA-type approach in healthcare requires an active incident reporting system (Tier 1, Fig. 1) to be run in parallel with the automated analysis of patient data (Tier 2), representing only a relatively small extension of existing approaches. Importantly, incorporation of contextual and intentional information into analyses and proposed safety interventions would offer a more powerful way to understand medication error in healthcare than present isolated methods allow. Once developed, an FOQA-type system in healthcare could achieve such outcomes on an ongoing basis with few overheads and at a fraction of the cost of achieving the same goals using independent observation or chart review. Safety initiatives in healthcare should not be peripheral add-ons, or conducted only during short-term safety studies, but be an integrated part of the process of healthcare delivery. An FOQA-type system could become centrally integrated by leveraging the increasingly computerised information technology systems that are already being widely adopted into all aspects of healthcare.[25]

As more healthcare technology becomes computerised and networked, more sources of patient data will become available for Tier 2 analysis, at little extra cost. Initially this may involve the central integration of patient data from various additional medical devices within the hospital (e.g. devices for medication infusion, mechanical ventilation, renal replacement therapy, or extracorporeal life support, some of which already have the capability to transmit data wirelessly). The inclusion of more data sources and the use of different trigger tools could create a system capable of detecting more than just medication errors.[20] In the longer term, an FOQA-type approach could be extended to involve the care of patients before they reach the hospital, for example by including paramedics and ambulance services (Fig. 1).

At the heart of the question of measurement and medication safety lies a substantially under-recognised issue: complexity. Simple or linear approaches are limited in their ability to measure or improve the performance of human clinicians managing patient medications, where clinicians act in, and interact with, multi-professional teams within complicated institutions as part of a complex healthcare system. Of course, there are linear elements within the complex system, and many of these (e.g. the manufacture of pharmaceuticals) are already managed to high standards of reliability. However, the real challenge lies in achieving dynamic control of all the varied and interacting elements of the larger healthcare system.[26] Consistent with this dynamic perspective, the WHO has recently launched its third Global Patient Safety Challenge: Medication Without Harm.[27] The WHO provides a strategic framework for this challenge that includes three important areas for action (transitions of care, high-risk situations, and polypharmacy), and across four domains (patients and the public, healthcare professionals, medicines and systems, and practices of medication). This framework lends itself to a multifaceted approach consistent with efforts to redesign aspects of healthcare systems to make them less error prone. Integrated, continuous, and potentially widespread safety monitoring systems such as FOQA offer a powerful approach to detect problem areas within non-linear, complex systems and provide insight into how the performance of various aspects could be constrained within safe limits. We suggest that this type of systems-oriented thinking does indeed justify the title of a 'new paradigm'.

Modern concepts of safety in complex systems, including healthcare, go beyond the elimination of adverse events. Aiming to eliminate adverse events in order to achieve a system where things go wrong as infrequently as possible has been called Safety-I. The development of Safety-II stems from more modern ideas concerned with understanding what makes complex systems resilient, and how everyday performance variability in such complex systems can be best managed, all concerns highly relevant to healthcare. Under a Safety-II approach the aim is to understand why things usually go right, in order to ensure that as many things go as right as possible, that is, improving good outcomes to make them better outcomes. Ideally, Safety-I and Safety-II approaches should complement each other. An FOQA-type safety monitoring system could provide the data needed for better promotion of Safety-II in healthcare.[28] Instead of only counting adverse events, such data would also allow an improvement of the process and outcome measures of routine successful procedures. For example, patients undergoing coronary artery surgery are primarily interested in the outcome of reduced angina, but also in low rates of perioperative death, myocardial infarction, and stroke. A unit that is achieving excellent results in these outcomes is unlikely to have a clinically important level of medication error. A shift to emphasising success and a focus on the actual objectives of therapy would indeed represent a paradigm shift. Such a shift could include a FOQA-type approach as a better way of monitoring the performance of the healthcare system than counting errors (whether by observation, chart review, or any other means).

We agree that a paradigm shift is needed in our approach to the improvement of patient safety, particularly in regard to medication administration, and that new approaches would be more effective if they did not rely solely on incident reports.[6] With the increasing adoption of computerised systems into all aspects of healthcare, it makes sense to take the opportunity to benefit from the data that are already being collected on patient care, and which could be collected in a

more integrated way, in order to improve medication administration, healthcare systems, and the quality and safety of care. Most importantly, however, there needs to be greater engagement in, and commitment to, the improvement of medication safety, and a more sophisticated recognition of what it will take to really make steps towards better patient care within the complexities of modern healthcare.

Authors' contributions

Conception: CSW
Writing and revision: all authors
Domain expertise contributions: all authors
Systems redesign and the psychology of human error: CSW
Aviation human factors and airline pilot: RH
Patient safety expert and consultant anaesthetist: AFM
Approved the final version of the manuscript: all authors

Declarations of interest

CSW and AFM own shares in SAFERsleep LLC, a company that aims to improve safety in healthcare. AFM founded and is a director of SAFERsleep LLC. RH has no competing interests to declare.

References

1. Grigg EB, Roesler A. Anesthesia medication handling needs a new vision. *Anesth Analg* 2018; **126**: 346–50
2. Webster CS, Merry AF. New visions and current evidence for safety in anesthesia. *Anesth Analg* 2018; **127**: 308
3. Webster CS. Technical solutions and the safety big picture. *Anesth Analg* 2018; **126**: 729–30
4. Grigg E, Litman R. Feedback and constraints: rethinking medication safety countermeasures. *Br J Anaesth* 2018; **121**: 1188–90
5. Litman RS. How to prevent medication errors in the operating room? Take away the human factor. *Br J Anaesth* 2018; **120**: 438–40
6. Feinstein MM, Castro P. A new paradigm for medication error research. *Br J Anaesth* 2019; **123**: e483–4
7. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients - results of the Harvard Medical Practice study I. *N Engl J Med* 1991; **324**: 370–6
8. Merry AF, Webster CS, Hannam J, et al. Multimodal system designed to reduce errors in recording and administration of drugs in anaesthesia: a prospective randomised clinical evaluation. *BMJ* 2011; **343**: d5543
9. Webster CS. Estimating and reporting error rates, and detecting improvements. *Eur J Anaesthesiol* 2018; **35**: 60–1
10. Bowdle TA, Jelacic S, Nair B, et al. Facilitated self-reported anaesthetic medication errors before and after implementation of a safety bundle and barcode-based safety system. *Br J Anaesth* 2018; **121**: 1338–45
11. Webster CS, Larsson L, Frampton CM, et al. Clinical assessment of a new anaesthetic drug administration system: a prospective, controlled, longitudinal incident monitoring study. *Anaesthesia* 2010; **65**: 490–9
12. United States Department of Transportation. *Advisory circular: flight operational quality assurance (FOQA), AC No: 120-82*. Available from: https://rgl.faa.gov. [Accessed 27 May 2020]
13. Jung JJ, Juni P, Lebovic G, et al. First-year analysis of the operating room Black Box study. *Ann Surg* 2020; **271**: 122–7
14. Catchpole K, Neyens DM, Abernathy J, et al. Framework for direct observation of performance and safety in healthcare. *BMJ Qual Saf* 2017; **26**: 1015–21
15. Webster CS. Evidence and efficacy: time to think beyond the traditional randomised controlled trial in patient safety studies. *Br J Anaesth* 2019; **122**: 723–5
16. Merry A, Brookbanks W. *Merry and McCall smith's errors, medicine and the law*. Cambridge: Cambridge University Press; 2017
17. Webster CS, Andersson E, Edwards K, et al. Deviation from accepted drug administration guidelines during anaesthesia in twenty highly realistic simulated cases. *Anaesth Intensive Care* 2015; **43**: 698–706
18. Nakarada-Kordic I, Weller JM, Webster CS, et al. Assessing the similarity of mental models of operating room team members and implications for patient safety: a prospective, replicated study. *BMC Med Educ* 2016; **16**: 229
19. Rozich JD, Haraden CR, Resar RK. Adverse drug event trigger tool: a practical methodology for measuring medication related harm. *Qual Saf Health Care* 2003; **12**: 194–200
20. Simpao AF, Ahumada LM, Rehman MA. Big data and visual analytics in anaesthesia and health care. *Br J Anaesth* 2015; **115**: 350–6
21. Webster CS. Health care technology, the human–machine interface, and patient safety during intravenous anesthesia. In: Absalom AR, Mason KP, editors. *Total intravenous anesthesia and target controlled infusions: a comprehensive global anthology*. Cham, Switzerland: Springer International; 2017. p. 667–83
22. Ohashi K, Dalleur O, Dykes PC, et al. Benefits and risks of using smart pumps to reduce medication error rates - a systematic review. *Drug Saf* 2014; **37**: 1011–20
23. Mansfield J, Jarrett S. Using smart pumps to understand and evaluate clinician practice patterns to ensure patient safety. *Hosp Pharm* 2013; **48**: 942–50
24. Bainbridge Health. Available from: https://bainbridgehealth.com/. [Accessed 27 May 2020]
25. Wachter RM. *The digital doctor: hope, hype, and harm at the dawn of medicine's computer age*. USA: McGraw-Hill; 2015
26. Leveson NG. *Engineering a safer world - systems thinking applied to safety*. Cambridge, Massachusetts: MIT Press; 2012
27. World Health Organisation. *WHO global patient safety challenge: medication without harm*. Available from: https://www.who.int/patientsafety/medication-safety/medication-without-harm-brochure/en/. [Accessed 27 May 2020]
28. Hollnagel E. *Safety-I and Safety-II - the past and future of safety management*. Boca Raton, FL: CRC Press; 2014