Evaluation of the extent of implementation of the Helsinki Declaration on Patient Safety in anaesthesiology: a mixed-methods action research project

Executive Summary

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Executive summary

Background

The Helsinki Declaration on Patient Safety in Anaesthesiology was initiated and developed by the European Board of Anaesthesiology (EBA) with support from the European Society of Anaesthesiology (ESA). It was launched in 2010 in Helsinki at the Euroanaesthesia meeting and has been widely recognised as a practical framework for improving patient safety. It sets out a vision for patient safety in anaesthesiology and lays down specific standards which European anaesthesiologists may aspire to in practice. It includes four distinct elements: standards for clinical care; protocols for management of clinical crises in anaesthesiology; critical incident reporting; and an exhortation to engage in audit and the compilation of an annual report, in order to reap the benefits of measurement to improve safety. The Declaration was signed by many European anaesthesiology societies attending its launch in Helsinki and also by the European Patients' Forum (EPF). It has since been endorsed or signed by many international societies beyond Europe. Despite the widespread endorsement of the Declaration's principles, and a number of promotional activities designed to aid its implementation, there remained some uncertainty regarding its usage and influence in practice, with limited studies performed assessing its impact.

Project outline

To address this gap in understanding, the ESA recently commissioned this three-part investigation to assess the uptake and use of the Declaration. The first phase of the project consisted of an online survey of ESA members to determine what aspects of the Declaration have been adopted. Respondents were also asked to express their opinions on the Declaration, its impact on patient safety, and limitations and barriers to embedding its recommendations in daily practice. We also sought to learn about patient safety practices and the Declaration's impact in greater detail, by conducting telephone interviews with national leaders in anaesthesiology in a number of European countries. Interviews were semi-structured, and the resulting qualitative data underwent thematic analysis, with themes developed inductively. The third phase involved site visits to hospitals throughout Europe, in order to examine patient safety practice directly. These three streams of data collection were designed to provide a 'snapshot' of safety in European anaesthesiology, a deeper understanding of practice context, and 'on the ground' sensemaking of safety practice and culture, respectively.

Phase I

In the first part of the first phase, we invited members of the European Society of Anaesthesiology to undertake a 16-item online survey to explore their understanding of the Declaration and compliance with its standards. We received 1589 responses (33.4% response rate), with members from all countries responding. The median (IQR) response rate of members was 20.5 (11.7 to 37.0%) per country. There were many commonalities across Europe. There were very high levels of use of monitoring (pulse oximetry: 99.6%, blood pressure: 99.4%; ECG: 98.1% and capnography: 96.0%). Protocols and guidelines were also widely used, with those for pre-operative assessment and difficult/failed intubation

being particularly popular (mentioned by 93.4% and 88.9% of respondents respectively). There was evidence of widespread use of the WHO Safe Surgery checklist, with only 93 respondents (6.0%) suggesting that they never used it. Annual reports of measures taken to improve patient safety, and of morbidity and mortality, were produced in the hospitals of 588 (37.3%) and 876 (55.7%) respondents respectively. Around three-quarters of respondents (1216, 78.7%) stated that their hospital used a critical incident reporting system. Respondents suggested that measures to promote implementation of the Declaration, such as formal set of checklist items for day-to-day practice, publicity, translation and simulation training, would currently be more important than possible changes to its content.

In the second part, we interviewed by telephone senior anaesthesiologists with a knowledge of patient safety and anaesthesiology practice in their country. Their responses were transcribed and analysed inductively for themes. We conducted 17 interviews between August 2018 and May 2019. The median (IQR) interview length was 56 (34-100) minutes. Guidelines and statements such as the Helsinki Declaration were thought to have a positive effect on safety, with the Declaration being seen as a vision statement, a catalyst and a mandate for safety. Clinical changes in anaesthesiology such as increased workload, pressure to cut down on preoperative assessment and preparation, and the fact that patients are older and sicker than in 2010, were seen as potential threats to safety. Financial austerity has affected safety in many countries, as has medical workforce migration. Relationships within departments and hospitals, with national anaesthesiology societies, with governmental agencies and with neighbouring countries, were all noted to have a bearing on safety. Critical incident reporting, discussion and sharing, and attitudes to patients and their role in safety, vary considerably across Europe. Postgraduate training and continuing specialist education in cultural aspects of safety and 'human factors' were cited as key drivers for improving safety in the future.

Phase II

In the second phase of the project, we aimed to extend beyond a simple assessment of whether or not the Declaration had been adopted, to a broader attempt to set it in the practice context of European anaesthesiology. We adopted a case study methodology and a broadly positive stance implying a 'Safety II' framework, which aims to understand why things go right in healthcare most of the time, rather than a 'Safety I' framework, which involves learning from errors. Our approach was essentially ethnographic, aiming to build up a picture of safety as practised which was both scientifically rigorous but which also 'made sense' to those under study, recognising the time constraints imposed by the short visit schedule. We collected a number of streams of data: policies and documents relating to safety in the anaesthesiology department; the annual departmental patient safety report on the template offered by the European Society of Anaesthesiology in support of the Declaration's requirement to complete such a report; Safety Attitude Questionnaires completed by anaesthesiologists and theatre staff before the visit; observation of facilities, equipment and safety practices; and face-to-face interviews with specialist anaesthesiologists, trainee anaesthesiologists and anaesthetic nurses. We also asked our contact person in each hospital to complete a short evaluation of the visit and report.

We visited 21 hospitals in 6 countries, chosen purposefully to provide a geographical spread within the continent of Europe, and a range of average national income. Currently we have 349 Safety Attitude Questionnaires completed from 17 hospitals, and we conducted 64

interviews (including 23 with consultant anaesthesiologists, 16 with trainees and 17 with anaesthesia nurses). Nine evaluation questionnaires have been received. The main output of each visit was a report written for the participating hospital containing a summary of the data, an evaluation of compliance with the Declaration's standards, and materials and resources for patient safety, including a compendium of processes and activities noted during previous visits. At the time of writing (March 2020), 14 final and 3 draft reports have been sent to participating hospitals. Further analysis of the large data set gathered will be undertaken in the coming months, with presentations and journal publication in due course.

Reflection and discussion

Results from both phases of our project provide an insight into current and future implementation of the Declaration. In summary, the Declaration is perceived variously as a force for good, a standardisation framework and a catalyst for change. It benefits from being broad in scope, with knowledge of the themes of the Declaration being better known than the more specific details. National leaders interviewed felt that it acts as a tool to help advance patient safety, both politically and scientifically. It could be argued too that the Declaration is also an improvement intervention, with 44.5% of ESA members surveyed agreeing that it had improved safety. This was felt to be largely through promoting the use of checklists in the areas of pre-operative preparation, and the management of crises during anaesthesia.

Our results suggest that the Declaration's impact is influenced by national practice context and local safety culture. Many respondents commented that safety practices such as monitoring standards have exceeded those set out in the Declaration for many years, especially in northern Europe. It is possible that the high levels of monitoring as recommended by WHO/WFSA standards (pulse oximetry: 99.6%, blood pressure: 99.4%; ECG: 98.1% and capnography: 96.0% throughout Europe), would have come about without the Declaration. Thus, the potential benefit of the Declaration in enabling change and improvement is greatest in areas where safety practices are less well established (such as in the use of data for improvement, whether they are routinely collected or reporting adverse incidents). The Declaration's impact has also been influenced by recent changes in anaesthesia, with anaesthesiologists throughout Europe reporting greater workloads, pressures to cut down on preoperative preparation, and more complex patients. This, along with financial austerity and staff shortages (with workforce migration reported by many) have resulted in a perception that more time is spent reacting to patient safety threats as opposed to progressing safety practices. Other factors, namely an organisation's safety culture and staffing issues, have influenced the uptake of the Declaration, for example in the production of annual safety reports and running morbidity and mortality meetings. The hospital visit process described above aimed to explore many of these contextual factors identified in the first two phases of the project.

Benefits of project.

Early feedback suggests several immediate benefits to hospitals from taking part in the project. Staff reported promotion of a safety culture through the planning and execution of the visit. Many staff were keen to complete the Safety Attitude Questionnaires, and it was generally perceived to be instructive, although for some the questionnaires were seen as more an opportunity to express their opinions on problems with the organisation. Anaesthesiology departments learnt much about their safety systems; for example, they

identified protocols that needed updating or revision, and they reviewed their position with regard to contributing to national audits of practice. In some cases, the visit provided an impetus to commence new safety projects. The report distributed to departments after the visit contained several recommendations, useful safety references and suggestions from other hospitals. At national level, several of the senior anaesthesiologists interviewed told us that the act of taking part and preparing for the interview was beneficial in itself and/or had has stimulated interest in the Helsinki Declaration once again. Indeed, the whole project was seen as an opportunity to revisit and revitalise awareness of patient safety. In addition, the involvement of a number of trainees and specialist anaesthesiologists in the project has spread knowledge of patient safety science and developed capability in the research methods used in the project.

Suggestions for further implementation of the Declaration

Survey and interview data suggested that future changes to the Declaration could take account of the challenges mentioned above, as well as the increased role of simulation, human factors and multidisciplinary training in anaesthesiology. But many respondents advocated greater adherence to the existing Declaration rather than changes to the Declaration itself. This could be brought about by introducing a formal checklist of items in the Declaration to guide day-to-day practice, and greater publicity. Efforts could be focused on areas that are less well implemented, such as annual safety reports. The Helsinki Declaration could be revitalised, by inviting signatories to confirm their continuing commitment on the Declaration's ten-year anniversary in 2020. The existing Declaration could also be translated into languages other than English where this has not already been done. A number of recommendations for education, research, policy and practice are made at the end of the report, but key possible measures include:

- Create and maintain structures for safety education both in training curricula and for established specialist anaesthesiologists.
- Promote a 'no blame' culture to encourage the reporting and open discussion of threats to patient safety.
- Greater involvement of patients in the promotion of safe practice.
- Make the scientific, clinical, humanitarian and economic case for thorough preoperative assessment.
- Establish and maintain regional networks within Europe to share practice and solutions appropriate to available resources.
- Encourage the participatory self/peer evaluation of safety using the site visit methodology and process described in this paper.
- Consider a concurrent, specific implementation evaluation plan if the Declaration is revised and/or relaunched.

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