**‘An arrow pointing somewhere’: qualitative study of the Helsinki Declaration on Patient Safety and its role in European anaesthesiology**

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**Supplemental Digital Content**

**Introduction**

The pursuit of excellent standards of patient safety has long been prioritised in anaesthesia.1 Although anaesthesia carries many potential risks, adverse outcome rates have reduced considerably over recent decades as a range of measures and standards to improve safety throughout the peri-operative period have been developed and applied.2 The Helsinki Declaration on Patient Safety in Anaesthesiology (hereafter ‘the Declaration’) was launched in 2010 by the European Board of Anaesthesiologists (EBA) and European Union of Medical Specialists (UEMS) in close co-operation with the European Society of Anaesthesiology (ESA).3,4,5 It set out a vision for patient safety in anaesthesiology, together with recommendations for specific activities which could improve safety. Most national European anaesthesiology societies signed the Declaration at its launch, to demonstrate their commitment to its ideals and standards, and its appeal has since grown such that approximately three-quarters of national societies worldwide have now signed the Declaration. Despite this widespread high-level adoption of its principles, there is still some uncertainty about its usage and influence in practice. Some local studies have been conducted to assess its impact,6 but more extensive data are lacking.7,8 The ESA has initiated a project designed to assess and improve the adoption of the Declaration’s requirements. As part of this project, the Society commissioned a three-phase investigation whose broad aims are to: explore the state of patient safety in European anaesthesiology; examine the uptake and implementation of the Helsinki Declaration and how it relates to patient safety practices; map the extent of coverage and identify differences in the implementation of the Declaration in different parts of Europe; and examine variation in the adoption of the various component elements of the Declaration. The second phase of this investigation, reported here, aimed to ask national leaders in anaesthesiology in a number of European countries about patient safety and the role played by the Declaration, and its benefits, limitations and barriers in daily practice.

**Methods**

In order to establish the need for Ethics Committee approval for the project, we used the UK Health Research Authority’s online triage tool on 3 November 2017. This tool comprises two sets of questions [http://www.hra-decisiontools.org.uk/research/]. The applicant’s responses to the first set determine whether the proposed work counts as research. Our study was classified as research. The second set determines whether Research Ethics Committee approval is required for the work. Our study did not. For further confirmation, we sent a copy of the proposal to the Health Research Authority. On 8 May 2018, we received an email from the Authority confirming that, if survey participants were selected by virtue of their membership of a professional organisation, then Health Research Authority approval is not expected (email on file). Participants were asked to consent specifically to their participation, and to the audio recording, at the start of each interview.

We sought our participants by initially contacting the ESA Council member and, where applicable, the country’s representative on the ESA’s National Anaesthesia Societies’ Committee (NASC). They were invited to participate or to nominate another individual, such as head of the country’s national anaesthesia society, or another anaesthesiologist working at national level who could speak knowledgeably about the state of anaesthesiology practice and patient safety in that country.

A semi‐structured interview guide with open‐ended questions, developed before data collection, was used during the interviews. This is shown in Appendix A. It was piloted before use in the project and proper and pertinent adjustments made.  Interviews were audio recorded and the recordings transcribed by a professional transcription service. Points which could not be transcribed initially (for instance, where specialist medical terminology was used, or where country-specific details were mentioned) were clarified by referring back to the original interviewer. Transcripts were not returned to participants for comment. The transcripts were de-identified before being shared with the rest of the research team.

Coding in qualitative research is the process of combing the data for themes, ideas and categories.9,10 The authors looked for similarities and differences in the data, within and across transcripts, initially working individually in isolation to code and analyse them. We then met to discuss and cross-compare our individual findings, establish analytical categories, select key overarching concepts and develop the framework within which to interpret the data. Similar passages of text from different interviews were marked with a label so that they could be retrieved at a later stage for further comparison and analysis.11,12 Analysis began before all the interviews were completed, thus informing subsequent data collection in an iterative manner. This is a key feature of qualitative work, and allows researchers the freedom to pursue interesting and relevant lines of enquiry as initial themes of interest emerge from the data. This has been termed the ‘constant comparative method’.13 In line with the positive focus of our questions, we drew on a theoretical approach known as ‘Safety II’, which aims to understand why things go right in healthcare safety most of the time, complementing the ‘Safety I’ approach which seeks to learn from error.1,14

This study was designed, analysed and reported in accordance with the Consolidated Criteria for Reporting Qualitative Studies (COREQ).15 Individual quotations from interviewees have been selected for inclusion in this paper to illustrate and support the themes identified in the data. A unique identifier (e.g. Int 1) was assigned for each interviewee to ensure anonymity and protect confidentiality.

**Results**

We approached the national anaesthesiology representatives from 38 countries. Between August 2018 and May 2019, seventeen interviews were conducted in total. Interviews lasted a median [range] of 56 [34 to 100] min. Respondents were asked to give their express consent to be interviewed, and for the interview to be tape recorded. In total, just under 16 h of interviews were conducted via a combination of video or audio connection over the Internet, whilst one interview was recorded in person during a conference. In those conducted via Internet connection, the interviewee was aware of the name, gender and nationality of the interviewer and that he (MN) was an anaesthesiologist, but none knew him otherwise. Sixteen interviewees had regular clinical anaesthesiology commitments, with one interviewee having ceased clinical practice to work full-time as a professor in medical education and simulation. Representatives from 21 countries were not interviewed, either because no response to initial approach or reminders was received, or due to difficulties in organising a convenient time for interview. Data saturation was perceived to occur after approximately 14 interviews, with similar themes recurring and few major new topics brought out in interview. Once this stage was reached, only those country representatives already in active contact were invited to interview.

Respondents mentioned a number of activities, structures and processes that they believed exert a positive influence on patient safety. These commonly included: education; guidelines and protocols (whether at European, national or departmental level); monitoring; pre-operative assessment; and training (especially around the use of new technology). The risk from medication errors was also frequently discussed. The Helsinki Declaration, too, was generally recognised as a beneficial force in the promotion of patient safety in European anaesthesiology. Other main themes are presented below.

**Clinical changes in anaesthesiology since 2010**

There were three commonly cited areas of change: intensifying workload; more challenging patients; and suboptimal pre-operative preparation.

Within this there was common agreement that day case surgery has become more widespread; however, with this has come a pressure to administer anaesthesia to older and multiply comorbid patients without the desired pre-operative investigations.

*“More patients arriving on the day of surgery with investigations not complete and they’ve not been seen in clinic… we have been under pressure for, yes, seven or eight years… we’ve written to the general director…. from our anaesthesia department asking for a pressure reduction… there was no response” -* Int 2

A sense of frustration and stress was apparent as a result. In addition, a high workload intensity has led to a perceived erosion of professional identity and patient safety.

*“The general director would call and said, ‘you should go and give your consent for the patient to go to the surgery’, though I do not think that he should go, whether he’s hypertensive or whatever, I think we could be prepared. But there is really, really a lot of pressures and it does not have good consequences on patient”’ –* Int 2

Similarly, there was an explicit appreciation, too, of this role of the anaesthesiologist in maintaining vigilance for the rest of the healthcare team, in the interests of the patient’s safety, one respondent comparing the anaesthesiologist to a ‘goalkeeper’:

*“If a goal keeper fails, all the team can have the possibility to fail and lose the match” -* Int 1

Workload pressure extends into the intra-operative period, with senior anaesthesiologists being less able to provide adequate supervision and being left feeling “*like a juggler, with a lot of balls in the air”*. Consequently, the deviation from nationally-agreed supervision ratios in countries where anaesthesiologists oversee the work of nonmedical practitioners has led to situations where anaesthesiologists *“can’t actually oversee what’s going on in all the rooms*”. The fact that problems seem to be uncommon (and may not be fully captured by quantitative audits or official governance systems) does not make compromises in safety standards acceptable. Respondents mentioned the temptation to ‘cut corners’ in order to get the work done.

*“It’s not okay. It might be that it’s because anaesthesia is so safe now that actually we are cheated into this. It’s so seldom that it actually has consequences” –* Int 4

**‘Fighting not to fall down’: external influences on patient safety**

Respondents focused predominantly on resource constraints, as well as relationships between hospitals, governmental bodies and national anaesthesiology societies. Although some mentioned the perceived benefits of improved pan-European professional relationships, there were a number of challenges such as anaesthesiology workforce migration, hospital finances, salaries, working conditions and staffing. Taken together, these were seen to threaten the maintenance of robust patient safety standards and led to the perception of reacting to problems as they occur without being able to make progress in safety.

*“Most of the anaesthetic departments are terribly understaffed because of the austerity measures from 2011… it was a disaster… underfunded and understaffed… you don’t fight to win, you’re fighting not to fall down” –* Int 6

We discerned within the responses two discrete types of relationship between hospital anaesthesiology departments and the broader healthcare system. In some countries, it was clear that departments are situated within hospitals that work within a national policy framework, within standards set by national anaesthesiology societies, national governmental bodies, and informed by the results of large-scale, organised safety and quality data reporting. In other countries, Ministries of Health and national societies are regarded as out of touch or ineffectual, with clinical practice working on a more ‘decentralised’ model. Within this, the departmental ‘chief’ was repeatedly cited as the source of departmental policy and the reference point for reporting of problems or arbitration.

Regional networks, for countries in similar economic and social contexts, were highlighted as a source of strength and ongoing potential. Such networks enable the establishment of achievable goals and avoiding unrealistic comparisons between challenged systems and those with more advanced systems of patient safety.

*“We have to learn from our neighbours and regional partners with the same social, economic, political, language, and so on” -* Int 13

**‘An arrow pointing somewhere’: what the Helsinki Declaration means and how it might develop**

The Declaration is perceived as a force for good, a standardisation framework and a catalyst for change. It benefits from being succinctly laid out, yet broad in scope. This has led to its acceptance and utilisation, though implementation requires tailoring from country to country. The general themes of the Declaration were better known than more specific details:

*“I recalled having heard of it before, but not really been conscious about what it was all about.” -* Int 17

Respondents felt that it acts as a tool by which anaesthesiology is able to *‘push forward in a political way, a scientific way’* (Int 5)and as a mandate to extend patient safety involvement to the entire peri-operative journey.

*“It definitely acted as a scaffolding… as an impetus to build on” -* Int 10

Respondents from a number of countries, typically from northern Europe, commented that their national safety standards and discourse are already more advanced than the contents of the Declaration might advocate. However, Europe is a diverse continent and the Declaration’s standards have been useful elsewhere in enabling change and improvement.

Even here, though, although positively viewed as a rallying point and unified statement of intent *(“an arrow pointing somewhere”*, Int 2), it was felt that some anaesthesiology systems would have reached the same outcomes eventually, though the Declaration had given these changes greater momentum.

*“Time would not have stood still if the Declaration hadn’t been published in 2010, we probably would have proceeded anyway. The consciousness was sharpened and the processes in patient safety have been accelerated”* – Int 5

The Declaration also seems to link into anaesthesiology education. Despite knowledge of the Declaration itself being considered as generally poor, the themes and overall aims of the Declaration were commonly reported to be present within anaesthesiology training curricula, albeit without referring to the document explicitly.

A commonly expressed idea was that greater moves towards implementation of the Declaration might be as important as changes to its content. Looking to the future, however, a revitalisation of, and commitment to, the existing Declaration was suggested rather than a complete rewrite. A possible future iteration of the Declaration would usefully stay brief, though respondents suggested variously that factors such as quantitative quality indicators, patient involvement and an appreciation of workload pressures and fatigue amongst anaesthesiologists, should be considered.

**‘Attitude education’: culture, training and human factors**

The vast majority of respondents highlighted the critical nature of safety culture, human factors and training systems in maintaining patient safety.

Culture plays a key role in the adoption of safety tools and practices. For instance, the uptake of the World Health Organization Surgical Safety Checklist is dictated by the context in which it is introduced. A respondent from one country suggested that their compatriots were unlikely to accept attempts to shape their behaviour, commenting that people *“tend to do what they like, not what they must”* (Int 2). Similarly, a workplace where staff feel familiar with each other does not necessarily create a perceived need to undertake introductions and talk through proposed operations:

*“We don’t follow [checklists], we feel that we are okay with that… everybody knows everybody… we know our patients. The surgeon knows the patient. They’re not like in a list and they haven’t met them before. So, it’d be more difficult for mistakes to happen” -* Int 6

In response to increasing workload pressures it is vital that educators and managers recognise the importance of resilience, fatigue and mental health upon the safety of the anaesthesiology team and ultimately that of patients.

*“Focus on stress and personal resilience and taking care of oneself. That’s a picture that the organisation is so pressured” –* Int 4

Simulation is regarded as a vital tool in the provision of training in both technical and non-technical skills, for trainees and senior anaesthesiologists alike. Despite this, the associated expense of dedicated simulation centres was noted as a barrier to implementation.

Several countries were in the process of publishing a new training curriculum, or else had recently done so, with an agreement that simulation, patient safety and human factors were a much more prominent feature:

*“It's not only a technical education, it's also an attitude education.” -* Int 12

The view was often expressed that this training should be shared with other peri-operative health professionals. Some go further still, for instance the provision of a standardised postgraduate qualification for anaesthesiology trainees focused in part on human factors training. Notably, however, some representatives reported that neither their training curricula nor current professional patient safety narrative contained any such content.

**‘A good anaesthesiologist can explain his work well’: the patient perspective in anaesthesiology**

Common themes included public understanding of anaesthesia, patient feedback and trust in healthcare systems.

Respondents in many countries suggested that patients typically focus on risks posed by surgery itself, rather than the wider peri-operative period or specifically anaesthesia. The role of the anaesthesiologist is often underappreciated, as is the influence of patient comorbidities on perioperative safety. Alternatively, some patients may simply ‘not want to know’ despite the fact that they implicitly recognise the inherent risk. Nevertheless, empowerment and education were seen as vital, with the pre-operative clinic and broader public health campaigns providing part of a solution. Here, appropriately tailored language, free of medical jargon, is important.

*“The patient is interested only to go through the surgery without any regards of anaesthesia risk…. the knowledge and appreciation are definitely not there” –* Int 2

Patients are in a unique position to observe and recognise threats to safety throughout the peri-operative ‘journey’, though may only express these if their opinions are explicitly sought. Such interactions may result in insights couched in terms such as “*I didn’t feel safe because…” or “this happened while you weren’t looking”* (Int 17), useful safety intelligence otherwise not captured by quantitative data collection or clinician-driven incident reporting. Respondents almost always described robust local feedback systems for patients; national patient safety representation was generally lacking, with national patient groups often relating to relatively uncommon medical conditions rather than dealing with anaesthesia itself.

*“Patients are actively encouraged to give feedback and also to complain, if they want, on a local level” –* Int 5

Attitudes and practices towards disclosure of problems and patient involvement vary. Some systems seek patient input in projects such as the design of new theatres, whilst also upholding a national duty of candour policy. Others address incidents on a case-by-case basis, balancing transparency against perceived severity.

*“If they discover it early enough to take the swab out, I think that no-one would tell the patient” –* Int 3

Litigation and defensive practice were also commented upon by several representatives, for whom a written consent form provides a degree of protection. A circular situation was commonly described of public mistrust in medical professionals and a reciprocal medicolegal paranoia from clinicians.

*“I usually go afterwards and speak to the patient, but I have no responsibility because he signed a consent, and things like dental damage is written in the consent. So as long as it’s covered by the consent and I have them as ASA III or ASA IV, I’m covered. Some of us feel that it’s necessary to explain what happened, not everyone” –* Int 2

**Critical incident reporting**

There is a lack of uniformity in incident reporting compliance and system availability. Standardised reporting systems were often found for specific incidents such as difficult airways, allergic reactions and drug events. However, national level data coordination, analysis and reporting are challenging or non-existent in some countries. Where this is the case, hospitals and individual anaesthesiologists may be unaware of which incidents occur commonly, nor of trends or areas on which to focus. On the other hand, some respondents reported trusted and dynamic national systems including features such as telephone notification to instigate a rapid investigation. Voluntary systems were often commented upon as ineffectual, usually cited as being due to competing time constraints.

In keeping with the previously described ‘decentralised’ healthcare systems, many respondents felt that incident reports went no further than departmental ‘chiefs’, and did not feel any further sharing took place. Indeed, these individuals were often frustrated that mandatory incident reporting did not lead to any regional or national reporting, thus they are unable to ascertain common themes, trends or potential solutions. Anaesthesiology incidents were sometimes grouped within surgical incident reporting systems, with differentiation impossible. Other representatives only experienced intradepartmental, informal discussion of clinical incidents.

Incidents may not be reported to the patient, department or higher-level systems. Factors influencing this include perceived severity, patient outcome, time pressures and attitudes towards the reporting system. Failure to report may also result from fear of potential consequences including litigation. In addition, respondents noted that trust and possible vulnerability (especially exposing one’s practice to colleagues locally or, through more widely shared incidents, in other hospitals or regions) might hamper reporting and/or discussion of problems. Finally, some well-established reporting systems were criticised for focusing on medicolegal claims, thereby failing to value ‘near misses’, or incidents considered as ‘low risk’ from a litigation viewpoint. Illustrative quotations relating to critical incident reporting and discussion of problems are shown in Figure 1.

A summary of respondents’ perceptions of positive and negative influences on patient safety is shown in Table 1 in the main paper.

**Discussion**

This study has explored influences on patient safety in European anaesthesiology, and the role which the Helsinki Declaration on Patient Safety in Anaesthesiology has played within it. It has documented the effect of changes within anaesthesiology practice and healthcare systems on patient safety, thus pointing the way towards a better understanding of how safety statements and standards might best be tailored in the future.

This work follows on from a more general online survey of ESA members.16 By adopting a broadly ethnographic approach,9,17 based on detailed interviews with senior anaesthesiologists throughout Europe, we have provided a complementary perspective on the subject. In particular, we have been able to construct an account of patient safety in anaesthesiology which reflects participants’ perceptions of, and meanings attributed to, patient safety within the social context of anaesthesiology practice. This is one of the main strengths of our approach.9 The potential for delineating a ‘sociology of healthcare safety and quality’ was reviewed by Allen et al.18, who argued that patient safety is not simply about individual or team psychology, but is subject to the sociocultural and political context of healthcare work. According to them, ‘a sociological perspective …reveals how these [patient safety] problems might be managed and by whom, as well as the everyday – and often invisible – situated practices through which quality and safety are accomplished’.18

To be effective in practice, quality and safety improvement tools and initiatives must take account of the complexities of healthcare practice and ‘make sense’ to practitioners within the context of their practice. Practitioners’ own views of the work they do are often somewhat different from how it is envisaged by policymakers and politicians (these are referred to, respectively, as ‘work as done’ and ‘work as imagined’ in recent safety scientific literature).14 The authors of a study of risk discourses amongst operating theatre staff note: ‘The failure to follow formal written rules relates not to a deficiency in the cognitive capacity of individuals acting in isolation, but to the identities which individuals occupy, create and negotiate and the social rules (as opposed to clinical guidelines or protocols) which correspond to those identities’.19 We suggest that our respondents’ accounts of their work and experiences can usefully be seen in terms of the anaesthesiologist’s professional identity and the informal roles anaesthesiologists play, thus building on previous work in this area.20 In addition to Larsson’s ‘professional artist’, ‘good Samaritan’, ‘servant’ and ‘co-ordinator’,21 and our own previous suggestions,22 we see references to other, hitherto unrecognised roles. These include: ‘goalkeeper’ (acting as the ‘last stop’ to prevent potential hazards from becoming real); ‘firefighter’ (purely responding to events rather than feeling able to influence safety proactively) and ‘individualist’ (acting according to personal preferences rather than formal protocol). Finally, this approach argues for an expanded view of ‘human factors’, one which moves beyond psychology and engineering to encompass how people relate to each other.1,23

The main limitation to this study relates to representativeness. We interviewed senior members of national anaesthesiology societies who typically work in tertiary, university hospitals. This raises the question of how representative our respondents are of their compatriots. We phrased many of our questions to seek national, rather than individual level intelligence, and it was clear that respondents were able to speak about practice more widely than within their own hospital (for instance many felt that their awareness of the Declaration was reasonable, though wider knowledge of the Declaration in other parts of many countries was felt to be poor). Second, we were able to interview representatives from only 17 out of 38 possible countries. In methodological terms, this was acceptable as we achieved ‘data saturation’ (the point at which no new themes emerge in analysis)24 before this number was reached, suggesting that further interviews would not enhance our understanding. Also, we were aiming in our analysis not necessarily to identify differences between counties, but rather to find a number of cross-cutting themes that would be universally applicable.

Two particular themes deserve further comment. Pre-operative assessment – for instance, of the patient’s airway,25 and optimisation through modification of intercurrent disease26 and lifestyle factors27 – is widely regarded as essential to high-quality anaesthesia care.28 The suggestion that resource constraints are preventing this is concerning. Also, critical incident reporting structures and practice vary widely and, whilst systems must be properly resourced, social cultural factors amongst anaesthesiologists seem to play a significant role in determining whether anaesthesiologists actually make use of the systems that exist. Many such factors have been elucidated in previous studies.29,30,31

Our findings have implications for the future of the Declaration and anaesthesiology practice and these are summarised in Table 2 in the main paper. The Helsinki Declaration would benefit from revitalisation, possibly by inviting signatories to confirm their continuing commitment on the Declaration’s ten-year anniversary in 2020, and a publicity campaign. A revision would also afford an opportunity to tailor this valued, succinct document such that it reflects the changes in anaesthesiology since 2010 and the current concerns of practicing anaesthesiologists, patients and policymakers.

Key issues for future consideration and/or research are those of anaesthesiology resilience and fatigue, an increase in workload and the delivery of a safe care throughout the whole peri-operative period, increasingly on a day case basis to an ageing and multiply comorbid population. Ultimately, these measures require investment from, and collaboration with, political stakeholders.

**References**

1. Plunkett E, Smith AF. People, systems and safety: resilience and excellence in healthcare practice. *Anaesthesia* 2019; **74**:508-517.

2. Staender SE, Mahajan RP. Anesthesia and patient safety: have we reached our limits? *Curr Opin Anaesthesiol* 2011; **24**:349-353.

3. Mellin-Olsen J, Staender S, Whitaker DK et al. The Helsinki declaration on patient safety in anaesthesiology. *Eur J Anaesthesiol* 2010; **27**:592-597.

4. Mellin-Olsen J, Staender S. The Helsinki Declaration on Patient Safety in Anaesthesiology: the past, present and future. *Curr Opin Anaesthesiol* 2014; **27**:630-634.

5. Staender S, Smith A, Brattebø G et al. Three years after the launch of the Helsinki Declaration on Patient Safety in Anaesthesiology: the history, the progress and quite a few challenges for the future. *Eur J Anaesthesiol* 2013; **30**:651–654.

6. Balzer F, Spies C, Schaffartzik W et al. Patient safety in anaesthesia: assessment of status quo in the Berlin-Brandenburg area, Germany. *Eur J Anaesthesiol* 2011; **28**:749-752.

7. Whitaker DK, Brattebø G, Smith AF et al. The Helsinki Declaration on Patient Safety in Anaesthesiology: putting words into practice. *Best Pract Res Clin Anaesthesiol* 2011; **25**:277-290.

8. Ringvold EM, Bekkevold M, Bruun AM et al. Norwegian standard for the safe practice of anaesthesia. *Acta Anaesthesiol Scand* 2018; **62**:411-417.

9 Shelton CL, Smith AF, Mort M. Opening up the black box: an introduction to qualitative research methods in anaesthesia. *Anaesthesia* 2014; **69**:270-80.

10 Charlesworth M, Mort M, Smith AF. An observational study of critical care physicians' assessment and decision-making practices in response to patient referrals. *Anaesthesia* 2017; **72**:80-92.

11 Goodwin D, Pope C, Mort M, Smith AF. Access, boundaries and their effects: legitimate participation in anaesthesia. *Sociol Health Illn* 2005; **27**:855-71.

12 Smith AF, Pope C, Goodwin D, Mort M. Communication between anesthesiologists, patients and the anesthesia team: a descriptive study of induction and emergence. *Can J Anaesth* 2005; **52**:915-20.

13 Miles MB, Huberman AM. *Qualitative data analysis: an expanded sourcebook*. 2nd ed. California, USA: Thousand Oaks, 1994.

14 Braithwaite J, Wears RL, Hollnagel E. Resilient health care: turning patient safety on its head. *Int J Qual Health Care* 2015; **27**(5):418-420.

15 Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32‐item checklist for interviews and focus groups. *Int J Qual Health Care* 2007; **19**:349–57.

16 Wu HHL, Lewis SR, Čikkelová M, Wacker J, Smith AF. Patient safety in European anaesthesiology and the role of the Helsinki Declaration on Patient Safety in Anaesthesiology: a continent-wide survey. *Eur J Anaesthesiol* 2019; (in press).

17 Leslie M, Paradis E, Gropper MA, Reeves S, Kitto S. Applying ethnography to the study of context in healthcare quality and safety. *BMJ Qual Saf* 2014; **23**:99-105.

18 Allen D, Braithwaite J, Sandall J, Waring J. Towards a sociology of healthcare safety and quality. *Sociol Health Illn* 2016; **38**:181-97.

19 McDonald R, Waring J, Harrison S. Rules, safety and the narrativisation of identity: a hospital operating theatre case study. *Sociol Health Illn* 2006; **28**:178-202.

20 Smith AF, Goodwin D, Mort M, Pope C. Expertise in practice: an ethnographic study exploring acquisition and use of knowledge in anaesthesia. *Br J Anaesth* 2003; **91**:319-28.

21 Larsson J, Holmström I, Rosenqvist U. Professional artist, good Samaritan, servant and co‐ordinator: four ways of understanding the anaesthetist's work. *Acta Anaesthesiol Scand* 2003; **47**:787-793.

22 Smith AF, Goodwin DS, Mort M, Pope C. Anaesthetists understand their work in different ways. *Br J Anaesth* 2004; **93**:303.

23 Smith AF, Shelly MP. Communication skills for anaesthetists: a practical introduction. *Can J Anaesth* 1999; **46**:1082-88.

24 Bowen G. Naturalistic inquiry and the saturation concept: a research note. *Qual Res* 2008; **8**:137–52.

25 Roth D, Pace NL, Lee A, et al. Airway physical examination tests for detection of difficult airway management in apparently normal adult patients. *Cochrane Database Syst Rev* 2018; CD008874.

26 Lewis SR, Pritchard MW, Schofield-Robinson OJ, Alderson P, Smith AF. Continuation versus discontinuation of antiplatelet therapy for bleeding and ischaemic events in adults undergoing non-cardiac surgery. *Cochrane Database Syst Rev* 2018; CD012584.

27 Egholm JWM, Pedersen B, Møller AM, Adami J, Juhl CB, Tønnesen H. Perioperative alcohol cessation intervention for postoperative complications. *Cochrane Database Syst Rev* 2018; CD008343.

28 Bougeard A, Brent A, Swart M, Snowden C. A survey of UK peri‐operative medicine: pre‐operative care. *Anaesthesia* 2017; **72**:1010-1015.

29 Smith AF, Goodwin D, Mort M, Pope C. Adverse events in anaesthetic practice: qualitative study of definition, discussion and reporting. *Br J Anaesth* 2006; **96**:715-21.

30 Smith AF, Mahajan RP. National critical incident reporting: improving patient safety. *Br J Anaesth* 2009; **103**:623-625.

31 Reed S, Arnal D, Frank O et al. National critical incident reporting systems relevant to anaesthesia: a European survey. *Br J Anaesth* 2013; **112**:546-555.

**Figure 1 Quotations from respondents relating to critical incident reporting and discussion**

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| --- |
| *“We tried it, it didn’t work. Nobody said anything” –* Int 6  *“It’s usually an older colleague, so he would say it’s okay, just the patient was tachycardic, whatever, we should reschedule and have a cardiologist or check-up”* – Int 2  *“So to give yourself additional problems and induce this self-damage, it’s… I think most of us think twice before reporting something that ended up in a good way” –* Int 9  *“I think [incident reporting] depends on the chiefs. Specifically in our hospital… he is very strict and criticises a lot. But there are also consequences in terms of salary, they could reduce your salary for a month or two. If something really serious happens, there are legal consequences also” –* Int 2  *“We are a small society and I believe people were afraid that they would be found out… you do not have anonymity… nobody has the time to dedicate to report… so many things to do and so few people, even if someone wasn’t afraid, he or she would be reluctant to spend time reporting”* – Int 6  *“Losing the opportunity to learn from… aggregated incidents… we want the information… not the names, the places… we want scenarios because we need to see, are there things happening there that are recurring? How can we include these in our training, in our simulation programmes” –* Int 8  *“When I speak to my colleagues and to surgeons, we’ve all got ideas how to improve patient safety, but because of the daily work, the daily practice… there’s no time to actually speak with each other and to exchange ideas… the potential is there, we’re just not getting it out. We do not have the time and the opportunity to actually speak with each other on that issue” –* Int 11  *“It takes knowing each other. You have to really know each other, you have to really trust each other to be able to really take potential of the debriefing at the end of the day… if it’s a really good team, you don’t make yourself vulnerable… you have to know each other more than we do now. We have to make time for that” –* Int 11 |

**Appendix A  Prompt questions used to guide interviews**

1. Please give your name and the organisation/country you represent.

2. Which hospital do you work in? What sort of hospital is this?

3. Have you read the participant information sheet? Are you happy and consent to continue?

4. Could you outline the main factors that ensure safety in anaesthesia and perioperative care?

5. Was the Helsinki Declaration (HD) translated in your country’s primary language?

6. Prior to this interview, how familiar were you with the Helsinki Declaration (HD)?

7. Your organisation signed up to the HD in 2010. What does the HD mean to you personally?

8. How do you think the Helsinki Declaration influences your organisation and hospital?

9. Do you think the HD widely known about in day to day practice?

   Did your national society respond in any way or take any particular action?

10. Has the HD, or the individual topics within it, been incorporated into your country’s formal anaesthesiology training?

11. Which elements of the HD have been most successful in your opinion?

     Why do you think this? Can you think of any particular success stories?

12. Which elements have been most difficult to address?

      Why do you think this is?

      What barriers/obstacles do you think there are to implementing the HD topics?

13. Have there been any significant changes in Anaesthesia since 2010 that the HD doesn’t address?

14. Do you think that HD has any strengths (or limitations) in the way that it is presented/written?      How could the ESA make the HD more accessible in your country?

15. Does the HD need revising?

      If so, what should the EBA and ESA focus on?

16. What practical steps might help improve patient safety in your country?

17. Is there any sort of incident reporting system either in anaesthesiology, or more generally?

     Are there any issues with these reporting systems?

18. What recurrent themes come out of these incident reports?

      Can the HD be used to reduce these incidents?

19. Do links exists between patient safety systems and government/national healthcare policy?

20. Are patient and patient representatives involved in patient safety in your country?

21. Are patients educated and empowered to provide feedback regarding their perioperative care?

     Do you think patient safety could be improved through their feedback?

     How do you think patients should provide this feedback?

22. Is teaching in human factors delivered as part of anaesthesiology training in your country?

     Do you think that ‘human factors’ should be included in the HD?

23. Do you have any other comments or further thoughts on the HD or aspects within it?

24. Can you suggest some hospitals in your country that we could approach for Phase II?

     Names of individuals?

     What type of hospitals are they?