

ORIGINAL ARTICLE

Patient safety and the role of the Helsinki Declaration on Patient Safety in Anaesthesiology

A European survey

Henry H.L. Wu, Sharon R. Lewis, Mirka Čikkelová, Johannes Wacker and Andrew F. Smith

BACKGROUND The Helsinki Declaration on Patient Safety was launched in 2010 by the European Society of Anaesthesiology and the European Board of Anaesthesiology. It is not clear how widely its vision and standards have been adopted.

OBJECTIVE To explore the role of the Helsinki Declaration in promoting and maintaining patient safety in European anaesthesiology.

DESIGN Online survey.

SETTING A total of 38 countries within Europe.

PARTICIPANTS Members of the European Society of Anaesthesiology who responded to an invitation to take part by electronic mail.

MAIN OUTCOME MEASURES Responses from a 16-item online survey to explore each member anaesthesiologist's understanding of the Declaration and compliance with its standards.

RESULTS 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 and 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 threequarters 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 a 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.

CONCLUSION Many patient safety practices encouraged by the Declaration are well embedded in many European countries. The data have highlighted areas where there is still room for improvement.

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Introduction

The pursuit of excellent standards of patient safety has long been prioritised in anaesthesia. 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. The Helsinki Declaration on Patient Safety in Anaesthesiology (hereafter 'the Declaration') was

launched in 2010 by the European Board of Anaesthesiologists (EBA) of the European Union of Medical Specialists in close co-operation with the European Society of Anaesthesiology (ESA).^{3–5} 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

From the Lancaster Patient Safety Research Unit, University Hospitals of Morecambe Bay NHS Foundation Trust, Kendal, UK (HHLW, SRL, AFS), European Society of Anaesthesiology, Brussels, Belgium (MČ) and Hirslanden Clinic, Zürich, Switzerland (JW)

Correspondence to Andrew F. Smith, Department of Anaesthetics, Royal Lancaster Infirmary, Lancaster LA1 4RP, UK Tel: +44 7768 226361; e-mail: andrew.f.smith@mbht.nhs.uk

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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 uptake 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. 9 As part of this project, the Society commissioned a three-phase investigation with broad aims 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 first phase of this investigation, reported here, is a continent-wide survey of registered members of the ESA, to ascertain whether, and to what degree, various aspects of the Declaration have been adopted, and provide an opportunity for respondents to express their opinions about the Declaration, its impact on patient safety, and limitations and barriers in daily practice.

Methods

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 E-Mail from the Authority confirming that, if survey participants were selected by virtue of their membership of a professional organisation, then Health Research Authority approval was not required. Participants gave their implied consent by choosing to take part in the survey.

The survey questionnaire was constructed in May and June 2018. We planned the 16-item questionnaire referring to literature detailing methods in conducting credible survey research^{10–12} and published surveys exploring medical professionals' views on, and attitudes to, patient safety. 13,14 The length of the questionnaire was set so as to ensure sufficient collection of data from respondents on demography, awareness and perceptions of impact of the Declaration and prevalence of specific measures for promoting safety recommended within it, but still allowing completion in a short time. We also allowed some free-text elements to permit respondents to submit more descriptive and detailed comments, if they wished. 12 The questionnaire was written and distributed in English only, this being the language used by the ESA. Both qualified and trainee anaesthesiologist members were invited to participate. The former were defined as registered doctors who have completed full specialist training in anaesthesiology and were recognised by their national society. We also offered respondents the opportunity to identify themselves as a clinical director within their department and, in this case, asked them to complete the survey from the viewpoint of a clinical director rather than simply a practising clinician.

A draft version of the questionnaire was piloted with 10 qualified anaesthesiologists (both native and nonnative English speakers) in June 2018 before an invitation to complete the final edited version (Table 1) within the online survey tool Survey Monkey was sent out to ESA members by electronic mail in July 2018. An initial analysis of responses revealed that a number of non-European ESA members were receiving the survey. As our focus was on patient safety within the continent of Europe (defined as the 38 countries listed in Appendix 1), we discounted responses received at this stage from such members, and sent our first reminder only to European ESA members late in August 2018. An article written by AFS and SRL about the survey was published in the ESA's electronic member Newsletter in September 2018 to increase awareness of the project and encourage responses.¹⁵ A further E-Mail was sent to the leaders of all national anaesthesia societies and ESA Council members in Europe late in November 2018 asking them to encourage members within their countries to respond; further reminders were sent directly to individual members in countries with more than 200 ESA members but fewer than 15 responses. A final invitation to take part was sent to members from nations with more than 200 members but fewer than 25 responses in early December 2018. These cut-off numbers were chosen to try to achieve either reasonable absolute numbers of responses, or a fair proportion of a country's members. The survey was closed on 11 December 2018.

The survey results were imported automatically into a Microsoft Excel spreadsheet for further analysis. Simple descriptive statistics were used for demographic data and the numerical responses to individual questions. Free text responses were grouped into themes where appropriate, using simple qualitative techniques. For the overall analysis, all responses from all countries were included. To assess the robustness and reliability of the data, we identified post hoc the 12 countries with response rates (RRs) of 35% and over, and the 12 countries with more than 25 responses overall. There were 20 such countries in total as there was some overlap between the two groups (see Appendix 1). We also performed a check for the internal consistency of responses, by



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qualitative scrutiny of proportions of different answer options chosen across all respondents from that country, to Questions 11 and 15 within each of five randomly selected countries within the middle two quartiles for RR. We also analysed the responses to Questions 9 (infection control element) and 11 from the 12 highest responding countries both by percentage of members responding and absolute numbers of responses.

Results

Numerical demography (Questions 1 to 3)

The invitation to take part in the survey was sent to 4764 members of the ESA. Of these, 1589 (33.4%) responded to the survey. We received responses from each of the countries listed in Appendix 1. RRs varied between countries, the median [IQR] RR being 20.5% [11.7 to 37.0], with a range of 5.2 to 100%. There were 1566 responses detailing the type of hospital in which respondents worked. Of these, 459 (29.3%) were national referral hospitals, 388 (24.8%) public hospitals, 331 (21.1%) regional referral hospitals, 172 (11.0%) private hospitals and 153 (9.8%) were district or rural community hospitals. The 1569 respondents to Question 3 on position within the hospital comprised 1202 responses (76.6%) from qualified anaesthesiologists, 217 (13.8%) from trainee anaesthesiologists and 150 (9.6%) from clinical directors.

Awareness and perceptions of impact of the Declaration (Questions 4 to 7)

Question 4 elicited 1450 responses, of which 1141 (78.7%) stated that they had heard about the Declaration through ESA events, publications, newsletters and E-Mail communication. A further 103 (7.1%) respondents

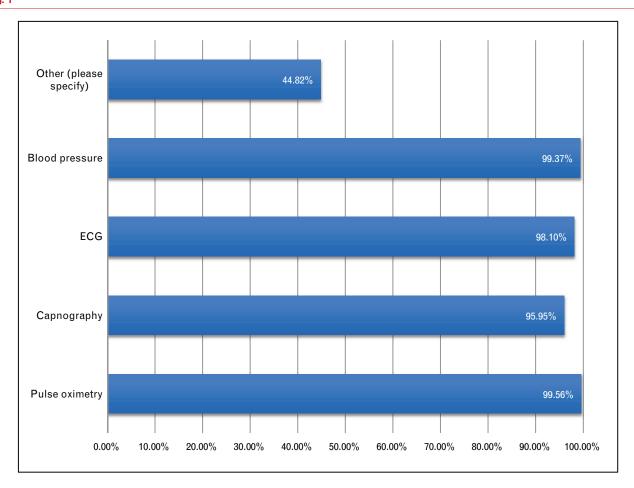
became aware of the Declaration by virtue of their clinical director roles in the department, while 88 (6.1%) and 64 (4.4%) heard about it as trainees or from fellow anaesthesiologists respectively. The remaining 54 (3.7%) cited direct observation during visits to other centres, and their own reading, as the source. In response to Question 5, 1093 of the 1580 respondents (69.2%) thought that their national anaesthesia society had signed up to the Declaration, 33 (2.1%) thought not and 454 (28.7%) were unsure. In terms of the timescale of adoption, out of the 1231 responses, 282 (22.9%) stated that their hospital began to implement the Declaration in 2010, 297 (24.1%) in 2011 to 2012, 273 (22.2%) in 2013 to 2014, 225 (18.3%) in 2015 to 2016 and 175 (14.2%) in 2017 to 2018. As to whether the Declaration had improved patient safety in their hospitals, of the 1530 respondents, 681 (44.5%) answered positively, 84 (5.5%) thought not, and 765 (50.0%) were unsure. Of the respondents who felt there were improvements, 32 provided further comment; most of these expressed the view that having checklists improved the fluency of pre-operative preparations and the management of during anaesthesia.

Prevalence of specific measures for promoting safety (Questions 8 to 15)

The answers to Question 8 'What monitoring standards for peri-operative anaesthesia care does your hospital use?' and Question 9 'Which of the following protocols or guidelines does your hospital use?' are summarised in Figs. 1 and 2. There were very high levels of use of monitoring (pulse oximetry: 99.6%, blood pressure (BP): 99.4%; ECG: 98.1% and capnography: 96.0%). The



Fig. 1



Distribution of answer choices from Question 8: 'What monitoring standards for peri-operative anaesthesia care does your hospital use? (n=1582).

answers of those 709 respondents who entered text to describe what further monitoring modalities they used are given in Table 2. There was widespread use of protocols and policies to guide care (Fig. 2). Further analysis of the data for Question 9 from the 20 countries with the highest RRs revealed no regional or national differences. For infection control policies the overall percentage was 71.2%; the median [range] percentage for the highest responding countries by percentage RR (828 responses in total) was 64% [42.9 to 100] and by absolute number of responses (1016 responses in total) was 71 [51.3 to 89].

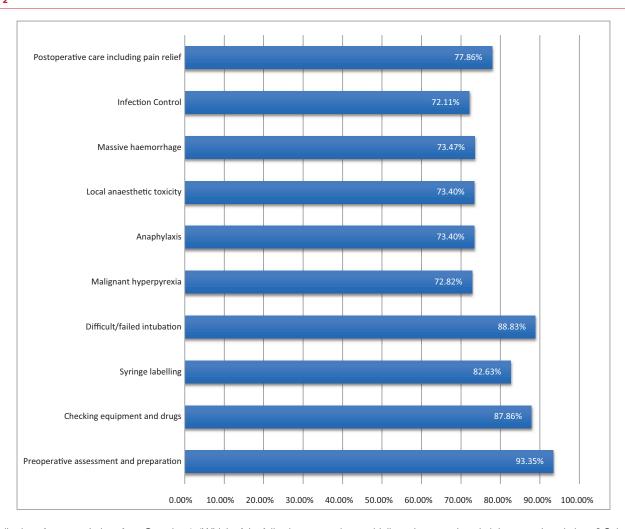
Question 10 related to sedation standards. Of the 1546 responses, 691 (44.7%) used local policies, 587 (38.0%) national guidelines and 117 (7.6%) regional policies. The remaining 374 (24.2%) were unsure which sedation standards their hospital uses.

The responses to Questions 11 to 15 are summarised in Table 3. Of the 248 respondents who answered 'sometimes' to Question 11 on the WHO checklist, 10 offered further explanation, with half referring to difficulties implementing the checklist due to poor motivation and collaboration from the anaesthesia department, whilst the other half noted it was forgotten occasionally despite being acknowledged as a useful patient safety practice. Further analysis of the data for Question 11 from the 20 countries with the highest RR suggested no within-country anomalies. Again, the overall percentage of positive responses was 78.4%; the median [range] percentage for the highest responding countries by percentage RR (852 responses in total) was 68% [28.6 to 100] and by absolute number of responses (1060 responses in total) was 79% [28.1 to 100].

Questions 12 and 13 enquired about annual reports. Question 12 (reports on patient safety measures) generated 1575 responses, of which 588 (37.3%) were positive, 424 (26.9%) negative and 563 (35.8%) unsure. Question 13 (reports on morbidity and mortality) yielded 1573 responses, 876 (55.7%) being positive, 250 (15.9%) negative and 447 (28.4%) unsure. Explanations from respondents who answered 'no' to these questions included poor organisation of data, lack of someone to take responsibility for compiling such reports, and lack of time to do so.



Fig. 2



Distribution of answer choices from Question 9: 'Which of the following protocols or guidelines does your hospital does your hospital use? Select all that apply.' (n=1549).

A total of 1576 responses were obtained to Question 14 on national audits; 586 (37.2%) were positive, 417 (26.5%) negative and 573 (36.4%) unsure. A variety of audits were specified in the free text comments, including Obstetrics, Intensive Care and Microbiology. Question 15 asked about critical incident reporting systems. Of the 1546

Table 2 Additional monitoring modalities as reported in answers to Question 8

Monitoring modality	Others, <i>n</i> =709
Temperature	636 (89.7%)
Neuromuscular blockade	620 (87.4%)
Bispectral edge	613 (86.5%)
EEG	495 (69.8%)
FIO ₂	297 (41.9%)
Gas monitoring	201 (28.3%)
Invasive arterial pressure	137 (19.3%)
Central venous pressure	110 (15.5%)

Only modalities with more than 100 responses are shown.

responses, 1216 (78.7%) were positive, 216 (14.0%) negative and 142 (9.2%) unsure. Six respondents who answered 'no' provided further explanation, either detailing lack of an established critical incident reporting system or lack of anonymity within their organisation. Again, the consistency check on data from the five countries round the median RR suggested no within-country anomalies.

Free text comments on safety and the Declaration (Question 16)

Excluding the 286 respondents who wrote 'no comment', there were 205 responses. Seventy of these (34.1%) commented that adherence to the Declaration would improve if a formal set of checklist items were provided to guide day-to-day practice. A further 51 (24.9%) suggested that greater publicity for the Declaration would increase awareness amongst the anaesthesia community, and that implementation is currently more important



Table 3 Responses for five aspects of the Helsinki Declaration recommendations

Question	Topic	n	'Yes'	'No'	'Unsure'
11	WHO checklist	1558	1222 (78.4%)	93 (6.0%)	243 (15.6%) ^a
12	Safety measures report	1575	588 (37.3%)	424 (26.9%)	563 (35.8%)
12	Morbidity and mortality report	1573	876 (55.7%)	250 (15.9%)	447 (28.4%)
14	National audit participation	1576	586 (37.2%)	417 (26.5%)	573 (36.4%)
15	Critical incident reporting	1574	1216 (78.7%)	216 (14.0%)	142 (9.2%)

^aThird answer option for Question 11 was 'sometimes'.

than possible changes to content. Twenty-five respondents (12.2%) felt that greater attention should be paid to translation into languages other than English, and to simulation training and education to increase awareness of the Declaration during anaesthetic specialist training. Less frequently expressed themes were reshaping the Declaration into pre-operative, intra-operative and postoperative phases; and voiced concerns that financial and other resources had not been made available to enable the principles of the Declaration to be enacted in practice.

Discussion

This is the first publication of a pan-European survey into the state of patient safety in anaesthesiology. It provides a snapshot of the use of patient safety tools and practices across the continent. Essential monitoring, as recommended by the WHO/World Federation of Societies of Anaesthesiology (WFSA) standards¹⁶ was widely used, approaching 100% for pulse oximetry and BP, 98% for ECG and 96% for capnography. There was also widespread use of the WHO surgical checklist, with over 90% of respondents stating that they 'always' or 'sometimes' used the checklist. There was a lower uptake of the opportunity to produce annual reports on safety measures, morbidity and mortality, but over three-quarters of respondents (78.7%) stated that their hospital had a critical incident reporting system.

The study has a number of strengths. First is the questionnaire's creation, which took into account guidance from recently published survey research on patient safety^{13,14} and advice from European anaesthesiologists. Second, the questionnaire was piloted on both native and non-native English speakers to check for accessibility and possible ambiguity. Third, it included both questions which could be answered with a simple 'yes'/'no'/'don't know' and those which invited further comments. This balance enabled us not only to collect data regarding the extent of adherence for each component of the Declaration, but also provided an understanding of practice context in which to frame the quantitative results. Fourth, the dissemination process was well coordinated and used a range of strategies to try to encourage members to respond.

The work also has some limitations. First, despite the piloting, some ambiguities remained. The categorisation of guidelines into 'local', regional' and 'national' was, in retrospect, not helpful, as 'regional' could refer both to an area within an individual country, and to an area comprising a number of countries, even to Europe itself (analogous to the WHO's regions, one of which is Europe itself). Second, there is also the potential for misunderstanding in Questions 12 to 15, when the word 'hospital' was used. The Declaration invites departments of anaesthesia to compile safety reports, and couching these questions at hospital level might have produced different responses from asking about the anaesthesia department instead. We cannot know whether this affected the responses. Third, the overall RR was generally low, although fairly typical for surveys of this type. ¹⁷ The RRs varied from country to country, which in themselves have a variable number and proportion of ESA members amongst their anaesthesiology workforce. It is perhaps inevitable there would be sizeable discrepancies in RR between nations, due to variable interest in ESA membership and to variable national promotion of the Declaration, its component elements and guidelines in general. 18 There was also a marked difference in the enthusiasm and engagement from national leaders in anaesthesiology between the different countries, with some rallying large numbers of responses from their country after we requested them to help; however, most did not succeed in boosting their country's numbers to the same extent. Nevertheless, we are confident that our data are sufficient for the purpose we require. Our check for consistency of responses to Questions 11 and 15, which might be expected to be nationally organised, suggested that even low responding countries are generating accurate data. Further, we are primarily interested in similarities and commonalities of different countries, and here the data (on monitoring modalities, for instance) are relatively robust. We have been careful, however, not to over-interpret the data, as there are many possible (but implicit) confounding biases, including differences in patient demography, roles and responsibilities of anaesthesiologists, socioeconomic contexts of healthcare and political factors within departments of anaesthesiology. We also need to bear in mind that there may be systematic differences between anaesthesiologists who choose to join a European professional and scientific organisation, and those who do not, as well as between those who chose to respond to our survey, and those who did not. Particularly relevant here would be the possibility that ESA member anaesthesiologists responding to our survey might tend to work in different types of hospitals and



anaesthesia departments, which might affect their responses, objective and factual though many of the data we sought were. For all these reasons, we have not presented an analysis of results by country of origin. We will, however, be feeding each country's results back to the national anaesthesia society concerned. Likewise, as the survey was only available in English, it is possible that this may have affected the patterns of participation and response. Finally, as the European Union's General Data Protection Regulation had only recently been implemented (May 2018), we were only able to send the invitation to participate to those ESA members who had agreed to accept such mailings. This was approximately 76% of members in our chosen countries.

Our study showed satisfactory levels of compliance to mandatory monitoring standards in peri-operative anaesthetic care across Europe. Pulse oximetry, capnography, ECG and BP monitoring are all considered 'highly recommended' standards in safe practice in the recently issued WFSA/WHO International Standards for a Safe Practice of Anesthesia.¹⁶ Though questions have been raised about their impact on postoperative outcomes, 18 these are currently considered essential measures of perioperative care. Why they have not been implemented unanimously should be determined. It is also encouraging that monitoring modalities such as temperature¹⁹ (listed 'suggested') and neuromuscular function^{20,21} (described as 'recommended')¹⁶ were extensively used as was bispectral edge monitoring.^{22,23} It is important to note that the monitoring standards set out in the Declaration have been met, if not exceeded, for many years in many countries surveyed.

Overall adherence to established safety-relevant protocols and guidelines was high, with observance rates all above 70%. Protocols relating to pre-operative assessment and preparation²⁴ and airway management²⁵ were reported as being more frequently followed compared with those associated with peri-operative and postoperative pain management.²⁶ There is clearly room for improvement, but part of the challenge must be for guideline working groups to produce usable and useful documents that are available in all European languages. Guidelines are used to summarise standards into a 'stateof-the-art clinical routine', 27 but it must be remembered that patients cannot be standardised, as they vary in comorbitidies and surgical and anaesthetic risks.²⁷⁻²⁹ One option to establish the possible influence of the Declaration on protocols used both before and after 2010 would be to obtain and analyse the versions used in the countries surveyed. However, this was outside the scope of this work.

The majority of respondents stated sedation standards in their daily practice were mainly directed by local or national guidelines (82.7% of total). It would have been informative to determine reasons why many respondents are unsure which sedation standards are being used within their organisation. Procedural sedation is often provided by nonanaesthesiologists, or in some countries, by nonphysicians. It is perhaps unrealistic to expect anaesthesiologists to influence (as the Declaration suggests) the sedation practices of other professional groups. Previous attempts in this regard have been controversial. ^{30,31} A joint working group of the ESA and the EBA published new guidelines for procedural sedation and analgesia in 2018. ³² It addressed previous reservations regarding sedation being provided by nonanaesthesiologists, financial issues with implementation and different workforce structures of anaesthesia teams, amongst other issues. ³³ This may help smooth the path towards harmonisation of practice.

Our results demonstrate generally widespread use of the WHO Safe Surgery Checklist.³⁴ However, it is interesting to examine why some anaesthesiologists would adhere to the checklist in certain situations and not others. 34,35 The reasons given in the survey, such as poor motivation and teamwork in organisations and being forgotten on occasion, are echoed by results from a surgery checklist programme in Michigan.³⁶ Trying to explain why a UK-based initiative to reduce infections associated with venous catheters did not match the success of its US model, Dixon-Woods et al. 36 suggested that success in applying the checklist approach to procedures requires collaborative 'complex, cultural and organisational change, not just the checklist itself'. Success requires early establishment of team roles and responsibilities, and maintaining the structured team communication (time out) even in emergency situations under time pressure, as these are the occasions where mistakes often occur.³⁷ The mere introduction of a checklist does not guarantee its effective application.³⁴

Though 78.7% of respondents reported clear pathways of incident reporting within their organisation, it is not optimal that some hospitals do not use an incident reporting system or that staff are unaware of one. Lack of anonymity suggests potential political barriers in establishing such a system across all levels that need to be overcome. Incident reporting is an important feature of patient safety practice, because identification of errors allows pro-active efforts for change and improvement. Incident reporting can be organised at local, departmental, hospital or national level. 38,39 Different countries have evolved different ways of handling incident reporting, and this is to be encouraged, as it takes into account the national context.⁴⁰ Finally, we note that the percentages of responses suggesting that annual reports on safety measures and/or morbidity and mortality were somewhat lower than the percentages under Question 7 about whether the Declaration had improved safety. This implies that these two aspects of the Declaration are relatively poorly taken up, but we would also suggest that Question 7 deals with respondents' perceptions rather



than objective data; more detail on this question would have been of interest.

Conclusion

The survey has revealed some suggestions for possible changes to the Helsinki Declaration on Patient Safety in Anaesthesiology and for a strategy to promote its use more widely. It has also demonstrated that, although compliance with many of its component elements is good, there is still room for improvement. In this respect, a better understanding of why uptake is incomplete may help identify measures to broaden use of the Declaration. This will be the subject of our future work.

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Conflicts of interest: AFS was one of the authors of the published version of the Helsinki Declaration for Patient Safety in Anaesthesiology. He has also acted as an expert advisor on patient safety to the WHO and the 2nd Global Ministerial Patient Safety Summit in 2017. JW was, until December 2018, the Chair of the Patient Safety and Quality Committee of the European Society of Anaesthesiology.

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Appendix 1: The 38 countries adopted as 'Europe' for the purposes of the survey. An asterisk denotes countries from which we received either more than 25 responses, or with a response rate of 35% or over (n=20)

Albania, Austria, Belgium, Bosnia-Herzogovina, Bulgaria, Croatia*, Czech Republic*, Cyprus*, Denmark, Estonia*, Finland, France, Germany*, Greece*, Hungary, Ireland, Italy*, Kosovo*, Latvia, Lithuania*, Luxembourg*,

Macedonia*, Malta, Moldova, Montenegro, the Netherlands*, Norway*, Poland, Portugal*, Romania, Serbia*, Slovakia, Slovenia, Spain*, Sweden, Switzerland*, Turkey*, United Kingdom*.