**This protocol has regard for the Health Research Authority guidance**

**FULL/LONG TITLE OF THE STUDY**

Evaluation of the extent of implementation of the Helsinki Declaration for Patient Safety in Anaesthesiology: a mixed-methods research project

**SHORT STUDY TITLE / ACRONYM**

Evaluation of the Helsinki Declaration on Safety in Anaesthesiology

**PROTOCOL VERSION NUMBER AND DATE**

1. 12 April 2018

# SIGNATURE PAGE

The Chief Investigator confirms that the following protocol has been agreed and that the study will be conducted in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor’s SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

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| **Chief Investigator:** |
| Signature:...F:\Andrew Smith.jpg.......................... |  | Date: 12/04/18 |
| Name: (please print):............Andrew Smith........................................................  |  |  |

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# KEY STUDY CONTACTS

Insert full details of the key study contacts including the following

|  |  |
| --- | --- |
| Chief Investigator | Andrew SmithConsultant AnaesthetistUniversity Hospitals of Morecambe Bay NHS TrustAndrew.f.smith@mbht.nhs.uk01524 583517 |
| Study Co-ordinator | n/a |
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| Joint-sponsor(s)/co-sponsor(s)  | n/a |
| Funder(s) | European Society of Anaesthesiology  |
| Key Protocol Contributors | Andrew Smith |

**STUDY SUMMARY**

This proposal outlines a plan for a research evaluation of the effects, uptake and implementation of the Helsinki Declaration, to be conducted in partnership with the European Society of Anaesthesiology (ESA), industry and the national anaesthesia societies. Not only will this achieve its aim of understanding the impact of the Declaration within the general context of patient safety in anaesthesia in Europe, it will simultaneously raise the profile of the Declaration still further and enable evidence-based revision of the Declaration to ensure it remains ‘fit for purpose’.

**FUNDING AND SUPPORT IN KIND**

|  |  |
| --- | --- |
| **FUNDER(S)** | **FINANCIAL AND NON FINANCIALSUPPORT GIVEN** |
| European Society of Anaesthesiology24 Rue des ComédiensBrusselsB 1000Tel. 0032-(0)2-743-3290Email: mirka.cikkelova@esahq.org | Euros 195 198 |

**ROLE OF STUDY SPONSOR AND FUNDER**

The sponsor will not play any role in study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

A member of the ESA Secretariat will provide administrative support during the project, but this will be the extent of the funder’s involvement.

**ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS**

The project will be overseen by the ESA Patient Safety and Quality Committee and the ESA National Anaesthesia Societies Committee (NASC), or a small subgroup of members of these Committees. The Committees, together with our industry partners, will also act as a ‘think tank’ for ideas, resources and contacts as necessary. In addition, we would be keen to draw on the expertise of Grant Aaron, Global Health Director, Masimo, who has already provided a preliminary framework for some aspects of the evaluation.

Day-to day management, with weekly project meetings, will be the responsibility of Professor Smith. The project team will report to the Patient Safety and Quality Committee, the NASC and/or the ESA Board every 3 months.

Financial monitoring and reporting will take place according to the standard procedures of the University Hospitals of Morecambe Bay NHS Trust.

|  |  |
| --- | --- |
| **KEY WORDS:** | Anaesthesiology; patient safety  |

**STUDY PROTOCOL**

Evaluation of the extent of implementation of the Helsinki Declaration for Patient Safety in Anaesthesiology: a mixed-methods research project

# 1 BACKGROUND

Preventable patient harm is an important challenge in anaesthesiology and peri-operative care. As a response, the Helsinki Declaration on Patient Safety in Anaesthesiology was launched in 2010 by the ESA and European Board of Anaesthesiology [1], 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 has been signed by all European national societies of anaesthesiology and many international societies. However, it is not clear to what extent the Declaration has been implemented. A survey in the Berlin-Brandenburg region of Germany suggested that, at the time the survey was conducted (2011), many of the Declaration’s standards were already met. It is likely, therefore, that these were already in place, in view of the short time period between the launch of the Declaration and the survey [2]. More recently, an internal survey found that many European departments of anaesthesia were trying to apply the Declaration’s standards in practice [3]. There is, however, very little other work evaluating its impact and effects.

The goals of the project are to map the extent of, and identify deficiencies and regional differences in, the implementation of the Declaration so far since its launch in 2010, thereby also improving adoption into clinical practice.

# 2 RATIONALE

The work will use a number of separate but interlinking approaches to examine the uptake and implementation of the Helsinki Declaration. The effects of the Declaration can be sought at various levels of organisation, illustrated in the diagram below. Ideally one would want to assess the impact on patient outcomes, but this is the most difficult to evaluate as many other factors affect these. Thus, no patient level data will be collected. Instead, our initial work will focus on the structures underlying anaesthesia care in Europe and how these may have changed since the launch of the Declaration. A second phase will target a number of individual countries, and examine how selected aspects of the Declaration have succeeded (or failed) in practice, and how these relate to the processes of patient care, through site visits to hospitals and interviews with clinical staff. The topics and countries will be identified from intelligence gathered during Phase I.



**3 THEORETICAL FRAMEWORK**

Also implicit in this model is the notion that the accounts provided of the Declaration, its coverage and impact, may vary depending on the organisational level where they are sought. Within organisations, there is sometimes a tension between ‘work as imagined’ (what ought to take place according to the ‘official’ organisational view) and ‘work as done’ [4]. In addition, the wider policy, regulatory and legal frameworks within which healthcare work takes place are not represented here, but should nevertheless be included in the comprehensive impact pathway mapping proposed as part of Phase I below.

# 4 RESEARCH QUESTION/AIM(S)

This project will:

• Examine the uptake and implementation of the Helsinki Declaration and how it relates to patient safety practices in European anaesthesiology more generally

• Map the extent of coverage and identify regional differences

• Identify discrepancies in implementation of the component elements of the Helsinki Declaration

• Inform updating, refinement and further promotion of the Declaration

• Identify patient safety tools (‘instruments’) for testing in further work

# 5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

We will collect the following data:

High-level quantitative data from electronic surveys of ESA members and hospitals throughout Europe, with intelligence on which elements of the Declaration are thought to have been most and least successful.

Documentary analysis of departmental policies and protocols, hospital and national incident reporting schemes and policies, annual safety reports of anaesthesia departments (as recommended by the Declaration), etc

Focused qualitative enquiry based on in-depth interviews, and observations of practice in a small number of individual hospitals, to understand local practice, culture and context [8] – currently this proposal is costed based on observations in four countries, which will not include England.

Quantitative data will be summarised with the usual descriptive statistical measures. Transcripts of interviews and observations will be analysed using the constant comparative method [9], a commonly-used and workable qualitative analytical strategy.

Triangulation of the intelligence gathered through the different approaches will allow both breadth and depth of understanding of the extent to which the Declaration has been adopted throughout Europe, the success or otherwise of the constituent elements of the Declaration, and an appreciation of why it has or has not ‘worked’ in different practice contexts.

# 6 STUDY SETTING

The work will be performed within the Lancaster Patient Safety Research Unit. The Unit was founded in 2008 with development funding from the UK National Institute for Health Research and has a track record of conducting complex projects, including evaluation and evidence synthesis, within the fields of healthcare quality and safety. Relevant projects include analyses of large datasets (e.g. of safety incident databases [10]), European-wide surveys [11], the application of qualitative methods to healthcare work [12] and mixed-methods evaluation of service changes [13]. Professor Andrew Smith will act as guarantor for the project and provide methodological and organisational support. We will also employ one full-time post-doctoral researcher to co-ordinate the work and undertake the main share of the data collection, analysis and reporting. In addition, we would like to work with residents from other European countries, to develop research methodology and an understanding of patient safety science more widely in the next generation of anaesthesiologists. Additional resource may also be available at no cost to the ESA from anaesthetists in training in the North West region of England, where there is an active trainees’ research network, the North West Research and Audit Group [www.nwrag.com].

We would also count on administrative support from ESA Headquarters for the duration of the project and close collaboration with the ESA NASC and the ESA Patient Safety and Quality Committee.

**7 SAMPLE AND RECRUITMENT**

**Detailed workplan: Phase I**

*Preliminary work*

We will make lists of national European anaesthesiology society contacts (based on the list in Appendix 2) and attend NASC/ESA Council meetings to brief them and enlist support. We will stratify the countries whose anaesthesiology organisations signed the Declaration into income bands, based on the World Bank’s list of high- and low-middle income countries. This will inform our choice of countries for site visits in Phase II. We will work with national societies to publicise the project and ‘prepare the ground’ at appropriate points during the work. We will also map out a more detailed impact pathway for the Declaration based on the diagram above and existing literature on health service coverage [14]. This will be useful not only to guide our work, but also serves to explain to those outside anaesthesiology what might be implicitly clear to anaesthesiologists and those within ESA. In addition, it will help to secure ‘buy in’ to the project from these partners and stakeholders. This will form part of our communications strategy, to be developed in collaboration with the ESA Communications Department and our industry partners.

*Background intelligence gathering*

Review implementation literature, existing tools and approaches for promoting safety initiatives (e.g. WHO), with particular reference to how this is achieved in resource-poor settings. Specific tasks are to document implementation methods for the Declaration so far (how do they measure up to the approaches identified from the literature above?) and to examine to what extent simple methods (‘nudges’) can change safety behaviours to the benefit of anaesthesiology departments and patient outcomes.

Review peer-reviewed and ‘grey’ literature for material relating to the implementation of the Helsinki Declaration

Review specific items in Declaration, performing a quick literature/policy search to ensure we have up-to-date background evidence on each item

Scan society websites for policies and other documents relating to the Declaration (may need to wait for interviews with national representatives to make full sense of these).

*Electronic surveys*

We will issue email invitations to take part in online surveys.

The target populations for such surveys might include any or all of:

• All ESA members (more specifically, a random sample of members in each European nation, at least 25 in each).

• The c. 700 anaesthesiologists who have previously responded to ESA communications indicating that they are especially interested in patient safety.

• Previous participants at the ESA Patient Safety Courses and Patient Safety Masterclasses

• Those who responded to the internal survey referred to above [3]

• All ESA trainee members

• An ESA contact at each hospital where ESA members work

Indicative questions for these surveys are set out in Appendix 3.

*Telephone interviews*

We will conduct semi-structured telephone interviews with a leader in anaesthesiology in each member European country (see Appendix 2). These might be that country’s representative on the ESA’s NASC, the country’s member on the ESA Council, or another individual identified by them, or the head of the country’s national anaesthesia society. Interviews will take place by telephone or Skype and will be recorded using digital audio-recording equipment. We will use interview prompts developed from the draft set out in Appendix 4.

*Further planning*

Within each group, we will identify candidate countries for the detailed site visits in Phase II. Within each World Bank income band, the choice will be influenced by practicality – access to potential study sites, and a high-level ‘project champion’ within the country would be important considerations. Existing individuals and/or anaesthesia departments who have signed up to the Declaration might also be useful contacts.

We will begin the recruitment process for European anaesthesiology trainees in candidate countries to take on freelance researcher role. We will design training materials and arrange training workshops/project meetings for these individuals.

**Detailed workplan: Phase II**

Working in conjunction with national societies, our key contact in each country and our trainee researchers, we will secure appropriate ethical clearance for the site visits, interviews etc, if required, within each of four or five European countries. Through a computer-generated random number sequence, we will create a list of hospitals within each target country, and make contact with departments of anaesthesia in the random order identified to explain the aims of the project and establish if the Declaration has been implemented or not. If a department of anaesthesia does not wish to take part, we will move to the next on the list [15]. We will repeat this process until four or five have been chosen. We expect that this sampling strategy will yield a mix of types of hospital (university/district general/specialist) across a wide geographical spread in each country.

Within each hospital, working with a native speaker, we will inspect policies and procedures relevant to patient safety in anaesthesiology, with the broad aim of establishing to what extent the hospital/department of anaesthesia has fulfilled the requirements of the Helsinki Declaration. We also intend to observe critical safety procedures such as the World Health Organisation surgical checklist carried out in the operating theatre before the patient’s arrival, and explore the layout, equipment and facilities and how they relate to safety. Within each site, we will conduct semi-structured interviews with 3 or 4 randomly selected anaesthesiologists, covering similar material to the questions in the schedule for the interviews in Appendix 4, but also to clarify queries arising from the procedures and observations. Again, data from different sources will be triangulated to build up a picture of patient safety and the role of the Helsinki Declaration within it.

**8 TIMELINES AND MILESTONES**

**Timeline**

* Months 1 – 3: Start Phase I of project. Directed review of relevant literature relating to implementation of similar programmes and necessary methodology for the research. Training provided to full-time research associate. Setting up email databases, project management, financial structures and reporting arrangements. Make contact with ESA Council, NASC Chair and national anaesthesia societies. Develop survey questions.
* Months 4 – 6: Send email questionnaires. Conduct interviews via telephone/Skype with leaders in anaesthesia. Process and analyse responses.
* Months 7 – 12: Write up, present and submit for peer-reviewed publication the conducted in Phase I. Identify target countries and departments with key stakeholders and ‘gatekeepers’ to access Phase II of project. Begin work on necessary national/European ethical approvals for Phase II if required.
* Months 13 – 18: Start Phase II of project. Develop observation agenda, to include questions to participating personnel during site visits. Arrange site visits and collect observational data. Aim to conduct analysis in tandem with data collection in order to focus on particular areas of interest.
* Months 19 -24: Continue analysis. Write up, present and submit for peer-reviewed publication. Provide recommendations for further implementation of Declaration and revision, if appropriate.

**Milestones**

* 3 months: Approvals with HRA. Databases of potential survey respondents constructed. Survey questionnaire designed and piloted. Contacts within national anaesthesia societies identified and briefed about purpose of project and their involvement.
* 6 months: Online survey questionnaires sent out. Telephone/Skype interviews commenced. Literature review completed.
* 9 months: Results from online surveys analysed and shared with Steering Group. Telephone/Skype interviews completed. Candidate countries for site visits identified.
* 12 months: Results from interviews analysed and written up.
* 15 months: Site visit schedule finalised. Observation agenda agreed.
* 18 months: Site visits completed.
* 21 months: Analysis of observational data completed, and written up. Nominate safety ‘instruments’ for further evaluation in a follow-up project.
* 24 months: Write study report of Phase I and Phase II for peer-reviewed publication. Submit final project report to ESA Board and Patient Safety and Quality Committee.

# 9 ETHICAL AND REGULATORY CONSIDERATIONS

## See IRAS form. Participants will be anaesthesiologists and other health care professionals being surveyed or interviewed about their work, or hosting site visits for documentary analysis or observation of practice.

## **9.1 Assessment and management of risk**

## As described above the risks of participating in the study are minimal.

## There is one possible instance of instances in which risk mitigation interventions will be made:

## • If the researcher feels that any patient is in danger of imminent harm during a Phase II observation, patient safety should take precedent over the objectives of the study and the researcher may intervene as in any other clinical situation. Any intervention will be recorded in the field notes.

**9.2 Research Ethics Committee (REC) and other Regulatory review & reports**

According to the HRA’s triage tool (3 November 2017), this project counts as research but would not require review by a Research Ethics Committee.

**Regulatory Review & Compliance**

Before observations begin in selected European countries, the Chief Investigator will ensure that appropriate approvals from participating organisations are in place.

**9.3 Peer review**

The proposal has been read by members of the ESA's Patient Safety and Quality Committee. In addition, at a meeting in October 2017, it was presented and discussed by a wider group of stakeholders in the project, including scientific staff with a background in evaluation and epidemiology. The final version of the proposal reflects their expert comments and review.

**9.4 Patient & Public Involvement**

Not involved.

**9.5 Protocol compliance**

This is not a study where a high degree of prior specification is required, as for instance the clinical trial of a new medicinal product. One of the strengths of the inductive approach is that it allows the flexibility to pursue previously unforeseen but scientifically rewarding lines of enquiry within the broad framework of intent set out in this protocol.

###

**9.6 Data protection and patient confidentiality**

Collection, storage, processing and disclosure of personal information and will uphold the Act’s core principles. The treatment of different data types is described below:

• Electronic transfer: all transfer of personal data will be encrypted.

• Use of personal contact details: a list of participants will be maintained in a physical file in a locked filing cabinet and destroyed once the project concludes. The purpose of keeping these data is to be able to contact participants for follow-up contacts if required.

• Publication of direct quotes: Material will be anonymised using pseudonyms for participants and locations, in order to maintain confidentiality as far as possible.

• Publication of data that might identify individuals: based on the information about the location of the institutions, their patient demographics, and the procedures reported, the institutions may be identifiable to an informed reader. It is conceivable that some key informants (e.g. heads of department) might be identifiable through such a process of deduction; this issue will be made clear on the consent form.

• Use of audio recording: Interviews will be recorded electronically on a password-protected digital audio recorder. Recordings will be anonymised during transcription and then destroyed once the accuracy of transcription is verified.

• Storage of Personal Data: Manual files will be used to maintain the list of contacts as described above. Audio data will be stored on the recording device, and will need to be transferred to a password-protected NHS computer or laptop. Personal data will be stored for the minimum possible time as described above. Once member-checking has taken place there will be no use for personal data and after this point it will be destroyed. Non-personal (anonymised) data will be stored electronically as password-protected files in a password-protected account on NHS computers for five years following the conclusion of the study. This is to allow time for additional analysis of the data.

9.7 Indemnity

Indemnity will be through the usual provisions of the Sponsor.

**9.8 Access to the final study dataset**

The research team would have access to the final dataset.

### 10 DISSEMINATION POLICY

### 10.1 Dissemination policy

Data arising from the study will be owned by the study sponsor, the University Hospitals of Morecambe Bay NHS Trust. On completion of the study the data will be analysed and tabulated and a final study report will be prepared. In addition to this, the research team will aim to publish a number of journal articles to disseminate key findings. The funding body will be acknowledged in any publications and presentations arising from this study. Participants will be informed of the publication of key findings, and directed to the appropriate open-access journal articles. There are no plans to make the protocol and full dataset publicly available.

**10.2 Authorship eligibility guidelines and any intended use of professional writers**

### The International Committee of Medical Journal Editors’ guidelines for authorship will be adopted. These guidelines state that an author must meet four criteria:

### • Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work.

### • Drafting the work or revising it critically for important intellectual content.

### • Final approval of the version to be published.

### • Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

### 11 REFERENCES

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### 12. APPENDICES

**12.1 Appendix 1- Required documentation**

The work will be based only at the University Hospitals of Morecambe Bay NHS Trust.

**12.2 Appendix 2 National European societies of anaesthesiology**

Those marked with # are member states of the European Union.

Albania

Armenia

Austria#

Belarus

Belgium#

Bosnia and Herzegovina

Bulgaria#

Croatia#

Czech Republic#

Denmark#

Estonia#

Finland#

France#

Georgia

Germany#

Greece#

Hungary#

Iceland

Israel

Italy

Kosovo

Latvia#

Lithuania#

Luxembourg#

Malta#

Netherlands#

Norway

Poland#

Portugal#

Republic of Macedonia

Republic of Moldova

Romania#

Russian Federation

Serbia

Slovakia#

Slovenia#

Spain#

Sweden#

Switzerland

Turkey

Ukraine

United Kingdom of Great Britain and Ireland#

**12.3 Appendix 3 Draft questions for online surveys in Phase I**

Please state which country you work in.

What type of hospital do you work in? (University/district/private/other)

Has your national anaesthesiology signed up to the Helsinki Declaration on Patient Safety in Anaesthesiology?

Has the Helsinki Declaration made a difference to anaesthesiology care in your hospital?

If so, why do you think that is?

If not, why not?

What protocols and policies do you work to for each of the elements?

Would you be willing to send us copies (all material will be treated in confidence)?

Would you and/or others in your hospital be interested in hearing more about the evaluation project as our work progresses?

Would you be interested in receiving a summary of ways to help implement the Declaration in practice when our researchers have prepared it?

Would you be interested in hosting a site visit during the later phase of the project?

**12.4 Appendix 4 Draft interview schedule for national societies’ representatives/ESA Council members etc**

Please give your name and the organisation/country you represent. Which hospital do you work in? What sort of hospital is that?

Your organisation signed up to the Helsinki Declaration in 2010. What does it mean to you personally, and to the organisation?

Was it translated into [language]?

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

Has it (or the topics within it) been incorporated into training in anaesthesiology?

Which elements of the HD have been most successful in your opinion? Why is this? Can you think of any particular success stories?

Which elements have been most difficult to address? Why is this? What barriers/obstacles do you think there are to safety and/or putting the Declaration into practice?

Has anything changed since 2010?

[Work through sections of Declaration for comment and further thoughts]

What should the ESA and EBA focus on if the HD is revised?

What practical steps might help improve patient safety/advance the Declaration in your view/in your country?

Tell me about patient safety in anaesthesiology in [country].

Is there any sort of incident reporting system either in anaesthesiology etc or more generally?

What recurrent themes come out of these?

What links to government/national healthcare policy are there?

What is the role of patients and their representatives in this?

Can you suggest some hospitals we could approach for Phase II? Names of individuals? What type of hospitals are they?