SPECIAL ARTICLE

THE HELSINKI DECLARATION ON PATIENT SAFETY IN ANAESTHESIOLOGY

Jannicke Mellin-Olsen, Sven Staender, David K. Whitaker and Andrew F. Smith

Anaesthesiology, which includes anaesthesia, perioperative care, intensive care medicine, pain therapy and emergency medicine, has always participated in systematic attempts to improve patient safety. Anaesthesiologists have a unique, crossspecialty opportunity to influence the safety and quality of patient care. Past achievements have allowed our specialty a perception that it has become safe, but there should be no room for complacency when there is more to be done. Increasingly older and sicker patients, more complex surgical interventions, more pressure on throughput, new drugs and devices and simple chance all pose hazards in the work of anaesthesiologists. In response to this increasingly difficult and complex working environment, the European Board of Anaesthesiology (EBA), in cooperation with the European Society of Anaesthesiology (ESA), has produced a blueprint for patient safety in anaesthesiology. This document, to be known as the Helsinki Declaration on Patient Safety in Anaesthesiology, was endorsed by these two bodies together with the World Health Organization (WHO), the World Federation of Societies of Anaesthesiologists (WFSA), and the European Patients' Federation (EPF) at the Euroanaesthesia meeting in Helsinki in June 2010. The Declaration represents a shared European view of that which is worthy, achievable, and needed to improve patient safety in anaesthesiology in 2010. The Declaration recommends practical steps that all anaesthesiologists who are not already using them can successfully include in their own clinical practice. In parallel, EBA and ESA have launched a joint patient safety task-force in order to put these recommendations into practice. It is planned to review this Declaration document regularly. Eur J Anaesthesiol 2010;27:592–597

KEYWORDS*: Education, patient safety, perioperative care, standards.*

INTRODUCTION

The notion of nonmalfeasance as one of the guiding ethical principles of medical practice is as old as Hippocrates. However, as possibilities widen and interventions become more powerful, introducing greater complexity into the healthcare process, the potential for harm has increased. Policy-makers, patients, politicians and the news media are no longer content to allow healthcare professionals to continue to manage the risks alone and without overt control.

Patient safety has three components: a set of guiding principles, a body of knowledge and a collection of tools (1). The principles are: the tendency for things to go wrong is both natural and normal, rather than an opportunity to find someone to blame; safety can be improved by analysing errors and critical incidents, rather than pretending they have not happened; and humans, machines and equipment are all part of a system, the component parts of which interact to make the system safe or unsafe. Knowledge is largely taken from other safety-critical, high-reliability industries such as mass transportation and nuclear power (2) and includes an understanding of how accidents arise and how they can be prevented. Finally, the tools include critical incident reporting (3–5), checklists (6), safe system design, communication protocols[7] and systematic analysis of risks (8).

Morbidity and mortality in medicine

Medical errors cause death and disability (9,10), and recently a number of studies have tried to quantify the scale of that problem. In a systematic review examining more than 70 000 records of a general patient-population, the overall incidence of in-hospital adverse events was 9.2%, of which 43.5% were thought to be preventable (11). More than half (56.3%) of these patients experienced none or only minor disability; however, 7.4% of the events were lethal. The majority of the events were surgery-related (39.6%) or medication-related (15.1%).

Morbidity and mortality in anaesthesiology

With regard to risks that are directly related to anaesthesiology, surrogates of safety must be considered. Before 1980, in an era that predates the widespread use of pulse oximetry and capnography, anaesthesia-related mortality rates were estimated between about 1 : 2500 and 1 : 5000.12–16 It has not been formally proven that the introduction of these new monitoring devices has had a beneficial effect on morbidity or mortality, but nevertheless the decrease in the rate of anaesthesia-related cardiac arrests, mainly related to respiratory causes, from2.1 to 1.0 per 10 000 anaesthetics over a 20-year period from 1969 to 198817 supports this assumption.

During the last decade, mortality rates in anaesthesia have been reported from France, the Netherlands, the United States and Australia.[18–20] In the Netherlands, Arbous et al.[18] found that, between 1995 and 1997, the incidence of anaesthesia-related deaths within 24 h of a procedure was 0.14 per 100 000 procedures (8.8 per 100 000 for only partly anaesthesia-related deaths). In France, Lienhart et al.[19] reported that, in 1999, anaesthesia-related in-hospital mortality rate was 0.7 per 100 000 and partially anaesthesia-related death rate was 4.7 per 100 000; 42% of deaths occurred within 24 h of the procedure. These rates were even lower for the American Society of Anesthesiology (ASA) I patients, in whom mortality solely or partially related to anaesthesia was found to be 0.4 per 100 000.[19] The study from Australia corroborates these findings; Gibbs and Borton[20] found for the period 2000–2002 an anaesthesia-related mortality rate within 24 h of anaesthesia of 0.55 per 100 000. In the United States, between 1999 and 2005, Li et al.21 reported an anaesthesia-related death rate of 1.1 per million population per year and 8.2 per million hospital surgical discharges. The authors estimated that the mortality risk of anaesthesia for surgical inpatients was 0.82 in 100 000 cases, which provides further support for the data from Australia and Europe. Overall, the mortality risk from complications and adverse events of anaesthesia today appears to lie at approximately 1 in 100 000 cases for Australia, Europe and the United States.

There are several limitations to the measurement of anaesthesia-related mortality because of the loose definition of what is meant when an event is described as solely or only partially related to anaesthesia, and also with such low incidences, the denominator needs to be very large in order to draw meaningful conclusions. Further, in long-term studies, study population, technology and patient care may change, making intrastudy and interstudy comparisons difficult.[22] Despite this, the overall improvement in the anaesthesia-related mortality rates over the years is obvious. The studies can only speculate as to what has been responsible for the improvement seen; better monitoring and equipment, new anaesthetic drugs, better training, availability of recovery room facilities and improved airway management are just a few advances worthy of mention.

A surrogate of safety is morbidity data. Studies of anaesthesia-related morbidity show that complications still remain frequent, though deaths solely due to anaesthesia are uncommon. A number of well conducted studies have found an overall incidence of minor anaesthesia-related perioperative events of 18–22%.[23,24] More serious perioperative complications were reported at a rate of 0.45–1.4%, and complications resulting in permanent damage were found at a rate of 0.2–0.6%.[23]

These numbers clearly put the low rates of anaesthesia mortality into perspective. In approximate terms, severe perioperative complications with permanent damage occur in 1 per 170–500 patients, whereas anaesthesiarelated death occurs in less than 1 per 100 000 patients. Adverse events that do not cause the patient any harm are much more common, but the exact numbers are unknown due to lack of a denominator.[25] These 'undesirable events' should be prevented not only because they may represent poor care in themselves, but also because such events have been linked to subsequent, more serious intraoperative and postoperative problems.[26] 'Undesirable events' should be investigated and analysed in order to learn why they happened and how they can be prevented from happening again.[27]

Patient safety in anaesthesiology

Since the very beginning, anaesthesiology has participated in systematic attempts to improve patient safety;[28] for example, in the setting of standards for colour codes of medical gas cylinders as early as 1932.[29] This important fact brings two equally important consequences. First, it is the duty of anaesthesiologists to build on their past achievements and not to allow the familiar and comforting image of the specialty as 'safe' to permit complacency.[30] Older and sicker patients, increased pressure on throughput, new drugs and devices and more complex procedures all increase hazards in the anaesthesiologist's work. Second, anaesthesiologists' care of patients is not limited to the perioperative period. In most European countries, our specialty is closely involved in intensive care medicine, in which patients are exposed to both similar and additional risks.[31] Anaesthesiologists are also involved in the treatment of acute and chronic pain patients. Finally, critical emergency medicine is another area where anaesthesiologists play an important role.[32] One UK study showed that anaesthesiologists were involved in the care of 60% of hospital inpatients, and this included all clinical specialties when their patients' degree of illness became critical.[33] In all these fields, anaesthesiologists share skills and experience to enhance patient safety. Thus, anaesthesiologists have a unique, cross-specialty opportunity to influence safety and quality of patient care.[34]

The Helsinki Declaration on Patient Safety in Anaesthesiology: a European initiative

As a response to this situation and in order to show leadership in such an important area, the European Board of Anaesthesiology (EBA), in cooperation with the European Society of Anaesthesiology (ESA), has developed a Declaration on Patient Safety in Anaesthesiology (see appendix).

METHOD

Starting in June 2009, the patient safety subcommittee of the EBA consulted widely before writing this document and many individuals and representatives of national societies have been involved in its drafting and development. The ESA scientific programme subcommittee 'evidence-based practice and quality improvement' as well as the 'patient safety' subcommittee were involved from the beginning. The first draft was discussed in a meeting in London with representatives from all over Europe in November 2009. Subsequently, it was ratified by all EBA representatives as well as the ESA Board of Directors. The Declaration in its present form is the result of a consensus between both the ESA Board of Directors and the EBA.

THE DECLARATION

The Declaration builds on earlier statements about safety and quality of care.[33,35,36] It represents a shared European opinion of what currently is both worthy and achievable to improve patient safety in anaesthesiology in 2010. The Declaration recommends practical steps that all anaesthesiologists who are not already using them should include in their own practice. These are relatively straightforward and, where they are currently being used, have a track record of improving patient safety. All European anaesthesiology institutions are expected to support the WHO 'Safe Surgery Saves Lives' initiative including the 'Safe Surgery Checklist', where anaesthesiology plays an important role and where other safety recommendations are made. The Declaration was endorsed by the EBA and ESA. It was officially launched at the Euroanaesthesia congress in Helsinki in June 2010 and was subsequently signed by several representatives of European anaesthesiology and other stakeholders [WHO, World Federation of Societies of Anaesthesiologists (WFSA), European Patients Federation (EPF)].

THE WAY FORWARD

Other healthcare stakeholders are welcome to endorse the Declaration and to join the EBA and ESA in their initiative in improving patient safety in Europe and beyond. Close cooperation between European organisations will be required to achieve this. A joint EBA and ESA task force for patient safety (David Whitaker and Guttorm Brattebø representing the EBA and Andrew F. Smith with Sven Staender (chairman) representing the ESA) has recently been launched to develop and support a variety of patient-safety initiatives and support research in that field in order to put the recommendations of the Declaration into practice in Europe. It is planned to review the Declaration document regularly.

This consensus statement provides an authoritative document that European anaesthesiologists can present to health authorities, politicians, policy-makers, funders, hospital managers or departmental directors in order to help persuade them to introduce the required safety measures locally and nationally. If this can be achieved, we are convinced that in due course the Declaration may become a tool for continual improvement in standards of patient safety in European anaesthesiology, serving the best interests of our patients.

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From the European Board of Anaesthesiology/UEMS (JM-O), the Patient Safety Committee of the European Board of Anaesthesiology (D-KW), and the Task-Force on Patient Safety of the European Society of Anaesthesiology (SS, AFS)

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APPENDIX

Helsinki Declaration on Patient Safety in Anaesthesiology

BACKGROUND

Anaesthesiology shares responsibility for quality and safety in Anaesthesia, Intensive Care, Emergency Medicine and Pain Medicine, including the whole perioperative process and also in many other situations inside and outside the hospital where patients are at their most vulnerable.

- Around 230 million patients undergo anaesthesia for major surgery in the world every year. Seven million develop severe complications associated with these surgical procedures from which one million die (200,000 in Europe).[1] All involved should try to reduce this complication rate significantly.
- Anaesthesiology is the key specialty in medicine to take up responsibility for achieving the goals listed below which will notably improve Patient Safety in Europe.

HEADS OF AGREEMENT

We, the leaders of societies representing the medical speciality of anaesthesiology, met in Helsinki on 13 June 2010 and all agree that:

- Patients have a right to expect to be safe and protected from harm during their medical care and anaesthesiology has a key role to play improving patient safety perioperatively. To this end we fully endorse the World Federation of Societies of Anaesthesiologists International Standards for a Safe Practice of Anaesthesia.[2]
- Patients have an important role to play in their safe care which they should be educated about and given opportunities to provide feedback to further improve the process for others.3,4
- The funders of healthcare have a right to expect that perioperative anaesthesia care will be delivered sa fely and therefore they must provide appropriate resources.
- Education has a key role to play in improving patient safety, and we fully support the development, dissemination and delivery of patient safety training.[5]
- Human factors play a large part in the delivery of safe care to patients, and we will work with our surgical, nursing and other clinical partners to reliably provide this.[6]
- Our partners in industry have an important role to play in developing, manufacturing and supplying safe drugs and equipment for our patients' care.
- Anaesthesiology has been a key specialty in medicine leading the development of patient safety. We are not complacent and know there are still more areas to improve through research and innovation.[7]
- No ethical, legal or regulatory requirement should reduce or eliminate any of the protections for safe care set forth in this Declaration.

PRINCIPAL REQUIREMENTS

Today we pledge to join with the European Board of Anaesthesiology (EBA) in declaring the following aims for improving Patient Safety in Europe. Close cooperation between European organisations will be required to achieve these goals, for which the input and efforts of the European Society of Anaesthesiology (ESA) will be instrumental:

1. All institutions providing perioperative anaesthesia care to patients (in Europe) should comply with the minimum standards of monitoring recommended by the EBA both in operating theatres and in recovery areas.[8]
2. All such institutions should have protocols[2,9] and the necessary facilities for managing the following
   - Preoperative assessment and preparation
   - Checking Equipment and drugs
   - Syringe labelling
   - Difficult/failed intubation
   - Malignant hyperpyrexia
   - Anaphylaxis
   - Local anaesthetic toxicity
   - Massive haemorrhage
   - Infection control
   - Postoperative care including pain relief
3. All institutions providing sedation to patients must comply with anaesthesiology recognised sedation standards for safe practice.[10–14]
4. All institutions should support the WHO Safe Surgery Saves Lives initiative and Checklist.[15]
5. All departments of anaesthesiology in Europe must be able to produce an annual report of measures taken and results obtained in improving patient safety locally.
6. All institutions providing anaesthesiological care to patients must collect the required data to be able to produce an annual report on patient morbidity and mortality.
7. All institutions providing anaesthesiological care to patients must contribute to the recognised national or other major audits of safe practice and critical incident reporting systems. Resources must be provided to achieve this.

CONCLUSION

- This declaration emphasises the key role of anaesthesiology in promoting safe perioperative care.

CONTINUITY

- We invite anyone involved in healthcare to join us and sign up to this declaration.
- We will reconvene to annually review our progress to implement this declaration.

SIGNED

Dr. Jannicke Mellin-Olsen,

President, European Board of Anaesthesiology/ UEMS

Prof. Paolo Pelosi,

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Prof. Hugo Van Aken,

Chairperson, National Anaesthesia Societies Committee on behalf of the ESA Member Societies

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