The Helsinki Declaration on Patient Safety in Anaesthesiology.

David K Whitaker

Introduction

Everyone wants patients to be as safe as possible and to do no harm is one of the guiding ethical principles of medicine dating back to least the time of Hippocrates. Ever since anaesthesiology started to develop the doctors practicing it were concerned for a successful outcome for patients in their care because the safety margins of drugs available were narrow and human physiology was much less well understood. Some of John Snow’s (1813-1858) anaesthetic records are available and he conducted research to improve practice and patient safety (1). Over 150 years later anaesthesiology encompasses anaesthesia, intensive care medicine, emergency medicine and pain medicine and Healthcare itself has become much more complex. For example the numerous and sophisticated advances in surgery made possible by parallel advances in anaesthesia have led to much more complicated processes involving numerous pieces of equipment, powerful drugs and large teams of personnel. Demographic changes mean that increasingly older and sicker patients are requiring treatment in the operating theatre and intensive care units. Changes in society accompanied by political interest and information in the media have made patient safety a topic of widespread interest. It is also now accepted amongst the profession that there is a normal and natural tendency for errors to occur but by identifying and critically analysing them their root causes can be addressed and their potential to cause harm patients reduced. Anaesthesiology has made considerable strides being the first specialty to address the subject (2-3) but it is not complacent and that is why in 2009 its leaders in Europe decided to take stock of what was already agreed and set out proposals of what might be done to continue improving patient safety in anaesthesiology in the years ahead. To this end the European Board of Anaesthesiology (EBA) of the UEMS in cooperation with the European Society of Anaesthesiology (ESA) drew up a document titled the Helsinki Declaration on Patient Safety in Anaesthesiology (4). This was endorsed by the two bodies together with the World Health Organisation (WHO), the World Federation of Societies of Anaesthesiologists (WFSA), and the European Patients Federation at the Euroanaesthesia meeting in Helsinki in June 2010

Helsinki Declaration: Background

(The actual text of the Helsinki Declaration is printed in Italics throughout)

Anaesthesiology shares responsibility for quality and safety in anaesthesia, intensive care, emergency medicine and pain medicine, including the whole perioperative process and also with many other situations inside and outside the hospital where patients are at their most vulnerable.

This highlights the fact that anaesthesiologists have knowledge and skills which are applicable for treating patients across a wide range of healthcare situations. The National Audit Office (NAO) in the UK showed that anaesthesiologists are involved in the care of 60% of patients in hospital (5) and outside they can be involved in prehospital and emergency care. All these areas have developed with the involvement of anaesthesiologists taking on new challenges and applying their experience and skills to provide safe care for patients in new situations. Intensive Care developed with anaesthesiologists transferring their techniques out of the operating theatre to deal with
critically ill patients. Many of the techniques such as, ventilation, monitoring e.g. pulmonary
artery catheters, syringe drivers and presently transoesophageal echocardiography and ECMO
were transferred from cardiac anaesthesia. Surprisingly continuous waveform capnography is one
monitoring modality which in many European countries has not been widely adopted in intensive
care (6) and this is one area for improving the safety of such patients in the future (7). As well as
being specialists in acute medicine anaesthesiologists play leading role in the management of
patients with pain, both acute and chronic, and some of the long-term conditions associated with it.
This was originally a natural extension of the skills of anaesthesiologists with needle techniques
for local blocks and experience in the use of opiates. Again however the treatment of patients with
chronic pain has developed enormously now requiring expertise in multiple pharmacology,
radiology and psychology (8).

Around 230 million patients undergo anaesthesia for major surgery in the world every year.
7 million developed severe complications associated with the surgical procedures from which
1 million die (200,000 in Europe). All involved should try to reduce this complication rate
significantly (9).

Around 2008 the World Health Organisation (WHO) started to concern themselves with the
burden of harm to patients as a result of mortality and complications following surgery around the
world. For the first time an accurate assessment of the number of operations being carried out
worldwide was made along with calculations of the mortality and incidence of complications (9).
This showed the harm to patients to be in excess of many of the other things which WHO regards
as epidemics, malaria and AIDS etc, As a result of this the World Alliance for Patient Safety set
up the project Safe Surgery Saves Lives (SSSL) led by Atul Gawande to address it and this
developed and published the WHO Surgical Checklist which is available on the WHO website.

In consideration of the data from Europe, which was amongst the most complete in Weiser's
paper, with a population of 560 million and 60 million operations a year, it is estimated that 1
million patients will die and 200,000 have severe complications after surgery. Weiser also
suggests that these figures could be halved using the WHO Checklist. Anaesthesia related
mortality and morbidity makes up part of this harm to patients but taken on its own this occurs at a
much lower rate. The current figures were considered in some detail by Mellin Olsen et al (4) who
have suggested specific anaesthesia related death occurs in less than 1 per 100,000 patients and
severe perioperative complications with permanent damage occurred in 1 per 170 - 500 patients.
This provides the context in which we are working and demonstrates that even within
anaesthesiology which has made considerable progress since the early days when mortality was
1 per 200 (still 1 per 50 for anaesthesia for Caesarean section in parts of Africa (10)) there is still
scope for considerable improvement. Also as part of the perioperative team anaesthesiologists can
play a role for example with checklists and promoting a safety culture and so help raise the whole
performance of the team within which they work.

Anaesthesiology is the key specialty in medicine to take responsibility for achieving the goals
listed below which will notably improve Patient Safety in Europe.

The goals listed in the declaration relate to anaesthesia, intensive care, emergency medicine, and
pain medicine and as such anaesthesiologists are the group to promote and implement them in
these areas of clinical practice. Many of the goals however are not exclusive to anaesthesiology
and through their promotion and development in our area of clinical practice the specialty can
show leadership and encourage them to be applied throughout the whole of medicine further
contributing towards the safety of patients in Europe.

Helsinki Declaration: Heads of Agreement

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 in 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.

The doctor patient relationship is such that every patient being treated would reasonably expect all possible attempts will be made within the context of their care for the risk of harm to be kept to a minimum. As highlighted before anaesthesiology has an overarching role involving patients' perioperative care from pre-assessment through the operating theatre to their recovery and treatment of any ensuing chronic pain. The World Federation of Societies of Anaesthesiologists (WFSA) produced a set of standards for the safe practice of anaesthesia in all countries around the world taking into account their healthcare system context. These were updated at the World Congress in Cape Town in 2008 and set minimum standards which should be achievable (11). All anaesthesiologists should be aware of these standards and try to work within them on every occasion.

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 (12-13). Patient centred health services have become the modern agenda, they always should have been, but maybe now some people are only just appreciating this. Patients need to be informed and given the opportunity to interact with their carers to assist in making their patient pathway as safe as possible. They also have responsibility to cooperate appropriately for both their own and other patients benefit. As with all services there should be adequate opportunity for them to give feedback which should be respectfully analysed and used to improve future care. Patients should always be listened to from the beginning of their medical history through to their experience of often completed treatment and this can provide a very valuable learning opportunity for other matters as well as patient safety.

The funders of health care have a right to expect that perioperative anaesthesia care will be delivered safely and therefore they must provide appropriate resources.

Average healthcare spending in the EU states is 8.3% of gross domestic product (GDP) and ranges from less than 6% in Cyprus and Romania to more than 10% in France, Switzerland, Germany and Austria (14). Depending on each country's arrangements this will be a variable combination of government spending from direct taxation, insurance funded schemes and cash purchase. Whichever it is all funders expect that the healthcare they are paying for will provide the safest outcomes not least for the reason that when taken overall this can provide the most cost efficient outturn. As a rule of thumb 50% of the total cost of caring for any group of surgical patients will ultimately be spent on 10% of the group who develop complications (15). Some of these complications may have developed from lapses in safe care and therefore if number of patients harmed by such complications can be reduced by even a small amount a considerable dividend will be paid. It is logical therefore that the necessary resources for safe care are appropriately funded otherwise it is unreasonable to expect the optimum care all parties aim for.

Education has a key role to play in improving patient safety, and we fully support the development, and dissemination of delivery of patient safety training (16).

Patient safety training both theoretical and practical is now being developed by anaesthesiologists throughout Europe. The declaration emphasises the key role that has to play in raising awareness of the issues and improving safety standards. It should of course begin in medical school and a number of training packages for medical students are now available including one from the WHO (17-18). European Society of anaesthesiology provides Patient Safety Training at its meetings and the EBA/ ESA Patient Safety Task Force (PSTF) will further stimulate its development.

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 (19-20).
The realisation that human factors are involved in 70% of critical incidents in other areas of activity suggests that it should be similar for incidents in medicine (21). There is an increasing amount of research about the role human factors play in anaesthesiology and a cross transfer of existing learning from other industries. Human factors are even more complicated when the workplace involves large teams in particular those that are multidisciplinary coming from a wide variety of training and backgrounds (22). It is therefore essential that any consideration of human factors fully involves anaesthesiologists, surgical, nursing and other clinical colleagues together and even more importantly, if possible, the particular individuals who we work with, day in day out. Simulation has a part to play but it does not always need to be at a distance in large purpose built facilities just rehearsing scenarios with the regular team in theatre or intensive care unit can be particularly valuable, especially if properly debriefed afterwards when most of the learning occurs. Communication is better when a shared common mental model is used like SBAR (Situation, Background, Assessment, and Recommendation) (23).

Our partners in industry have an important role to play in developing, manufacturing and supplying safe drugs and equipment for our patients’ care.

The wider health care team includes the whole supply chain and this is particularly important in anaesthesiology because of the considerable amounts of drugs and equipment that our profession uses. The development of safe and effective pharmaceuticals has become a massive undertaking and randomised controlled trials that can cost up to £100million are verging on the prohibitive to new therapeutic interventions (24). Randomised controlled trials with drugs given in tightly defined circumstances to a limited number of patients are not ideally suited to ensuring the ultimate safety of the drug. These days it is only through rigorous post marketing surveillance by clinicians that this knowledge can be acquired. Simplifying the clinical trial and research process is one of medicines current challenges along with reducing the time span for new drugs to be introduced into clinical practice.

Anaesthesiologists are very dependent on having safe and reliable equipment to use. The industry that provides it has a good track record of responding to clinical requirements and we must continue to support and develop this partnership. The laryngeal mask provides an excellent example of how an innovative clinician’s idea, pushing the envelope, also required a pioneering manufacturer to have the confidence to back it and revolutionise one area of anaesthesiologists patient care worldwide (25). The National Patient Safety Agency in the UK recommends a “Purchasing for Safety” policy (26). If two products are similar the safest should always be purchased. As well as providing safer equipment at the time longer term it influences the culture of the market supporting companies who are designing safer products and incentivising the others to do the same.

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 (3).

As mentioned above and anaesthesia related mortality rates were formerly much higher than at present but through a whole series of step changes including the use of safer drugs, better understanding of human physiology, improved equipment, better training, and analysis of critical incidents anaesthesia led the way to improving this significantly. Learning from the continuum of patient safety improvements in the past we know this must continue and a focusing of research and promotion of tested innovations in this area will translate into further reducing the number of patients who are harmed.

No ethical, legal or regulatory requirement should reduce or eliminate any of the protection for safe care set forth in this Declaration.

The signatories to this document see patient safety as paramount but are well aware of the law of unintended consequences where changes in other areas such as ethical, legal or regulatory which
may when seen standing alone appear appropriate but when fully implemented can have knock-on effects with deleterious effects on patient care (27). A number of targets set by the UK government for the NHS management to carry out were shown to be distorting the clinical priorities by which patients are treated and have since been withdrawn. Anaesthesiologists should remain vigilant to the wider picture influencing the safety of patients in their care and raise any legitimate concerns they have.

**Helsinki Declaration: Principal Requirements**

The heads of agreement mentioned above summarise the current issues thought to be significant for patient safety in anaesthesiology in Europe. Ensuring they translate into significant improvements in clinical practice is the even more difficult second stage. This was recognised by all involved who thought that some concrete practical advice should also be specifically be put forward to provide guidance to support anaesthesiologists taking the issue forward (4).

It was thought that these principal requirements should be practical, clearly set out, readily attainable, have plenty of information and examples to follow (28). The list was reached by consensus and represents what was considered potentially achievable by anaesthesiologists applicable for the care of every patient and by departments and institutions for the anaesthesiology services they provide. In this way the words of the Helsinki Declaration will be put into practice.

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.

As a result of this the EBA and ESA have set up a joint Patient Safety Task Force (PSTF) which will facilitate the implementation of the Helsinki Declaration taking this work forward and providing access to the necessary protocols and tools that anaesthesiologists may need to carry it out. In connection with this the task force will set up a patient safety webpage providing background information and links to documents, templates and other safety resources. One of the templates they will provide will be for the annual report on patient safety departments of anaesthesiology are encouraged to produce. The PSTF will invite departments who are willing to submit their annual reports and in this way track progress and share good practice and lessons learned with other European anaesthesiologists. Similarly the task force will act as a clearing house for incident reporting sharing individual incidents of outstanding importance and national recommendations arising out of incident reporting systems. The task force will also facilitate research and audit related to patient safety and the first project is planned to be a study on drugs syringe labelling.

1. All such institutions providing perioperative anaesthesia care to patients (in Europe) should comply with the minimum standards of monitoring recommended by the EBA in operating theatres and in recovery areas (29).

Minimal monitoring standards for every anaesthetised patient of non-invasive blood pressure measurement, ECG, pulse oximetry and capnography were first introduced in 1984 in the United States in the Harvard group of hospitals (30). In the ensuing years there was a marked reduction in the number of patients with hypoxic brain damage and subsequent reduction in medico legal premiums for anaesthesiologists. Other countries introduced similar minimal monitoring standards with similar results and 2007 European Board of Anaesthesiology recommended similar up-to-date standards for both operating theatres and recovery areas (29). Recovery areas have sometimes been overlooked in the past and it is particularly important that patients continue to receive high standards of monitoring and care until they are fully awake and safe to return to the ward. More standardisation of monitoring equipment dedicating colours to specific parameter traces e.g. red for arterial pressure and specific tones for particular alarms could further enhance safety (31).
2. All institutions should have protocols (32) and the necessary facilities for managing the following.

The key to having a high reliability safe organisation is to do the right thing to every patient all of the time. Having protocols developed by consensus to say what is normally the right thing to do in a particular set of circumstances is one way to set about doing this. Standardisation of routines, drugs, equipment and documentation will also ensure that care can be more reliably and safely given. The Helsinki Declaration suggests 10 topic areas where protocols are already available and used by some hospitals. Adopting these directly or modifying them appropriately for local use is a relatively simple way to provide safe up-to-date patient care in these 10 significant areas of practice. As well as the protocols the necessary facilities for delivering them are required and if they are not all completely in place the very existence of an accepted protocol elsewhere strengthens the case for having them funded and acquired locally.

**Preoperative assessment and preparation**

Preoperative assessment of elective patients ensures that they are fit for the intended operation and also provides time for any comorbidities to be adequately treated and optimised prior to anaesthesia and surgery. Not only is this cost-effective and avoids unnecessary last-minute cancellations but also ensures the patient is this in the safest of medical condition to undergo the stress of surgery (33). There is not the same luxury of time for emergency patients but they can still be preoperatively assessed and for example appropriate resuscitation begun prior to anaesthesia and surgery. As well as optimising co morbidities preoperative preparation may involve simple measures such raising the patient’s haemoglobin to the upper end of the normal range prior to blood losing surgery to provide extra margin of safety in the perioperative period and avoid unnecessary donor blood transfusion (34).

**Checking equipment and drugs**

Checklists for anaesthetic equipment and machines were one of the early safety measures introduced by anaesthesiologists to mirror those of preflight checks by airline pilots (35-36). These have become more sophisticated as have the anaesthetic machines but one core component remains a readily available alternative source of ventilation patient with a self inflating bag and mask and an independent supply of oxygen for a cylinder. Every anaesthetic venue should have this and all relevant staff be familiar with its location and operation. Checklists for drugs are also used in particular those that are required in emergency situations and cardiac arrests. Keeping drug filled syringes on trays in standard positions can reduce errors and omissions.

**Syringe labeling**

Medication safety is a whole subject itself and covered in detail in chapter 4. It is however probably the next area after minimal monitoring where significant advances can be made. Anaesthesiologists prepare and give more intravenous drugs than any other doctor and since the introduction of plastic disposable syringes and needles more than 50 years ago very few safety improvements have been made. User applied syringe labels using the international code (37) were recommended and European Board of Anaesthesiology for use in anaesthesia, intensive care, emergency medicine and pain medicine throughout Europe in 2008. Used correctly, drawing the drug up into the syringe and applying the correct label whilst the syringe is still in the anaesthesiologist’s hand before putting it down can reduce drug errors caused by syringe swaps, distraction and other human factors (38). This is seen as a low-cost safety intervention and one of the early pieces of work supported by the EBA/ESA Patient Safety Task Force will be a Europe wide survey to look at this.

**Difficult/failed intubation**

Airway management is a fundamental key skill for anaesthesiologists but a number of patients still come to harm from poorly managed difficult or failed intubation situations. Difficult intubation protocols are now widely available and every anaesthetist should be familiar with one
and periodically rehearse it ideally with the theatre teams they regularly work with (39-40). Various pieces of equipment from gum elastic boogies upwards are now available to help with these difficult situations and again an appropriate selection with which local anaesthesiologists have been trained should be readily available for all anaesthesia locations (41).

**Malignant hyperpyrexia**

Malignant hyperpyrexia is fortunately a rare condition that can specifically be triggered by some drugs that anaesthesiologists use and can lead to patient deaths. For this reason a protocol for recognising, managing it and all the necessary drugs should again be readily available in all anaesthesia locations (42).

**Anaphylaxis**

Anaphylaxis is a more frequent occurrence which can be caused by almost any drug, some intravenous fluids, latex and other substances (43). This again causes anaesthetic related mortality and morbidity and protocols for its diagnosis and treatment are now widely available (44). The necessary drugs and resuscitation equipment must be kept at all appropriate clinical locations.

**Local anaesthetic toxicity**

Local anaesthetic toxicity continues to occur and as techniques involving local anaesthetics increase its incidence may similarly increase. Preventative measures such as first knowing, then not exceeding, the toxic dose of the local anaesthetic agents are essential but inadvertent intravascular injections can still occur. Every department of anaesthesiology should have an up to date protocol for its diagnosis and treatment including a readily available supply of 10% intralipid (45-46).

**Massive haemorrhage**

 Massive haemorrhage is clearly a life-threatening situation which anaesthesiologists should be prepared to deal with and again protocols are available which can be adapted to coordinate and fast-track the local supply of blood (47). In the United Kingdom the highest cause of death associated with the blood transfusion is no longer administrative or clerical error but the physical non-availability of blood in a timely manner to patients experiencing massive haemorrhage. There have been 11 deaths and 83 incidents in the last four years. Institutions had been recommended to improve their lines of communication and blood delivery when the critical nature of a massive haemorrhage has become apparent and unusually large quantities of blood and blood products requested urgently (48). On large sites additional supplies of O negative blood can be kept in satellite fridges close to clinical areas.

**Infection control**

The importance of infection control has been emphasised by the appearance of prion related disease and a number of antibiotic resistant infections. Anaesthesiologists have a particular role to play in the way they practice in the perioperative period and intensive care. Protocols have been devised to guide anaesthesiologists in these situations and it is important that they tie in with other local protocols that are addressing this issue (49). Many additional pieces of equipment are now available as disposable items but all round considerations of patient safety need to be taken into account when thinking of introducing them.

In the United States there have been more than 35 outbreaks of viral hepatitis relating to unsafe medication injection practice in the period 1998-2008. Over 100,000 individuals were exposed and hepatitis B virus (HBV) or hepatitis C (HCV) was transmitted to more than 500 patients (50). Many cases were caused by staff using 50 ml bottles of propofol for more than one patient (51-52) and in 2010 the first of at least 145 patients infected in Nevada was awarded $500m from the pharmaceutical companies who continued the market the 50ml bottles despite warnings from the earlier episodes. A public health “One and Only campaign” has now been launched to inform patients and staff about safe injection practices: ONE Needle, ONE Syringe, ONLY ONE time (53). Where ever possible multidose containers should no longer be used for injections (54) and
500ml saline bags often used e.g. on intensive care for filling syringes for line flushing and drug preparation, should never be used for more than one patient. These are best replaced with separate saline ampoules and pharmacy prepared drugs in prefilled syringes.

Post operative care including pain relief

Protocols for postoperative care and pain relief are available (55-56) (57). Many patients now benefit from acute pain techniques such as post-operative pain relief from patient controlled analgesia and continuous epidural infusions. Whatever these are used protocols should be drawn up for their safe management and all staff in the post-operative areas where such patients are nursed should be familiar with them and the management of possible complications.

3. All institutions providing sedation to patients must comply with anaesthesiology related sedation standards for safe practice (58-62).

An increasing range of procedures are being carried out under sedation in areas outside the operating theatre such as radiology departments, cardiac catheter laboratories and other remote sites around the hospital. The same high standards of care should maintained wherever sedation is carried out and recognised up to date guidelines should be followed paying particular attention to oxygen and recommendations for using capnography (63).

4. All institutions should support the WHO Safe Surgery Saves Lives initiative and Checklist.

It is now recognized that surgical mortality is of the same order as in epidemics that WHO considers as global public health problems (64). In 2008 the WHO World Alliance for Patients Safety took surgical safety as its second Global Patient Safety Challenge, the first was the Save Lives Clean Hands campaign (see chapter 5). A large part was the development and promulgation of a 3 section checklist with “Sign in”, ”Time out” and “Sign out” to be used for every surgical procedure. It is freely available in many languages for local and specialty adaption still following the original key principles. Having fully functioning anaesthesia monitoring in the “Sign in” was one of these and the WHO checklist sets pulse oximetry as the minimum standard for every patient about to undergo anaesthesia worldwide. This has extended onto a further Global Oximetry project to provide cheap pulse oximeters to hospitals in poor countries (65-66). Countries where minimal monitoring standards already exceed this should substitute their existing standard in their local checklist in its place. Team training in connection with the use of checklists, briefing at the start of the list and debriefing at the end can be particularly valuable and reduce mortality (67-68).

There is an international lack of data about perioperative activity, so called Surgical Vital Statistics and the final section of the SSSL project includes data collection which is essential to inform providers and funders about the available resources for surgical patients’ care.

<table>
<thead>
<tr>
<th>Data Collection at a National Level (Surgical Vital Statistics)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Number of surgical procedures performed in the operating theatre per 100,000 population per year</td>
</tr>
<tr>
<td>• Number of Operating Theatres per 100,000 population</td>
</tr>
<tr>
<td>• Number of surgeons per 100,000 population</td>
</tr>
<tr>
<td>• Number of anesthesia professionals per 100,000 population</td>
</tr>
<tr>
<td>• Day-of-surgery mortality rate</td>
</tr>
<tr>
<td>• Postoperative in-hospital mortality rate</td>
</tr>
</tbody>
</table>

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.

One of the ways to raise the topic of patient safety up the agenda of any department of anaesthesiology’s priorities is to create opportunity for everyone to reflect on the current situation
locally and how it might be improved in the future. Producing an annual report provides just such an opportunity to focus on this particular aspect and then use it to inform the rest of the department, hospital colleagues and other parties further afield. Some departments may already do this. The EBA/ESA Patient Safety Task Force has produced a template for any department that wishes to use and also an example of a completed report to inform the process and show what might be possible. These are available on the PSTF website. The suggested departmental patient safety report begins with a few demographic details about the department to set the context and then provides a checklist to measure progress on the implementation of the principal requirements for having protocols available as included in the Helsinki declaration. There is a section for the department to outline the measures taken and results obtained in improving patient safety locally in the last 12 months. Each safety initiative can be outlined in terms of how the safety hazard was officially first recognised, what action was taken and what improvements to outcomes had been obtained. It is suggested that departments should be able to cover at least three of these a year and reporting them in this way will be useful if the report is shared with other departments who could then learn from their initiative and experience. There is a section for the department to identify safety hazards or risks they have recognised but which are still waiting attention. Listing the top three may help guide the department’s safety initiatives over the coming year and again if these are shared with other departments they in turn may be able to offer solutions or improvements they have already made in these areas. The next section provides opportunity to comment and reflect on factors that may have prevented patient safety initiatives progressing over the last 12 months which again if shared with others may provide an opportunity for potential solutions to overcome these barriers to be imported into the home department.

In the next section the department can highlight the important patient safety lessons it has learnt over the past 12 months that it would wish to share or promulgate to others. Section 7 of the Helsinki Declaration requires participation in appropriate national and other major audits of safe practice and critical incident reporting and the departmental report can record this here as well. Section 6 of the Helsinki Declaration requires all institutions providing anaesthesiological care to patients to collect data on patient mortality and morbidity and there is opportunity to include this data in the departmental report. As outlined above the value of producing such report occurs at several levels. The first and maybe most important is the internal reflection within a department about patient safety and how its actions and processes currently deliver this locally and how it could be improved in the future. Such a report could remain an internal document having already provided the department with the opportunity for it to scrutinise its own performance. If however it is decided to share the report with a wider audience even just within the local hospital it will raise awareness of how their department of anaesthesiology is developing patient safety and encourage other hospital departments to raise their game. Sharing the report and its data further afield with other departments nationally or internationally will provide a wider opportunity for sharing learning and exchanging solutions to current safety problems. The EBA/ESA task force plans to be a focus for departments who voluntarily wish to submit their reports and share the lessons learned.

The first annual report for each department will have a learning curve but repeating the process every 12 months should become easier and more refined and become built into the work and culture of the department.

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.

Most institutions collect this type of data and there are variable requirements to submit some of this to different organisations on a regional or national basis. The WHO SSSL initiative decided that almost every healthcare institution in the world should have the capability with even the most rudimentary of records system to be able to determine the number of patients dying on the same
date as they had their surgery. More sophisticated systems often collect the number of patients dying within 30 days of surgery and even more refined ones can track patients until their deaths are eventually reported to the National death register. The number of patients dying on the day of surgery however is a way of picking up say deaths on the table and other catastrophic events which may be associated with anaesthesia and therefore all institutions and nations should collect this as recommended by the WHO. The Helsinki Declaration implies that institutional morbidity and mortality data should be such that it can be related to anaesthesiological care and that the institution should provide the resources to gather this. The subgroup of such data in the institutions annual report will be able to be used by departments in their own without having to duplicate data collection.

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.

There are now a number of recognised national and major audits of safe practice that doctors can contribute to. e.g. National Confidential Enquiry into Patient Outcome and Death (NCEPOD) (69) in the UK and all clinicians should see it as part of their practice and responsibility to take part. Similarly a number of critical incident reporting systems have been developed and again good practice would dictate that all appropriate incidents are reported. e.g. The Swiss Anaesthesia Critical Incident Reporting System (CIRS) (70) and the UK Anaesthesia reporting system “e-form” (71). Because of the importance of this activity all institutions should recognise it and provide the necessary time and resources for their clinicians to fully take part.

Helsinki Declaration: Conclusion

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

As stated at the outset of the Helsinki Declaration anaesthesiology encompassing anaesthesia, intensive care medicine, emergency medicine, and pain medicine is intimately involved with patients throughout the whole of their perioperative pathway and everything anaesthesiologists do can have a direct effect on their safety. Because anaesthesiologists recognised this from the early days of the specialty and started to put measures in place to reduce anaesthetic related mortality and harm to patients a track record and culture of safety related behaviour has developed which confers a key role on them to lead further such developments in the future. The declaration sets down agreement as to how far the specialty is along this road today and provides pointers for what are widely considered the next areas where effort should be directed by individual clinicians, departments of anaesthesiology and their related institutions. This chapter tries to put these words into practice by explaining their background and purpose and outlining some of the actions that all three groups can now take to implement them.

Helsinki Declaration: Continuity

We invite anyone involved in health care to join us and sign up to this declaration.

This declaration was primarily a European initiative and to get consensus from a professional group caring for a population of around 560 million is no mean achievement and that in itself reinforces the confidence that it represents the current core of thinking. Healthcare today is increasingly based around teams and this document was always intended to be inclusive therefore the signatories invite would like to invite anyone else involved in healthcare to join them and sign it. The initial signatories were Dr. Jannicke Mellin-Olsen, President, European Board of Anaesthesiology/UEMS, Prof. Paolo Pelosi, President, European Society of Anaesthesiology, Prof. Hugo Van Aken, Chairperson, National Anaesthesia Societies Committee on behalf of the ESA Member Societies. They were closely followed by a representative of the World Health
Organisation (WHO), Dr Angela Enright, President, World Federation of Societies of Anaesthesiologists, President, European Patients Federation. By 2011 it had received a further 50 entries representing many other national societies of anaesthesiologists and other professional groups.

We will reconvene to annually review our progress to implement this declaration.

Good words are only as good as their implementation and right from the start it was agreed that they should be kept under annual review. Patient safety in anaesthesiology is a dynamic and continually developing process and as progress is made in one area new hazards become apparent in another and so the emphasis of the Helsinki Declaration will need to take these into account. The EBA and ESA have set up a joint Patient Safety Task Force (PSTF) to take this effort forward and provide and coordinate the tools and protocols that anaesthesiologists, departments and institutions may need to implement the declaration. For the time being the Helsinki foundation has been laid, the patient safety principles set out, and it just remains for each and every anaesthesiologist not to hesitate a moment longer and start to carry out the hard work of putting these words into practice.

Practice points

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.
2. All such institutions should have protocols 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 recognized sedation standards for safe practice.
4. All institutions should support the WHO Safe Surgery Saves Lives initiative and Checklist.
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 recognized national or other major audits of safe practice and critical incident reporting systems. Resources must be provided to achieve this.
Medication safety is high on anaesthesiologists’ research agenda and studies are required to look at the labelling of syringes, the pre-filling of syringes, the methods of checking syringes immediately prior to administration and infection control. Research is required into the standardisation of concentrations of intravenous drugs used by anaesthesiologists, in operating theatres and intensive care their provision in prefilled syringes. Research is required into the value of standardising procedures, equipment, documents and the perioperative environment. Evidence needs to be gathered to the extent of the role human factors play in medical incidents and lessons learned from other industries that can appropriately transferred to medicine. There is an urgent need conduct a study of the practicality and value of simulation exercises in the workplace. Studies need to be carried out to evaluate the most effective ways of communicating with patients about safety in anaesthesiology and educating them about the different levels of risk.

Dr Whitaker is a Consultant Anaesthetist with an interest in Cardiothoracic Anaesthesia and Intensive Care at Manchester Royal Infirmary where he also set up the Acute Pain Service and developed blood conservation techniques. He is a Past President of the Association of Anaesthetists of Great Britain and Ireland (AAGBI) and currently is an elected member of the Council of The Royal College of Anaesthetists (RCA). He sits on the European Board of Anaesthesiology of the UEMS Chairing their Patient Safety Committee and in connection with the EBA Helsinki Declaration on Patient Safety in Anaesthesiology 2010 he is a member of the EBA/ESA Patient Safety Task Force (PTSF) set up to help implement it. He is a member of the Safety Committee of the World Federation of Societies of Anaesthesia (WFSA) and his current interests are promoting the Helsinki Declaration on Patient Safety, Medication Safety, Global Pulse Oximetry (see www.lifebox.org/) and the more widespread use of capnography

References

38. National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines 1: Australian Commission on Safety and Quality in Health Care; 2010. Available from:
54. Feinmann J. Doctors call for ban on multidose vials after hepatitis C outbreak in US. BMJ 2010;341:c4057.


70. The Anaesthesia Critical Incident Reporting System (CIRSC©); Available from: http://www.anaesthesie.ch/cirs/.