Perioperative patient safety and quality

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1. Perioperative patient safety - nature of the problem, concepts for solutions

The following is the summary of a workshop about perioperative patient safety and quality for anaesthesiologists during the Vth CEEA in Košice, Slovakia, on November 27, 2019. Basic concepts and practical suggestions for the clinical practice of anaesthesiologists were presented and discussed. However, this workshop was designed to be interactive in order to integrate the clinical experiences of the participants and the local characteristics of their hospitals and health care environments. Therefore, this summary is only a framework of the workshop, presenting a short epidemiological outline of perioperative patient safety based on the international scientific literature, selected models that describe why perioperative patient harm occurs, and approaches to improve perioperative patient safety and quality. Particular emphasis is on the patient safety requirements recommended by the Helsinki Declaration on Patient Safety in Anaesthesiology[1] (hereafter referred to as 'HD'), which represents the most important patient safety initiative of the European Society of Anaesthesiology (ESA). The HD was launched in 2010 by ESA together with the European Board of Anaesthesiology, and with other partner organisations.[1]

But what do we mean when talking about patient safety? Several definitions of patient safety are available, and in the context of this workshop the definition proposed by Charles Vincent, Professor of Psychology at the University of Oxford, UK, in his textbook "Patient Safety" of 2010 is used.[2] According to this definition, patient safety is "*The avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare*".[2] In other words, adverse events or injuries stemming from what we as clinicians do, and what our healthcare processes do - and not from the underlying disease or injury. Consistently, the focus of patient safety should be on preventable patient harm. Ideally, protective elements within healthcare systems should be strengthened if possible. James Reason, another British psychologists, has developed the "Swiss Cheese Model" to illustrate how usually many "layers" of defenses, barriers and safeguards prevent errors from leading to major harm – but if weaknesses within such layers - like holes in a Swiss cheese - are aligned, they may allow a critical event to lead to harm.[3] Another concept of patient safety, called "resilience", emphasizes protective elements within the system that prevent the occurrence of harm: Strengthening the "resilience capacities" would mean for example "*supporting individuals, teams and organizations to anticipate changes, to achieve success in a complex world through dynamic trade-offs, and to learn from everyday experience*".[4]

Indeed, healthcare-related patient harm is a significant problem: Around the turn of the millennium, alarming numbers about patient harm in healthcare have first been publicized widely by several landmark reports.[5,6] Many study results have added since to the knowledge base about patient harm in healthcare.[7,8] According to the WHO, every 1 in 10 patients is harmed during hospital care.[9] As a very recent systematic review reported, 20% of surgical and 34% of ICU patients were harmed during their hospital stay – and importantly, the authors found that 50% of these harms had been preventable.[10] As a specialty, anaesthesiology has contributed significantly to improve perioperative patient safety, and the specific risk of anesthesia is very low today.[11] However, anaesthesia contributes to the overall perioperative risk of patients: Anaesthesia management has an impact on respiratory, infectious, neurologic, cardiovascular, thromboembolic, and other complications.[12] Importantly, surgical in-hospital mortality may be as high as 4% on average in Europe,[13] and even higher if measured later after surgery.[14] But obviously, mortality as such is not a good indicator for safety and quality because it depends on patient risks and case mix. In contrast, mortality after major complications, also called "failure to rescue" (FTR),[15-17] is increasingly seen in the surgical literature as an indicator for the safety and quality of hospital care, because it tells something

about the ability of hospitals to manage complications once they occur.[18]

Research actually indicates that failure to rescue rates may differ significantly even between hospitals that have comparable complication rates.[16] To know more about failure to rescue as an indicator of quality and safety in a given hospital, local measurement of complications and of deaths following complications is needed. Furthermore, singular measurements are unlikely to reflect failure to rescue along the time axis: As other studies show, preventable adverse events vary over time.[7] It seems plausible that ongoing knowledge of the current failure to rescue rates as an institutional safety and quality indicator would require constant measurement – monitoring - of complications and death rates.

As anaesthesiologists, we are usually part of such hospital settings, and we usually do a lot to improve patient safety throughout the perioperative course: Preoperatively (e.g., by risk assessment and preoperative optimization[19]), intraoperatively (e.g., by using protocols[1] and checklist,[20] or when trying to optimize (or avoid, if possible) handovers during cases[19,21-23]), and during the postoperative course (e.g., by engaging in intensive care, or in acute pain services[24]). Importantly, most of the perioperative complications occur during the postoperative period, or as Dan Sessler has put it during his 2016 Severinghaus lecture at the ASA meeting: "*30-day postoperative mortality is 1,000 times greater than preventable intraoperative mortality*"[25]!

Some organizational factors, services, and interventions correlate with lower complications, or even with lower FTR, and anaesthesia services may contribute or influence some of them: For example, better staffing and training levels of nurses and staffing of some physician groups correlate with lower mortality and FTR,[26-28] and so does hospital and surgeon volume and the availability of a rapid response team.[26,27,29] Acute pain services correlate with fewer adverse events.[24] Continuous monitoring of vital signs or early warning scores correlate with fewer ICU transfers,[30] and according to some studies with mortality.[30-32] Furthermore, communication is important to avoid delays – and a care escalation protocol has been found to be associated with lower mortality.[27] Interestingly, measuring and monitoring outcomes as such is associated with lower morbidity[33] and mortality.[33,34] As anaesthesiologists, we are already involved in postoperative care, and in many of these activities – for example in intensive care medicine, and in pain management.[25,35] However, the significant rate of preventable complications and FTR raises the question if we can do more – and the answer is most likely: Yes we can! – but this costs time and resources of course, and would need the support of our institutions and professional societies.

In view of the important extent of perioperative patient harm, ESA and its partner organizations have launched the HD in 2010 with the goal to improve patient safety in anaesthesiology.[1] The HD should not be mistaken for the World Medical Association's Declaration of Helsinki that defines ethical principles for medical research involving human subjects.[36] In contrast to the Declaration of Helsinki, the HD is a landmark patient safety declaration addressing the field of anaesthesiology.[1] It provides a framework of patient safety principles (called "heads of agreement") and a practical list of protocols and requirements (called "principal requirements") for anaesthesia departments in order to provide anaesthetic care safely.[1] The requirements include protocols about preoperative assessment and preparation, checking equipment and drugs, syringe labelling, difficult/failed intubation, malignant hyperpyrexia, anaphylaxis, local anaesthetic toxicity, massive haemorrhage, infection control, as well as other requirements like collecting data about morbidity and mortality, and collecting and using critical incident reports.[1] Some of these requirements are based on a solid fundament of evidence, e.g., the WHO Surgical Safety Checklist.[20,37,38] The HD has been signed by all European National Anaesthesiologist's Societies, and by many other societies and organizations worldwide.

However, it remains unclear to what extent the requirements of the HD have been translated into clinical practice across Europe.[39,40] A survey of members of the ESA Council of National Anaesthesiologists' Societies and of ESA members conducted in 2012 suggested that the implementation of the HD into clinical practice was slow, and incomplete in most European

countries.[40] According to a review of the current state, implementation of the HD still seemed a "major task" in most countries.[41] Individual experiences and communications by European anaesthesiologists add to this impression.

To improve implementation of the HD, ESA has started numerous educational strategies (e.g., patient safety publications, an online patient safety "starter kit", a patient safety basic course and masterclass, and instituted a patient safety task force that later was transformed into the current Patient Safety and Quality Committee. At present, a research project is investigating how well the HD has been adopted by anaesthesia departments across Europe, and what potential barriers may hinder better implementation.[42] Meanwhile, individual anaesthesiologists can check the local level of compliance with the HD patient safety requirements by downloading the HD from the ESA homepage and using it as a checklist while "walking the hospital".

2. Perioperative quality of care - realising and measuring improvement

As outlined above, quality-defining characteristics like failure to rescue vary significantly between hospitals,[16] and need therefore to be measured locally. In addition, preventable harm may vary over time, and should therefore be monitored. So whereas patient safety provides insights into the nature and the human factors background of patient harm, and provides concepts and models to understand connections and potential causes and to develop strategies for improvement, "quality" deals with applying such tools and monitoring and measuring which improvements have been achieved, and whether they prevail over time.

How can the difference between "patient safety" and "quality" be described? According to one definition, patient safety is just one of several particular aspects ("attributes") of quality.[43] Other attributes of healthcare quality include: appropriateness, availability, continuity, effectiveness, efficacy, efficiency, prevention, respect and caring, safety, and timeliness.[43] More generally, quality is a much broader concept. So to speak, "quality" describes the different and sometimes competing expectations of different groups in healthcare: This can be the expectations of patients and their families, of healthcare professionals, of administrators, authorities, politicians, and of the general public.[43] Quality indicators are used to collect data according to defined criteria, e.g. in order to compare institutions or systems, or to monitor changes over time while trying to improve quality. What would be a motivation to know these numbers? Certainly the goal of improving patient safety and quality locally. Or as Lord Kelvin, (Scots-Irish mathematical physicist and engineer) has put it: "*if you cannot measure it, you cannot improve it*". https://de.wikipedia.org/wiki/William_Thomson,_1._Baron_Kelvin.

How should the dimensions of quality be assessed? Avedis Donabedian, a pioneer of quality in healthcare, has described the areas (dimensions) of healthcare quality that should be assessed by distinguishing structures, processes, and outcomes.[44] Thereby, "structures" describe the fixed framework, e.g. personnel, equipment etc.; "processes" describe activities; and "outcomes" describe results.[44] In particular, measurement of „*outcomes that matter to patients*"[45] is considered crucial for improving the so-called "value" in healthcare. Michael Porter has described value as follows:[45] "Value" equals the health outcomes that matter to patients divided by the costs of delivering these outcomes.[45] When considering these dimensions of healthcare quality one should keep in mind that from the patient's view, outcomes are usually the most important dimension.

There are several approaches to practically measure patient safety and quality. Three clinically important measurement methods are presented in the following. First, "*incident reporting*" (IR) (e.g., using critical incident reporting systems, CIRS[43,46]) means qualitative, usually anonymous reporting of rare but potentially serious events to learn about the „nature of problems". Incident analysis using the „London Protocol"[47] may identify system weaknesses, but generalisability is limited. Second, "*quality reporting*" is used to collect routine data systematically according to rate-based quality indicators for every patient to measure the „extent of problems".[43,48] If data quality is good, rates may be used to monitor the process of care. Information about the details of specific quality events is limited. Third, "*safety culture*

surveys" are (usually questionnaire-based) surveys of staff perceptions of institutional safety culture features that provide additional information.[49] Interestingly, safety culture has been found to correlate with morbidity and mortality (M&M).[50-53] Frontline clinician's (but not senior manager's) perceptions predict M&M.[54]

How can clinicians choose meaningful quality indicators? Quality is a nonquantifiable „construct" and cannot be measured directly.[43] Quality indicators are „flags" that point to cases or areas in need of particular review, because quality of care may not have been optimal.[43] However, QI are not a direct measure of quality, because they may be influenced by factors other than quality (e.g., by patient profile).[43] Indicators can be (1) sentinel event indicators (e.g., data collected by incident reporting) or (2) rate-based indicators (e.g., collected by prospective quality reporting).[43] Once an area in need of improvement is identified and an appropriate QI indicator chosen, "plan-do-check-act" (PDCA) (or "plan-do-study-act", PDSA) cycles can be used to realise the improvement systematically and stepwise.[55] Thereby, small, local tests are used to learn from taking action.[55]

Is there any "*gold standard*" for perioperative quality indicators? Unfortunately, no generally accepted „gold standard" set of QI exists for use in anesthesia. A systematic review conducted in 2009 identified 108 quality and safety indicators for anesthesia.[43] The majority of these indicators was based on a low level of evidence.[43] Furthermore, a set of 11 perioperative patient safety indicators has been suggested and tested for practicability for internal use of hospitals.[56] This set is not suitable for benchmarking between hospitals, and includes only few outcome indicators.[56] More recently, a systematic review of perioperative quality indicators found that the majority of safety and quality indicators in perioperative care are not supported by a high grade of scientific evidence, and patient-centered metrics were less frequently found in the literature.[57] As outlined above, "failure to rescue" may represent an example for a meaningful QI at the hospital level: Whereas crude mortality is not considered a valid indicator of quality because it may be influenced by factors other than quality of care, „failure to rescue"[27] is considered an indicator of hospital performance.[19]

Several barriers have been described in the literature that may impede the collection of quality and incident data. Three major groups of such barriers can be distinguished: **The first group** includes barriers related to practical working conditions (e.g., too complex reporting systems; lack of time;[46,58] additional workload caused by the reporting;[46,58] interruptions and noise[46,59]). Countermeasures include steps to unburden clinical staff e.g. by delegating data entry to secretarial staff,[60] or to use automated data export.[61,62] **The second group** includes barriers related to institutional culture and data management (e.g., concerns of legal actions,[46] blame,[63,64] and of being assessed by the data;[64] no feedback about the results[46,63]). Accordingly, countermeasures include e.g. a trustworthy departmental culture[60] and the use of the data for feedback to clinicians during M&M meetings.[63,65] **The third group** includes barriers related to general beliefs and attitudes, e.g., lack of belief that reporting actually improves quality (physicians are reportedly more skeptical than nurses).[46] Among potential countermeasures are e.g. education that may impact attitudes,[66] or advocacy by professional societies.

When dealing with quality data, common pitfalls should be avoided. For example, it may be tempting to use for example monthly numbers of reported incidents as a proxy for patient safety and quality. For a number of reasons, such an approach would not be valid: **First**, the numerator of a valid measure should be well defined – but few critical or adverse events are actually well defined.[67] **Second**, the denominator (the population at risk) can usually not be determined with IRS because of the anonymous way of reporting.[67] **Third**, underreporting is frequent with IRS, and the anonymous way of reporting precludes assessment of reporting reliability.[67,68]

In conclusion, preventable perioperative patient harm including failure to rescue remains an important challenge. The HD provides a useful framework of safety requirements and protocols to address this challenge. Among these patient safety tools, practical methods to measure local morbidity, mortality, incidents, and safety culture are particularly important, because "*if you cannot measure it, you cannot improve it*". However, the HD has been

inconsistently adopted in clinical practice. ESA has started several efforts designed to better understand the potential obstacles to implementation, and to improve the realization of the safety strategies promoted by the HD at the clinical frontline.

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