The global challenge for patient safety: scope and definition

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Patient safety is normally defined as omission of harm during medical care in hospital. Relative to the global challenge, a wider scope is needed, including the primary care sector and coverage of care, or lack thereof, as well as quality of care. There are no global statistics on deaths caused by medical error. Estimates vary greatly. A review of US-based studies[1] indicates that the number of deaths in US hospitals alone may be between 200,000 and 400,000 per year. Extrapolating these numbers may give a global estimate of 3–5 million deaths per year. However, the death toll is likely to be much larger than this estimate. In low- and middle-income countries (LMICs), where 82% of the global population lives, most medical care takes place in primary care institutions and is delivered by non-physicians. Many deaths that may have a root cause in lack of access to care and poor patient safety end up being classified in other categories. Given the magnitude of the problem, it may appear as a paradox that patient safety is not referred to specifically in any of the 17 sub-goals of the United Nations (UN) Sustainable Development Goal (SDG) 3, to secure health and well-being for all.[2] One explanation may be the misclassification of patient safety issues and another may be patient safety's vaguely defined nomenclature, measurement indicators and reporting requirements. What is not measured tends to get less attention. In comparison, two other categories of death, death from sudden cardiac arrest (SCA; under 70 years of age) and maternal/newborn death, are more clearly defined and part of SDG3, with goals set for reduction by 2030 of one-third and two-thirds, respectively. These categories each claim about 5 million lives per year if 1.3 million fresh stillbirths are also included. What lessons can be learned from fighting these categories of death that are relevant to the global challenge of patient safety? (Figure 1).

LESSONS FROM FIGHTING SUDDEN CARDIAC DEATHS

Today, 60 years after the introduction of cardiopulmonary resuscitation (CPR), in-hospital survival from SCA in the USA is about 25%, representing 50,000 survivors among 200,000 patients.[3] More recent studies have shown that the quality of CPR delivered greatly impacts patient outcome. Whereas poor CPR has marginal clinical impact, high-quality CPR may enhance the chances of patient survival by three to four times.[4] Therefore, the American Heart Association (AHA)[5] recently declared that 'Poor quality CPR should be considered to be a preventable harm'. Evidence now shows that what is increasingly referred to as 'low-dose, high-frequency training'[6] is significantly more effective for the acquisition and maintenance of CPR skills than traditional 2-yearly certification.

To secure more efficient in-hospital resuscitation practice, the AHA and Laerdal have developed the Resuscitation Quality Improvement (RQI) Program, which enables practitioners to refresh their skills in low doses every month in the workplace. They can do this during a short break and do not need to be absent for up to a day, as is the case with traditional CPR training methods. Since its introduction, approximately 300 hospitals in the USA have adopted the RQI Program, enrolling and improving the competency of over 300,000 healthcare providers. At the 6th World Summit on Patient Safety held in London in February 2018, the AHA presented a 2025 commitment to help save 50,000 more lives each year by widespread adoption of the RQI Program across US hospitals, combined with strategies to prevent cardiac arrest and implementation of practices known to improve survival.

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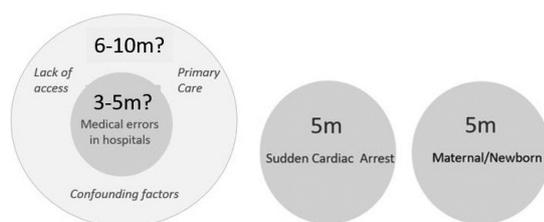
Figure 1. *Scope and magnitude of the patient safety challenge relative to sudden cardiac and maternal/newborn deaths.*

Out-of-hospital survival from SCA is estimated to average around 10% in high-income countries (HICs) and to be as low as 1% in LMICs. However, there is a 10-fold or more difference in survival from the worst- to the best-performing emergency medical systems (EMSs), even between and within HICs.[7] What might explain such differences when all systems have access to the same science and use similar education curricula and equipment? This question was first addressed in 1990 at an expert meeting at Utstein Abbey outside Stavanger, Norway. The meeting resulted in widely endorsed recommendations on reporting outcome data. Without good measurement, it is difficult to improve. The Utstein Formula for Survival[8] stipulates that the chances of survival may be expressed as the product of three factors: medical science, educational efficiency and local implementation (Figure 2). There are strong reasons to believe that the last two factors in this formula are the weakest and where most additional impact could be achieved. Without effective education and implementation, there will be little impact of advances in medical research.

At another Utstein meeting in 2015, experts from around the world made a call to establish a Global Resuscitation Alliance, with an objective of helping increase survival from cardiac arrest by 50% by 2020 by adherence to 10 suggested steps for best practice in the community (Box 1). A report published in 2018, *Acting on the Call*,[9] details 27 case examples on progress, giving hope that the goal of 50% increased survival may be realistically achievable. This is supported by strong case examples from Japan and Denmark, with both showing an impressive tripling in survival over the past 10 years by leveraging national registries for measuring all out-of-hospital cardiac arrests (OHCAs) as a basis for systematic improvement plans.

A meeting convened in Singapore in August 2017 concluded that the same 10 steps were also relevant for developing EMSs in LMICs, but they needed to be applied in a local context. Factors that the individual EMS service may influence include strong local leadership, efficient training, quality improvement and establishing a culture of excellence. Factors that represent additional challenges in LMICs include restricted healthcare budgets, cultural attitudes to helping strangers, ignorance of lifesaving techniques among bystanders and poorly developed emergency dispatch systems and ambulance services. Addressing such factors may often require a longer term perspective.
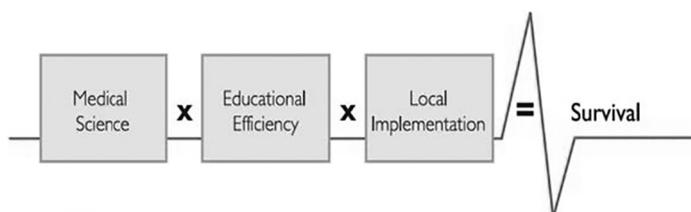
> **Box 1. The 10 best practice steps for increasing survival from out-of-hospital cardiac arrest**
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> 1. Cardiac arrest registry
> 2. Telephone CPR for more and better CPR
> 3. High-performance EMS CPR
> 4. Rapid dispatch
> 5. CPR performance data
> 6. First-responder automated external defibrillator (AED) programmes
> 7. Smart technologies to expand CPR and public access defibrillation (PAD)
> 8. CPR/AED training in schools and the community
> 9. Accountability
> 10. Work towards a culture of excellence

LESSONS FROM FIGHTING MATERNAL/NEWBORN DEATHS

In total, 800 babies and 80 mothers die at birth every day, nearly all in LMICs. Over 80% of these deaths could be prevented by well-trained and equipped birth attendants. Asphyxia is the leading cause of early newborn death, officially claiming 700,000 lives every year. In addition, some 1.3 million babies classified as 'fresh stillbirths' have a heartbeat during labour. Many of these could be resuscitated and would likely more correctly be classified as being asphyxiated. On top of this, a million babies survive with brain damage as a result of a compromised oxygen supply during labour.

Some 10 years ago, Laerdal had the privilege of partnering with the American Academy of Pediatrics to develop the Helping Babies Breathe (HBB) programme[10] to address this challenge. Today, more than 500,000 birth attendants in over 80 LMICs have been trained by this programme. Studies in Tanzania, Nepal, Uganda and Ghana[11] show that, when well implemented, this programme can reduce early infant mortality by as much as 50% and fresh stillbirths by 25%. The HBB programme makes lifesaving easier to learn and remember through use of a simple action plan, using a traffic light colour-coding system. Ten per cent of babies, in both HICs and LMICs, are born in the yellow colour zone, needing help to start breathing to move to the green zone. The traffic light stays yellow for only 1 minute, the 'golden minute'. If the right help is not given, the light will shift to red and the baby is likely to die. In rich countries, babies get this help; in poor countries, where close to 90% of all babies are born, more than half of the cases do not receive the necessary help.

The course uses scenario-based training in pairs. A low-cost, culturally adapted newborn simulator includes three simple squeeze bulbs enabling realistic training in addressing the three essential questions: Is the baby crying? Is the baby breathing normally? Does the baby have a heartbeat? Thus, the course makes use of two of the main recommendations in the landmark *To Err is Human* report by the

Figure 2. *The Utstein Formula for Survival.*

Medical Science × Educational Efficiency × Local Implementation = Survival

US Institute of Medicine:[12] train in teams those who work in teams and use simulation whenever possible.

Birth attendants must also be prepared to handle mothers at risk: 100,000 mothers are dying on the day of birth. Encouraged by the success of the HBB programme, Jhpiego (https://www.jhpiego. org), an affiliate of Johns Hopkins University, Baltimore, USA, and partners have developed with Laerdal the Helping Mothers Survive programme.[13] These partners include the International Confederation of Midwives, the International Pediatric Association and International Federation of Gynaecology and Obstetrics.

A realistic and affordable simulator has also been developed to facilitate hands-on training in the control of bleeding after birth, the leading cause of maternal death. It is worn by the instructor like an apron and includes a blood tank and a uterus that can be made to contract. Having the facilitator and students in turn act as the delivering mother also facilitates training in *patient communication and respectful care, two important dimensions of patient safety*. The same educational methodology has been used to develop six more educational programmes. Together, these programmes address over 80% of the causes of deaths for both mothers and newborns through the continuum of care, from pregnancy through the first 4 weeks of life.

An Utstein meeting in 2015 established 10 steps for best practice implementation of these programmes[14] (Box 2).

The SAFE (Safer Anaesthesia From Education) (https://www.aagbi. org/international/safer-anaesthesia-from-education) programme,[15] introduced by the World Federation of Societies of Anaesthesiologists (WFSA) in collaboration with the Association of Anaesthetists of Great Britain & Ireland (AAGBI) in 2013, utilises many of the same educational principles. This course in obstetric and paediatric anaesthesia has already reached over 3000 anaesthesia providers in 30 low-resource countries.

Box 2. The 10 best practice steps for implementation of the HBB and Helping Mothers Survive programmes

1. Secure Ministry of Health buy-in
2. Form a working group for planning, training and monitoring
3. Develop a national roll-out plan, for pre-service and in-service training, in both the public and the private sectors
4. Provide learning materials and equipment at the time of training
5. Identify and support local leaders and champions
6. Establish low-dose, high-frequency refresher training
7. Establish facility-level quality improvement teams
8. Monitor performance
9. Establish a system for reporting and feedback
10. Engage healthcare professionals, families and the broader community

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CONCLUSION

Three lessons that pertain to the global challenge of patient safety can be learned from fighting sudden cardiac arrest and maternal/newborn deaths:

1. more clearly defined nomenclature and criteria for data reporting may help increase awareness of the problems and provide a required basis for measuring and reporting patient safety;
2. strong local leadership, regular refresher training and quality improvement are essential for programme success;
3. partnerships play a key role in implementing and sustaining patient safety programmes.

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