Global Surgery: Progress and Challenges in Surgical Quality and Patient Safety

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"Of all the forms of inequality, injustice in health care is the most shocking and inhumane."

—Dr. Martin Luther King, Jr.

Introduction

A provision of care for surgical disease should be a prerequisite for all health systems in all countries, worldwide. The delivery of this surgical care should be high quality and safe. The international recognition and propagation of landmark works, such as *To Err is Human* [1], and involvement in quality reporting databases (e.g. the *American College of Surgeons National Surgical Quality Improvement Program*, ACS NSQIP) [2] has brought the topics of quality and safety to the fore in the minds of health leaders and policy makers.

While there is an ever growing body of peer-reviewed literature on both patient safety and surgical quality, neither holds a uniform definition, presenting something of a dichotomy, since we must firmly establish what we mean by "*quality*" and "*safety*" before if we are to consider these attributes in a robust manner across diverse health contexts. The World Health Organisation (WHO), define patient safety as

> … the absence of preventable harm to a patient during the process of healthcare. The discipline of patient safety is the coordinated effort to prevent harm, caused by the process of healthcare itself, from occurring to patients [3].

We consider health care quality in terms of three core areas: clinical effectiveness, patient experience, and patient safety [4]. Hence, there are extensive links between a health system that is considered safe and one that is considered of high quality—as we discuss further below.

In this chapter we discuss surgical care provision globally, making reference to the limited progress that has been made to date in the fields of quality and safety, while isolating the ongoing challenges we all must look to address in the future.

The Donabedian Model

In 1988, Donabedian published a model that conceptualizes quality in health care as three interrelated components, namely "structure," "process," and "outcome" [5]. While a plethora of other quality of care frameworks have been proposed over the subsequent years, Donabedian's work remains the dominant paradigm over a quarter of a century later.

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While quality and safety have two distinct definitions, there are considerable overlaps when applied to health care. It has been stated "*high-quality systems are safe systems*" and indeed, the two concepts should not be considered mutually exclusive [6]. These similarities are echoed in the work of Provonost, and others, who have developed models for patient safety that use Donabedian's original quality paradigm as a skeleton structure [7–9]. In a similar vein, we consider the facets of quality and patient safety under the headings of Donabedian.

Structure

The term "structure" is better phrased as "infrastructure" as it comprises all the physical equipment, levels of staffing, training and, obviously, the financial situation of a health care system. Since it measures finite, definite things, it is easily quantifiable and is seen as the base upon which other components of quality build. It is also something that, we, as practicing surgeons in high-income countries (HICs), take for granted.

Globally, the greatest burden of surgical disease is found in low-income and middle-income countries (LMICs), yet these countries are exactly those whose infrastructure is often severely limited. This is borne out when considering that while more than 200 million operations are performed across the globe each year, only 3.5 % are for the poorest third of the world's population and therefore accessing surgical care remains a major challenge [10]. Indeed, it has previously been estimated that approximately two billion people lack access to an adequate level of surgical care [11].

The Lancet Commission on Global Surgery [12] defines access to surgery in any country as the existence of four components, capacity in terms of staff and infrastructure and ability to access it in a timely, safe and affordable way. By applying this stepwise model to the global population it is possible to estimate the probability that an individual has access to surgical care. Unbelievably the Commission found at least 4.8 billion people do not have access to surgery worldwide, a figure that represents almost 95 % of the population of many LMICs [13]. By comparison only 14.9 % of the population of HICs lack access. This estimate is over double previous reports [14] but is important when thinking about the challenges facing LMICs in supplying safe and effective surgical care as it recognizes that access is about more than capacity alone. It is the lack of timely, safe and affordable access that results in the majority of the world's population having to forego appropriate surgical care.

A major hurdle then is that of national infrastructure to enable patients to reach the hospital in a timely manner. We know that where appropriate surgical and intensive care facilities exist these can prevent morbidity and mortality in the sickest patients however, these patients are often presenting late to hospital resulting in poor outcomes [15]. The reasons for this are complex and multifaceted since not only are health care facilities in LMICs often vast distances away from where patients require them but those that are able to reach the door of the hospital can find lengthy queues ahead of them owing to overcrowding, poor facilities, and a lack of adequately trained staff [16, 17]. In the face of limited resources and huge demand, providing high-quality care is extremely challenging [18].

Patients are often also discouraged from seeking surgical care due to the direct and indirect costs associated with it. The World Bank estimates three billion people earn less than US $2.5 per day which makes even modest hospital fees of US $133 unaffordable [16] added to this in some places the lack of hospital supplies requires patients to provide their own [19].

For those that do access appropriate care it has long been recognized that outcomes are influenced by the complex interplay of multidisciplinary teams and the systems that they work within [20]. At its simplest level this can be broken down into four parts: the staff, the equipment, the buildings they use and the systems that allow the staff and equipment to effectively work together in the shared space [13]. Access to all of these components is limited in resource-poor settings and will therefore impact on a nation's ability to provide effective surgical care to its population.

In many LMICs the equipment and space to work is woefully inadequate. An analysis of the number of operating theaters available in 792 hos-

pitals participating in the WHO's safe surgery saves lives campaign showed gross disparities [14]. Low-income countries, which accounted for over 2.2 billion people, had on average less than two theaters per 100,000 people and in the worst affected, such as west sub-Saharan Africa, only one operating theater per 100,000. Compare this with the global average of 14 or 25.1 per 100,000 in Eastern Europe and you get an idea of the scale of the problem. Even if a patient is fortunate enough to have access to an operating theater around 77,700 of these worldwide do not have access to basic equipment necessary to provide safe surgical care such as pulse oximetry [14].

Basic infrastructure gaps such as unreliable electricity and water supplies will further hamper efforts and impact on outcomes [15]. In 12 sub-Saharan countries reliable electricity was fully available in only 35 % of health facilities [21]. In Sierra Leone the situation is even direr with a lack of electricity, running water, oxygen and fuel at the government run hospitals, only 20 % had running water [19].

The final barrier limiting access to surgical care is a drastic shortage of trained surgical providers, with general surgeon density ranging from 0.13 to 1.57 per 100,000 population in LMICs [22], contrasting with an equivalent figure of 5.8 per 100,000 population in the USA [23].

Recent estimates suggest that, by 2030, an additional 806,352 surgical providers will be required in LMICs [24]. This is an ever worsening surgical workforce crisis and somewhat crucially, the question remains as to how this can be solved. Current approaches have broadly been either short term humanitarian based projects or "*missions*" (where international surgeons from HIC provide work in LMICs) or, more challenging, longer term projects focused on increasing levels of training for both existing and new practitioners.

HIC Surgeons Practicing in LMICs

An estimated 55 % of all surgical care in LMICs is delivered through international charitable organizations and, for the years 2008–2013, this required funding to the tune of $3.3billion [25]. Not only does this require considerable financing it also requires a large body of willing volunteers—though surveys confirm that there are increasing numbers of surgeons and surgical trainees from HICs, especially those from Europe and North America, expressing a desire to provide such services in LMICs [26].

Many of the international organizations providing surgical care in LMICs do so in response to acute health care crises: as a result of natural disasters, conflict, famine, or sudden disease outbreaks. This generates considerable overlap between the "routine" work these organizations provide and more wide-ranging acute humanitarian relief projects. It is difficult to fully appraise the burden of surgical disease treated by such mission work as there is little by way of data reporting outside of their organizations [27]. However, a recent survey across 99 such organizations showed provision of care across the entire breadth of surgical specialties though it also revealed considerable variation as to the scale of care provided—with a third of organizations performing less than 200 operations a year and only five performing more than 1000 surgeries [28].

One of the largest of these international organizations is Médecins Sans Frontières (*Doctors without borders*, MSF) which, despite being a French-based organization, recruit surgeons internationally and coordinate projects both in response to emergency crises and in other areas of desperate need [29]. Over four decades, MSF have provided surgical care in Afghanistan, Angola, Cambodia, Chad, Ethiopia, Haiti Libya, Sierra Leone, Somalia, and Sudan to name but a few, and in 2006 alone they performed over 64,000 procedures across 20 countries worldwide [30].

While the efforts of HIC surgeons on these short-term missions have undoubtedly improved the lives of countless individuals in LMICs, their ability to confer any long term effects on the actual infrastructure within these countries is somewhat more limited [31, 32]. Some authors have also expressed concerns that, as the cost of health care worldwide continues to increase, that the funding needed by these charitable organizations will increase concurrently and that there is therefore an acute need to move towards sustainable health care in LMICs—without such a reliance on international aid [33].

Enhanced Training for LMIC Surgeons

The majority of long-term projects have taken a particular interest in workforce initiatives to expand surgical and perioperative training for surgical providers in LMICs. Much progress on this front has been made since it has been adopted by the World Health Organization (WHO), though there are some who have chastised the WHO for not recognizing the inadequacies of surgical care in LMICs until this point [34].

In 2004, the WHO launched the Emergency and Essential Care Programme. This program provides a basic training package for surgical providers in LMICs based around the *Integrated Management of Emergency and Essential Surgical Care* toolkit and the text "*Surgical Care at the District Hospital*" [35, 36]. A key facet of this project is a strong emphasis on "Training the trainers" courses, where local staff are empowered to propagate this training program elsewhere, leading to large scale dissemination. While the availability of longer term data is limited by the implementation date of the programme in individual settings, Henry et al. reported its impact within Mongolia over a 6-year period, noting its adoption in over half of all health care centers during this time and a conferred 74% increase in the number of emergency procedures performed [37].

The WHO is also able to lead on aims to improve infrastructure through its influence on global health policymakers and the coordination and integration of stakeholders at multiple levels within LMICs, including the relevant Ministry of Health, international partners and non-government organizations [34]. The clearest path to long-term solutions is through sustained dialogue and collaboration within each country.

Those in HICs can also have an effect on the number of trained surgeons in LMICs through international recruitment strategies. Indeed, the net shortage of 4.3 million health professionals across 57 LMICs prompted the WHO to issue a formal code of practice for the responsible recruitment of health care workers by HICs [38].

What health care organizations in HICs must rather do is establish links with their counterparts in LMICs for the exchange of training and experience [39]. Collaborations such as these would also increase opportunities for surgeons working in LMICs, further increasing workforce retention and going against the clinician "*brain drain*" currently seen all too frequently within these countries [40, 41].

It has been suggested that if the WHO publish surgical workforce data (in the way it already does for other specialities within health care), to allow recognition of the global shortfalls in surgical personnel as only by delineating the problem can we begin to plan and direct targeted initiatives in the future [22].

Unfortunately, the dearth of qualified surgeons and anesthesists is not the only problem faced globally. Another neglected issue is the lack of equipment to permit surgical practice in many LMICs. Simply increasing the funding for health care in these settings is not a viable option in most circumstances and so we must approach this problem more creatively to find more innovative solutions. This is what provides the catalyst for frugal innovation.

Frugal Innovation

Increasingly, there is a recognition that the dissemination, or "flow," of ideas does not have to be one-way traffic from HICs to LMICs. The concept of *reverse* of *frugal* innovation is a relatively new one within the sphere of health care, where we often tend to focus on the refinement of established practices in developed countries with a trickle-down effect to the developing world, but it has been an accepted phenomenon within other fields for some time [42].

LMICs are continually seeking to expand and improve the quality of health care for their populations but they do so under considerable restraints in terms of physical and financial resources. The coupling of these limited resources with their, often acute, health needs drives innovation at levels not seen in HICs. Furthermore, often working from a blank slate, without an established health care framework, they can be considered freer to experiment and innovate [43].

There are countless occasions one can recall where surgical equipment we now see as commonplace was conceived by colleagues working under

the confined of restricted resources. For example, the use of a polyethylene urine bag to temporarily cover large laparostomy wounds was first employed by Borraez in 1984, while working in a hospital in a deprived area of Bogotá, Columbia [44]. The use of the "Bogotá bag" for abdominal wall closure is now a recommended technique and is considerably cheaper than alternate methods [45].

The city of Bogotá was also the birthplace of another frugal surgical innovation in the creation of the first unidirectional valve for the drainage of cerebrospinal fluid in patients with normal-pressure hydrocephalus by Hakim [46]. As with the Bogotá bag, this device can also be produced at low cost and, indeed, the Indian company Surgiwear produces the Chhabra Micro Precision ventriculo-peritoneal shunt system, based on the original Hakim mechanism, for only $35 [47].

Ilizarov developed his eponymous frame for the external fixation of a fracture while working as an orthopedic surgeon in a remote part of western Siberia in the 1950s with very limited resources [48]. It was only some 25 years later, when Ilizarov present his work at a conference in Italy, that his frame began to be adopted by surgeons globally and it continues to be utilized in operative fracture management today [49, 50].

These are but three of the innovations conceived and developed in the context of suboptimal resources. Each was designed to meet a specific need and by the simplest, and so cheapest, way possible. Not only are such frugal innovation low cost but also they are often more suited to their environment, utilizing the materials or resources that are present. More work is needed to make sure that frugal innovations can be recognized and their benefit shared among the health care providers that need them the most. A current project, based in the USA and supported by the Commonwealth Fund is attempting to advance this very issue and we await its results eagerly [51].

Process

"Process" refers to the actions of health care delivery itself, including not only all diagnostics and treatment but also every conceivable event or action that a patient could be exposed to during their health care episode, including unsafe care.

Surgical Quality Improvement in LMICs

Changes in these processes, usually referred to as exercises in quality improvement, should confer downstream beneficial changes in measured outcomes. It is important that we define processes in terms of their associated outcomes as they are what allow us to quantify the effect of a given improvement initiative. Quality improvement (QI) itself is a term becoming increasingly commonplace in health care parlance. One of the best definitions of QI was phrased by Batalden and Davidoff who state QI is the:

> … combined and unceasing efforts of everyone—healthcare professionals, patient and their families, researchers, payers, planners and educators—to make the changes that will lead to better patient outcomes (health), better system performance (care) and better professional development (learning) [52].

This, and in essence all definitions of QI, views health care as a series of processes within a system. The isolation and fine-tuning of these processes is what QI is principally concerned with.

QI has long been accepted as a vital part of the manufacturing industry and a number of specific methodologies have been developed in this sector to reduce variation and error while increasing reliability, thus improving not only quality for the customer but reducing cost for the manufacturer [53]. Many of these methodologies have been adopted by the health care sector including:

- *Plan-Do-Study-Act* (*PDSA*) *cycles*, which consist of four stages in an iterative cycle.

  In the "plan" stage the change for improvement is determined, the "do" stage comprises the testing of this change, the "study" stage examines the effects of the change, in comparison to what was before, and the "act" stage analyses these difference to inform a further cycle of improvement [54, 55]. PDSA cycles have been used successfully in endovascular surgery to reduce atrial closure complications in the UK [56], and in trauma surgery in a large

study to reduce operative waiting times in Finland [57].

- *Six Sigma* (*SS*) was developed by the Motorola Corporation in the USA in 1986 and aims to generate QI through the identification and correction of errors at source—to reduce the rate of errors to a six sigma level of 3.4 defects per million opportunities. SS methodology has been used to reduce morbidity in rectal cancer surgery in India [58], to reduce infection in the surgical ICU in the USA [59] and to improve efficiency in theater in both the Netherlands and the USA [60, 61].
- *Lean* methodology evolved from the Toyota Production system in 1988 and is a continual QI process where all sources of waste from a process are systematically eliminate, leaving only the steps which confer value [62].

  Published studies successfully utilizing Lean methodology in surgery include a significant reduction in mortality in patients with fractured neck of femur following introduction of Lean academy meeting and the standardization of care with dedicated daily theater slots [63].

It should be noted that, despite numerous success stories of QI methodologies from the manufacturing industry conferring benefit when applied to processes in surgery, the results of each are context dependent and so it is not possible to make definitive evidence-based recommendations. Recent systematic reviews exploring the impact of PDSA, SS and Lean methodology make reference to the striking heterogeneity between different interventions preventing any kind of meta-analysis of data [64, 65].

While there is considerable evidence to support the use of QI methodology in health care, we should recall that the initial step in any QI project is a full and thorough determination of the processes and systems already in place locally [66]. Thereafter any innovation, no matter its strategy should, ideally, be configured specifically for the setting in which it will be implemented [67]. The limitations encountered when reviewing reports of QI in the peer-reviewed literature have been noted previously and it is hoped that future reports conform to standardized reporting frameworks, such as *Standards for QUality Improvement Reporting Excellence* (SQUIRE) which will permit more rigorous assessment [68].

As discussed above, the principal issue affecting quality in many LMICs is a lack of access to adequate surgical care and other problems relating to the existing health care infrastructure. This does not, however, mean that improving the processes within the health care system in LMICs is not an ongoing challenge.

There is evidence that a raft of QI projects take place within LMICs, especially within the topic of trauma care, but there is a recognized need to strengthen system improvements in these settings [69].

Qualitative research, carried out among surgeons practicing in LMICs, has suggested that that the first priority should be to move towards standardized outcome data collection, to establish current quality baselines and thereby allow the impact of subsequent QI initiatives to be assessed [70, 71].

Given that many health care professionals in LMICs have differences in exposure to the field of QI and development [69], we must also look to increase training in this field and promote awareness of QI, especially among hospital leadership levels [70, 71].

To further advance this cause, the establishment of formalized working-groups, such as the *Asia-Pacific Trauma Quality Improvement Network* (APTQIN), can only further elevate the QI on the agenda within LMICs [70].

Implementing Surgical Safety Processes in LMICs

The challenges to reducing adverse events in LMICs are substantial. They face all of the difficulties found in HICs, where there has been only limited improvement and avoidable adverse events remain a persistent problem [72]. In addition LMICs lack essential resources and have disproportionately low levels of funding for health services research, which further exacerbates financial difficulties. There is an assumption that access to care and basic public health issues remain the most pressing needs of low-income countries. This explains why over the decade between 1998 and 2007 the Bill and Melinda

Gates foundation awarded 36.5 % of its total funding to basic science research and 24.1 % on health care delivery but only 4.7 % on health services research [73]. While lack of access is of course a priority and will cause significant harm the safety of the care being offered must not be overlooked.

To address this ongoing issue the WHO have launched several campaigns focused on patient safety. The most well known of these is the "Safe Surgery Saves Lives" which not only assessed the global volume of surgery and issues with access, but developed the Surgical Safety Checklist (SSC) [74]. This came from an understanding that merely implementing protocols from high-income countries was unlikely to improve patient safety and so was devised by a group of clinicians from around the world, representing the full range of environments in which surgery is practiced.

This team, led by Dr. Atul Gawande, was faced with the challenge of how to devise a low-cost, universally applicable intervention to reduce the harm associated with surgery. Taking inspiration from other industries such as aviation [75] and construction they developed a checklist to prompt routine checks at three critical stages in the operation: before the induction of anesthesia (sign in), before the skin incision (time out) and before the patient leaves the operating room (sign out). The checklist was trialed in eight hospitals around the world and reduced errors and consequently improved outcomes. Mortality overall fell from 1.5 to 0.8 % and complications fell from 11 to 7 % following implementation of the SSC [76]. These figures included both HIC and LMIC and the effect was even greater when low-income sites were looked at in isolation [76], which would suggest that the SCC is particularly useful and relevant to LMIC where it has the greatest impact. Unlike HIC where operative lists are limited and surgeons subspecialize; in LMIC surgeons may have to perform higher numbers of operations that are not in their areas of expertise. In these settings it is perhaps not surprising that simple steps are forgotten given the increased workload and lack of familiarity.

Despite the remarkable success of the WHO SSC its usage worldwide remains as low as 12 % in some studies [77] and there is clearly room to improve compliance. Studies in LMIC have identified challenges to implementing the checklist in these settings including infrastructure, resources, safety culture, and social norms. For example, in Thailand, lack of equipment affects the use of pulse oximeters and surgical site marking [78]. This is also impacted by the societal norm that you should not make a mark on another person. Similarly, in Thai culture people only introduce themselves upon first meeting and are reluctant to do so subsequently which impacts on surgical team members introducing themselves during the timeout period [78].

When tackling these local issues, particularly in LMICs, it is important to develop focused solutions, which may require the modification of the SSC, training and feedback, all while taking cultural variations into account. A team in Uganda was able to increase the compliance rate from 29.5 to 85 % with relatively simple interventions of a stepwise incremental change and standardizations of practice to address societal and cultural norms [79]. PDSA cycles informed regular structured feedback to generate improvement in health care through changing the local behaviors. They were able to do this with minimal external input and instead relied on strong local leadership and staff engagement with the project. Understaffing and lack of equipment remain challenges and areas where external input by way of training programs and funding would be beneficial.

A recent interview study with surgeons from both HICs and LMICs (within an international collaborative of surgeons working in LMICs) suggested that, while the majority of surgeons expressed an emphasis on cultural sensitivity and respect for local traditions, they also highlighted a need to change the existing surgical culture within LMICs [80]. Proposed changes included increased personal accountability and responsibility, greater advocacy for patients and the introduction of mortality and morbidity meetings to foster an environment of healthy reflection and learning [80].

Fostering a healthy culture within a health care system has been described as "*the key to quality improvement*" [81], but discussions around *health care culture* and *organizational health* can be challenging since both are abstract constructs which can be complex to define, before one even considers their measurement with any degree of

certainty. That being said, the need to forge a healthy and productive organizational culture has long been recognized in the world of business and can be found in the management literature as far back as 1958 [82]. Healthy organizations have a culture promoting trust, openness and engagement and enabling continuous learning and improvement [83]. The link between healthy organizational culture and health care quality and patient safety is being increasingly recognized and it is something that all health care providers, globally, can look to in the future to imprint long term high-level care [84].

Outcomes

"Outcome" relates to the downstream effect of health care delivery and so can be considered a more intuitive indicator of quality and safety. Unfortunately, within LMICs the challenges are not just related to access to surgical care but also *unsafe* care—where patients are harmed by the care they receive—is a major cause of poor patient outcome. This also generates waste in an already poorly resourced setting and will affect patient confidence in the system. In these settings it is suggested that patients may even opt out of formal health care systems, thus creating a further barrier to accessing surgical care. For these reasons patient safety is not just an issue for HIC although the degree to which unsafe medical care is a problem for developing countries is not well known.

The WHO has estimated the global burden of unsafe care for both high and low-income countries using disability adjusted life-years (DALYs). This provides a standard metric with which to compare how much suffering is caused by a specific disease or other public health danger such as road traffic accidents. The global burden of disease (GBD) can be used by policy makers at all levels to direct funding and resources. The WHO's estimates suggest that there are approximately 12.7 adverse events for every 100 hospitalizations in low-income countries which is 25.9 million per year. This equates to 15.5 million DALYs lost per year in these countries, the majority of which were due to premature death [85]. These estimates, however, are limited by the lack of availability of high-quality data such that the research was only able to look at seven different adverse events despite having previously identified 20 topics of importance to patient safety. They were unable to include clinically important and common adverse events related to surgery due to the paucity of data available. The GBD from just these seven adverse events ranked unsafe medical care as the 20th leading cause of DALY loss worldwide. Furthermore, when including estimates for unsafe injection practices the resultant GBD would be placed as 14th, comparable to tuberculosis or malaria [85]. Thus preventable adverse events are a leading cause of morbidity and mortality worldwide.

While measuring the outcomes of surgery can be straightforward as an exercise, being able to establish causality between specific processes and outcomes can often prove fraught with difficulties, requiring large sample sizes and considerable time periods of observation [86]. Indeed, the recognition of a need for outcome monitoring has increased dramatically over the last few decades. We have come a long way since the turn of the twentieth century when Ernest Codman, a surgeon then based at Massachusetts General Hospital, vocalized his ideas around the collection of patient outcomes for quality improvement purposes [87]. While his ideas were originally shunned, now, a century later, those of us practicing in HICs find ourselves inundated with an incredible range of datasets on surgical quality and safety. Determining the value, and indeed limitations, of specific datasets and the extrapolations that can than can be made from each can remain a daunting task.

The challenge now is to develop methods of data collection that will identify the different needs and priorities that LMICs have when trying to improve patient safety. Simply adopting best practice from HICs is unlikely to address the underlying causes and may even cause harm. Given that resources are lacking, these methods need to be inexpensive and therefore should be independently assessed for their cost-effectiveness.

Since the Harvard Medical Practice Study in 1991 [88] unsafe care has been extensively studied in high-income countries. This was based on a retrospective case note review and identified the incidence of adverse events in New York State hospitals. An adverse event is defined as an unin-

tended injury or complication caused by health care management, rather than the disease process, leading to prolonged admission, disability at discharge or death [88]. An error is the failure of a planned action to be completed or the use of a wrong plan to achieve an aim and may be errors of commission or omission [89]. These need not necessarily cause harm and are therefore distinct to adverse events. Some literature refers to these as potential adverse events [90].

Measuring these events is challenging and even Codman was subject to criticism for his methods, predominantly as his data did not account for variation in case-mix. Data collection requires a robust infrastructure and well-defined metrics to measure outcomes. Although retrospective case note review has been the most widely used methodology for assessing harm in HICs there are many other methods including incident reporting or clinical surveillance, routine administrative data, malpractice claims and national or regional audits.

LMICs do not routinely have access to much of the data required for these methods because of the variation in the detail and quality of the case notes. Furthermore current strategies employed in HIC such as clinical surveillance, observation of patient care and retrospective chart review are expensive and require trained observers [91]. A lack of trained personnel affects not just access and ability to deliver safe surgical care but also a health care system's ability to adequately assess outcomes. Alternatives including administrative data analysis and electronic medical records are equally unfeasible because of high implementation costs and rudimentary medical record systems. Finally strategies such as malpractice claims analysis and national or regional audits do not have equivalents in LMICs.

To address this, the WHO have studied whether standard retrospective case note review was feasible in LMICs and found that while it is possible it is only useful in the main flagship hospitals of these countries. Elsewhere, the cost, organization, and limited information contained in the notes made the methodology unsuitable. Having identified a need for new methodologies they developed modified tools for research into unsafe care in hospitals with low resources and variable data quality [92]. They tested retrospective case note review, current inpatient case note review, staff interviews, nominal group meetings and direct observations across 13 different countries. The key was to assess how relevant, feasible, acceptable, and valid the tools were. Following this they produced a "Methodological Guide for Data Poor Hospitals" to allow institutions to choose which method is most suitable to meet their individual needs including the availability of good quality medical records and to facilitate its use and understanding [92].

Conclusions

Many global health improvement efforts in LMICs focus on infectious disease, maternal and neonatal disease and nutrition [93]. However, access to safe, affordable surgical care is essential for a "*functional*, *responsive and resilient health care system*" [12]. Furthermore surgical care is now accepted to be cost-effective relative to other medical interventions when it can be applied safely and effectively [77]. Unfortunately accessing surgical care in LMICs remains a major challenge due to severe limitation in infrastructure at multiple levels. Further challenges exist around issues of appropriate staffing, and a lack of funding which remains the largest hurdle for the majority LMICs. The engagement and involvement of a number of international organizations has been a welcome boost for many patients in LMICs but long-term sustainable strategies are required to meet spiralling health needs.

The ability of LMICs to implement international, well-validated programs given these challenges is not clear but studies have not been optimistic. It is suggested that less that 2 % of providers in Africa have the resources available to implement some international health care guidelines [94]. There are clearly severe shortages in all aspects of access for the populations of LMICs and these will not be filled with generic efforts or guidelines. In these resource-poor settings targeted or modified solutions need to be devised to achieve safe and affordable surgical care when needed. There are a number of success stories we make reference to in this chapter, and their progress should not go unmentioned, but without the coordinated efforts of all invested

parties to improve capacity, infrastructure, and ability to access it in a timely, safe, and affordable way the patient safety and surgical care in LMICs will remain on the brink of crisis.

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