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WHITE PAPER

Global Surgical Ecosystems: A Need for Systems Strengthening

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Abstract

BACKGROUND As surgery is gaining recognition as a critical component of universal health care worldwide, surgical communities have come together with unprecedented unity to advocate for systems to support surgical care. This community has long believed that much care could be performed in a cost-effective manner even in low resource settings, despite skepticism voiced by many in public health. To do so will require the development of new systems and re-vamping of old systems that are not effective. In the last five years, coalitions, expert panels, commissions, consortia and alliances have emerged to address these issues and there has been landmark success in advocacy with a new resolution at the 2015 World Health Assembly to include surgical care as a component of universal health coverage. It is critical to understand the ecosystem that constitutes the surgical environment. A surgical ecosystem could be described as a network of people, processes, and materials necessary for surgical services in the context of the facilities and environment in which it functions.

METHODS We describe components of a functioning surgical ecosystem in terms of administration, support staff and clinicians, and the necessary sub-systems for providing consumable materials such as anesthetic medication and suture and sterile instruments. Related systems that must be integrated are facilities and utilities such as electricity, lighting, plumbing and waste management and even laundry. But especially in low and middle income countries (LMICs) lack of any one of these may be rate-limiting. The World Health Organization (WHO) has developed situational analyses and checklists for first level district hospitals to identify missing elements.

CONCLUSIONS A siloed approach cannot solve a systems problem. However, to scale up rapidly and to develop and sustain quality standards, a holistic “ecosystem” approach, including local and global professional societies and advocacy organizations will need to become engaged.

KEY WORDS global surgery, ecosystem, health systems strengthening, surgical facilities standards, surgical quality

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Both authors had access to data and participated in writing the manuscript & creating illustrations.
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INTRODUCTION

Momentum for addressing the unmet burden of surgical disease in resource-constrained settings has been building over the last 40 years.[1-9] As surgical care in wealthy countries has developed ever more technical sophistication, the gap in access to safe and affordable essential surgical care between wealthy and poor countries has widened.[4] Diverse groups, including nongovernmental organizations (NGOs), academic institutions, and missionary organizations have tried to fill these gaps by providing direct care or surgical education. These programs have temporarily eased the burden on overworked local hospitals, especially for specific procedures not available at those hospitals. However, visiting surgeons rarely have offered sufficient capacity to sustain ongoing care provision at a local level.[10] In disaster settings, mobile platforms dispatched from governments and NGOs have provided critical short-term surgical care, but they too have failed to mitigate systemic problems that require improvements in facilities, surgical infrastructure, equipment supply chain, personnel, and education. Despite the apparent need for such improvements, surgery has been largely absent from global public health advocacy and policy, and surgeons have been tasked with proving to skeptics that treatment can be cost effective.

Over the past 10 years, the emergence of robust global surgery and anesthesia communities has led to a new cooperation to strengthen global health care systems through collaborative academic initiatives, advocacy, policy, and interdisciplinary partnerships. As global surgery and anesthesia communities have explored avenues for improving surgical capacity, they have also continually refined their understanding of surgical ecosystems. Much successful surgical advocacy has historically focused on singular disease entities like vesicovaginal fistula, cataracts, or river blindness. However, a new model is emerging that incorporates the role of surgery within broader modalities like maternal and child health, a topic traditionally discussed within the public health domain. The ecosystem model builds on the idea that investment in surgical systems can improve care across all surgical domains and specialties. For example, system requirements critical to providing caesarian sections are similar to those necessary to treat a perforated appendix or fractured femur. These same systems requirements support 4 major categories of surgical care provision, also known as "G4"[7]: surgery, anesthesia, trauma, and obstetrics and gynecology—or, put another way, the "SAO": surgery, anesthesia, and obstetrics. However they are categorized, these systems have a very similar appearance.

The Ecosystem Concept: Deconstructing the Black Box of the "Surgical System". Donella Meadows, in *Thinking in Systems,* states that "A system is a set of things—interconnected in such a way that they produce their own pattern of behavior over time."[11(p2)] Further, "A system is an interconnected set of elements that is coherently organized in a way that achieves something."[11] Google defines ecosystem as "a biological community of interacting organisms and their physical environment (in general use), a complex network or interconnected system."[12]

Every type of ecosystem has its own characteristics and physical constraints, but most would agree that except in disaster situations, sustainable surgery of acceptable quality occurs within the physical construct of a hospital facility in a dedicated restricted access room, or "theater" capable of supporting invasive operations. It is an isolated and closed environment having requirements for sterile field, movement of a surgical team, and placing of necessary equipment. At the most fundamental level, every surgical operation requires 4 essentials: light, medication, sterile instruments and supplies, and a practitioner or team trained to perform the necessary tasks. From the most basic surgical care setting to tertiary hospitals, the complexity of technical considerations increases exponentially. But even the most basic systems require consideration of the patient and the work flow in order to minimize the inherent risks and cost of surgery and to maximize efficiency and patient-centered outcomes.

Within the black box of the operation room (OR) and separated entirely from the primary care and public health community, many surgical staff members and physicians are not well versed in the roles of others in the complex system that supports safe and successful surgical care. For example, surgeons are often unaware of sterilization standards, anesthesiologists and anesthetists often do not interface with primary care or the community, and nursing and support services may struggle to establish a culture of respect where their skills and expertise are recognized for the important role they play in surgical outcomes.

THE SURGICAL ENVIRONMENT: FACILITIES

As in any ecosystem, health providers function in a physical environment. The building structure has its own special needs beyond the general needs of a clinic or medical hospital. A greatly simplified depiction of the OR from a surgical team's view might look like the image in Figure 1. Although there are many design details in the layout of the OR and its surrounding semirestricted space, for the clinical team to function efficiently, it doesn't need to know about them. For surgeons in wealthy countries these features may seem so basic as to not warrant mentioning, but in lower resources countries, facilities standards are often not present, and even when present, vary from room to room, hospital to hospital. Poorly designed facilities hamper workflow and can also affect patient and staff safety. General principles apply whether referring to isolating infectious agents inside or outside a facility. Referring to the recent Ebola epidemic in West Africa, Dr. Paul Farmer has said, "You can't stop Ebola without staff, stuff, space and systems. And these need to reach not only cities but also the rural areas in which most people in West Africa still live."[13]

To scale up surgical volume, many hospitals must be retrofit or planned forward. The building or barrier system must account for a separation of preoperative and immediate postoperative patients, with a dedicated postanesthesia care area or unit (PACU). The design of operating theaters and the surgical environment can be conceived from several points of view: the anesthetists, the surgeons, the support staff, nurses and technicians, and others, including biomedical engineers, radiology technicians, and others who often use the space. A useful design manual created by the Facility Guidelines Institute details the critical components that could be scaled according to workload and types of surgery to be done.[14] The manual can serve as a guide to hospitals when either designing or retrofitting first-level hospitals.

The guidelines state that "As surgical procedures previously performed primarily in an inpatient setting are increasingly taking place in outpatient facilities, the Health Guidelines Revision Committee (HGRC) members believe the physical environment for surgery should meet the same standards no matter where that surgery takes place." In a hospital or dedicated area designated for surgery, there should be a preoperative area for nonemergency cases where the anesthetist can verify that the patient is ready for anesthesia. Baseline vital signs can be ascertained correct side, site and other checklist items performed throughout the perioperative workflow. The WHO offers a checklist that is used in most countries, if somewhat intermittently.[15] The 2 physical areas essential to the most basic surgical suite are the semirestricted and restricted areas. The concept of the restricted area is a designated space that can only be accessed through a semirestricted area, and an operating room is a room that meets the requirements of a restricted area where invasive operations requiring an aseptic field can be performed. Peripheral areas around a restricted area, like storage or clean and sterile processing rooms, can be considered semirestricted. Specific guidelines for room size were previously considered to be a function of the type of anesthesia to be given. Newer guidelines for OR size are based on the type of equipment to be housed and the number of staff to be accommodated. Square footage of an OR can be calculated for the minimum number of personnel needed and a safe traffic pathway on all 4 sides of the sterile field. For example, the sterile field includes the operating table width of 1.75 feet plus 2 feet on either side for personnel (surgeons) and patient armrests. Further minimums for equipment are detailed in the recommendations and include supply carts, buckets, suction, sharps disposal containers, and so on.

Within the building envelope of a hospital, in wealthy countries it is common for operating theaters to be designed as interior rooms within a core. It is assumed that electricity will be available from municipal sources or from generators, and therefore natural light is not required. Most ORs in high-income countries have built-in air exchange or even laminar flow and evacuation systems for anesthetic gases. In LMICs, where reliable electricity can't be guaranteed and there are no built-in gas evacuation systems, central oxygen, or vacuum, these must be retrofit for safe, sustainable surgery.

A dedicated post anesthesia care room with sufficient light for examination, electricity for suction and pulse oximetry is a standard feature of well functioning surgical systems. Although the PACU concept is ingrained in most hospitals in high-income countries, it is common in public hospitals and many other hospitals throughout the world that patients are taken directly from the operating theater to large wards with many patients with no postoperative observation whatsoever except for the families and ward nurses who may also be caring for 5 to 15 other patients. Ward nurses may not be trained in postoperative care and resuscitation and often do not have resuscitation equipment readily at hand. Sometimes an auxiliary room

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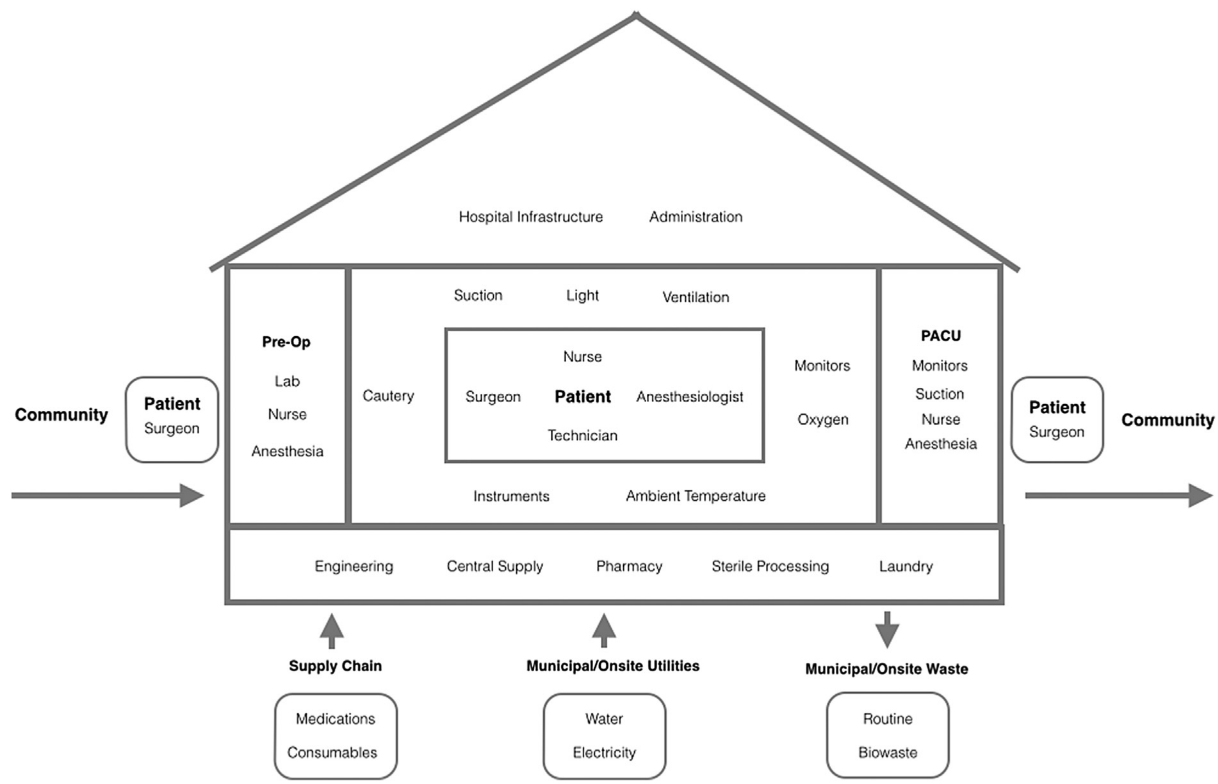

Figure 1. Simplified schematic of flow elements as might be seen by the operating team. When telescoped out, further details including operating room space requirements, restricted and semirestricted areas, hospital support systems and community resources play critical roles in defining the surgical ecosystem. Abbreviations: PACU, postanesthesia care unit; Pre-Op, preoperative.

adjacent to the OR is temporarily commissioned as a PACU in a surgical camp or permanent theater. But nondedicated PACUs are never satisfactory as long-term solutions unless completely retrofit for the purpose with sufficient space, lighting, equipment, and proximity to the operating theater and anesthesia staff. It is well documented that more deaths occur in the postoperative period as a result of insufficient management of airway, bleeding, and other causes. Therefore special attention should be directed to supporting safety during the postoperative recovery period.[16-18]

Other often-neglected aspects of surgical care involve basic facility sanitation. It is exceedingly common in LMICs that throughout hospitals, staff and patient toilet facilities have nonfunctioning toilets or sinks and for these facilities to lack soap or toilet paper. When basic sanitation is not adhered to in the OR environment, no surgery can be considered safe. Water, sanitation, and hygiene programs, though common around LMICs, are often ignored in the most vulnerable area of risk for infection—the OR and surrounding areas. The Lancet Commission on Global Surgery has used the presence of pulse oximetry in hospitals as a proxy for surgical safety.[2] Yet, risk in hospital settings is not limited to airway management as measured by use of oximeters. A more useful safety measure would also consider water, sanitation, and hygiene standards. These are identified in the WHO toolkit for situational analysis for emergency and essential surgery.[9]

Electricity. A lack of consistent electricity plagues hospitals from rural to urban across much of Africa, Asia, Central and South America, and the Caribbean. Even in the United States and Asia, recent hurricanes have emphasized that energy infrastructure is often deficient to meet unusual circumstances. In health care, surgery is particularly dependent on electricity for lights, monitors, cautery, sterile process, laundry, and a host of other machines and processes. A major cost of any hospital is energy,[19] and hospitals in high-income countries typically use 3 times as much energy as typical commercial buildings.[20] Lighting, heating, and hot water constitute the greatest cost in temperate climates, whereas lighting and equipment is the major cost in tropical settings. US hospitals spend US$8.8 billion per year on energy, greater than any other building type. The cost of energy, either through municipal services or through the cost of diesel for generators, is a major contributing factor in the cost of surgical care at the facility level, especially in small, first-level hospitals. Typically, users like hospitals pay not only for consumption but for demand (eg, the amount of energy that they might use at maximum draw, or peak demand). Within hospitals, surgical facilities can be high users of electricity, along with radiology suites and some laboratories. If surgical facilities are to offer round-the-clock services for caesarian section or laparotomy, they will need adequate funds and infrastructure for energy and redundant systems such as batteries and generators to handle grid instability. Quantifying the needs for energy involves establishing the needs and the existing infrastructure as well as efficiency improvement opportunities. A hospital energy manager is a human resource employee who has qualifications in costing, management, and implementation. Neglecting this critical component of the surgical ecosystem contributes to loss of access to surgical care even when other factors, such as nurses and doctors, are available. Widely variable voltage swings and few on-site, in-OR voltage regulators also contribute to the cost of surgery because they shorten service life for electronic equipment such as anesthesia monitors and some sterilizers.

STERILE PROCESSING AND CENTRAL SUPPLY

The professional organization most engaged with setting standards and certification for sterile process and surgical instrument management is the International Association of Healthcare Central Service Material Management.[21] The Association of Surgical Technologists also has published standards for sterile process.[22,23] International standards for sterilization and care of instruments become particularly important with the evolution of highly technical endoscopes for orthopedics, anesthesiology, urology, general surgery, obstetrics and gynecology, and others, many with small channels, and equipment made from a variety of materials with their own requirements for cleaning, disinfecting, and sterilization. Much harm and great cost can come from inadequate attention to maintenance of surgical and anesthesia equipment, even at first-level hospitals (Fig. 2).

Biomedical Engineering. In the surgical ecosystem, much depends on engineering for repairing monitors, lights, anesthesia machines, and a host of other devices critical to safe surgery. A limited supply and availability of engineers contributes to the closets full of broken equipment often seen in LMICs, and it also contributes to poor access to surgery when critical equipment in limited supply breaks down. Investments in personnel for the surgical ecosystem such as central supply and biomedical engineering ensure better functionality of hospitals and greater efficiency of use of devices—and hence cost management.

Waste Management. In small rural hospitals, as well as some urban ones in LMICs, it is not unusual to see septic systems located immediately adjacent to and within 25 feet of wells or to see piles of medical waste, sorted or unsorted, on the hospital grounds awaiting incineration (Fig. 3). In addition to the public health concerns, a major reason to include waste management in the surgical ecosystem is that surgery is a major generator of waste. In some countries, solid medical waste from hospitals is dumped at sea, where syringes and other debris wash up on distant shores. There is no convention of international standards governing medical waste. According to Healthcare Without Harm, 75%-85% of medical waste is like municipal waste—low risk unless it is burned.[24,25] The remainder, infectious waste, sharps, chemical waste, and wastewater, is more problematic. Planning, monitoring, and budgeting in the operating budget are key to functioning ecosystems, as well as appropriate training. Because many countries, especially low-income countries, lack local standards, the WHO guidelines and toolkit provides excellent guidance.[26] The United Nations Development Programme's many publications also include several on hospital waste policy and guidelines.[27] However, retrofitting existing ORs and hospital systems remains a challenge. Waste management should be considered in all programs aimed at scaling up surgical services.

Supply Chain and Pharmacy. Hospital supply management and pharmacy are rarely brought up in discussion of surgical capacity building, but lack of consumables, including suture, catheters, and bandages appropriate to the surgical case type, and lack of antibiotics and emergency and essential anesthesia medications in addition to lack of suction tubing and other ventilation and gas evacuation systems cause increased risk in the OR. The Healthcare Supply Chain Association in the United

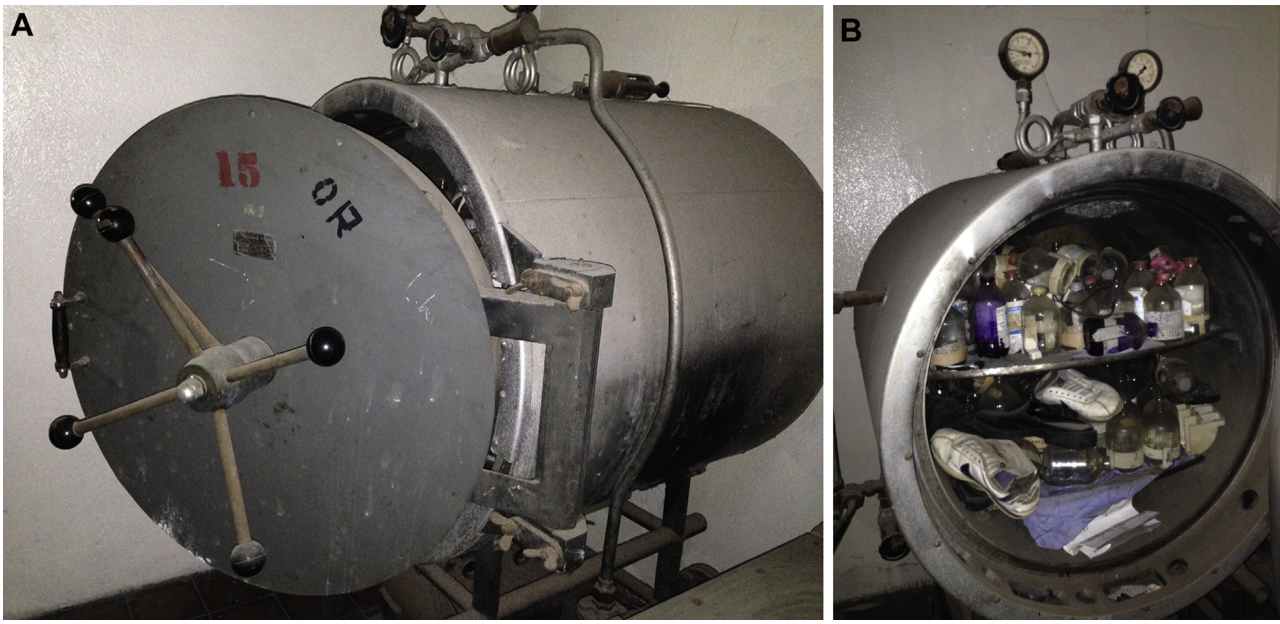

Figure 2. Challenges faced in reorganizing and retrofitting an urban hospital in Liberia. (A) Repurposed autoclave, 2013. (B) Waste storage.

States is an example of a trade association representing many group purchasing organizations and verifying quality standards by vendors.[28] However, in LMICs, limited regulation and certification has led to variable but sometimes widespread intrusion of counterfeit medications into hospitals; in many systems, patients are left to fend for themselves. A patient scheduled for surgery may receive a list of necessary items for a planned operation. He or she must then shop for and purchase all items, from surgeons' gloves to intravenous fluid to sutures and bandages and antibiotics. Only after these have been obtained can surgery proceed. A system where patients are accountable for the quality of products that they purchase for surgery inappropriately preys on the poor and the poorly informed. Such systems preclude safe, effective, affordable surgery. International procurement agencies such as UNICEF, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and UNITAID for distribution in LMICs have not focused on surgery, and the WHO Prequalification of Medicines Program could be better focused on prequalifying medications particularly important to safe anesthesia to modern (but not prohibitively expensive) standards. Scaling up surgical care will require similar advocacy and commitment to supply chain and pharmacy both in the public and private sectors.

Figure 3. Waste management: incineration facility and waste pile at a general hospital in Liberia, 2013.

Innovation and Donations. A study by Perry and Malkin examined 112,040 pieces of equipment in 16 LMICs.[29] An average of 38.3% were out of service because of lack of training, technology management, or infrastructure. These data do not support the commonly held notion that 70% of medical equipment in sub-Saharan Africa is out of service, but they do verify that a substantial portion of it is. From the surgical point of view, the fact that more than 30% of

Figure 4. Depiction of professional networks and human resource support systems necessary for regulation, certification, and professional strengthening for operating room and support personnel. Abbreviations: NGOs, nongovernmental organizations; UN, United Nations; WHO, World Health Organization.

diagnostic ultrasounds, x-ray machines, and anesthesia machines were out of service and more than 40% of tabletop autoclaves and sterilizers were dysfunctional is cause for worry. Most equipment that requires purified water, stable electricity, or pressurized gas will not work for the 2-5 billion people who currently lack access to surgical care. New technologies will need to bridge the gap until utilities and municipal infrastructure can fill the requirements. Furthermore, according to Perry and Malkin, "investments in capacity building, health technology management, and infrastructure could nearly double the amount of working medical equipment without the expense of collecting, testing and shipping used medical devices."[29] However, if donations are to be made, the American College of Clinical Engineering has developed Guidelines for Medical Equipment Donation available online,[30] and the WHO maintains a list of organizations engaged in donation acquisition and distribution that operate within WHO guidelines.[31]

The entrepreneurial environment for medical device and supply innovation, in general, mostly remains poor in LMICs, although in wealthier areas of middle-income countries a renaissance of entrepreneurial spirit is gaining traction. However, regulatory agencies and intellectual capital protection are often weak, decreasing incentive to innovate. These factors apply broadly to all industries, and not just to medicine. However, even limited investment in local capacity could significantly enhance the availability of such basic items as sterile water and saline in bags, which are required for most surgical operations. Depending on hospitals to manufacture and store their own sterile water and saline in sufficient quantities is inefficient and not cost effective.

Community and Human Resources for Surgical Care and Culture. Beautiful operating rooms can be positioned in locations where there are no support systems, no patient need, or no appropriately trained staff. It is not unusual to see such theaters or hospitals built by well-meaning donors or by foreign countries currying exchange for favorable deals on local commodities. These facilities are often built as standalone structures but are not linked to health systems or academic training programs. Often the health community, including the community of surgeons, is not invested in the enterprise. Donated surgical suites consisting of used and donated equipment have an additional set of problems for maintenance, sustainability, and disposal of nonfunctional equipment. If local nurses, doctors, support personnel are not sufficiently invested in the development and maintenance of the operating environment, and if there is insufficient administrative support and government or private financing, including material resources and salary, no infrastructural development will be successful for the surgical care of patients. An illustration of the community network needed to support surgical care is depicted in Figure 4.

Of the estimated 2-5 billion people who lack access to safe, affordable care, most are living in poor countries or low-resource parts of middle-income countries where charity will continue to

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play a significant role, even as the global economic climate improves, according to the United Nations Sustainable Development Goals for 2030.[32] Shrime et al performed a systematic review on charitable platforms in global surgery, addressing the charity model's effectiveness, cost effectiveness, sustainability, and role training.[10] The study reflected that most surgery offered by charities falls into 1 of 2 categories: specialized hospitals like children's hospitals or neurosurgery units, or temporary platforms like surgical brigades or camps. A survey of 99 surgical organizations revealed that most provided fewer than 500 operations per year. There is large variability in surgical outcomes across platforms and procedures, but it is generally reported that outcomes are inferior to similar operations provided by the same practitioners in hospitals in their home (high-resource) countries. The reasons for the discrepancies will be fruitful grounds for future research.

On the local level, government hospitals—especially first-level hospitals—will continue to provide the bulk of surgical care to the world's poor for the foreseeable future. Developing a holistic approach, with support from the world's academic, professional society, and oversight organizations and NGOs, will help ministries of health identify the choke points in a systems-based approach to surgical care. Identifying resources and working in collaboration with networks such as the G4 Alliance will facilitate sharing of resources from the world's web of potential support—a crowd-sourcing approach to surgical systems problems.

CONCLUSIONS

The application of a systems approach to the study of surgery has implications in cost control, capacity building, and quality improvement. Conceptualizing surgery as an ecosystem will provide a springboard for future studies related to surgical care, particularly in wider public health and health care contexts. In Meadows' words, "Seeing systems whole requires more than being 'interdisciplinary.' …Interdisciplinary communication works only if there is a real problem to be solved and if the representatives from the various disciplines are more committed to solving the problem than to being…correct.[11] With surgical conditions accounting for as much as 28% of the global burden of disease, approaching the problems from a systems perspective will prevent fragmentation of effort and focus energy on improving patient care.

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