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25 Years of Health Care Delivery in Low- and Middle-Income Countries

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A failed coup attempt in August of 1991 left former Soviet leader Mikhail Gorbachev's power irreparably damaged and he resigned in December. The Soviet Union crumbled and Boris Yeltsin took over in Russia where, in the beginning of 1992, he lifted most of the remaining price controls.ⁱ In 1991, India's economy was, as one author put it "on the brink of collapse."ⁱⁱ That year, PV Narasimha Rao took over as prime minister. Rao and his Finance Minister, Manmohan Singh, are credited with putting reforms in place that would fundamentally change the economic landscape in India. Deng Xiaoping engaged in a series of speeches designed to ensure the continued economic liberalization within China,ⁱⁱⁱ and a 1992 vote in South Africa ended Apartheid and created a multiracial government. This was also the year that William Davidson established the William Davidson Institute (WDI) at the University of Michigan. Much has changed in the years since WDI was first established, but the Institute continues its commitment to the mission William Davidson laid out 25 years ago: "to equip economic decision-makers in...emerging countries with the tools of commercial success."

This is one of a series of articles, collectively titled "25 Years of Market-Based Solutions," that presents an overview of the activities and research that has taken place over the past 25 years in Health Care Delivery, with an eye toward what we can expect in the coming years.

—Paul Clyde, WDI President

i www.washingtonpost.com/archive/politics/1992/02/28/russia-set-to-remove-most-price-controls/b8f4237f-34e7-49c5-bcb5-a743dbf3d1d3/?utm_term=.2156d93c3745.

ii www.qz.com/799883/how-narasimha-rao-fixed-the-indian-economy-and-the-congress-party-only-to-be-forgotten.

iii www.ft.com/content/a1b03b56-f33c-11e0-8383-00144feab49a.

1. Background

“In the past fifty years, the world beyond North America and Western Europe has seen improvements in health care and living conditions as breathtaking in their sweep as the technological changes experienced in richer areas of the Northern Hemisphere” (p. 3).¹ That statement, based on data from about 25 years ago, is equally appropriate today. Health care has continued to improve at a remarkable pace, especially in low- and middle-income countries (LMICs). Life expectancy in low-income countries (LICs) increased from 39.1 to 50 between 1960 and 1992, and continued on a similar path to 61.3 by 2014.² Infant mortality in LICs is less than half of what it was in 1992.³ The reasons for the improvements since 1992 are different from the reasons for the health care improvements in the decades before 1992, in many cases, because of the success of the preceding decades. Similarly, the reasons for improvement in the next 25 years can be expected to be different than those for the past 25 years, in large part because of the successes that have taken place over the past 25 years. Much of the focus has been on the actions and effects of multinational institutions and/or governments. However, much of the health care is provided by private health care institutions and there is no reason to believe that their impact will decrease in the future.

As part of the William Davidson Institute’s celebration of 25 years of market-based solutions, this paper reviews the changes that have taken place in health care delivery in low- and middle- income countries since 1992, highlighting the role of the private sector. This is an enormous task and in the present paper we do not attempt a comprehensive overview. Instead, we will begin with a look at changes in causes of death and follow that with a more in-depth view of a few areas that appear likely to take on more prominence (primary care, surgical care, care for the elderly and mental health) and/or change health care delivery significantly in the coming years (medical device innovations and telemedicine). We will review both literature and data, but also discuss some examples of work in the field. The goal is to describe what is happening and, to an extent, what the implications are for the future. Much of the discussion about the future is based on an expectation of where money is likely to be spent in LMICs by both the global development community and private individuals (or companies). We also look at models that have been successful and are thus likely to become more prevalent in the future. We will not be addressing arguments about where the greatest social impact is likely to take place except to the extent that affects the current and future state of health care delivery. This paper will serve as a primer for anyone interested in understanding health care delivery in emerging markets. Such an understanding will benefit efforts to a) anticipate what changes can be expected in the future and b) determine the most productive future investments.

2. Health Care Delivery

Health care delivery focuses on the individuals (e.g., clinicians and village health workers) and institutions (e.g., hospitals, clinics and community centers) that interact directly with patients. A call to focus on health care delivery and, in particular, primary care^{iv} dates back at least to 1978 when World Health Organization (WHO) member countries gathered in what was then known as Alma-Ata, USSR (Almaty, Kazakhstan today), and signed a declaration proclaiming that health care is a basic human right and that primary care is the key to providing health care.^v The declaration advocated comprehensive primary care and emphasized community health workers. Following the declaration, nurses and health extension workers were trained to work in community health centers. Over the next decade, with limited progress in many regions of the world, some started advocating a more modest goal—to institute interventions that would have the greatest impact on under-5 mortality.⁴ In 1987, African ministers of health adopted the Bamako Initiative at a meeting sponsored by WHO and UNICEF. The Bamako Initiative emphasized the role of the local community in the management and funding of primary care due to lack of resources in sub-Saharan Africa.⁵ This decentralization of health care was often accompanied by a discussion of privatization.⁶

Whether because of these initiatives or simply due to a lack of public funding, private funding of health care plays an important role in LMICs. Private health expenditures in low-income countries (using World Bank classifications) accounted for 59% of total expenditures on health in 2000.^{vi} By 2015 this had dropped to 47%, but still remained much larger than government expenditures which accounted for 20% of total expenditures. The remaining 31% was external expenditures (foreign funding). Out-of-pocket expenditures accounted for 40% of total health care expenditures in 2015, down from 46% in 2000. In middle-income countries, the percentage of private expenditures dropped from 62% of total health care expenditures in 2000 to 46% in 2015. Government expenditures made up the difference as external expenditures are minimal in middle income countries. Out of pocket expenditures dropped from 47% to 36% in middle income countries over the same time period. However, these expenditure data don't necessarily reflect the role of the private sector in providing services, and it is difficult to disentangle government from private provision in the data. For example, in Uganda in 2004, almost half of the hospitals in the country were private, with most in the private-not-for-profit sector. The government accounted for many more clinics than the private sector but the private sector accounted for over one-third of the health care work force in the country. However, many of the doctors in the private not-for-profit sector were also civil servants and some doctors in the government facilities had their own private practices nearby. Further complicating the calculation, about 30% of the private sector revenue came in the form of government subsidies.⁷ Estimates of the percentage of primary care provided by the private sector range from one-third to three-quarters.⁸

Within the private sector, there is wide variation in the quality of private health care provision. In almost every country expertise in the private sector varies widely, ranging from the expert, evidence-based practitioners located in well-funded health care systems to the charlatans and quacks treating the same disease nearby. Perhaps the best example is the interview of a practitioner in India who, when asked how he came to practice medicine, replied “I graduated from

iv The term “primary health care” dates back to at least 1970 when it was often used to describe interaction with patients at the community level through community health workers and other non-physicians.¹⁰⁹

v This declaration was, itself, a product of a collaborative effort between WHO and UNICEF on primary care that started earlier in the 1970s. This effort was viewed as an alternative approach to the vertical approaches to diseases such as malaria that had not had the desired success.¹⁰⁹

vi World Bank changed their expenditure data beginning in 2018 and expenditure data now only date back to 2000. All expenditure data used here are from the new data set.^{110, 111, 112}

high school and couldn't find a job, which is when I decided to set up as a doctor" (p. 52).⁹ There are, however, many spectacularly successful and financially sustainable examples of private health care provision. Aravind Eye Care and Narayana Health are two of the more prominent examples that serve the poor, though there are many others. CURE, for instance, has hospitals all over the world, one of which has revolutionized treatment for hydrocephalus, and also offers a highly effective club-foot program in partnership with the public hospitals in 18 countries around the world. Apollo and Fortis in India and IHK in Uganda are all largely serving the higher-income groups within their countries. Franchising models such as CFW shops in Kenya continue to pursue a long-term viable model. Grace Care, a diabetes model in Sri Lanka, also falls in this category. The empirical studies reflect this wide variation in the quality of private health and find no evidence that either public or private are consistently more effective than the other.¹⁰

3. Changes in Global Health Outcomes and Inputs

A. Changes in health outcomes

Measuring the quality and accessibility of health care in LMICs over time is extremely difficult for a variety of reasons including the various ways data have been classified and collected over time and across geographies. The most recent Global Burden of Disease study explores these issues in detail.¹¹ We make no attempt to replicate that here; in the present paper, we will only explore some highlights. There are many different measures for health that could be used and we will not make an attempt to enter the debate,^{vii} but will focus on cause of death and years of life lost (YLL) due to death. Admittedly, this oversimplifies "health" but it has the advantage of being available at some detail over the relevant time period. Two prominent sources for cause of death data are WHO and The Institute of Health Metrics and Evaluation (IHME) at the University of Washington. IHME cause of death data are used in the following charts. It is important to recognize that all of these data are estimates and some are more precise than others.^{viii}

Figure 1 shows the number of years of life lost by disease in 1992 and 2015 in low-income countries.^{ix} This provides an aggregated picture of the burden of each disease; however, it doesn't account for the increase in population over time and it doesn't allow us to distinguish between the two components of YLL: death rate and the average age at death.

Figure 2 plots the percentage change (between 1992 and 2015) in death rate in low-income countries on the x-axis and the percentage change in the average age at death on the y-axis. The size of the bubble in **Figure 2** represents the total number of deaths in 2015 in low-income countries. Note that, while YLL increased for a number of diseases, after controlling for population changes, the death rate declined and the average age at death increased for virtually every disease.

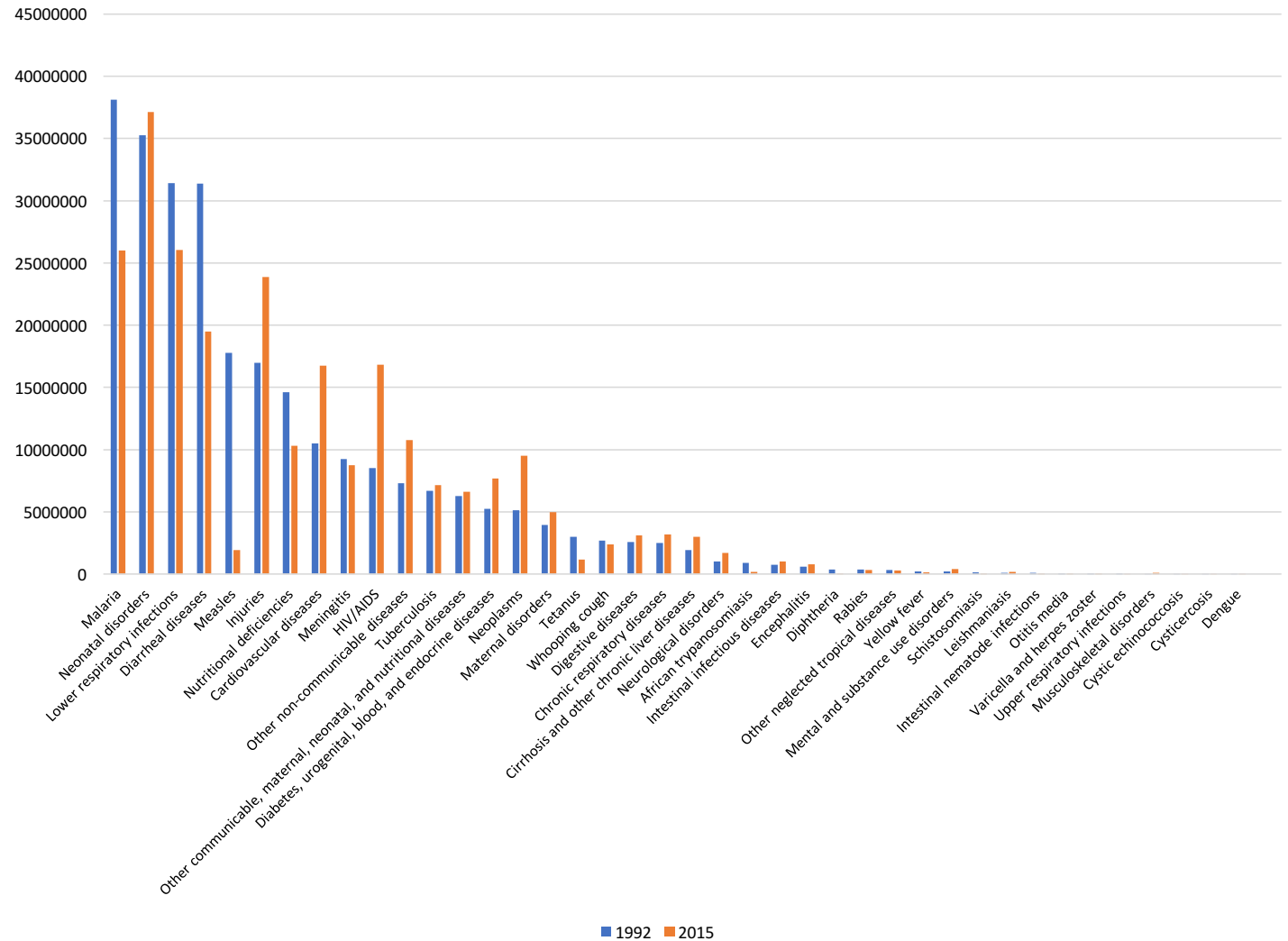
One explanation for these improvements is the success of global efforts to target specific diseases, sometimes called a "vertical" approach. There have been many significant vertical efforts started since 1992. In 2000, Gavi, a

vii For a more detailed exploration, see Deaton.¹¹³

viii The estimate of total deaths has a relatively narrow 95% confidence interval (55 to 56.6 million total deaths). However, the specific cause of death is difficult to know in many cases, especially in remote areas of low-income countries where resources are limited and the reason for the death is not explored. The data on specific diseases often show wide confidence intervals. Yellow fever, for instance, is estimated to cause 5,000 deaths but the confidence interval ranges from 1,000 to over 14,000. In an absolute sense, this is still narrow, but when looking at percentage changes it is a large variation. This imprecision should be kept in mind in the discussion that follows. Nonetheless, as will be seen, the order of magnitude of the changes in the various causes gives some comfort to the idea that we can safely draw some broad conclusions about changes since 1992.

ix IHME uses a socio-demographic index (SDI) that is based on per capita income, educational attainment and total fertility rate. In some cases, countries are divided into regions within the country, but most countries are not. The countries included are very similar to the countries included in World Bank's low-income country measure.

Figure 1: YLL in Low-income Countries by Disease



Source: Institute of Health Metrics and Evaluation Global Burden of Disease data as accessed in 2017.

collaborative effort of the private sector and governments largely funded by governments and the Gates Foundation, was created to focus on increased access to vaccines. In 2002, the Global Fund, also a partnership between the private sector and governments, but largely funded by governments, was established to fight HIV/AIDS, tuberculosis and malaria. The (U.S.) President's Emergency Plan for AIDS Relief (PEPFAR) was established in 2003 to combat HIV/AIDS. In 2005, the (U.S.) President's Malaria Initiative (PMI) was established to reduce malaria deaths by 50% across 14 countries with the greatest malaria burden. Diarrhea has been addressed by a focus on oral rehydration therapy (ORS), with a combination of zinc and ORS recommended by WHO and UNICEF since 2004.

The death rates from the targeted diseases saw some of the largest decreases. The death rate (deaths per 100,000) for malaria dropped by 64% from 1992 to 2015. The death rate for tuberculosis dropped by 42%. The death rate for diarrhea dropped by 64%. For vaccine-treatable diseases, the reductions were even greater, with death rates decreasing by 78% for tetanus, 90% for diphtheria and 94% for measles between 1992 and 2015. The only exception was HIV/AIDS, which remained virtually constant at a death rate of 56 per 100,000. However, the rate had been increasing dramatically since the 1980s, rising from 37 per 100,000 in 1990 in low-income countries to 128 in 2003. Since then it dropped, reaching 56 in 2015.

Importantly, however, generalized improvements in socioeconomic status in these nations functions as a potential confounding factor, and not all of the improvements in metrics can be traced to the well-funded vertical efforts described above. Some improvement is due to better overall living conditions, changes in behavior and improvements in primary care, which, in the low-income settings, is largely focused on expecting mothers and children under 5.^x The neonatal mortality rate, for instance, dropped by 47%.^{xi} Death rates from nutritional deficiencies dropped by 61%. Care for the youngest improved almost across the board. With the exception of whooping cough and neonatal disorders, the average age at death for all of the major killers either rose significantly or was already high in 1992. This improvement in care for the youngest leads the way to the decrease in death rate across most diseases. With the exception of dengue, musculoskeletal disorders and mental and substance use disorders,^{xii} every category saw a decline in death rate between 1992 and 2015. This result is all the more impressive because the composition of the countries in the low-income group changed between 1992 and 2015. Countries that improved in socioeconomic status since 1992 are not included in the 2015 numbers. Using World Bank classifications, there were 55 countries in the low-income group of countries in 1992. By 2015, 22 of those had become lower-middle-income countries and four had become upper-middle-income countries by World Bank classifications. Only two countries were added to the low-income list from a middle-income list. All of this suggests that at least some of the improvements observed in the diseases targeted by these vertical approaches would have been achieved regardless.

Figures 1 and 2 show some of the changes over the past 25 years, but can we say anything about the next 25 years? One approach is to look at the cause of death in the higher-income countries.^{xiii} This approach is far from perfect. We will

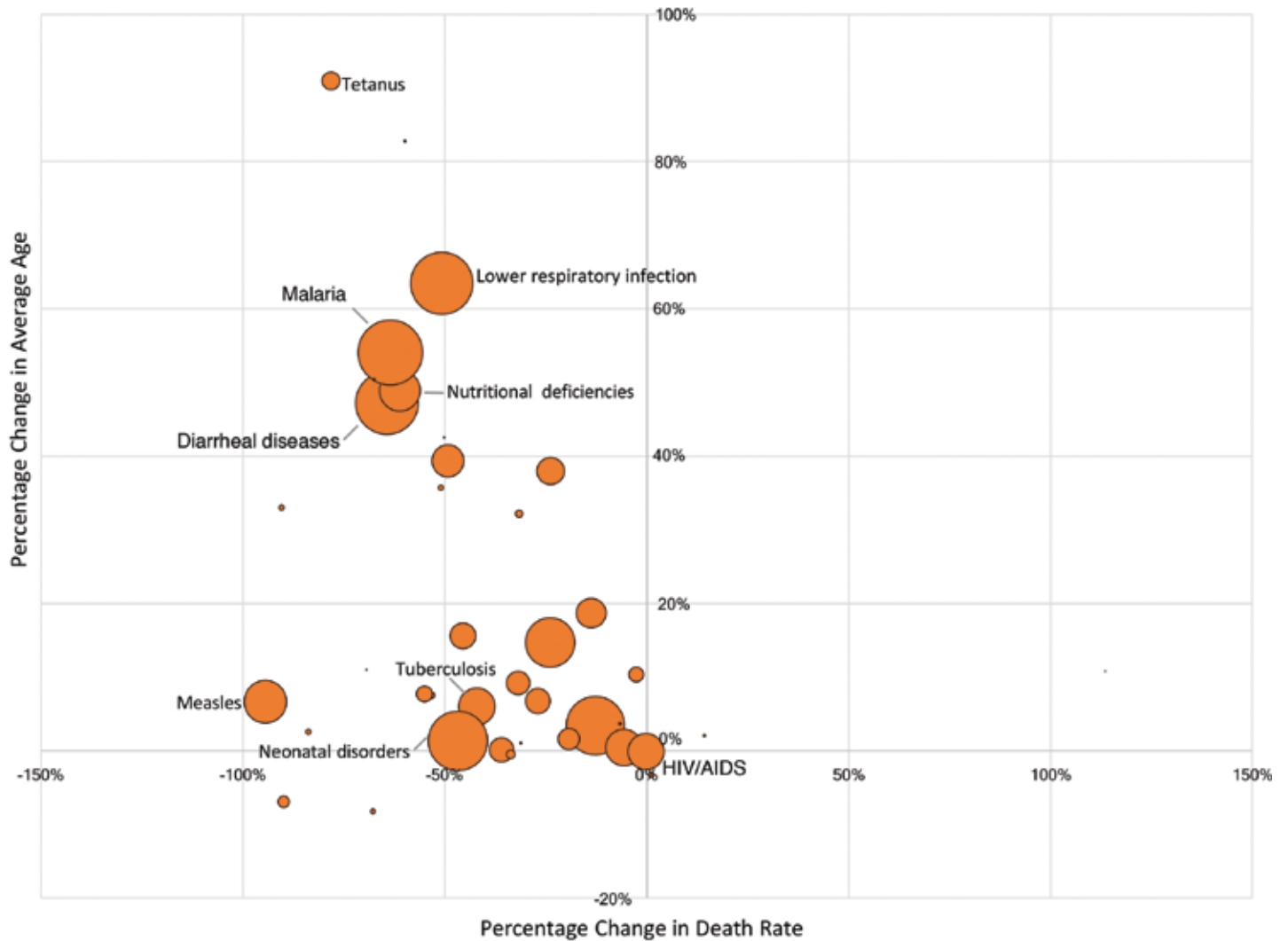
x This was, in part, a practical response to the spirit of the Alma-Ata declaration on making primary health care accessible to all.¹¹⁴ Women and children under 5 are often explicitly called out by programs.¹¹⁵ Some of these approaches not only have vertical components but also a more integrated approach.¹¹⁶

xi While one could imagine a targeted approach here, vertical approaches are not considered effective in the case of neonatal care.¹¹⁷

xii Even for some of those that increased, the confidence intervals on the estimates are such that they may have actually declined and, in any case, accounted for relatively few deaths (death rates of .04, .46 and 1.8 per 100,000 respectively).

xiii This is not to say that LICs will be HICs in 25 years; the idea is just that YLL in HICs will give an idea of the direction of change for LICs in the coming years.

Figure 2: Percentage Change in Average Age at Death and Death Rate from 1992–2015 in LICs.



Source: Institute of Health Metrics and Evaluation Global Burden of Disease data as accessed in 2017.

turn to the shortcomings of such an approach below, but first consider the merits. The logic for this approach is that as a country increases in income, the causes of death are more likely to parallel those of countries with similarly high levels of income. There has been a good deal written about the causal relationship between health and income across and within countries.^{xiv} For our purposes, whether higher incomes result in better health (or at least the metric we are using here: longer lives), better health leads to higher incomes, or other factors cause both to increase doesn't matter. If incomes will continue to grow, this suggests that health outcomes will improve as long as they are correlated.¹² The income growth is, of course, not guaranteed. However, over the past 25 years, real GDP per capita rose by 45% worldwide, and this was not driven by the high-income countries. The poorest 25% of the countries in 1992 for which the World Bank had data in 1992 and 2016 experienced growth rates in real GDP per capita of 146% on average and 85% of them had positive growth rates.^{13, xv}

Looking at death rates of high-income countries to give insights into what the future in LMICs will look like has a number of problems. First, lower-income countries would like to avoid some of the costly health characteristics of high-income countries such as drug use and obesity (though these problems are already prevalent in many LICs). Second, the health challenges in all countries are likely to change significantly over time as more medications become available, lifestyles change and technologies improve. Third, there may be geographic and environmental differences that mean some differences in cause of death will persist even if the LICs become high-income countries. Nonetheless, the prevalence of diseases in high-income countries can give us some guidance as to what is possible using health care products, technology and know-how available today. That is, differences that are due to resource constraints can be expected to become smaller as LICs increase in income and resource constraints become less binding. Part of this will be due to the shift in payers from large global organizations such as Gavi, Global Fund and the UN, who cover the costs of vaccines and many of the communicable diseases, to paying customers who are more similar to the paying customers in high-income countries.

With those caveats in mind, we look at differences in YLL and death rates between high- and LICs in 2015.

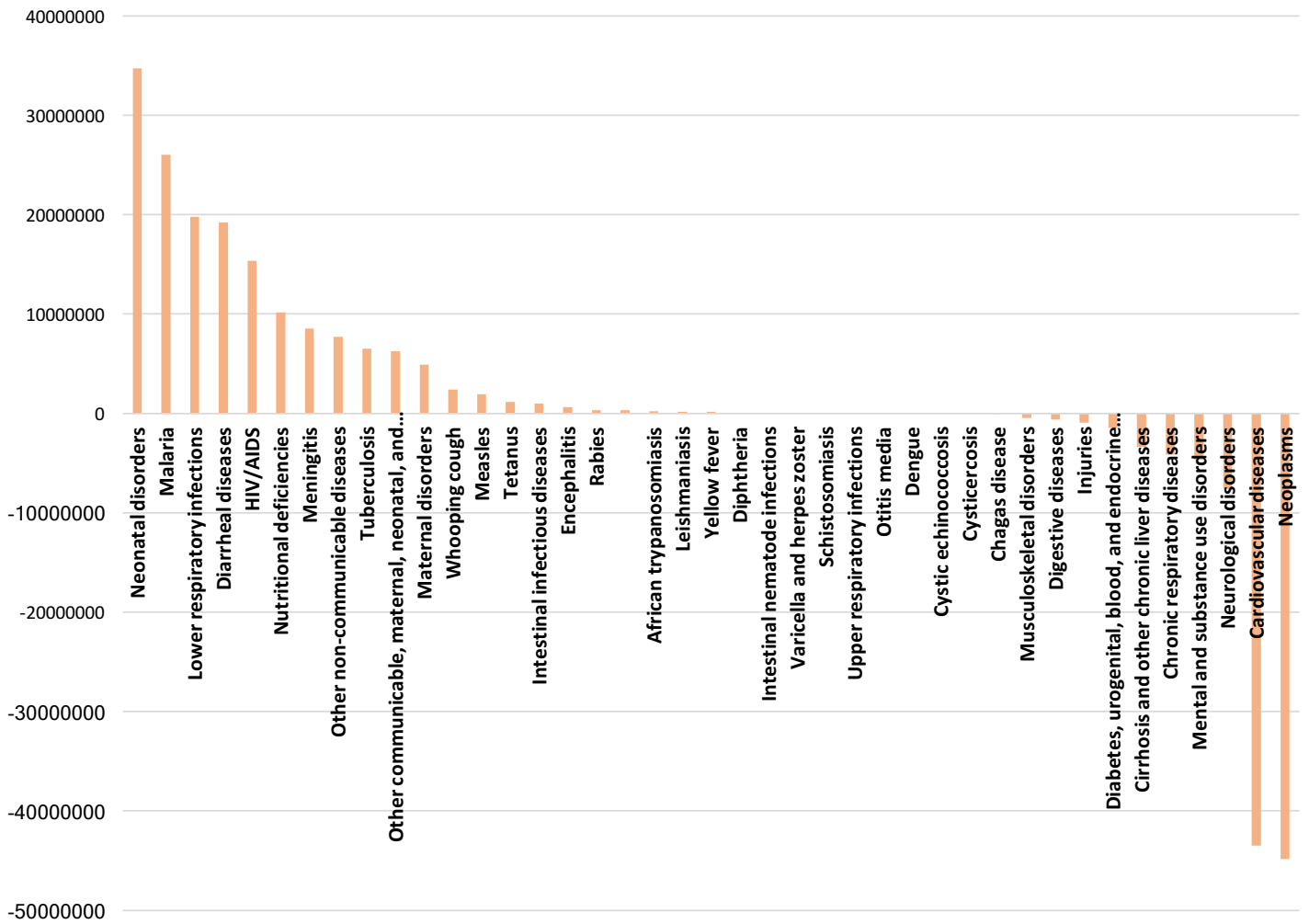
Figure 3 shows the difference in YLL between high-income and LICs by disease. **Figure 4** plots the difference between the death rate in low-income countries and the death rate in high-income countries along the x axis and the difference in the average age at death in low-income countries relative to high-income countries along the y axis. The size of the bubble represents the magnitude of the death rate in low-income countries in 2015.

Figures 3 and **4** show that some of the biggest differences in 2015 are the diseases that have seen significant improvements over the past 25 years: malaria, TB, HIV/AIDS, diarrhea, neonatal disorders and malnutrition. That is, many of the diseases that have been targeted over the past 25 years continue to kill many people and kill them at young ages. However, **Figure 4** also shows that if low-income countries continue to gravitate toward the path of high-income countries, we can expect the death rate for chronic diseases to increase in what are now LICs. None of the causes on the left of **Figure 4**

xiv See Deaton for a comprehensive discussion of this topic.¹³

xv We use the poorest 25% of countries in 1992 instead of a low-income classification because some countries moved from one classification to another during the time period.

Figure 3: Difference in YLL between High-Income and Low-Income Countries in 2015 by Disease



Source: Institute of Health Metrics and Evaluation Global Burden of Disease data as accessed in 2017.

are communicable diseases and almost all are chronic. This is not surprising, but **Figure 4** also shows that these diseases are already accounting for a large number of deaths in low-income countries in 2015. This is a good sign: More people are living to an age when they can be affected by these diseases (though the average age at which a person dies from these diseases is lower, sometimes much lower, in the LICs, indicating that there is also room for improvement in the treatment for these diseases using existing technologies). The point is not that those diseases that have been and continue to be responsible for large numbers of deaths at young ages will be ignored, though there is some concern that the success may lead to less investment due, in part, to complacency induced by the recent success.¹⁴ The point is that we should expect that the death rates from chronic diseases and other causes of death that are not the subject of vertical efforts, such as injuries and neonatal disorders, will take on more prominence. The implications of this are discussed below.

B. Changes in trained personnel in health care

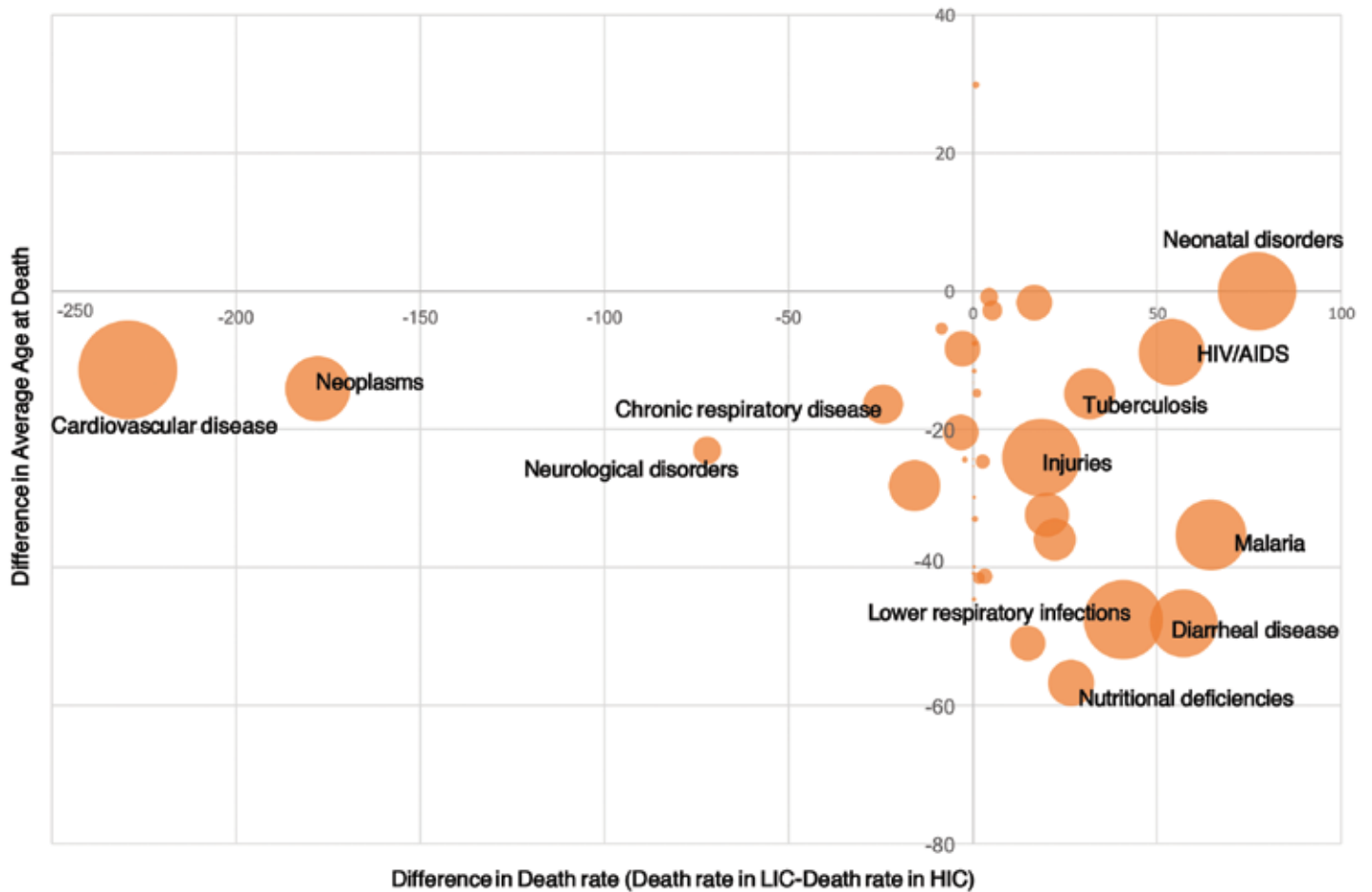
We can credit some of the health improvement to an increase in resources. Real spending on health care in LICs almost tripled between 1995 and 2014, from \$32 to \$91 per capita (PPP). Middle-income country health care expenditures more than quadrupled, from \$138 to \$581, over the same period.

These increases in spending did not lead to commensurate increases in one key input: skilled health care professionals. World Bank data on nurses, midwives and physicians are available only in 2000 and 2011. In LMICs, the number of nurses and midwives increased during that 11-year period but only from 1.34 to 2.2 per 1000, a rate that is not proportionate to the increase in spending and is still far below the rate of 8.6 in high-income countries. Similarly, the increase in doctors lagged behind spending increases and remained extremely low, rising only from .06 to .07 per 1000 in low-income countries and 1.08 to 1.35 in middle-income countries. By comparison, high-income countries average 2.9 physicians per 1000.

The global health community is now making a concerted effort to address the shortage of skilled health care professionals. The Global Health Workforce Alliance, which included governments, research organizations, international institutions and financial institutions, was created in 2006 “as a common platform for action to address the (human resources for health) crisis.”¹⁵ In 2014, the World Health Assembly formally requested the WHO to develop a strategy for human resources for health (HRH). In 2016, the WHO organized the inaugural Global Health Workforce Network (GHWN), the successor to the Global Health Workforce Alliance. The GHWN objectives include fostering policy discussions on HRH and monitoring progress toward the HRH goals.

Some of the shortage of skilled health care professionals can be addressed by decoupling clinical functions and using the trained personnel only for the functions that require their expertise. An operation in Sri Lanka is developing a program to identify specific questions to be asked by someone who does not qualify as a skilled health care professional, but is trained in the questioning. The idea is to use a questionnaire protocol that distinguishes between

Figure 4: Difference in Cause of Death between High-Income and Low-Income Countries in 2015 by Disease



Source: Institute of Health Metrics and Evaluation Global Burden of Disease data as accessed in 2017.

diabetes cases that require clinical attention versus those that do not. Combining the software, the protocol and the decoupling of tasks, clinicians can effectively increase the number of patients they serve by a factor of 2 or more.

More advanced technologies may also play a bigger role in developing economies sooner rather than later. Robotic surgeons are already being developed for abdominal, pelvic, thoracic, cardiac and even brain surgery. Veebot is developing a robotic blood draw machine. Zebra Medical Vision uses machine learning to read and diagnose medical images. Combined with improved telecommunication in LICs, Zebra Medical Vision could eliminate the need for radiologists. These options may have more difficulty taking hold in economies that have a large number of capable clinicians in place (high-income countries) than in those with a shortage (LMICs).

4. Implications and Opportunities in Four Clinical Areas

What do all of these data mean for health care delivery in the future? There is considerable literature about the future in global health. We will examine a few of these in more detail. These areas were chosen based on the data in Section 3 and on our collective experience in the field; however, it is not our claim that these will be the only significant areas of changes. In particular, we will explore the implications of the changes that have been and are taking place for 1) primary care, 2) surgical capacity, 3) elderly care and rehabilitation, and 4) mental health.

A. Primary care

Historical look at primary care

With the Alma-Ata declaration and the Bamako Initiative, clinics took on an increased importance in the first line of care.^{xvi} In most LMIC countries, these are government-run clinics, though they often interact closely with private not-for-profit hospitals. While the coverage for some forms of care in some regions may be quite good, there is often significant variation within regions and across regions.¹⁶ There is also variation across types of care. As seen above, the number of deaths associated with some vaccines has dropped dramatically, indicating a high level of coverage; however, the World Health Organization estimates that only half of births in Africa are attended by a skilled professional.¹⁷ The World Bank and World Health Organization's 2017 Global Monitoring Report Tracking Universal Health Coverage¹⁶ finds that less than half of the population has access to what it calls "essential health services."^{xvii}

There is, of course, a distinction between access to care and access to quality care, but measuring quality is difficult. Das and Hammer¹⁸ examined the literature on the quality of health care in low-income countries and identified a few challenges. First, quality relative to what? Do we want to compare the level of quality to quality in high-income

xvi Pharmacies and kiosks that deliver drugs are also, in a sense, an important provider of primary health care. Here we focus on delivery by skilled health care professionals and/or institutions such as clinics or hospitals that serve patients.

xvii The WHO includes 16 essential health services, four each in four categories: reproductive, maternal, newborn and child health; infectious diseases; noncommunicable diseases, and service capacity and access.¹¹⁸

countries or to what is efficient given the available resources? Second, quality can vary significantly from transaction to transaction. Third, quality can be low either because of overprovision (e.g., over-prescription of antibiotics) or under-provision (e.g., amount of time spent with a patient). They find considerable evidence that quality is low but it is largely because of lack of effort (or misdirected effort)—not lack of training, infrastructure or supplies.

A number of studies have compared the quality of private providers with that of public providers.^{19, 20, 21} One might expect private providers to be more responsive than public clinicians and thus be higher quality; or more likely to take advantage of the patients and thus be lower quality. There are examples of both. As mentioned above, private care ranges from the exceptionally good to the exceptionally bad. Many providers have no formally trained clinician on staff. However, public health provision is equally variable. In many of them, the trained clinicians don't show up. One study found that in both private and public clinics, most of the care was provided by someone who had no formal training.²² Comparisons are further complicated by the fact that a given doctor may serve in a public hospital but also a private clinic across the street to which he refers certain cases. Perhaps not surprisingly, the evidence is mixed and there is no clear conclusion.²² Consumer behavior is consistent with this. The same patient will sometimes go to a public provider and sometimes to a private provider, depending on the treatment being sought.²³

Perhaps the more important question is about the incentives regardless of whether it is a private or a public facility. A few examples will illustrate the different effects observed from built-in incentives. One study observed the actions of doctors who worked in both public clinics and in their own private practice. The same doctors were found to provide the correct treatment significantly more frequently in their private clinics than in the public clinics,²⁴ suggesting that incentives can have a positive effect on effort. However, incentives can also lead to worse care. In a study in which audit patients presented with the same symptoms to all doctors in the study—fatigue, sore throat and a low-grade fever – further questioning should have led to the conclusion that no antibiotics should be prescribed. However, the study found that 63% of all these patients were prescribed antibiotics. That number dropped to 12% when the patients indicated that they were not going to purchase from the hospital's pharmacy.²⁵ Just as it makes sense to have your home inspection done by someone who doesn't have a construction business, it appears to make sense to have tests and drugs prescribed by someone who doesn't have a medical testing or pharmaceutical business.

The lack of appropriate primary care is not only due to supply-side shortcomings. There are also demand-side challenges. In fact, Das and Hammer¹⁸ argue that access to healthcare may not be lacking at all.^{xviii} Comparing the frequency of treatment sought for children for some typical diseases in low-income countries to the frequency of treatment sought for (other) typical diseases in high-income countries, Das and Hammer found the percentage was similar in both cases and, combined with evidence from other studies, concluded that “access to health care may be more widespread than usually imagined” (p. 5).¹⁸ Das and Hammer's evidence relates to illnesses (acute respiratory failure and diarrhea) for which a patient (or patient's parent) would recognize

xviii They make it clear that they are not talking about access to quality health care. Access to quality health care is lacking.

treatment might be beneficial. But ideally much of the health care will be preventive. Treating someone for something they can't observe or don't know that they would need (as opposed to a clear injury or illness) requires a different interface between patient and provider. Namely, it requires trust between patient and provider. The benefits of pre-natal care, for instance, are not immediately obvious to an expecting mother. Expecting mothers have observed other women having babies in their communities for their entire lives, often without any skilled professional. As mentioned above, the World Health Organization data show that only half of all births in Africa were attended by a skilled health care professional.¹⁷ While the maternal and neonatal mortality rates in such cases are unacceptably high from a global health perspective, the majority of births do not kill the mother or the baby. In the absence of clear evidence of the benefits, even after the birth, providers must build trust with the expecting mothers if they expect the mothers to seek and receive prenatal care. There are plenty of examples of the importance of trust in health care delivery. Sewa Rural in India hires women from the villages and then trains them, relying on the trust the women have within their village to persuade expecting mothers to receive proper care.²⁶ Aravind works closely with village leaders to offer mobile eye camps to encourage people, many of whom have never set foot in a hospital, to allow doctors to operate on their eyes.²⁷ Community health workers and clinics provide an opportunity to develop that trusting relationships between provider and patient, but it is an unrealized opportunity unless there is an investment in it along the lines of Aravind and Sewa Rural.

Primary care looking forward

Whether through the community health workers, clinics or hospitals, once the trust is established, the data from Section 3 suggest that the first-line interface with the patient will need to be more versatile and sophisticated moving forward. There are a few reasons for this. First, the vertical approaches that characterized past successes are less likely to work with the chronic diseases or other causes of death such as injuries or neonatal disorder. Most of those vertical approaches are straightforward, at least relative to chronic diseases, and do not require as many interactions with different specialists and medicines. Vaccine delivery requires access to the patient, access to the medicine (including the necessary refrigeration), consent of the parent, access to the skilled health care provider injecting the vaccine, and some way to track the vaccine with the patient. Malaria prevention requires either spraying or bed net distribution. Malaria treatment requires diagnosis via rapid diagnostic tests and/or microscopy and then treatment, generally with some sort of artemisinin-based combination therapy.^{xix} There can be more complicated cases, but the vertical approaches aren't necessarily designed to deal with them. If a malaria patient is cured, no more monitoring is required for that bout of malaria. Cancer, diabetes, chronic respiratory diseases and heart disease are significantly different. These diseases require constant monitoring, multiple specialists, and access to many different types of medicines. Cancer treatment, for instance, is best when teams of specialists in a given cancer (surgeons, medical oncologists, radiation oncologists, radiologists, pathologists and some internal medicine subspecialties) come together to evaluate and recommend treatment for a given patient. These chronic diseases require mechanisms to individually track what treatments have been tried, what medicines are used and what the health history is. Perhaps most difficult, much of the treatment and prevention takes place away from the clinic and with no skilled health care professional. Behaviors are at the core of these diseases; exercise, diet and smoking all have

xix WHO's "A Framework for Malaria Elimination" outlines a proposed process in detail.¹¹⁹ This is more complicated but nothing like what would be required to pursue a similar goal with cancer or heart disease or diabetes.

a significant impact on chronic diseases. Of the diseases focused on by Gavi or Global Fund, HIV/AIDS as a chronic disease has some of the same characteristics. However, the approach to treating that is often a parallel system to the main health care system, with buildings and financial systems separate from the general health care facility even though it may be right next door.

Second, diagnostics and the ability to do something about a condition once identified are improving in LMICs. A doctor from the United States who conducted rounds in a rural hospital in sub-Saharan Africa a few years ago said he could see 4–5 times as many patients a day in Africa compared to the U.S. There were two reasons for this: a lack of diagnostics and an inability to do anything about many conditions even if diagnosed. The improvement in treatment options and diagnostics has increased the options and thus the benefits of a patient interface that is more versatile and sophisticated than the typical interface that takes place with the vertical approaches.

Third, major killers such as injuries and neonatal disorders typically require an approach that allows for a variety of treatments. Injury as a category tells us nothing about what specialties or what treatments are required. In fact, these particular sources of morbidity and mortality must be approached in a multidisciplinary fashion.

Finally, an emphasis on primary care does not preclude the continued work required to ensure continued progress within communicable disease processes. This can be important if, as a September 2017 report from the Gates Foundation discussed, the attention and spending on diseases like malaria and HIV/AIDS declines for some reason. If that happened these diseases could reverse their current trend and increase in prevalence. This would not diminish the importance of a versatile primary care system, which would be able to deal with them as well.

Exactly what form this increased versatility will take may be very different from what we expect today. Telemedicine and innovations in medical equipment and devices will play a role. (Both are discussed in more detail below.) In the not-too-distant future, as mentioned above, much of this may be automated. Some already is. Software can be programmed to interpret vital signs, read images, provide diagnoses and learn as it goes. However, at least some of this increased versatility and sophistication is likely to show up in human capital requirements.

B. Surgical care

Historical look at surgical care

The data used for **Figure 4** show that surgical procedures are an important part of treating three of the top four causes of death today in low-income countries (cardiovascular, neonatal disorders and injuries). The increasing importance of these and other diseases such as malignancy (see **Figure 1**) has brought to light the scarcity of surgical resources in

developing nations. We are now in the midst of an epidemiological transition in which surgically treatable diseases represent one of the most common, preventable and growing contributors to the global burden of disease.

In a recent report, the Lancet Commission on Global Surgery argued for an urgent shift in paradigms for health care delivery to one that includes surgical procedures. According to the report, over 5 billion people worldwide lack access to safe, affordable surgical services; of the 313 million surgical procedures that are performed each year, only 6% occur in developing nations, with the fewest number of surgeries occurring in sub-Saharan Africa and South Asia; 9 in 10 people in low- and lower-middle-income countries do not have access to basic surgical care.²⁸

Various social, economic and cultural considerations are responsible for the lack of basic access to surgical services. First, in most low-and-middle-income countries, hospitals and surgical centers are primarily located in urban areas.²⁹ Due to a lack of sufficient health care resources and institutions in rural areas, patients in these regions are forced to travel considerable distances to receive care, often delaying access to necessary interventions and, consequently, increasing morbidity and mortality. Second, there is a deficit in the number of well-trained health care personnel available in developing nations, particularly within surgical subspecialties. The patient to staff ratio in many of these regions is too high and unsustainable to provide high-value care. In some countries, the majority of the surgical workforce is composed of non-physician providers and nurses.³⁰

³¹ Compared to the United States, which reports 2.55 physicians for every 100,000 people, low-income countries such as India and Ghana have only 0.72 and 0.09 physicians for every 100,000 people respectively.³² Other countries, particularly in sub-Saharan Africa, report even lower physician densities, with the minority of these providers harboring specific surgical expertise. Due to limited financial incentives, restrictions on resource utilization, lack of technology and insurmountable patient volume, many well-trained providers including surgeons and anesthesiologists emigrate from low-income countries to more developed nations.³³ Finally, the inability to access basic, routine forms of health care on an ongoing basis results in severe, progressive and complex cases that are of higher acuity than can be managed by already overwhelmed centers.

Surgical care looking forward

Despite the need, investments in surgical procedures can't be expected to increase unless payers are willing to purchase the services. There are three reasons to believe that payers will be willing to increase their expenditures on surgical services.

First, the global health community is more likely to invest if the social benefits are on par with other investments in global health. A series of recent studies suggest, at least for some surgical procedures, that may be the case even today. The Lancet Commission report estimates a cumulative welfare loss due to surgical diseases of \$12.3 trillion USD in low-and-middle-income countries over the 15-year period 2015–2030. The estimation relies on WHO's Projecting the Economic Cost of Ill-Health model and is focused on the benefits of surgery in five burden of disease areas: injury, neoplasm, digestive diseases, maternal complications

and neonatal disorders. The cost of developing the capacity to provide the surgeries was estimated to be between \$420 and \$550 billion over the same time period, indicating a significant return on the investment.³⁴ As measured by WHO effectiveness ratios, the implementation of improved surgical practices in district hospitals for certain surgeries has proven to be highly cost-effective, paralleling those gains seen with vaccination programs, bed net distribution for malaria prophylaxis, and medical management of HIV.³⁵ Based on cost effectiveness, the World Bank recently identified 44 surgical procedures as essential.³⁶

Second, and related to the first, the Sustainable Development Goals (SDGs) call for actions that depend on increased surgical capacity. Specifically, the SDGs call for an end to preventable deaths of newborns and a reduction in maternal mortality. Maternal, digestive and neonatal disorders are estimated to account for 26% of the welfare loss (due to lack of surgical capacity) in LMICs compared to 4% in high-income countries.³⁴ The SDGs also call for a halving of the deaths and injuries from traffic accidents. Injuries are the single largest cause of welfare loss due to surgical diseases.³⁵

Third, private expenditures on surgical procedures are likely to increase as the wealth in LMICs increases. World Bank data show that the share of income held by the highest 20% of the population in sub-Saharan Africa has remained roughly constant at an average of about 50% since 2000 while GDP has increased dramatically in these countries.³⁷ This increases the percentage of the population who can afford to pay directly for surgical services. And there is no reason to believe the increase in wealth will decrease the need for surgery; many conditions that benefit from surgery are not negatively correlated with wealth. In LMICs, injuries account for the majority of the welfare loss due to surgical disease, and the cost in terms of percent of GDP doesn't differ much from that in high-income countries. Cancer-related surgery is the other major surgical disease in all countries, and while it is lower in low-income countries today, it still accounts for a significant portion of the economic loss due to lack of surgery.³⁴

If demand for surgical services does increase as expected, it will necessarily affect the demand for medical equipment, human capital and processes. Surgery requires expensive diagnostic equipment along with other less expensive equipment. Some of the equipment needs are already being addressed by a shift in health care technology to more affordable, reusable equipment. The cost of health care in developed nations is often several orders of magnitude greater than that in lower-income countries, and existing technology is not always transferrable to the developing nations given associated costs and maintenance. Importantly, developing nations represent a massively growing ecosystem for both private and public investors. Innovations will be discussed more below, but we mention here a few that are specifically related to surgery. In many hospitals in resource-limited settings, oxygen levels were unable to be monitored during surgery given a lack of pulse oximeters. A non-profit organization known as Lifebox invented a portable, battery-powered pulse oximeter that cost \$250. To decrease costs associated with laparoscopic surgery, Dr. John Langell has created low-cost, almost disposable camera and light systems inspired by cell phone technology to be used during minimally invasive surgery. An additional benefit of these new low-cost technologies is that they may be applicable and transferable to health care delivery in high-income countries.

Human capital, more generally, is discussed above and will not be repeated here, but two points specific to surgery are touched on here. First, the demand for physical capital described above also translates into an increase in the demand for human capital: trained technicians. Technicians are needed to install, maintain and repair the equipment. Without such technicians, expensive equipment is useless. One operator in sub-Saharan Africa said that if imaging equipment isn't properly maintained, it can break down 3–4 times per year. Each time it breaks down, it can take 6–8 weeks to get it back up because parts are not readily available. This means that the equipment could be down for more than half the year—compared to fully operational for a year if it is properly maintained. An increased demand for surgical services would compound this challenge. Second, academic partnerships all over the world are developing to address this human capital need. For example, the University of Michigan's Center for Global Surgery builds on multiple collaborations established between the Department of Surgery and other institutions across the world. The All India Institute of Medical Sciences (AIIMS)-Michigan Collaborative has fostered an inter-country partnership focused on developing solutions to deliver low-cost, highly effective care. Work with St. Paul Hospital Millennium Medical College resulted in the first kidney transplant in Ethiopia.

In terms of processes, some of the most innovative advances are coming from LMICs. For example, Aravind Eye Care's operations, mentioned earlier, allow surgeons to perform as many as 100 or more operations in a day with results that are as good or better than those realized in high-income countries. Since much of the cost of surgery is fixed, these high volumes can significantly lower the average cost per surgery. Narayana Health also keeps average costs low by focusing on high volume. Other hospitals develop surgical processes that are specifically designed for low-resources settings. CURE hospital in Uganda treats hydrocephalus patients. The problem with the accepted treatment, the installation of a shunt—still the primary form of treatment in the U.S.—is that the shunts eventually fail. In a low-resource setting, this can be a death sentence. In response to this problem, Dr. Benjamin Warf developed a process that requires no further treatment in 70% of the cases.³⁸ The process, developed because they had no options in Uganda, has been so successful that it is beginning to be used in the U.S. even when other options exist. The lack of resources forces innovations in LMICs, a trend we can expect to continue moving forward.

Other processes that are being used have applications across different types of surgeries and have the potential for significant life-saving effects. Many pre- and post-operative interventions, for example, can decrease morbidity and mortality. Surgical site infections (SSIs) are the most common complication acquired in the health care setting, accounting for 38% of all nosocomial infections each year. SSIs are a major cause of morbidity and mortality, and contribute significantly to the economic burden of post-surgical care and antibiotic resistance patterns both nationally and internationally. Among postsurgical patients who develop infections, 75% of the resultant mortality in this population is directly attributable to the infection itself. While many factors including surgical technique, duration of surgery and patient comorbidities are known to affect the likelihood of developing a surgical site infection, preoperative antibiotic prophylaxis is one of the most effective, easily documented and modifiable measures available to decrease the incidence of SSIs. Without

such considerations, rates of multidrug-resistant organisms will rise dramatically in the setting of increasing surgical volume; this will have broad-based implications not only for surgical patients, but for the entire population.

Sophistication in streamlining the pre- and post-operative process will provide substantial opportunity for freeing up surgeons and surgical wards in low-resource settings. In a trauma ward in Ghana, all patients are managed by busy surgeons and only 17% receive even cursory rehabilitation services.³⁹ In countries with rehabilitation medicine, care would be transferred to a rehabilitation ward, decreasing non-surgical work of the surgeons and improving both length of stay and long-term independence. However, one study found only seven specialists in rehabilitation medicine in all of sub-Saharan Africa, all located in South Africa.⁴⁰

Telemedicine, covered in more detail below, has a specific application to challenges of surgical capacity. Given the dearth of specialist workforce, using providers from areas in which specialty care is readily available to triage patients and evaluate postsurgical complications remotely has the potential to improve postoperative outcomes.

Current transportation infrastructures present a barrier to safe and timely surgical care. In some markets, this has already precipitated a market response. Emergency transportation systems like Ziqitza's Dial 1298 service in India have been developed to address the need for emergency treatment.

All of these process improvements are likely to increase the quality of care, lower the cost of care or do both. From the perspectives of the global health community and the private sector, investments in process improvements like these increase the overall (private or social) rate of return on surgical services, which will, in turn, increase the investment in these services.

C. Elderly care and rehabilitation

Historical look at elderly care and rehabilitation

An estimated 58 million people worldwide turn 60 each year, which is about two people per second. In 2012, 810 million people were 60 years old or older, representing 11.5% of the global population.⁴¹

Increasing lifespans are a cause for celebration, as they are an indicator of the successes of scientific developments and medical advances. However, the over-age-60 population can also present a set of social, economic, political and cultural challenges to families, societies and the global community. A large aging population, when accompanied by changes like declining fertility rates and shifts in leading causes of death from infectious diseases to non-communicable diseases (NCDs) and chronic conditions, can put immense pressure on the health systems at the

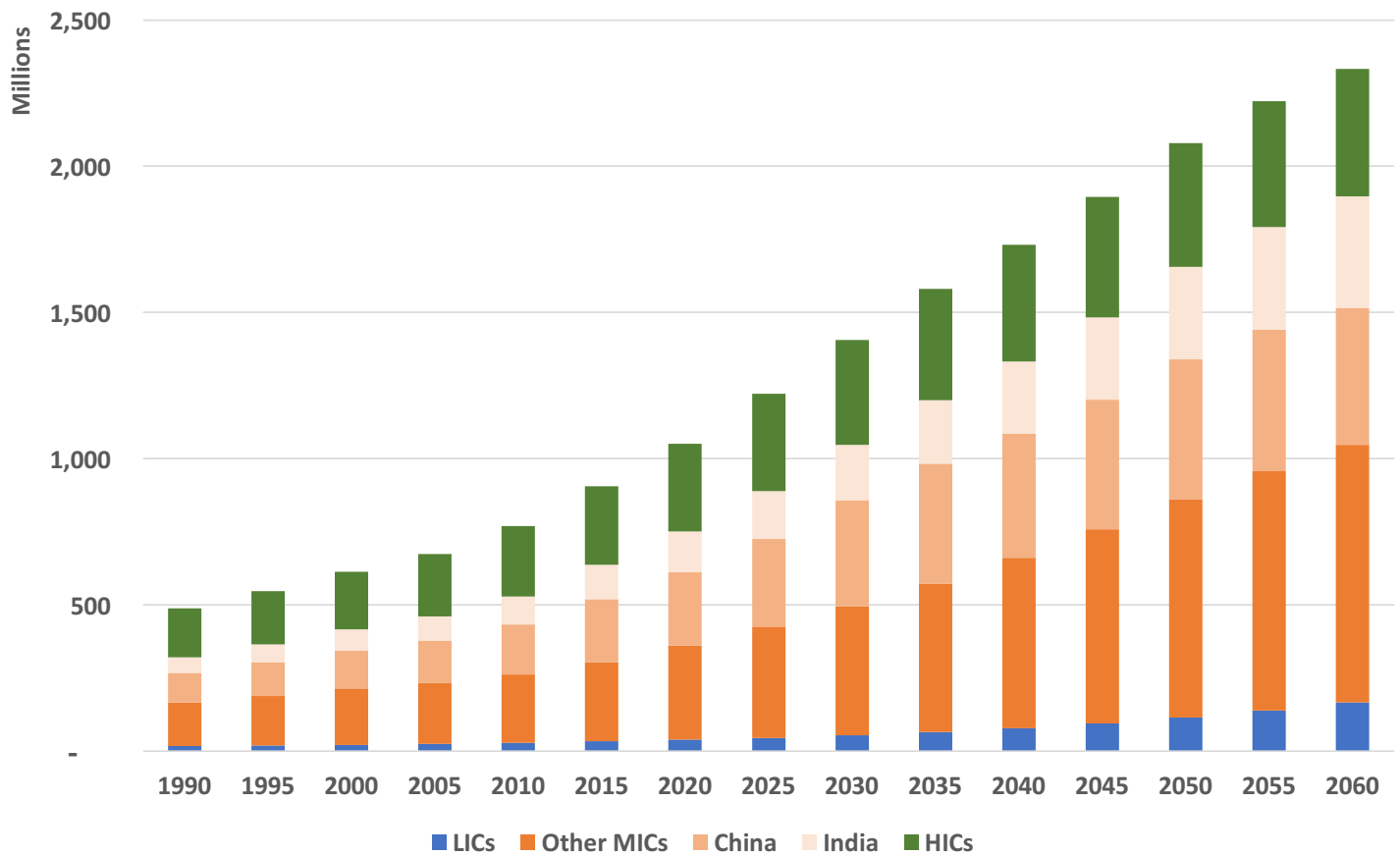
country level and on caregivers at the family level. As former UN Secretary-General Ban Ki-moon put it, “the social and economic implications of this phenomenon is profound, extending far beyond the individual older person and the immediate family, touching broader society and the global community in unprecedented ways.”⁴¹

All countries are wrestling with this unprecedented demographic shift and determining how best to address the challenges. This balance between opportunities and challenges that an aging population brings will largely be dependent upon the health status of the elderly, which in turn will depend upon the elderly care system and policies that countries have in place.

Some question whether any of the current elderly care systems are equipped to cope with the rising demand.⁴² To the extent they are right, the challenge is even greater in LMICs for at least two reasons. First, while the overall world is aging, the speed of population aging is faster in the LMICs (see **Figure 5**). Most of that increase is coming from middle-income countries of which China and India account for about 50% combined. Second, LMICs rely on their social structure to care for the elderly, a social structure that is rapidly changing. Countries such as China, Japan and South Korea have followed the “Confucian teaching of filial piety,” meaning that elders were taken care of by their children.⁴³ Urbanization and China’s one-child policy has led to a shift to the Western style of care where elderly live in separate homes.⁴² The Lancet report quotes statistics from the China Health and Retirement Longitudinal Study that show there were 185 million elderly residents at end of 2011; 32% of them reported poor health, 38% indicated difficulty with daily living, 40% had symptoms of depression and 23% lived below the poverty line. The clearest sign of changing times may be China’s “Elderly Rights Law,” which requires that children visit their parents or possibly face punishment ranging from fines to jail time.⁴⁴ Children in India have also historically taken care of their aging parents. But things are changing there too. The younger generation is more transient, often living in different cities or countries due to job opportunities. This has led to a change in family structures—from living in joint families to nuclear ones. The younger generation often served as the informal caretakers of the elderly. This changing social fabric has led to changes in perception of old-age and retirement homes that were previously unheard of, as such used to have the social stigma of abandonment of parents by their children.

Others believe that the effect of the aging population is overstated. The assumption in the alarming version of the rapidly-rising-aging-population story is that the functional independence of the elderly in the future will be similar to the functional independence of elderly persons in the past, thus they will be a new burden on society. This is not altogether true now, and important changes can make this untrue in the future. Many reasons for the observed increased survival of older people are also causative of increased independence in older people: Better nutrition, less smoking and improved acute care for myriad diseases have the consequences of decreasing frailty, not just mortality.⁴⁵ Also, numerous interventions are available to improve the functioning of healthy aging persons. Most obvious is exercise, called by one group “the anti-aging pill” because it has been proven to improve physical functioning, cognition, emotional health and overall independence, while decreasing the mortality

Figure 5: Number of people aged 60 and over: High-, Middle-, and Low-Income Countries, 1950–2060



Source: UNDESA, Population Division (2017). World Population Prospects, Medium Projection Scenario: The 2017 Revision, DVD Edition.

rate through prevention of heart disease, cancer and other disorders.⁴⁶ Finally, especially in LMICs where there has historically been little investment in rehabilitation, there is a huge opportunity to alter the current consequence of disabling illnesses on functional independence of older people. Through the provision of acute medical rehabilitation in the hospital, community-based rehabilitation that supports and integrates the person back into the community, and environmental rehabilitation that removes physical and social barriers, older persons currently seen as burdens can be returned to their usual societal functions.

Elderly care and rehabilitation looking forward

By 2050, the elderly population is expected to reach 2 billion, representing 22% of the population, double what it is today.⁴¹ This change in the social fabric across developing countries presents new opportunities. For the elderly population that require constant care for their chronic ailments or any post-surgery care, many health care companies have started providing home-based care. Many service providers currently offer hospital-like services in a home setting; services include visiting doctors, access to specialists, diagnostics and continuous bedside care. Some also provide ventilators and other critical hospital equipment. Given that this approach has been estimated to cost as little as 15-30% of the cost of equivalent care in the hospital, it is reasonable to expect it will become more prevalent in the future. Indeed, health care companies such as Portea Medical, Medwell Ventures and Health Care at Home have already entered this space and others have plans to do so.⁴⁷

Other organizations have come forward to establish physical rehabilitation centers. One such center, LiveWell Institute of Rehabilitation Medicine, was established in 2011 and is located in the city of Madurai in southern India. In general, patients and their families have limited knowledge of rehabilitation, and limited financial resources due to lack of insurance. LiveWell prices to make the required rehab care available to as many as possible, but still covers all of its costs. Latest statistics from LiveWell show that approximately 63% of incoming patients were 50 years and above, 73% of which were males. About 74% of total patients were inpatients, i.e. staying at the center for number of days, for treating disabilities due to severe ailments/injuries such as stroke, brain injury, spinal cord injury, traffic accidents, neurological disorders, orthopedic conditions, Guillain-Barré syndrome and Parkinson's disease. As populations become wealthier and older, the market size for such services increases. LiveWell opened an affiliated operation in Hyderabad in 2017 and is planning one for Chennai.

In addition to new specialized services available to the elderly such as physical rehabilitation, trends elsewhere suggest that the primary care system will also need to adjust to an older population. Across the world, the overwhelming burden of disease in the elderly is from NCDs. Indeed, the main causes of death for this population are ischemic heart disease, stroke and chronic respiratory disease, and the main causes of disability for this population are visual and hearing impairment, dementia and osteoarthritis. Further, the underlying risk factors of some diseases, like ischemic heart disease, are chronic diseases such as diabetes and hypertension, which require provision of continuous care to the elderly both from medical providers and family caregivers.⁴¹ These demands feed into the importance of the primary care system, discussed earlier.

D. Mental health

A historical look at mental health

Mental illnesses are the leading cause of disability adjusted life years worldwide, accounting for 37% of health years lost from non-communicable diseases.⁴⁸ The global cost of mental illness was estimated to be \$2.5 trillion in 2010, with a projected increase to over \$6 trillion by 2030, compared to the entire global health spending in 2009 of \$5.1 trillion.⁴⁹ Mental health services are limited by the shortage of trained professionals and infrastructure, as well as by the stigma associated with mental illnesses, especially in LMICs, leading to a treatment gap between available services and the needs of a given population. Global mental health (GMH) strives to close the gap, often focusing on LMICs where the gap is thought to be the largest due to an unequal distribution of resources. In recent years, there has been increasing focus on a systems approach to addressing the problem of inadequate services to meet population mental health needs. There have been calls to action at the governmental and academic levels to prioritize mental health care using an integrated and system-wide approach that takes into account all of the entities capable of delivering health care services.⁵⁰ The public sector alone is not able to meet the health care needs of populations in the resource-limited settings of many lower-income countries. Though the public sector encompasses entities beyond governmental ones (e.g. some academic institutions and community groups), mental health care problems can be extremely complex, requiring a more comprehensive approach. The private sector is a vital part of this system-wide approach.⁵¹

This section explores three different models of GMH private sector interventions to both gain a better understanding of private sector approaches and to identify potential best practices. This will be done by examining organizations that exemplify each of the three models: the academic non-profit model, the non-profit model, and a model of mental health interventions embedded within medical organizations.

HealthNet TPO and Partners In Health (PIH) are two examples of nongovernmental organizations (NGOs) that address problems in mental health coverage. Both multinational organizations use close partnerships between multiple stakeholders, including local governments and academic institutions, to improve health systems. HealthNet TPO describes itself as an NGO that “develops evidence-based interventions to strengthen the health of populations in distress.”⁵² As this organization spans several countries, its overall strategy is summarized in more general terms: It seeks to rehabilitate health systems employing action research and implementing country-specific interventions. Partnering with “local populations and stakeholders” as well as expanding the overall evidence base are important parts of its strategy.^{52, 53} HealthNet TPO has partnered with large academic research efforts such as the PRogramme for Improving Mental health care (PRIME) and Emerging mental health systems in low- and middle-income countries (EMERALD) in an effort to scale-up packages of mental health care.^{54, 55} The extent of the NGOs’ public-private partnerships or collaborations between the organization and its public-sector counterparts are country-specific.

While HealthNet TPO focuses on distressed populations emerging from conflicts or disasters, Partners In Health works with “the world’s poorest and sickest communities” not necessarily limited to LMICs.⁵⁶ PIH reports that it uses the resources of large institutions like Harvard Medical School and Columbia University to provide direct services and to build capacity within the ten countries in which it operates. In contrast to a top-down approach, the organization strives toward a more equal partnership through collaboration with stakeholders and local governments. Mental health care is provided through the primary care system already linked to the NGO. A team oversees all of the mental health programs to ensure collaboration with local clinicians, and resource-sharing such as technical assistance and clinical supervision. Program evaluations are done through academic research.

The use of for-profit models to treat mental illness in developing countries has the theoretical potential to improve the efficiency of publicly funded services, allow a greater focus on measurable outcomes, increase autonomy, and make systems more efficient through competition.⁵⁷ However, critics have questioned whether competition is truly advantageous in low-income settings due to the lack of resources, and they have voiced concern about the possibility of undermining national and regional health systems already in place.⁵⁸ The global mental health field is more motivated in terms of mental health care as a human right rather than capitalistic gains, though the field does look at interventions in terms of minimizing disease burden in order to maximize the productive potential of individuals. Due to the lack of clearly successful for-profit endeavors, we focus on the not-for-profit models that have shown to be effective.

Though academic institutions play central roles in some types of private-sector interventions, there are examples of non-profit models that function without them. The Center for Victims of Torture is an example of an NGO that built its original treatment facility within a high-income country (in this case, in the United States) and expanded services with the help of private donations.⁵⁹ The original facility treated torture survivors and refugees living within the U.S. by providing services like direct health care (e.g. psychotherapy) and case management. As the organization grew, it extended its reach through partnerships (e.g. with the International Rescue Committee located in Georgia) as well as capacity-building activities both in the U.S. (e.g. working with the National Capacity Building Project)^{xx} and abroad. The CVT website provides useful manuals, guides and tools for working with torture survivors and refugees. The organization also provides more hands-on capacity building through its work in post-conflict settings and within refugee camps; CVT trains members of the local population to provide specialized mental health services within these settings. Unlike the nonprofit organizations linked to academic institutions, CVT’s practices tend to be followed more through monitoring and evaluation than complex research protocols necessary for studies like randomized controlled trials.

A third model of a private sector intervention is having mental health services embedded with a medical organization. Two well-known examples are Doctors Without Borders (MSF; Médecins Sans Frontières) and International Medical Corps. MSF delivers medical humanitarian aid to populations in distress (e.g. armed conflict, natural disasters, etc.) who may not receive

xx According to the National Capacity Building Project website, the project “provides training and technical assistance to the emerging network of U.S.-based torture treatment programs.”¹²⁰

medical help otherwise. As the organization was focused more on emergency medical treatment, mental health services were not a part of its regular operations for its first 27 years. Since then, interventions have focused on treating the most common mental illnesses and incorporating mental health treatment into other programs such as for HIV/AIDS. MSF acknowledges that mental health treatment is an important component of other services, especially in terms of reducing symptoms and improving overall functioning.⁶⁰ Like the other private sector models, MSF builds capacity by training local counselors to provide mental health treatment and may provide more direct patient care in complicated or severe cases. They do, however, acknowledge the difficulty in promoting continuity of services given the unstable settings in which they operate. Though MSF does conduct research, most of this research focuses on infectious diseases; mental health research is conducted through partnerships with other organizations (e.g. PIH) or, more commonly, followed through routine monitoring and evaluation.^{61, 62, 63}

Like MSF, International Medical Corps (IMC) provides health care in humanitarian settings. However, IMC not only focuses on providing emergency care but also aims to strengthen health systems through development programs, capacity building and policy work. A major part of the organization's mission is to promote "self-reliance" among the populations it serves; the IMC website reports that 89% of IMC staff are local.⁶⁴ The organization plays an important role in developing mental health treatment guidelines (e.g. contributing to WHO's mhGAP guidelines) and helping other organizations adhere to those guidelines and policies in humanitarian settings. Unlike MSF, IMC partners with governmental as well as non-governmental organizations.^{xxi} Through these relationships, the IMC aims to promote continuity of services. Research is also conducted through a variety of partnerships.

Mental health looking forward

On some fundamental level, each of the models attempts to close the mental health treatment gap. The existence of more than one model calls to mind what Balabanova et al. and others have previously pointed out: "No blueprint is available for producing a strong health system."⁶⁵ Although there is no gold-standard health system, case study data from LMICs have shed light on health system patterns that were thought to be linked to better health outcomes.^{65, 66} The referenced case study did not specifically focus on mental health outcomes, but many of the identified marks of success bring one back to a system-wide approach. The case study suggests several important characteristics, including: cooperative interaction between health sectors, being in tune with population preferences, and collaboration with relevant parties to create mental health policies. Among the three private-sector models discussed in this paper, one can find examples of interventions that have these characteristics. In particular, HealthNet TPO relies on stakeholder involvement to both design and implement its interventions. On a similar note, PIH partners with local clinicians to integrate additional mental health treatment into the existing health system. As far as impacting policies, CVT has a Washington, D.C., office that advocates for victims of torture while IMC regularly presents to different governments on mental health issues (e.g. "integrating psychosocial support with the Ebola response") and collaborates with other agencies on writing mental health treatment guidelines.⁶⁷

xxi In its effort to maintain neutrality, MSF is careful about sources of funding (i.e. the vast majority of funding comes from independent, private sources) and reports that it conducts its own needs assessments.⁷²¹

The health system case study also identifies “the ability to innovate and adapt to resource limitations” as important characteristics. This is especially relevant to GMH interventions, which may have limited influence on most levels of a health care system (at least initially) but could offer the resources and knowledge necessary for innovation. In other words, GMH interventions are rarely in a position to start closing the mental health gap by way of large systemic changes in the organization of a country’s health sector. More commonly, interventions enter the arena at the community/household level or the service delivery level.⁶⁶ These are “on the ground” approaches that have to do with what treatments are available and how to connect those in need of services with treatment. Some examples include stigma interventions to remove barriers to obtaining services and providing better training or supervision to those delivering care. In these cases, simply delivering more of what is already in place (e.g. increasing the number of psychiatrists in a developing country) will not close the mental health treatment gap. Innovations are necessary for improving the foundations of the system. Once the innovation is shown to be useful through evaluation or more sophisticated research, then the intervention may start to influence other levels of the health system. For example, demonstrating that there is both a need for mental health services in a given population as well as tailored, affordable treatment that works may be a convincing argument for mental health policy changes and allow a call for increased funding.

Through the three models discussed above, one can find many examples of interventions that are both innovative and designed to work in resource-limited settings. Another innovative approach that has not been previously mentioned is the use of technology to deliver mental health awareness and/or services. With advances in technology and the widespread use of devices like cellphones, technological innovations have been used to both track and treat mental illnesses. Tele-psychiatry, or providing mental health care through video conferencing, has received more attention in the last few years; this treatment modality seeks to overcome barriers to care such as geographic distance, thereby delivering care to otherwise isolated populations. As Malhotra and colleagues point out, tele-psychiatry is starting to be implemented in developing countries, but its use is often limited by lack of connectivity and fluctuating bandwidths throughout different regions. In countries like India, the short supply of mental health providers is often unable to provide direct care through tele-psychiatry even if barriers like distance and travel time are overcome.⁶⁸ Still, this technology has promising applications in education, supervision and training: Tele-psychiatry can be another modality of promoting other innovative approaches like task sharing.

Given that effective innovations are tailored to specific populations, one must look at distinct programs to obtain a better understanding of both their level of innovation and relevance to each level of the health system.^{xxii} In this case, readers will be walked through a specific branch of one of the larger research programs connected to HealthNet TPO. HealthNet TPO has partnered with PRIME, which spans five countries and aims to scale-up packages of mental health care by working from the ground up.⁵⁵ Looking closer at how this large program impacts a health system on the ground or at the service delivery level, PRIME-Nepal used formative research to customize the

xxii According to the six-level conceptualization of the health system as defined by Anne Mills.⁶⁶

WHO mhGAP Intervention Guide.^{69, xxiii} At the community level, PRIME-Nepal employed task-sharing techniques and incorporated other local programs (e.g. a culturally sensitive case-finding tool) into its overall package. The results of these efforts helped form the district-level mental health care plans; their implementation and evaluation is an example of innovation at the policy and health sector management level. Once the package of mental health care is fine-tuned and scaled up to remaining districts, the innovation will have reached the government policy level.

There are no formal recommendations for how GMH interventions could optimize or fit into developing health systems, but there are ideas about the properties of a successful health system that includes the private sector. During times of severe health care system disruption due to an acute crisis (e.g. natural disaster), private organizations like MSF have stepped in to provide care. Even with the existence of functioning health systems, private-sector organizations have helped countries like Bangladesh meet national health targets.⁶⁵ Governments can use the resources brought in by the private sector both to directly fill in treatment gaps (e.g. contracting out) or by using their data to inform policies and health care system changes.⁶⁵ Public-private partnerships and having a system-wide approach are important and include involvement with all relevant stakeholders and collaboration with all entities having the ability to deliver mental health care. Innovative strategies and interventions are critical to developing effective strategies in a resource-limited world. These ideas about the properties of a successful health system could potentially be used to guide GMH private-sector best practices. This could optimize the efficacy of GMH interventions while keeping the larger picture in mind, thereby minimizing any unintended harms that could fragment developing health systems.

5. Changes in Tools Available

There are many changes in mechanisms and processes for delivering health care that will profoundly change how it is delivered. We have already discussed a number of the processes in Section 4's discussion of specific areas of health care delivery. In terms of products, including software, automation may have the biggest potential for impact in delivery, though it is in very early stages of development. Two other trends that will have a large impact are the focus of this section: telemedicine and innovations in medical devices.

A. Telemedicine

Rashid Bashshur, the early pioneer of telemedicine, was commissioned to write a book on the history of the field in 2009.⁷⁰ It reflects a recurrent pattern of good ideas, visionary leaders and successful trials. Yet most of the projects mentioned have now disappeared. The majority of surviving projects are supported artificially by government grants, special taxes, transfer of funds from other profitable endeavors, or donations. Very few programs have expanded beyond the control of their original, often visionary and entrepreneurial leader. In a review of telemedicine in Africa, Mars puts it this way:

xxiii In other words, the Nepal branch of the larger innovation employed qualitative research methods (a formal evaluation of information obtained from local stakeholders such as health workers and members of the community) to identify both barriers and potential solutions to closing the mental health gap in a specific location. The results of this study were used to customize the "core" of the intervention, which was based on more general guidelines put forth by the WHO in the document known as the "mhGAP Intervention Guide for mental, neurological and substance use disorders in non-specialized health settings."^{69, 122, 123}

“Telemedicine initiatives in Africa are often announced in a fanfare of press and Web releases, but few survive beyond the pilot phase to become integrated into routine clinical practice and published data on their use are sparse.”⁷¹

The mixed success of telemedicine projects may reflect the mixed clinical results of many studies.^{73, 74, 75} Many of the studies are focused on a very narrow set of conditions. While this is necessary to draw conclusions about that specific condition in that specific setting, it limits the ability to generalize the results. Some focus on outcomes such as feasibility or acceptability by patients or staff. Again, these are important to understand especially in implementing, but do not give guidance as to whether or not such interventions are worth implementing.

As researchers in the field have pointed out, these mixed clinical results are not surprising.⁷⁶ The benefits of telemedicine are going to vary disease by disease and even patient by patient. Global health organizations, governments and private investors will increase investments as the benefits in either lowering costs, improving quality or both are shown through research and fieldwork. Clinical, technical, business and legal issues will bear on both the quality and the costs. Before looking at those in more detail, we briefly discuss what we mean by telemedicine.

What is telemedicine?

The World Health Organization’s 2010 report claims there have been 104 different definitions of telemedicine in peer-reviewed journals.⁷⁷ A list of the services that are included in different definitions of telemedicine includes diagnostic consultations, distance learning, tele-imaging, activity or disease monitoring, disease management, and medication management. Some industry analysts separate telemedicine from remote monitoring and mobile health.⁷⁸ Our discussion adopts WHO’s relatively broad definition: “the delivery of health services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities.”⁷⁷

Clinical factors

From a clinical perspective, as the studies mentioned above illustrate, it is impossible to create a single answer to the question of whether telemedicine is effective. Instead the question might be: Where is telemedicine likely to be effective and how is it most effective (e.g., tele-consultation, imaging, etc.)? There are important variables to consider in addressing this question such as the complaint, the disease and its stage, the competency of providers and the appropriateness, accuracy, convenience and safety of distant care. Broadly, these can be divided into human capital and disease (stage and type) issues that must be addressed if telemedicine is to work.

The value of telemedicine in referrals depends on the skill of the primary care provider. Patients don't necessarily present with a disease. They present with a complaint. A cough could be the common cold or it could be lung cancer. The former requires little care while the latter requires highly specialized advice often available only from a distance. The local provider must be able to tell the difference.

Telemedicine that taps into specialized expertise is beneficial only if specialists have excess capacity. This excess capacity could be in numbers of specialists or in the time spent by existing specialists (i.e., their time might not be spent in a way that takes advantage of their expertise). If expertise is not currently used, or at least not used as effectively as it could be, telemedicine increases the geographic reach of a given specialist, thereby enabling the specialist's skills to be used more effectively. However, if there is no excess capacity, telemedicine will not provide any benefits—the bottleneck is the specialist. In fact, if the current expertise is capacity-constrained, the opportunity to access more expertise at a distance may be costly. Telemedicine lowers the cost of access to specialized knowledge, potentially increasing access to that knowledge. But lowering access cost also increases the probability that the specialist is presented with cases that do not require the specialist's opinion. If, as is likely in low-resource settings (indeed all settings), the expertise is scarce, the opportunity cost of time spent on cases that don't require that expertise is great. Put differently, if the specialist is already at capacity in working on cases that require the specialist's expertise, the ability to tap into telemedicine is no benefit—the capacity constraint still exists—and may even be costly if it means the specialist is now spending time on activities with lower value add (such as filtering through possibly relevant cases).

The use of telemedicine is specific to the stage of the disease. Consider, for example, spinal problems. Most of the important decisions regarding back pain rely on the patient's history rather than a physical examination. Further, oral medications do not act on specific joints. And, at least initially, the effectiveness of a local physiotherapist is dependent on their skills more than on the clinical impression of a specialist. Thus, at the initial stage, a protocol can be employed, in which specific findings or specific failures of treatment are “hard-wired” to seek in-person evaluation by a clinical specialist. At a later stage of spine care, if an MRI is needed, the actual imaging will take place where the specialized imaging equipment is located, but the radiologist doesn't need to be near the equipment. If surgery is required, the surgeon must be in the same place as the patient, but if the surgeon trusts the training of the local site clinicians, then laboratory tests, physical examination to screen for anesthesia and most other aspects of surgical preparation can be done locally. The surgeon's post-operative visit could be done by asynchronous telemedicine: essentially a photograph of the wound, an X-ray, and a patient questionnaire, read by the surgeon in about five minutes. Thus, in each of these phases, a combination of telemedicine and personal interaction can work, with the specifics depending on the situation.

The type of disease also matters from the patient's perspective. One company that started a teleconsulting practice that generated revenue by charging a per-minute fee found that two of the most common questions centered around sexually transmitted diseases and mental illnesses. The anonymity of the telemedicine was an important feature for many customers.

Technical factors

The change that has taken place since 1992 that impacts the viability of telemedicine the most is the cost of transferring information. The change has been particularly dramatic in LMICs. Access to phone services as measured by phone subscriptions (either fixed or mobile) rose from less than 1% in 1992 to about 60% in LICs in 2015.⁷⁹ The cost of sending data in 1992 was prohibitively high in most parts of low-income countries; today internet access makes it viable in many parts of these countries. Technologies designed for the purposes of entertainment or general convenience become familiar, readily available and relatively inexpensive medical tools. Many clinicians already have cell phones if not smart phones. Thanks to social platforms like Facebook, Skype, What's App, SnapChat and others, the current generation of clinicians throughout the world have familiarity and sophistication about electronic communication. This hasn't always been the case.⁸⁰

Because of these technological changes, telemedicine's viability in a variety of applications in low-resource settings has increased but, at least in the short run, significant obstacles remain. Cell phones and even electricity are not always available in all low-resource areas. Internet connections in much of the low-resource world are spotty and slow. Unreliable communication virtually eliminates the ability to use synchronous telemedicine with any confidence. Asynchronous store-and-forward telemedicine will still work and is used; however, even there, unreliable communication can affect productivity. In a program designed to send images to radiologists remotely, the diagnostic centers were operating at only one-third of their capacity because of internet interruptions.⁸¹ Access to internet is changing quickly, but it is still a problem in some locations today.

The potential for telemedicine in low-resource settings is also limited by the hardware that is available. This isn't just the expense of the imaging equipment itself or its servicing. More advanced MRI and CT scan images are best seen on a platform where contrast, amplification and markings can be manipulated and measured by the viewer. Management of intensive-care-unit and other complex patients may require transmission of electronic signals from electrocardiogram, oximeter, blood pressure monitors and indwelling catheters. Intraoperative monitoring requires multi-channel communication, often including visualization of the operating room, measurement of brain waves, and a screen full of variables relating to the patient's vital signs and the anesthetic process. Certain fields, especially ophthalmology and dermatology, require highly refined and magnified images. Specialized equipment is not always able to provide that precision. Other specialties such as neurology or psychiatry require reliably streamed videography to watch tremors or walking patterns. When the transmission sputters or freezes these assessments become impossible. Again, technological changes are taking place quickly here, but in the short run these continue to be a challenge.

Patient records are not readily accessible through computer systems yet, but this can be expected to change dramatically in the coming years.⁸² Repeating or spending time transmitting a patient's history during a telemedicine interaction is inefficient, yet the lack of critical information ranging from drug allergies to failed past treatments and imaging can severely hamper treatment from a distance. Incorporating electronic medical records in the health care system will be costly, but extremely valuable, and global organizations appear poised to push for and fund this in low-income countries as well.⁸³

Revenue sources

Haig and Steins identify a number of potential revenue streams for telemedicine:

1. Governments value the ability of telemedicine to provide remote care or to save the cost of transportation.
2. Hospitals that are able to keep patients they would not otherwise be able to keep (stroke patients with a distant neurologist), or organizations where the cost and timeliness of transportation drive telemedicine, are sometimes willing to bear the cost. Contracts with prisons, oil platforms, ships and/or wilderness stations often fund infrastructure used for less lucrative work.
3. Patients seeking distance specialty care may be willing to pay directly to avoid the cost of transportation, lost work time and family inconvenience.
4. Specialist clinics may find it worthwhile to cover costs. Whited found an impressive drop in time spent with patients during teledermatology consultation from 24.2 minutes to 7.2 minutes with store-and-forward telemedicine.⁸⁴ The cost of space, personnel, paperwork and other resources are avoided when the patient is on a computer screen. Specialists also benefit from telemedicine by leveraging their expertise over a wider geographic region or reducing the patient and clinician cost of screening. Fewer return visits to a surgeon means the surgeon has more opportunity to see new surgical patients, thus furthering profit or mission.
5. Research grants and philanthropy can fund telemedicine, or at least fund the beginning of a program.

Legal and cultural factors

In the absence of an international framework/universal guidelines, offering care over distance raises issues of liability, licensure, quality, continuity of care, confidentiality, data security, consent, authentication and remuneration.⁷¹ In many services, the referring doctor is responsible and liable in cross-border practices. Cross-border practice also raises the issue of jurisdiction. Malaysian law, for example, requires registration of international consultants in Malaysia, under penalty of fine or imprisonment, a clear impediment to cross-border telemedicine practice.⁷¹

Challenges related to data security, privacy and confidentiality are dealt with differently or not at all in developing countries due to lack of laws, illiteracy and lack of familiarity with the latest technologies. Most uses of asynchronous telemedicine, for example transmitting files via the internet, can jeopardize privacy. In fact, data safety was identified as the biggest obstacle that could derail an India-UK bilateral telemedicine relationship.⁸⁵ In countries such as India, telemedicine centers don't take written informed consent before sending patient data, which is a common practice in countries like the United States.⁸⁶ This can clearly be a common challenge across other developing countries.

B. Medical device innovations for low-resource settings

In 2010, Dr. Margaret Chan, then director-general of the World Health Organization, stated that 70% of the more complex medical devices did not function when they arrived in low-income countries from high-income countries.⁸⁷ A 2011 study found that 40% of medical equipment in developing countries was out of service.⁸⁸ While this number was lower than many expected, it was much higher than the 1% of medical equipment out of service in high-income countries.⁸⁹ One reason a high percentage of the medical equipment in low-income countries doesn't function is that it was designed for high-income environments. Manufacturers assumed that trained personnel would run and service the equipment, and that reliable electricity and supplies would be readily available to the user. Over the past 25 years, this situation has improved. Particularly over the past 10–15 years, there has been a marked increase in the number of medical device innovations designed specifically for use in LMICs. These technologies have largely been developed using a human-centered design process that emphasized the needs and wants of the user and other stakeholders rather than the designer.⁹⁰ Easy to maintain and durable products are more likely to increase uptake and effectiveness in low income settings. Work in this area is being done in the academic communities and the private sector. The work is driven by the opportunities to use and sell the product in low-resources settings. It will have an impact on the way health care is delivered in the years to come.

Global health innovations take on many forms. We have already mentioned some process innovations at Aravind and Narayana and surgical innovations at CURE. A focus on innovations in medical devices for application in low-resources settings is relatively recent. In 2007, the WHO began a project to identify the Priority Medical Devices, 30 years after the first list of essential medicines was introduced by WHO. In 2010, the WHO held its first global forum on medical devices. Similarly, some of the largest corporations and academic institutions involved with medical devices have only recently started to focus on these settings. A number of the academic efforts are tied to companies. As with drugs, some of the early development can take place in academic settings, engaging the larger corporations who typically have an advantage in approval processes, marketing and distribution. This section summarizes and describes some of the leading institutional activities in medical device innovation in these institutions.

Academic institutions and medical product innovations

In 2007, Rebecca Richards-Kortum started The Rice University 360° Institute for Global Health (Rice 360°). The most mature of the global health design programs in academia, Rice 360° offers academic courses for undergraduate and master's students as well as a minor in Global Health Technologies for undergraduates and a Master of Bioengineering track in Global Medical Innovation. Rice 360° has a well-established partnership with University of Malawi Polytechnic and College of Medicine, which is also its primary site for student internships (Richards-Kortum, Gray, & Oden, 2012). Rice 360° has also partnered with 3rd Stone Design, a product design, strategy and development company, to commercialize technologies including the Pumani Bubble CPAP and DoseRight Clips.

Other examples include the Center for Innovation in Global Health Technologies (CIGHT) at Northwestern University, which partners with corporate, not-for-profit and education institutions, to develop and commercialize health care solutions for LMICs. Many other universities, including Case Western Reserve, University of California Berkeley, Johns Hopkins, University of Michigan and MIT, offer programs or courses in developing innovative health technologies.

As an example of how these programs are structured, University of Michigan's engaged-learning global health design offerings emphasize the use of design ethnography, direct interactions with stakeholders and firsthand exposure to the contexts in which solutions will be implemented. Students in the program observe and interview diverse stakeholders in the field (Ghana, Ethiopia, Uganda, etc.) including clinicians, nurses, procurement officers and ministry of health officials to identify and define unmet health needs in resource-constrained settings, and apply human- and user-centered and co-creative design approaches to address these needs. The core elements of the program are pre-clinical immersion training, clinical immersion and front-end design work.

Educational objectives include exposure to and experiential training with: identifying and defining engineering design opportunities through clinical immersion; applying co-creative user- and context-centered design processes; gathering, synthesizing and using information to inform design decisions; considering the cultural influences on an engineering problem and the implications of technology introduction to a community; considering a wide range of unique constraints; developing interdisciplinary and intercultural communication skills, and understanding the local and broader contexts of design. Program outcomes include the identification of more than 700 unique unmet global health needs, completion of more than 100 student design projects at multiple institutions, publication of student-led design-based conference and journal articles, technology transfer, and peer-to-peer mentoring within traditional capstone design courses (i.e., clinical immersion and design ethnography experience students partner with capstone design students that have not completed fieldwork and provide insight into the broader contextual issues of the design problems).

Programs from universities within LMICs also present opportunities to global health practitioners and investors. Students from Makerere University in Uganda caught the attention of the global community at a 2017 competition.⁹¹ Many universities in these countries are partnering with other schools around the world. The All India Institute of Medical Science (AIIMS) and the Indian Institutes of Technology (IIT) are partnering with schools such as the University of Michigan, Stanford and schools in Australia and Japan.⁹² Northwestern partnered with University of Cape Town; Case Western partnered with Makerere; University of Michigan has partnered with University of Ghana Biomedical Engineering Department and Korle Bu Teaching Hospital in Accra, Ghana, and St. Paul's Hospital Millennium Medical College in Ethiopia; and, as mentioned above, Rice is in a longstanding partnership with University of Malawi Polytechnic and College of Medicine.⁹³

Although the majority of global health design activities within the academy described above originated as courses or programs geared for undergraduate students, faculty involved in the creation and implementation of these activities have leveraged their experiences to expand their research portfolios to include scholarship centered around the design and evaluation of novel medical devices and design methodologies, as well as implementation engineering. Furthermore, the majority of the faculty leaders of these initiatives have broadened their technology innovation portfolio to include medical devices designed specifically for use in LMICs. Robert Malkin from Duke University has characterized barriers to the introduction of health care technology within LMICs and quantified the amount of out-of-service medical equipment in resource-poor health settings.^{88, 94} Richards-Kortum from Rice University has designed and assessed point-of-care portable optical imaging devices that have the potential to improve screening and detection of disease at primary health care settings in low-resource countries.^{95, 96, 97} David Kelso from Northwestern University has developed low-cost point-of-care HIV diagnostic devices including a dipstick p24 antigen assay and a PCR test for low-resource settings.^{98, 99} Kathleen Sienko at the University of Michigan has developed design methodologies for use in resource-limited settings to improve processes for identifying and defining global health needs, eliciting medical device product requirements from diverse stakeholders, and engaging stakeholders during the front-end phases of medical device design.^{100, 101, 102, 103} She has also formalized design ethnography methodologies for use in low-income country contexts for medical device design and developed multiple family planning task shifting devices.^{104, 105}

Some of the academic institutions' work is done in partnership with the private sector. In 2011, Michigan partnered with Covidien, a medical device company, and modified the model to accommodate minimally invasive surgery as a clinical theme. Multiple clinical immersion field sites were piloted in China with a group of U-M undergraduate engineering and business students. Cancer and cardiovascular surgical themes were implemented in China with support from Covidien and Medtronic.

Private sector innovation

As global funding for non-communicable diseases increases, medical product manufacturers are searching for ways to expand markets in LMICs. In addition to partnering with universities, medical device

companies have been developing their own approaches. Seven of the top ten medical device companies have innovation programs that specifically target LMICs highlighted on their websites.^{xxiv}

While some of these have features of corporate social responsibility programs, more are becoming part of the long-term strategy for the company. In conversations with executives from these companies, there is a recognition that growth is going to come from LMICs and they are not just talking about the BRIC countries. However, there is also an understanding that they will need to adjust their business models and, in some cases, come up with products that are more suitable to lower-resource settings.

Efforts to provide products to LMICs face a number of challenges. First, the price must be much lower than that charged in high-income countries. Medical product manufacturers are modifying their products through frugal innovation. Second, the product must be durable and require little maintenance. The demand for low-cost and reliable medical products in China and India is forcing Western companies to adopt an indigenous focus. Companies such as GE and Johnson & Johnson have distributed global product development and R&D operations as a result. Localization of R&D requires contextualized development and design, which in turn requires open technology transfer and mentoring of indigenous talent. While loss of intellectual property has been a concern to multinational national corporations (MNCs) doing R&D in developing countries, a process of managing the risk is slowly taking shape. Third, the product must be able to operate in environments with more challenging infrastructure. Most medical products are designed for a robust infrastructure supporting their use and implementation. Many MNCs are now looking at the prevailing infrastructure and innovating to modify and adapt their products to local conditions. Fourth, market entry requires being able to operate with limited trained personnel. Many MNCs are implementing training programs that couple with remote communication to support hospital operations. Others are designing their products in ways that require less training to operate. On an experimental level, robotic surgery is also being studied as a means to alleviate the acute shortage of trained surgeons in the developing countries. Further, several programs are under way to use mobile phones as a means for diagnosing and monitoring patients in developing countries (e.g. Medtronic's Shruti).¹⁰⁶

MNCs have a variety of approaches available to them. One is to contract with other entities who come up with the innovations and then take those innovations to market by efficiently testing, manufacturing, distributing and/or marketing the product. The university partnerships described above fall in that category, but there are others. The Odon Device, for example, is designed to extract fetuses in cases that would normally require forceps or a cesarean section. It can be used with minimal training and therefore has the potential to significantly reduce maternal and newborn complications in low-resource settings. The device has been praised by Grand Challenges Canada and by Dr. Margaret Chan when she was director-general of the WHO. The device was designed by a mechanic from Argentina; in 2013, Becton Dickinson agreed to work with WHO to get it through clinical trials and then manufacture and distribute the product worldwide.¹⁰⁷

xxiv As ranked by Medical Product Outsourcing magazine, July/August 2017 issue.

A second approach is to develop the organizational structure for low-resource market innovation internally. General Electric's electrocardiogram is a good example of that. GE used a local growth team to develop a product without the typical constraints imposed on product development. That is, the team was local and not subject to GE's short-run performance metrics.¹⁰⁸ These are success stories and it is not clear that, if we had all of the data on all of the investments made trying to develop products that would thrive in low-resource settings, we would see a positive return on investment, but it does give an idea of how this area might unfold in the future.

The private sector is active outside multinational firms as well. The WHO publishes a compendium of innovative health technologies for low-resource settings. Many of these are developed by much smaller organizations. It is not clear whether universities, large MNCs, smaller private-sector firms or some combination of these will play a more important role. However, the market potential is such that localization of product design and frugal innovation are likely to continue to develop and probably at an increasing pace. With the advent of robotics and 3D manufacturing, for example, remote product maintenance and creative knowledge transfer will become universally available.

Implications

The implications for health care delivery are significant. Many of the innovations are designed to operate a) with limited expertise, b) without a need for constant reliable electricity, and/or c) at a very low cost (including initial purchase price). For instance, the Odon device is specifically designed to be used without significant levels of training. GE's ECG is a low-cost device designed for settings without reliable electricity and with limited trained personnel. The 2011–2014 WHO compendium of innovative health technologies for low-resource settings includes 45 medical devices. Table 1 reports all of the devices and their benefits. The table shows that 22 claimed no need for reliable electricity, 20 emphasized the ability to operate with less skilled labor, 14 claimed to lower operating cost and five indicated a low price. Many had more than one of these benefits and some of the others used terms that could have included one of these benefits but didn't explicitly state it.

All of these benefits will have the effect of making services available in more distributed settings such as clinics or rural hospitals. If reliable electricity or skilled professionals are not required, the device does not need to be located at one of the central hospitals in a capital city. There is still expensive equipment such as imaging equipment and equipment for cancer care that is likely to be found only in centralized facilities, but the number of services that can take place in more distributed centers will increase with the increase in innovations along these lines.

Table 1: Beneficial Features of Innovations Documented in the WHO's Compendium of Innovative Health Technologies

Year	Product* *benefits are based on description in "Developer's claims of product benefits" in 2012 and "Suitability for low-resource settings" for 2013-2014	Low Operating Cost	Low Purchase Price	Reliable Electricity not Required	Reduced Need for Trained Personnel
2014	anesthesia delivery of low resource settings			1	1
	cooling mattress for neonates	1		1	
	infant radiant warmer	1	1	1	1
	infant resuscitation and suctioning device	1	1	1	1
	infant t-piece resuscitator			1	1
	infusion pump	1			1
	integrated respiratory blower and humidifier				
	low-cost computed tomography scanner			1	
	low pressure anaesthetic machine with pneumatic ventilator			1	1
	mobile-enabled non-invasive measure-through machine		1		
	neonatal bag mask			1	
	non-invasive haemoglobin monitoring device			1	1
	oxygen reservoir filling system			1	
	pulse oximeter			1	1
	trans-oral nasopharynx brush biopsy-quantitative PCR for Epstein Barr virus DNA detection	1		1	1
Z-arm digital x-ray					
2013	bedside newborn phototherapy				
	compact portable ultrasound			1	
	dry blood spot screening				
	electro-hyperthermia	1		1	1
	focal occult blood test				
	infant radiant warmer			1	
	infant warmer			1	1
	infrared ear thermometer	1			1
	LED phototherapy for neonatal jaundice	1			
	low pressure anaesthesia machine			1	
	mandibular repositioning device	1		1	
	oscillometric ankle-arm measurement		1		1
	oscillometric blood pressure measurement			1	
	oxygen concentrator-drive bubble CPAP	1			
	telecardiology				1
umbilical artery doppler analyser	1				
2012	automated solar-powered blood pressure monitor			1	
	interventional cardiovascular lab				
	intraosseous nail and interlocking screw system		1		
	mobile ECG with web-based telemedicine platform				
	multi-parameter remote diagnostic kit	1		1	
	non-invasive hypothermia indicator for newborns				1
	non-invasive vascular age risk prediction	1			
	non-surgical male circumcision device				1
	oral syringe dosing clip				1
	point-of-care diagnostic device for total WBC				1
	portable anaesthesia machine	1		1	1
	sputum mobilization device				
	urine albumin test				1
		14	8	22	20

Source: Compendium of Innovative health Technologies, World Health Organization 2012–2014.

6. Conclusions

Health outcomes have improved dramatically over the past 25 years and health care delivery is changing at a rapid pace all over the world. There are a variety of reasons for this, but some of the more prominent reasons include changing causes of illness and death (in particular, from acute to chronic), changing technologies and changing processes. The changes in low-income countries are likely to be even more pronounced than those in countries with higher income levels. Operational efficiencies such as high-volume surgical operations at Aravind Eye Care and Narayana Health illustrate the potential of improving the use of human and physical capital. Technical efficiencies such as Becton Dickinson's Odon Device, GE's electrocardiogram or many of those developed in universities are designed specifically for low-resource settings. New techniques such as the hydrocephalus surgical procedure developed at CURE in Uganda are developed because there isn't an alternative. These are just a few of the examples from low-income countries that are having an impact in high-income countries. The lack of existing processes and products for those settings enables trials that would never be considered in high-income settings where there are alternatives. Low-resource settings are thus likely to be fertile ground for innovations both because they don't have other options and because they don't have existing infrastructure, products or processes to get in the way.

Nowhere is this more true than in chronic care. Chronic care is not just a high-income country problem—it is already prominent in low-income settings and can only be expected to become more so. Chronic care was not covered as a separate topic here, but every topic discussed will be impacted by or have an impact on chronic care. Solutions are more easily developed in settings without existing structures when those structures are largely designed to deal with acute care.

This paper does not attempt to cover all important areas in health care delivery—important areas that are missing include obstetrics and gynecology, chronic care, infectious diseases and pediatrics—but it is clear even in this limited discussion that the private sector already plays an important role in providing the care as well as paying for the care in LMICs. As pointed out in the beginning, private sector care is not always good. However, some of it clearly is and the emphasis on health care in the Sustainable Development Goals, along with the increase in income available to spend on health care even in parts of the poorest countries, presents opportunities for these organizations to make significant and lasting contributions. Importantly, many of the changes and innovations will also benefit high-income countries (some already are), thereby further increasing the incentives to invest in solutions in low-resource settings.

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