



2016 Top Markets Report **Health IT**

Overview and Key Findings

Introduction

Health Information Technology (Health IT) is a dynamic, multifaceted sector that has the opportunity to dramatically influence delivery, efficiency, patient care and cost for healthcare markets worldwide. Health IT can be described as the use of a suite of products and services designed to improve and coordinate patient care, address growing health costs and confront the long-term burden of disease through the use of technology. Countries at all levels of development and sophistication in the healthcare and Information and Communication Technologies (ICT) sectors can derive benefits from implementing Health IT in their jurisdiction. The widespread potential for Health IT

Developments in the Internet of Things area will likely have a significant impact on the Health IT sector in 2016 and beyond.

implementation, along with the fact that other countries are facing concerns about providing affordable healthcare, makes the sector an attractive opportunity for increased exports by a wide variety of U.S. companies.

This Report is designed to inform decision makers and stakeholders of key trends, challenges, and opportunities in foreign markets for Health IT products and services and to make recommendations for how the U.S. Government can improve U.S. companies' access to these markets. Health IT (and healthcare more generally) is changing at a rapid pace; therefore the observations, recommendations and the ranking of priority markets will likely require reassessment in the future.

Before discussing recent Health IT sector activities in detail, data on the size of the overall healthcare and ICT markets give a sense of the huge possibilities for the Health IT sector. As seen in Figure 1 below, estimated healthcare expenditures worldwide were more than \$7 trillion in 2015 and are expected to exceed \$9 trillion by 2020, while the global IT market should reach \$1.7 trillion by 2020, up from \$1.36 trillion in 2015.¹ As healthcare and ICT expenditures continue to grow, more partnerships will likely be established, including in the areas of medical data analytics and remote monitoring, both of which apply to individual patients, as well as larger populations.

2015 Key Developments

One of 2015's key policy developments occurred in March in the United States, as Stage 3 Meaningful Use rule and certification criteria were released for comment by the U.S. Department of Health and Human Services' Office of National Coordinator (ONC) and the Centers for Medicare and Medicaid Services (CMS). The draft criteria offered more flexibility to physician practices and hospitals to meet information exchange requirements without being penalized for non-compliance, with an increased focus on system interoperability and patient outcomes.ⁱⁱ The primary Meaningful Use program objective is that Health IT should be used to improve patient care, lower healthcare costs and deliver more effective treatment, rather than solely focus on gathering data and information through deployment of products, services and technology. As of late June 2016, the final Stage 3 Meaningful

components to exchange information and to use the information that has been exchanged."ⁱⁱⁱ The December 2015 report noted that:

“Although substantial interoperability amongst all stakeholders in American health care has not been achieved to date, there are pockets of meaningful health information exchange developing and momentum is starting to build.”^{iv}

In October 2015, ONC released “Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap, Final Version 1.0,” outlining steps needed to make information flow more easily through the U.S. healthcare system by emphasizing interoperability. The Roadmap contained a number of actions that have target

Figure 1: Healthcare and IT Markets Continue To Grow
Global Healthcare Spending and IT Market Value Expenditures



Source: BMI¹

Use rule has not yet been issued, leading some industry observers to believe that the Meaningful Use program might conclude or be de-emphasized before Stage 3 criteria are issued.

In addition, a December 2015 report from the Health Information Technology Policy Committee, a federal advisory committee to the ONC on Health IT policy, outlined a set of challenges and barriers to achieving interoperability in the United States, in response to a Congressional request for information.

Interoperability is a frequently used Health IT term, defined by the Institute of Electrical and Electronics Engineering as “the ability of two or more systems or

completion dates in 2017, with other objectives to be achieved over a longer time horizon.”^v

In December 2015, the United States and European Union announced a stakeholder consultation for companies, individuals and institutions to map out future opportunities for collaboration in the Health IT sector and update the existing U.S.-EU Health IT/eHealth Roadmap (hereafter “Roadmap”). The Roadmap has developed into a useful resource for U.S. and EU stakeholders to work together on mutually agreed-upon initiatives that can serve as models for adoption by other countries around the world. The most recent version of the U.S.-EU

Roadmap had two work-streams, one focused on standards and interoperability (efforts to develop integrated systems to encourage data sharing), and another focused on education and development of the Health IT workforce. The next version of the Roadmap will include an Innovation Ecosystem work-stream, designed to encourage greater collaboration and sharing of best practices between companies/organizations on both sides of the Atlantic, and cities/regions interested in learning from each other to deploy cutting-edge technologies, among other options. The next Roadmap version should be released in summer 2016.

One other significant Health IT policy development came from Germany, with consideration of a new eHealth Law (hereafter “Law”) through most of 2015 and its passage in December. Germany has an approximately \$300 billion healthcare market, but only spends about 1 percent on Health IT, according to official figures (see the Germany Country Case study for more details). The promulgation of regulations to carry out the Law will likely extend into 2017 at the earliest, but early reviews of the Law indicate that it will not completely address many of the outstanding issues needed to raise the use and profile of Health IT in Germany.

A large-scale (although not policy-related) development that requires watching is the increasing interest in the “Internet of Things (IoT)” and the range of possibilities for the healthcare sector. Creating interconnections and linkages between electronic devices such as sensors and medical devices that can monitor, detect and exchange information have generated a lot of company and consumer interest across many sectors. Much of the current health-related activity is in the consumer market, with wearable devices, such as FitBit and Jawbone, being able to track a consumer’s vital health signs, creating a readily accessible, data-rich profile of a person’s health condition and potentially leading to customized solutions. Healthcare companies, hospitals and governments are also looking closely at this trend to determine how best to gather and analyze the real-time health information being created by these devices and use that information to prevent acute care episodes among individual patients, with the ultimate objective of providing better care while reducing costs. The collected data can also improve

treatment and care of a larger population, such as patients with a specific health condition. It is worth noting that concerns about cybersecurity and privacy (long-standing issues in healthcare, appearing in new ways), along with slow uptake by government officials, may delay the gathering momentum of IoT.^{vi}

Other significant 2015 Health IT market developments include mergers and acquisitions, announcements of Health IT investments and partnerships, and company efforts to explore opportunities in data analytics and increased patient engagement in taking care of their health condition (to name two examples). Regardless of one’s area of interest, a lot of activity took place in the Health IT sector during 2015. Examples (and long-term historical data points) include:

- August 2014—Cerner Healthcare announces purchase of Siemens’ Health IT business for a reported \$1.3 billion; deal closed in February 2015;^{vii}
- February 2015—as the Cerner/Siemens merger closes, the two companies announce a strategic alliance; initial plans are to integrate diagnostics and therapeutics with electronic health records (EHRs);^{viii}
- February 2015—insurer Anthem announces that hackers entered computer system; eventually reports that 80 million patient records were placed at risk;^{ix}
- 2015—**GV, Google’s** venture capital fund, invests 31 percent of its total capital into healthcare and life sciences;^x
- June 2015—American Health Information Management Association (AHIMA) completes global curriculum for Health Information Management education;
- July 2015—Aetna and Humana announce plans to merge in a \$37 billion deal;^{xi}
- August 2015—HHS reports that 143.3 million people in the United States have been compromised in 1,282 separate breaches at organizations handling protected health data since 2009;^{xii}
- September 2015—**Rock Health**, a digital health-focused venture capital fund founded in 2010, surpasses \$500 million worth of investment since its launch;^{xiii}
- September 2015—Qualcomm Life purchases Capsule Technologie, a global company

providing medical device integration and clinical data management solutions;^{xiv}

- September 2015—Implementation underway of a new health information system in Barbados called Med Data, managing public health system medical data;^{xv}
- December 2015—Shareholders for Anthem and Cigna separately approve a \$54 billion merger between the two companies;^{xvi}
- December 2015—ONC and the European Union’s DG CONNECT directorate announce a stakeholder consultation for updating the U.S.-EU Health IT/eHealth Roadmap;
- January 2016—Novartis leveraging Qualcomm Life’s connectivity solutions to power the Breezhaler, an inhaler meant to address Chronic Obstructive Pulmonary Disease (COPD) which will be connected to Qualcomm Life’s 2net platform, a home gateway device;^{xvii}
- February 2016—National Health Service (NHS) in England launches a \$5.7 billion digital transformation initiative seeking improvements in Electronic Health Records, prescriptions and consultations;^{xviii} remote patient monitoring is also a key component;^{xix}
- February 2016—Healthcare Growth Partners reports a record 328 Health IT mergers and acquisitions in 2015, up from 222 in 2014;^{xx}
- March 2016—Qualcomm Life and United Health announce a collaboration to deliver consumer-oriented connected health solutions across the United States;^{xxi}
- March 2016—The U.S. Bureau of Labor Statistics announces that the healthcare sector has added 503,000 jobs over the past year;^{xxii}
- March 2016—Philips announces fourth quarter 2015 financial results, notes that the largest share of company sales (46 percent, or \$3.66 billion) comes from healthcare,^{xxiii} and
- March 2016—Digital health institute DigitalHealth. London announces launch of first start-up accelerator program in the United Kingdom, to be run jointly with NHS; the

accelerator plans to work with 20 to 30 businesses each year over the initial two to three-year period.^{xxiv}

An ongoing trend that continues to accelerate is the continuing and increasing entry of technology and medical device companies into the Health IT space. Although not new, it is worth noting that some of the most active companies in this sector (such as Qualcomm and Intel) have their roots in the IT sector, while medical device firms (such as Philips, Siemens and Medtronic)^{xxv} are also increasing their activity in the Health IT sector. Some analysts believe that it is even possible that most of the disruptive Health IT technologies in the future will come from non-healthcare companies.^{xxvi}

Key Findings: Top Markets and Methodology

The first Health IT Top Market Report was released to the public in July 2015. During the report drafting process, the industry specialists learned that there were (and still are) no North American Industrial Classification System (NAICS) or Harmonized Tariff System (HS) codes assigned specifically to Health IT products or services, making accurate measurement for the market size in individual countries, and analyzing import/export levels and corresponding trade balances, very challenging. Therefore, the metrics used to rank countries were proxy indicators covering six categories that might influence the overall Health IT market.

In the 2015 and 2016 Top Market Reports, healthcare expenditures are used as a proxy for Health IT spending; countries with high health spending per capita often appear near the top of each Report’s rankings. This parameter alone, however, does not necessarily indicate whether the country has significantly invested (or plans to invest) in Health IT technologies or infrastructure.

The 2015 Report methodology leaned heavily on ICT usage and demographic data in each country, with some data on healthcare expenditures, research and development spending, physician density, and Health IT policy development. The results using this methodology, however, were not always defensible, as demonstrated in the following examples:

- 1) Japan received the number one ranking, even though the Health IT sector faced some business-unfriendly policies, making it a difficult market for U.S. companies; and
- 2) South Korea ranked number six, even though usage restrictions were so extensive that Korea essentially had no market for many telehealth and mobile health applications.

Similar circumstances currently exist in Japan and South Korea, but the new methodology (described further below) presents more defensible rankings in both cases.

It is also important to note that Health IT is a sector where export opportunities exist even for countries with less-developed healthcare systems, so markets with solid export potential exist below the top 10 ranked countries. This report contains Country Case Studies on Mexico and Turkey, two good examples of this situation.

The 2016 Report methodology retains some 2015 metrics (per capita health spending as the best available proxy for per capita Health IT spending, urban population density, and mobile phone and Internet services). Some metrics, however, have been tweaked (including use of a longer-term measure of the aging of a population rather than a point-in-time metric), and others are new (using

several measures of the health of a country's population). The rankings of 2016 generally look reasonable and defensible in many cases, particularly among the top 10 countries, even though the 2016 data sources are markedly different than the ones used in 2015.

Figure 2 lists the top 20 Health IT markets using this methodology. As expected, there is a strong concentration of developed countries that rank highly, particularly in Western Europe, the Nordic region, and Singapore and Japan in Asia. Many of these countries have aging populations and consequently are seeing increased healthcare costs, making the deployment of Health IT a key component of their future healthcare strategies.

In 2016, metrics used did not receive the same weighting across the board, as was the case in 2015. ICT-specific metrics (mobile subscriptions, Internet subscriptions and type of ICT service) received less weight in 2016, with new information about the health of the population, current spending on elderly citizens and the rate of aging in each country receiving greater importance. Shifting the weighting to increase the significance of health metrics over ICT metrics (or vice versa) will have an impact on the rankings. More details on the metrics used for this Health IT Top Market Report appear in Appendix 1.

Overall Health IT Top Market Report Caveats

The metrics that were chosen for this Report's analysis were based on available data and the industry specialists' reasoned assessment of the factors that influence the Health IT market. Future availability of metrics that more directly measure Health IT activity (for example, Health IT research

Figure 2: Near-Term Health IT Export Market Rankings

1.	Luxembourg	11.	Belgium
2.	Norway	12.	France
3.	Netherlands	13.	Canada
4.	Denmark	14.	Switzerland
5.	Singapore	15.	United Kingdom
6.	Iceland	16.	Austria
7.	Germany	17.	Malta
8.	Finland	18.	New Zealand
9.	Japan	19.	Italy
10.	Sweden	20.	Spain

and development expenditures; Health IT expenditures as percentage of GDP; more direct measures of Health IT policy formulation and implementation; etc.) likely would affect subsequent rankings and conclusions.

In addition, country reporting for some selected metrics is poor and/or not current; updated statistics for the metrics used may someday become available and impact the rankings. Some less-developed markets also do not have sufficiently sophisticated statistical agencies to supply the information categories needed so that this methodology could generate a ranking. This resulted in several mid-level markets that could have strong potential for Health IT deployment not appearing in the rankings, such as Malaysia, Hong Kong, Kenya, Kuwait, Qatar, United Arab Emirates, Algeria, Egypt and Tunisia. In general, there is an underrepresentation of low and middle-income countries (LMICs) in the rankings, particularly in Africa, which may be partly due to incomplete data for the metrics chosen.

Separate from the absence of trade data and NAICS codes, the industry specialists that did each of the Health IT Top Market Reports would have liked to incorporate additional metrics (including physician/nurse/other healthcare worker density, number of hospital beds and facilities, taxes and tariffs, burden of disease, and more specific spending on Health IT products and services) into both the original 2015 or revised 2016 methodologies but could not do so because of insufficient data.

Finally, the methodology used does not include a factor measuring the presence of local competition. This could be important for some countries, because competition in the Health IT sector can come from multiple industries, either individually or in combination (ICT, health services, health products and medical devices, just to name a few), and strong local competition might make a market less attractive to U.S. Health IT companies.

The Report's scope is primarily limited to mobile health and telehealth (including remote monitoring, outpatient care, home care and self-care). While some of the Report's information may have an influence and relevance to other Health IT subsectors (such as EHRs, disease surveillance, drug monitoring, and wearable technologies), additional

information should be consulted along with this Report when assessing those subsectors.

Three Specific Caveats in Using Report Methodology to Assess Market Potential

The following caveats should be kept in mind when assessing the metrics used and how these caveats can impact the country rankings when assessing a market's potential.

Health Expenditures

First, the methodology tends to favor countries with high health expenditure levels. It can be argued that lower health spending might increase the need to deploy mobile health and telehealth solutions, influencing how one would interpret the rankings. Determining how low the level of health expenditure needs to be for reevaluating mobile health and telehealth deployment is arbitrary, so the Report's methodology did not penalize countries that had a high level of health expenditures. The health expenditures metric received a lower weighting due to this consideration when compared to the methodology used for the 2015 Report.

Interpretation of Mobile Phone/Internet Usage

The second caveat concerns interpretation of mobile phone and Internet usage. Using measures of mobile phone usage in isolation, such as penetration rates or number of subscribers, does not provide a complete portrayal of a market's mobile health/telehealth potential. For instance, the reported penetration rate of a given market is often measured based on sales of SIM (Subscriber Identity Module) cards. In many economies, a single consumer will often have two to four SIM cards at any given time, with only one card being active. Some consumers have multiple mobile devices for different purposes; for example, one device for personal use and another for professional use.

As a result, many countries analyzed in this Report had relative rankings of mobile phone and/or Internet subscriptions based on figures for these metrics that exceed 100 percent. Therefore, these numbers can be deceptive, as consumers owning multiple SIM cards and communication devices (work phones, home phone, tablet) at a given time leave some markets appearing to have a mobile

phone subscription rate as high as 168/100 people. These announced penetration rates likely overstate the true number of people who own (or have consistent access to) a mobile device. It also explains why the reported figure for the number of people having mobile phone subscriptions closely rivals the world's population (as noted below). Based on the Report's methodology, high numbers in these metrics can offset low healthcare spending and therefore boost a country's ranking, so these metrics received a slightly lesser weighting in the 2016 Report.

It is worth noting that, in developing markets, a single mobile phone may be shared among multiple people (such as between family members or within a village). Global mobile phone use has increased 25 percent since 2010 but is expected to increase worldwide at a low rate in the future because of market saturation.^{xxvii} A large percentage of the world's population has access to a mobile phone; however, it is important to distinguish between the number of existing mobile phone subscriptions (7.1 billion as of November 2015)^{xxviii} and the number of unique mobile phone users (approximately 4.5 billion).^{xxix} It is estimated that 350 million people worldwide live in places still out of reach of mobile phone service and that only 29 percent of the 3.4 billion people living in rural areas can access a 3G signal (compared to 89 percent in urban areas).^{xxx}

To a lesser degree, this is also a relevant issue for Internet subscriptions. A January 2016 United Nations (UN) Broadband Commission for Sustainable Development meeting in Davos, Switzerland reported that only about 3.2 billion people (43 percent of the world's 7.4 billion population) have Internet access, with the remaining 4.2 billion being offline. The International Telecommunications Union (ITU) estimates that it would cost \$450 billion to connect the next 1.5 billion people worldwide to the Internet.^{xxxi}

Mobile Data-Access/Capacity Limitations

The third caveat (which cannot be easily controlled statistically) is the importance of prepaid versus postpaid mobile phone subscriptions, and its impact on the Health IT market in each country.

Consumers in most countries worldwide utilize prepaid mobile phone subscription plans, which

often limit the amount of data consumers can access per billing cycle. With limited data available under these plans, consumers are less likely to purchase and adopt data-hogging applications and services (such as those using images and/or video), which may constrain the potential for more sophisticated mobile health and telehealth services to enter these markets. Additionally, the terms of subscription phone plans can restrict the growth potential for advanced wireless services and applications (such as mobile health and telehealth) directed at consumers. While the pervasiveness of mobile phones would appear to be a prerequisite for analyzing the potential for mobile health and telehealth service delivery, these figures need to be viewed in association with other measures to accurately assess each market.

The preference for prepaid versus postpaid phone plans among consumers in many emerging markets can be sizable. For many countries in Southeast Asia (such as Indonesia, Philippines, Thailand and Vietnam), it is estimated that prepaid mobile plans account for 80 to 90 percent of the mobile subscription market.^{xxxii} This is in contrast to other countries in the region, like Singapore and Australia, where post-paid plans comprise 85 percent and 65 percent of the market, respectively.^{xxxiii} Until service providers can incentivize and persuade consumers to make the switch to post-paid plans, the growth potential of advanced mobile applications and services will likely be limited. Few countries have successfully converted consumers on a large scale from prepaid to postpaid plans.

Finally, some mobile health technologies under development are targeted for people younger than 65 (such as the maternal and child health population), meaning that a country with a very young population could still benefit from particular Health IT products and services targeting this demographic.

Industry Overview and Competitiveness

Mobile health is medical health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants and other wireless devices.^{xxxiv} As noted above, global mobile phone use has increased 25 percent since 2010 but is expected to increase worldwide at a low rate because of market saturation.^{xxxv}

A November 2015 report from MarketsandMarkets estimates that the global mobile health market is expected to experience a compound annual growth rate of 33.4 percent over the next five years, reaching \$59.15 billion by 2020.^{xxxvi} A September 2014 report from BCC Research estimated that the market for telehealth was expected to grow 17.7 percent globally between 2014 and 2019 to \$43.4 billion.^{xxxvii} While telehealth in the hospital setting has accounted for the majority of the market to date (60 percent in 2013), new growth will be primarily in reaching out to individuals in their homes or in outpatient settings, reaching 55 percent of the global market by 2019.^{xxxviii}

As mobile health applications continue to be a priority for research and development, technologies and affordability continue to improve at a rapid rate. Additionally, many countries are upgrading mobile network services, particularly those supported by large telecommunications companies. With 3G technologies readily available and 4G and 5G infrastructure upgrades being announced,^{xxxix} the delivery capabilities of mobile platforms for increasingly sophisticated healthcare solutions should continue to improve. While increasing use of smartphones will drive mobile health use globally, developers have taken advantage of more basic technical capabilities, such as SMS, to develop effective health technologies that can be implemented worldwide, particularly in low and middle-income countries (hereafter LMICs). Therefore, opportunities exist for mobile health entry into countries at all stages of development.

Telehealth services include surveillance, health promotion and public health functions like e-prescribing. It is broader in definition than telemedicine, as telehealth includes computer-assisted telecommunications to support management, surveillance, literature and access to medical knowledge.^{xl} Telehealth products include video conferencing, Internet-based systems and communications systems. Currently, telehealth is used primarily by healthcare facilities such as hospitals and clinics, rather than purchased directly by individual consumers, and serves as a way to virtually connect providers with patients or providers with colleagues.

The G7/G8 started supporting telehealth as early as 1995 by outlining strategies to create networks for international information exchange and Internet connectivity.^{xli} While deployment of telehealth remains a priority,^{xlii} coordinated efforts toward universal standards and policies have been slow, and most progress has been made at the country level, particularly by countries outside of the G8. Though the increasing popularity of mobile health may eventually constrain the size of the telehealth market, it should continue to grow, particularly in countries with a large rural population or unequal geographic distributions between trained medical professionals and the general population.

One of the noteworthy features of the Health IT sector when looking at increasing the presence of the sector worldwide is the tremendous opportunities for developed markets to learn from developing countries (and vice versa) about innovative diagnostic and treatment delivery options, with technologies, disease states, resource capabilities and patient demands that often vary widely between countries. The bi-directional nature of Health IT usage and deployment today offers many countries and companies opportunities for collaboration at an early stage, unlike some sectors. In addition, the intersection of health and ICT offers opportunities for technology development that may cause significant disruption—or “creative destruction”—to the healthcare sector, often based on practices found in other industries.

Although LMICs rank primarily in the lower half of the market rankings for this report, they offer a variety of opportunities to test emerging Health IT models. This partly reflects the lack of human and financial resources available or invested in health and ICT. However, LMIC countries frequently represent medium to high-risk, high-reward opportunities for companies in the Health IT sector, particularly those with breakthrough technologies.

This is because healthcare systems in LMIC countries are not limited by legacy paper or antiquated electronic systems. LMIC governments often feature Health IT (particularly mobile health and telehealth) in their healthcare strategic plans to quickly improve services and increase coverage and deployment; and the burden of disease (both communicable and chronic) is often high, thus generating immediate demand for products and services. By establishing

proof of concept in LMICs, companies displaying disruptive technologies, services or applications can use this route as a platform to develop export opportunities for other markets. The eventual shift away from pilot studies to large-scale implementation of Health IT in LMICs will further support market growth. As noted earlier, this version of the Report has relatively few LMICs, so companies making decisions about possible markets to enter should not be entirely beholden to this Report's rankings.

Health IT technologies and delivery systems can help citizens both in urban and rural areas. Healthcare professionals are often concentrated in urban areas, leading policymakers to primarily focus on delivery to rural communities (including mobile and telehealth services). Many countries also have an insufficient number of well-stocked hospitals and clinics, and lack an adequately trained healthcare workforce. Therefore, U.S. companies looking to invest overseas should consider making these technologies and applications available to both urban and rural populations, as urban consumers can also benefit greatly from the introduction of mobile health and telehealth services.

U.S. companies are generally considered globally competitive in the Health IT sector, primarily because of the capitalist orientation of the U.S. economy, entrepreneurial approach of companies seeking to disrupt the healthcare sector, presence of incubators and accelerators to nurture start-up entities (before they become established companies), and the roughly 55/45 split between private sector and public sector healthcare provision and expenditures. As a result, U.S. companies often have a wide array of opportunities to test different approaches in other countries.

A key challenge can be how to persuade U.S. companies to take a rational, sensible decision on exploring countries overseas. Complicating this to some degree is that most companies cannot enter overseas markets on their own and not just because of ownership or partnership requirements. Many companies have one or two important component products or knowledge base to contribute to a system for overseas deployment, but a successful entry overseas (in many cases) might require a systemic installation or replacement, meaning that a

U.S. company will need to partner with other firms to enter or expand their presence in the market.

Global Industry Landscape

As noted above, the lack of Health IT trade data makes empirical analyses of potential export markets difficult. A case can be made, however, that, with appropriate preparation and an appetite for manageable risk, sometimes less sophisticated markets can be a promising export option if the technology, product or service is suitable for market conditions. The absence of local competition and the ability to quickly meet and negotiate with the appropriate government official(s) may make the market less bureaucratic to enter, and the widespread need for countries to effectively manage their patient's health condition at a reasonable cost may offer chances for companies of any size to successfully venture into these countries.

Some of the largest Health IT countries (based on country-reported revenue data, which may be inconsistent either with the Health IT product/services scope listed above or between countries) appear to be Japan, Germany and South Korea, but all three are very challenging markets from a policy and/or competitive perspective. Canada is also a fairly large market, with the challenge there primarily resulting from most of the purchasing power (and nature of healthcare delivery) taking place at the provincial level. Smaller markets, such as the Nordic countries (Denmark, Finland, Norway and Sweden), can be very receptive to new products and technological approaches, so with the right products/services, they can offer promising potential as well.

Opportunities

Both mobile health and telehealth have the potential to revolutionize the way that health care is provided to populations. As the global burden of disease, primarily non-communicable diseases, continues to grow and populations age, the costs of healthcare globally are expected to continue rising. Mobile health and telehealth solutions, while initially more costly to implement, are integral tools to reduce healthcare costs, increase system efficiencies and improve treatment.

Mobile health and telehealth technologies can be implemented in both rural and urban settings,

expanding the reach of healthcare services to a larger percentage of the population, and have been shown to improve efficiency and continuity of care, making them attractive opportunities for preventive and personalized medicine and in-home care. These technologies can also serve to effectively connect a relatively small, well-trained local healthcare workforce to large populations in many countries.

For instance, mobile health and telehealth can make it easier for patients to receive care from world-renowned specialists, particularly for rare conditions, without the need to physically travel to the specialist's office, and better monitor a chronic condition for a mobility-challenged individual from their home and then connect to healthcare professionals should the need for intervention arise. In addition, these technologies can allow for improved treatment for patients in remote areas or if healthcare specialists are highly concentrated in major metropolitan areas or across long distances (within or between countries).

New ICT technologies under development and being deployed have an opportunity to further reshape and disrupt healthcare delivery. In addition, the Health IT market responds to influences and possible disruptions from many other sectors beyond ICT and healthcare, including energy, education, finance, transportation, software and global supply chains. Consequently, Health IT can be found in many forms and has become part of many initiatives. Therefore, diverse types of companies offer products or services relevant to the Health IT sector, not just those coming from a healthcare background.

Challenges and Barriers

Systemic/Infrastructure Challenges Facing Health IT Sector

In reviewing the many challenges hindering the wider application and acceptance of Health IT technologies, it is important to differentiate those that impact the entire sector from those primarily affecting mobile health and telehealth (although several impact both). For clarity, the mobile health and telehealth challenges will be listed separately from those affecting Health IT as a whole.

Health IT products and services can address many demonstrated needs, but resources and priorities need to be closely aligned in many countries to

promote widespread adoption and use.

Development of a global telehealth infrastructure, and the ICT network to support this system, became one of the priorities of the G7 in 1995.^{xliii} Since then, international emphasis on use of ICT for healthcare has increased. For example, WHO and ITU published the "National eHealth Strategy Toolkit in 2012 to help countries in their development of Health IT policies,"^{xliiv} though little is currently known on how widely the Toolkit has been used and the success countries have had using the Toolkit to implement these policies.

One of the Health IT sector's noteworthy features is that countries at all levels of technological and healthcare system sophistication can benefit from the deployment of Health IT products, services and applications. In fact, many countries around the world (particularly LMICs) can obtain significant benefits from the introduction and large-scale rollout of relatively simple ICT technologies, such as text messaging patients to encourage them to take their medicines or to visit a physician. Tailoring products and services offered to a country, region or population will significantly increase the probability that the company's investment will be beneficial and/or profitable.

Policy Challenges Facing Health IT Sector

In the global marketplace, companies face challenges resulting from antiquated, inadequate or nonexistent policies or regulations, such as data exchange and data storage provisions for health information (discussed further below). These can impact Health IT, mobile health and/or telehealth, and can complicate a company's decision-making process regarding which markets to enter with their products and services. Further exacerbating this issue is the fact that the policy and regulatory gaps/inadequacies vary from country to country, meaning that the approach to address these gaps will need to be customized for the specific country. Although some best practices are starting to be seen worldwide, until these policy/regulatory challenges are addressed, the rollout of Health IT will remain a gradual process in many countries.

Additionally, policies are often promulgated at a national level but are implemented on a state or regional level. This can be particularly problematic, given that healthcare funding happens at the

national level, but delivery of healthcare services often happens at the sub-national level, possibly resulting in a fragmented and inconsistent system that does not support widespread adoption and integrated use of Health IT. As the rate of Health IT development continues to outpace regulation and policy change, maintaining supportive, integrated policies and regulations for Health IT will continue to be a challenge well into the future. Specific policy barriers that the Health IT industry faces include:

Preferential Procurement Processes and Budgetary Limitations for New Technologies

Procedural transparency and elimination of preferential treatment in government procurement policies affect many exporting sectors in the United States, but these issues are particularly acute in the health sector, as many countries operate wholly or largely government-run healthcare systems, with the government often playing a major role in developing procurement procedures. Furthermore, in light of possible fiscal pressures, governments may not have the resources and/or incentives to rapidly support the introduction of new technologies, such as those offered by mobile health and telehealth vendors and consortia (see below regarding reimbursement).

In some countries, private sector and academic health facilities have sizable latitude to purchase new technologies and systems. However, absence of transparent bidding processes, and preferences for local competitors, can undercut otherwise promising market opportunities. U.S. companies need to be aware of these issues as they seek to enter overseas markets.

Funding limitations are causing both government payers and private sector insurers to intensely examine both the business case for introducing Health IT-based applications, as well as the medical rationale for providing those services. Stakeholders are increasingly demanding proof that Health IT reduces healthcare costs and improves health outcomes, and technology and applications that do not demonstrate improved care at lower cost likely will have a hard time receiving approval from insurers or governments. Most mobile health and telehealth applications using phones, tablets and other technologies likely will obtain reimbursement but will first need to demonstrate a worthwhile care/cost tradeoff. It is possible that governments

will eventually develop the political will to support these deployments as best practices are identified and the financial incentives behind use of Health IT are demonstrated and realized.

Medical Liability Concerns

If Health IT is used to carry out (among other things) medical procedures or provide consultations across national boundaries, then the regulations between jurisdictions in those areas will also have to be harmonized. Legal requirements within (and between) countries will need to be reviewed to determine whether a country permits remote care of citizens by physicians, regardless of whether the doctor and patient are in the same state/district or different ones. Other legal issues related to Health IT include allowing cross-border medical licensure of healthcare professionals offering treatment or diagnosis from a remote location (the United States is making some notable progress in this area)^{xlv} and medical liability, both regarding inaccurate or faulty treatment and diagnosis using mobile health/telehealth, as well as where and how one can seek legal redress. Even issues related to power interruptions and blackouts during consultations or procedures can lead to medical liability questions. Companies need to be aware of these differences in rules between countries and between jurisdictions within countries.

Data Privacy/Security

Privacy protections will likely need to be implemented in many countries to reassure consumers of the quality of Health IT products and services.^{xlvi} Questions remain as to how best to protect patient privacy and ensure security of Health IT, and it is important to note that these questions are inextricably intertwined with broader questions of data privacy, security and storage that affect many industries across economies. Health is just one sector impacted by policy decisions made on these issues, and since the implications of improper, inaccurate and/or illegal access, entry or use of health information can be extremely injurious (or deadly) for patients, special handling and procedures in these areas may need to be considered for the health sector. Consensus around these issues has not yet been reached, but the United States and the EU are discussing some of the broader issues as part of the Transatlantic Trade and Investment

Partnership (T-TIP) negotiations. The February 2016 announcement of the U.S.-EU Privacy Shield agreement^{xlvii} (not in force as of June 2016) also touches upon this topic.

Standards

As with many other sectors, adoption of internationally agreed-upon standards^{xlviii} would facilitate generation of a global system for Health IT. Such discussions are ongoing in international fora, such as the International Organization for Standardization (ISO), Health Level 7 (HL7), Integrating the Healthcare Enterprise (IHE) and the Institute of Electrical and Electronics Engineers (IEEE), but consensus on the appropriate standards has not been reached in many areas, and the standards approval process itself can purposefully move rather deliberately. The sector's intersection between ICT and health also broadens the number of standards-setting bodies and committees who need to be involved in the standards development process, which can elongate the process of reaching consensus on these topics. The absence of consistent standards and the need for users to carefully choose between competing standards have also hindered the development of the Health IT sector.

Integration into Medical Practice

Health IT also needs to fit within current medical practice for it to be adopted widely. Many experts in the sector recognize that the entrance of high-tech products and services into healthcare delivery needs to be paired with a close examination of physician and health professional workflow so that the technology will be used appropriately and have maximum impact. The review of medical practice and how to effectively integrate Health IT has occurred at some hospitals and clinics in the United States, but has not yet occurred on a broad scale, and this effort will need to be replicated on a far larger scale as these technologies become available internationally. As a result, more advanced mobile health and telehealth technologies have yet to gain broad adoption.

Market Challenges Facing Health IT Sector

In order for healthcare providers to increase usage of Health IT generally (and mobile health and

telehealth more specifically), several economic challenges also need to be addressed:

Provider Reimbursement Systems

Appropriate reimbursement for services provided remotely through mobile health and telehealth applications will need to be implemented among both public sector and private sector sources. This is part of a broader trend; rather than reimburse physicians and healthcare providers on the volume of care provided, insurance and healthcare provider policies will need to shift (as has started to happen in the United States) in favor of emphasizing high-quality care (reducing readmissions to hospitals and lowering the number of acute interventions needed, just to name two examples), preventing emergency room visits and increased adherence to medication regimens.

There will likely be great variation in terms of reimbursement trends worldwide, as most countries have government-run healthcare systems, and many of them are dealing with tight budgets while patient needs and demands continue to rise. In some countries, patients pay a significant portion of healthcare expenses, so companies considering the question of reimbursement for their product or service need to closely understand this element of the market in each country where they plan to export.

Mobile health and telehealth applications can offer many benefits leading to more efficient use of healthcare resources and lower costs by encouraging more frequent transmission of vital health statistics and earlier intervention to treat a health condition, which should result in fewer emergency room and physician visits. It should also increase patient involvement in managing their health (see immediately below). In 2015, more than 200 telehealth bills were introduced in state legislatures in the United States, many designed to make the provision of telehealth, and reimbursement for it, easier.^{xlix}

Consumer Acceptance

Consumer acceptance of Health IT (and mobile health/telehealth more specifically) will also be needed for widespread adoption to take place. A focus on developing technologies that are easy to

use by consumers without medical training, while being customizable enough to meet individual health needs, will be critical in improving adoption. Additionally, in many countries, consumers do not have much choice in selecting physicians and hospitals based upon their digital capabilities to manage a patient's condition, but this factor is becoming a consideration for some U.S. consumers.

A related challenge is the consumer's reaction to use of these technologies. Individuals most likely to benefit from Health IT may lack the knowledge and understanding to fully adopt and maintain use of these applications once introduced (sometimes called "digital literacy"), which may inhibit the widespread utilization of Health IT in a country, region or population. Increased use of wearable technologies (such as FitBit or Jawbone) may help with consumer awareness and acceptance of their important role in each individual's healthcare journey. Improving awareness of available Health IT products and services, and their benefits, including addressing common misconceptions about security, will likely result in increased adoption. The United States has had some experience educating consumers about the benefits of Health IT and may be able to assist other countries with this effort, but other countries may also have beneficial lessons to share with the United States on this topic.

Healthcare Workforce Training

One of the necessary, but often less highlighted, aspects of Health IT deployment is the need to adequately train the healthcare workforce on development, implementation and use of the appropriate systems. This issue impacts both healthcare workers with many years of experience and those new to the sector. Training often involves education on a multitude of related, but distinct, issues ranging from information governance to management of medical records and associated systems to quality assurance of health information. The impact of this training can also have a direct impact on the career development path of healthcare workers. A careful review of the processes and workflow involved in patient care and treatment is often suggested for health systems and hospitals when instituting new administrative and records management systems, and this review will be even more complex when mobile health and

telehealth processes (which often take place outside the hospital) are involved.

The Department of Commerce's International Trade Administration (ITA) entered into a cooperative agreement with the American Health Information Management Association (AHIMA) from 2013 to 2016, which consisted of a comprehensive update and expansion of existing health information management (HIM), Health IT and health informatics education, both for career workers and those new to the sector, through ITA's Market Development Cooperator Program. A finalized curriculum (with a distinct focus on standardizing workforce competencies in a variety of areas) was released in June 2015, and as of March 2016, governments and institutions in India, Nigeria, Saudi Arabia, Qatar and the United Arab Emirates have committed to implementing the new curriculum.^l

Specific Challenges for Mobile Health and Telehealth

Provider Legal Protections

Establishing provider legal liabilities and protections for virtual treatment decisions is an area where policies and procedures need to be aligned for increased use of mobile health and telehealth concerns. Since the patient and physician are not in the same physical location, making an accurate medical diagnosis depends on many factors, including lighting, clarity of the image transmitted to the physician, speed of the Internet/broadband connection, interaction between different service providers in transmitting the images, and existence of a consistent power supply, among other considerations (the Medical Liability section above also mentions some of these topics).

Scaling-up Mobile Health and Telehealth Solutions

Pilot studies for mobile health and telehealth products are being implemented throughout the world. Some countries have many pilot projects ongoing simultaneously in different regions. For instance, India has approximately 290 ongoing projects and Kenya has over 200.ⁱⁱ In addition, pilot projects in mobile settings (involving mHealth, mAgriculture, mobile money and mEducation) can also provide important insights to broaden the presence of mobile health and telehealth; recent

statistics show 109 deployments in Kenya, 80 in Uganda, 59 in Tanzania and 17 in Rwanda.^{lii}

An issue connected to the proliferation of pilots relates to making these initiatives long-term, viable businesses. For example, some countries have tried new technology on a national level with resounding success, only to have these projects fail because they lacked sustained funding and support. Unfortunately, a significant number of these projects are supported by international donor organizations. When the grant money runs out, the successful implementation of Health IT at scale also ends. Countries need to develop plans for the long-term viability of Health IT, which includes mechanisms to sustainably fund projects rather than relying on external sources, such as grants. Once these pilot projects demonstrate long-term success, they offer excellent potential for becoming viable businesses, and these technologies and services can then be used to assist patients around the world.

Successful mobile health and telehealth products and services already exist but are often not widely known, indicating that increased visibility and awareness of successful Health IT products and services would increase adoption and use of these technologies in the United States and other countries. Doing so would also provide viable, demonstrable examples of “business cases” that mobile health and telehealth can both improve treatment and delivery paradigms (pertinent to many Health IT-related projects primarily dependent on donor funding for their existence, often located in LMICs), while being profitable for the vendor or consortium of companies.

ICT Infrastructure

Besides the issues referenced above relating to data privacy, storage and exchange, the structure of the physical network used to transport the information is another area of possible policy challenges. A number of mobile application developers and smaller enterprises are pushing for use of more open systems and architecture in Health IT to develop integrated systems, encouraging data sharing based on commonly agreed-upon standards. It is still unclear how open architecture and data sharing can adequately accommodate intellectual property

protections and privacy concerns. In addition, the perceived need of some vendors to keep their Health IT solution proprietary in an effort to make a profit may slow the sectors’ drive towards interoperability.

Most experts agree that limiting the depth and breadth of proprietary databases and exchange protocols (just to name two examples) to promote interoperability is desirable and necessary to permit Health IT to attain its optimal impact, but several Health IT vendors have not publicly advocated for an open architecture approach. There has been some movement in this area over the past year, highlighted by an “interoperability pledge” effort announced at the 2016 Healthcare Information and Management Systems Society (HIMSS) Annual Conference by the Office of National Coordinator (ONC)^{liii} and at the 2013 creation of the CommonWell Alliance.^{liv} From an export perspective, this could lead to greater use of foreign markets as a “proof of concept” for management and collection of information using open source systems and eventually lead to the U.S. introduction of systems first demonstrated overseas.

Health IT requires a robust ICT infrastructure to be in place before more advanced mobile health and telehealth applications can be instituted. This includes widespread coverage for broadband communications and reliable electricity,^{lv} including in rural areas. While 3G and 4G networks increase the speed and types of data that can be reliably shared, the presence of less advanced ICT infrastructure can become a barrier to widespread use of more sophisticated mobile health and telehealth services. As of November 2015, 89 percent of the urban population worldwide had access to 3G coverage,^{lvi} but only 29 percent had access in rural settings.^{lvi} Broadband and mobile phone affordability is still a challenge in some countries, with citizens in almost 50 countries as of early 2015 paying more than 5 percent of their average monthly income for broadband service, which is above the United Nations Broadband Commission for Sustainable Development target.^{lvii} Many countries continue to upgrade and expand broadband coverage. Smartphone adoption is still low and restricted primarily to developed countries and higher income brackets.^{lviii}

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^{iv} “Report to Congress: Challenges and Barriers to Interoperability,” December 2015, Health IT Policy Committee, pages 4-5.

^v On the HHS website at:

<https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf>. The report also contains a detailed list of achievements in advancing interoperability in the United States between 2004-2015.

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^{xxi} “United States - Connectivity Expanding Applicability Of Medical Data,” BMI’s Daily Sector Alert – Medical Devices, March 4, 2016.

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