G20 GERMANY 2017
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Stepping Up Global Health

Towards Resilient, Responsible and Responsive Health Systems

B20 HEALTH INITIATIVE

POLICY PAPER 2017

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Foreword by the Chairs

The world is becoming increasingly globalized and complex. The motto of this year's G20 presidency "shaping an interconnected world", is therefore well-chosen. This theme extends into all spheres, including trade, digitalization, security, and finance. Neither can global challenges in these areas be tackled by individual countries alone, nor can the benefits be fully realized if countries try to go-it-alone. This also applies to health, which is becoming more important for the G20 every year. We, the B20, agree: There is a need to improve resilience and sustainability of health systems, ensure a more sustainable, pro-innovation environment and establish a more collaborative culture among all stakeholders.

Health is an essential component of ensuring sustainable and inclusive economic growth and development throughout the G20 and beyond. Communicable (infectious) and non-communicable (non-infectious) diseases seriously endanger individual wellbeing and global health and threaten the global economy. Medical innovations such as vaccines can save millions from death or disablement and are essential to economic prosperity. Improving health is central to achieving the United Nations' Sustainable Development Goals. A healthy population is essential to delivering sustainable and inclusive economic growth and security: one extra year of life expectancy has the potential to raise a country's GDP per capita by about four percent. Roughly 400 million people in low- and middle-income countries currently lack access to effective and affordable healthcare. This has to change.

The global health challenges are manifold, including antimicrobial resistance, pandemics, and neglected tropical diseases. The G20 countries share a great responsibility in this regard. The G20 is the premier forum for international economic cooperation. It holds the necessary weight and legitimacy: Its members are not only responsible for 85 percent of global gross domestic product (GDP) and three-quarters of global exports (goods and services), but also represent about two-thirds of the world's population. Improving global health requires joint efforts – by all stakeholders and across borders. Therefore, the B20 lauds G20 Germany for placing health high on the agenda of this year's summit. Health is a quintessential G20 issue: economic growth, financial stability, and development prospects – all traditional G20 topics – are greatly affected by global health. At the same time, the prospects for improving global heath are greatly affected by G20 decisions in these areas.

The world's current health challenges are significant but not insurmountable. By its power to innovate, the healthcare sector contributes substantially to economic growth and wellbeing around the world. We are part of the solution to the various healthcare challenges. Healthcare innovation is key to improving health, whether in medical research and development, evolving healthcare models that empower citizens, or digital health. We, the B20, stand ready to partner with the G20 in its aim to improve global health.

Kemal Malik

Chair of the B20 Health Initiative

Member of the Board of Management, Bayer AG

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Recommendations

Recommendation 1: Driving Innovation in Healthcare – The G20 members should adopt policies that ensure that the benefits delivered by research and development for more effective diagnostics and therapies are adequately recognized. They should also adopt policies that improve access to healthcare by establishing a pro-innovation ecosystem that prioritizes self-care and empowerment of individuals.

Policy Action 1.1: Encouraging Innovation – The G20 members should value innovation in all its forms, including major and incremental advances from all sectors through market-based incentives. They should encourage the ongoing nature of research and development where, at times, small steps cumulatively lead to progress, particularly in medicine, and substantial gains for patients.

Policy Action 1.2: Fostering Results-Focused Approaches – The G20 members should foster a results-focused approach to healthcare systems by facilitating regulations that evaluate innovations based on their contribution to the sustainability of healthcare systems, by reducing inefficiencies in the entire system, by advancing R&D collaborations, and by offering patient-centric care while securing fast access to innovation.

Policy Action 1.3: Improving Universal Health Coverage and Self-Care – The G20 members should promote access to essential healthcare services to their citizens by sharing best practices, building improved healthcare policies, incentivizing private sector involvement, and empowering citizens by enabling self-care and health literacy.

Recommendation 2: Combating Antimicrobial Resistance (AMR) – The G20 members should combat antimicrobial resistance, including multidrug-resistant tuberculosis (MDR-TB), by incentivizing R&D of new medicines, advancing preventive measures, and promoting responsible use of antibiotics, as well as supporting capacity building in low- and middle-income countries.

Policy Action 2.1: Scaling up R&D – The G20 members should improve the conditions for developing new antimicrobials, vaccines, therapies, diagnostics, and better technologies for infection control by increasing the predictability and sustainability of R&D funding, improving the convergence of the regulatory environment across borders, and incentivizing cooperation between business and research organizations.

Policy Action 2.2: Setting Guidelines – The G20 members should call on the World Health Organization (WHO) together with the Food and Agriculture Organization (FAO) and the World Organization for Animal Health (OIE) to devise guidelines for responsible and sustainable use of antibiotics, and to disseminate the information to all stakeholders. Guidelines are also needed to improve infection control measures and education.

Policy Action 2.3: Advancing Capacity Building – The G20 members should assist low- and middle-income countries in their fight against AMR, including MDR-TB as well as other neglected diseases that may impact AMR, and support R&D capacity building in the countries that require it most.

Recommendation 3: Fighting Neglected Tropical Diseases (NTDs) – The G20 members should fight NTDs by increasing funding for public health interventions, strengthening cooperation with governments of endemic countries and capacity building, as well as agreeing on more financial support for R&D.

Policy Action 3.1: Advancing Cross-Cutting Approaches – The G20 members should advance cross-cutting approaches to tackle NTDs as specified by the WHO's five public-health interventions to prevent, control, eliminate, and eradicate NTDs.

Policy Action 3.2: Increasing Funding for Research and Product Development – The G20 members should agree to scale up research and product development to battle NTDs.

Recommendation 4: Improving Pandemic Preparedness and Response – The G20 members should support ongoing efforts to improve pandemic preparedness and response, including efforts to foster public-private partnerships in a variety of sectors.

Policy Action 4.1: Promoting PPPs in Infectious Disease Research and Product Development – The G20 members should support initiatives to accelerate R&D relating to infectious diseases.

Policy Action 4.2: Promoting PPPs in Preparedness and Response – The G20 members should support efforts to develop effective public-private partnerships for pandemic preparedness and response.

Policy Action 4.3: Incorporating Pandemic Risk in Macro-Economic Assessments – The G20 members should encourage incorporating the economic risks of infectious disease outbreaks into macro-economic assessments to build greater risk awareness and encourage investment in preparedness.

Recommendation 5: Advancing Digital Health – The G20 members should endorse the use of Big Data in health by promoting translational data flows as well as protecting individual data. They should also accelerate the provision of a high performance digital health infrastructure by setting clear targets and deploying broadband and mobile connectivity.

Policy Action 5.1: Facilitating Big Data – The G20 members should endorse making use of big data in digital health by facilitating and promoting translational and cross-border data flows, while at the same time protecting patients' health data by implementing clear governance rules.

Policy Action 5.2: Improving Digital Health Infrastructure – The G20 members should accelerate the provision of a high performance digital health infrastructure by setting clear targets, agreeing on international standards for technical and semantical connectivity, and boosting investment in high capacity and mobile connectivity.

Introduction

Patients are living longer, healthier, and more productive lives today thanks to innovative medical products such as vaccines, medicines, and diagnostics. For example, polio has been eradicated nearly completely since 1988, after it paralyzed 350,000 people every year in 125 countries around the world.[1] Immunization through an initial vaccine, and later through an improved vaccine, has reduced the number of cases by 99 percent, saving more than 13 million children from paralysis.[2] This is testament to the enormous benefits that medical innovation can bring to the world. However, the lack of effective medical tools in many areas still spells enormous costs for the global economy today: the Commission on a Global Health Risk Framework for the Future (GHRF) estimates that pandemics cost the world economy US$ 60 billion every year.[3] Research and development (R&D) is essential to ensure that new medical products can prevent, treat, and cure diseases that threaten and impact lives and economies.

The healthcare sector is one of the largest business sectors in the G20. In Germany, for example, the healthcare sector contributed € 324 billion to the economy in 2015 (12 percent of Gross Domestic Product, GDP), while India's healthcare sector could increase to US$ 280 billion by 2020.[4] The healthcare sector is also an important employer. For example, the sector contributed 12 percent to employment in the United States (2014), 12.5 percent in Canada (2014), and 12.6 percent in Australia (2015).[5] Its research intensity and power to innovate, its large share in employment, and its outward-orientation make the sector an important driver of economic growth and development for the G20 members and beyond.

At the same time, the global healthcare sector faces unprecedented challenges, including demographic change, aging populations, increasing life expectancies, and changing lifestyles. Together with increasing demand for healthcare products as well as services and tight budgetary constraints, these developments place a growing burden on healthcare systems. Global healthcare expenditure is estimated to grow from US$ 7 trillion in 2015 to US$ 8.7 trillion in 2020. The increase of Non-Communicable Diseases (NCDs, also known as chronic diseases, including: heart disease, stroke, cancer, diabetes, brain disorders, and others) is going to be amongst the most challenging health issues. The three most significant causes of death – cardiovascular diseases, cancer, and respiratory diseases – could account for 50 percent or roughly US$ 4 trillion of global healthcare expenditures by 2020.[6] In addition, the high prevalence of communicable diseases, including emerging and re-emerging diseases, exacerbate the enormous pressure on the healthcare sector. Mental health issues such as Alzheimer's pose another big health challenge.[7]

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[1] The Bill and Melinda Gates Foundation, *Polio – Strategy Overview* (2017), accessed May 15, 2017, http://www.gatesfoundation.org/en/What-We-Do/Global-Development/Polio.
[2] The Bill and Melinda Gates Foundation, *Polio – Strategy Overview*, 2017, op. cit.
[3] Commission on a Global Health Risk Framework for the Future (GHRF), *The Neglected Dimension of Global Security – A Framework to Counter Infectious Disease Crises* (2016), accessed May 15, 2017, https://nam.edu/wp-content/uploads/2016/01/Key-Messages-The-Neglected-Dimension-of-Global-Security1.pdf.
[4] I. Kickbusch, *Why the G20 Must Embrace a New Health Agenda*, G7G20 (2015), accessed May 15, 2017, http://www.g7g20.com/articles/ilona-kickbusch-why-the-g20-must-embrace-a-new-health-agenda; Bundesministerium für Wirtschaft und Energie, „Die Gesundheitswirtschaft in Ost- und Westdeutschland" (March 2016), accessed May 15, 2017, https://www.bmwi.de/Redaktion/DE/Publikationen/Wirtschaft/gesundheitswirtschaft-in-ost-und-westdeutschland-fakten-und-zahlen-2015.pdf?__blob=publicationFile&v=14.
[5] Bureau of Labor Statistics, *Employment by Major Industry Sector* (2015), accessed May 15, 2017, https://www.bls.gov/emp/ep_table_201.htm, Statistics Canada, *Employment by Industry* (2017), accessed May 15, 2017, http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/econ40-eng.htm; Parliament of Australia, *Employment by Industry Statistics: A Quick Guide* (2016), accessed May 15, 2017, http://www.aph.gov.au/About_Parliament/Parliamentary_Departments/Parliamentary_Library/pubs/rp/rp1516/Quick_Guides/EmployIndustry.
[6] Deloitte, *Global Health Care Outlook*, Overview and Outlook (2017), https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-2017-health-care-outlook.pdf, 3.
[7] Alzheimer's disease International, *World Alzheimer Report* (2016), https://www.alz.co.uk/research/world-report-2016.

Exhibit 1 | Non-Communicable Diseases (NCDs)

The main types of Non-Communicable Diseases (NCDs) are cardiovascular diseases (like heart attacks and stroke), cancers, chronic respiratory diseases (such as chronic obstructive pulmonary disease and asthma), diabetes, and brain disorders. NCDs tend to have a long duration and are the result of a combination of genetic, physiological, environmental, and behaviors factors.

NCDs kill approximately 40 million people each year, equivalent to 70 percent of all deaths globally. Each year, 17 million people die from a NCD before the age of 70; 87 percent of these premature deaths occur in low- and middle-income countries. Key components of the response to NCDs are detection, screening, and treatment of NCDs, as well as palliative care.

Goal number 3 of the UN Sustainable Development Goals sets the target to reduce premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being by one third by 2030.

Source: WHO, *Noncommunicable Diseases,* Factsheet (WHO: April 2017), accessed May 15, 2017, http://www.who.int/mediacentre/factsheets/fs355/en/; UN, *Sustainable Development Goal No. 3*, accessed May 15, 2017, http://www.un.org/sustainabledevelopment/health/.

Health is a key aspect of human and economic development. A healthy population is essential to delivering sustainable and inclusive economic growth and security: one extra year of life expectancy has the potential to raise a country's GDP per capita by about four percent.[8] Roughly 400 million people in low- and middle-income countries currently lack access to effective and affordable healthcare.[9] The poorest nations tend to suffer most from health problems.

There is ample evidence of the effects of health on development: countries with weak health and education conditions find it harder to achieve sustainable growth and development. Weak health systems create a significant financial burden in the form of healthcare expenditures and lost productivity. Governments in less and least developed countries are struggling to offer adequate access to healthcare to their populations, often due to workforce shortages, patient locations, infrastructure limitations, and budgetary constraints. The importance of health is reflected in the United Nations' (UN) Sustainable Development Goals (SDGs). Goal 3 of the SDGs stipulates that universal health coverage (UHC) and access to quality essential healthcare services, as well as safe and effective vaccines and medications, should be available for all by 2030.[10] The health gains associated with global health investments translate into economic returns in the form of averted future medical costs, enhanced productivity, and improved outcomes for children and future generations.

Key components to effectively addressing today's health challenges are innovative and accessible health products, efficient health systems, and distribution channels, trained medical professionals, and informed patients. Industry plays a central role by researching, developing, and refining new health solutions, increasingly in partnership with non-profit research organizations and product development partnerships (PDPs).

Improving global health requires joint efforts – by all stakeholders and across borders. Therefore, the B20 lauds G20 Germany for placing health on the agenda of this year's summit. Health is a quintessential G20 issue: economic growth, financial stability, and development prospects are greatly affected by global health. At the same time, the prospects for improving global health are greatly affected by G20 decisions in these areas. For example, clean air and water, curtailing climate change, investment in infrastructure, financial and digital inclusion – all issues on this year's G20

[8] D.E. Bloom, M. Canning, J. Sevilla, *The Effect of Health on Economic Growth: A Production Function Approach*, *World Development*, 32:1, (2012), 1-13.
[9] WHO, *New Report Shows That 400 Million Do Not Have Access to Essential Health Services* (2015), accessed May 15, 2017, http://www.who.int/mediacentre/news/releases/2015/uhc-report/en/.
[10] United Nations, *SDG, Goal 3: Ensure Healthy Lives and Promote Well-Being for All at All Ages*, accessed May 15, 2017, http://www.un.org/sustainabledevelopment/health/.

agenda – are fundamental in improving global health.

G20 countries have led the global fight to end the worldwide burden of AIDS, tuberculosis, and malaria over the last decade and a half. 15 years since the creation of the Global Fund to Fight AIDS, TB, and Malaria, the impact of global health investment has been startling.[11] The G20 should build on this positive experience and lift the joint efforts of G20 counties to a new level.

Medical innovation and policy changes take years to develop and take effect. Only a sustained and long-term commitment can ensure progress. Health should therefore become a permanent agenda item for the G20. Five issues call for immediate attention:

1. *Driving Innovation in Healthcare*: Innovation in the healthcare sector – in therapies, vaccines, diagnostics, monitoring systems, health applications, as well as in infrastructure delivery and access – is fundamental to improving a population's health and ensuring a country's financial and economic stability. A precondition for successful innovation is a robust and predictable regulatory environment. Innovation in healthcare will also help to improve access to health.
2. *Antimicrobial Resistance (AMR):* Drug-resistant diseases and infections are some of the biggest health challenges the world faces today. AMR is a quintessential "One Health" issue, as it is connected to human, animal, and environmental health. It therefore requires collaborative efforts by all stakeholders around the world.[12]
3. *Neglected Tropical Diseases*: The WHO estimates that neglected tropical diseases (NTDs) affect more than one billion people annually around the world and cost low- and middle income countries billions of dollars.[13] NTDs can be tackled most effectively if governments, non-governmental organizations (NGOs), foundations, and industry work together to devise appropriate solutions.
4. *Pandemic Preparedness and Response*: The Ebola outbreak in West Africa and the recent outbreak of the Zika virus in the Americas made it clear that the world is still woefully underprepared for pandemics. Several initiatives aim at rectifying this situation including the Coalition for Epidemic Preparedness Innovations (CEPI), which was launched at the World Economic Forum (WEF) in January 2017, and the Private Sector Roundtable (PSRT) of the Global Health Security Agenda (GHSA). But more needs to be done.
5. *Digital Health*: Digital Health holds a wealth of opportunities for patients, governments, and industry. Big Data can be a powerful tool to devise new personalized medicines and increase our understanding of diseases. Digital healthcare technologies can empower people through unprecedented access to information, connect physicians to patients, and create new sources of data through continuous monitoring of patients. However, these opportunities can only be harnessed in a suitable regulatory environment.

[11] Friends of the Global Fight Against AIDS, Tuberculosis and Malaria, *The Case for U.S. Investment in the Global Fund and Global Health (2017)*, Issue Brief, accessed May 15, 2017, http://www.theglobalfight.org/wp-content/uploads/2017/03/global_fight_brief_3-28-17.pdf.
[12] CDC, *One Health* (2017), accessed May 15, 2017, https://www.cdc.gov/onehealth/, T.P. Robinson et. al., *Antibiotic Resistance Is The Quintessential One Health Issue*, Transactions of the Royal Society of Tropical Medicine and Hygiene (2016), 110:7, 377-380.
[13] WHO, *Neglected Tropical Diseases* (2016), accessed May 15, 2017, http://www.who.int/neglected_diseases/diseases/en/.

Recommendation 1: Driving Innovation in Healthcare

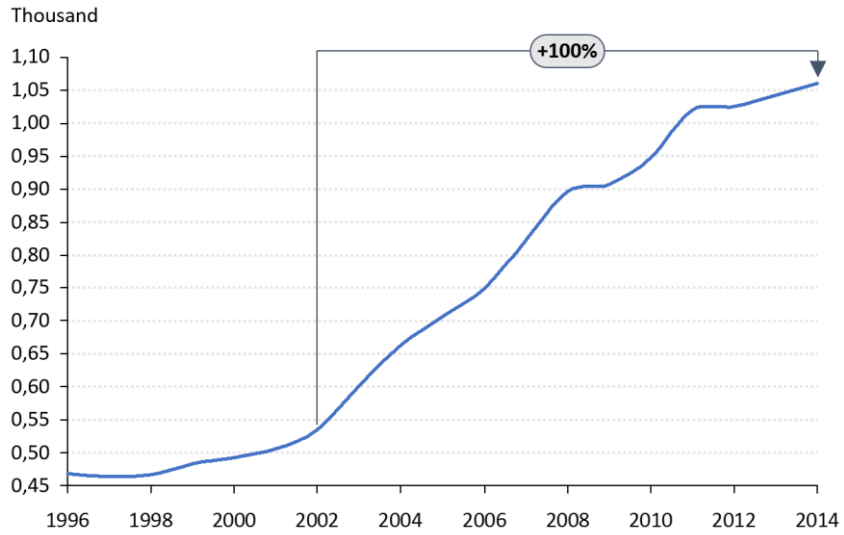
The G20 members should adopt policies that ensure that the benefits delivered by research and development for more effective diagnostics and therapies are adequately recognized. They should also adopt policies that improve access to healthcare by establishing a pro-innovation ecosystem that prioritizes self-care and empowerment of individuals.

Policy Actions	
1.1	**Encouraging Innovation** – The G20 members should value innovation in all its forms, including major and incremental advances from all sectors through market-based incentives. They should encourage the ongoing nature of research and development where, at times, small steps cumulatively lead to progress, particularly in medicine, and substantial gains for patients. • The G20 members should create and nurture innovation ecosystems by cultivating predictable, transparent and robust legal and regulatory regimes, and by training skilled workers in a climate that promotes knowledge exchange and local absorption capacity. • The G20 members should reaffirm the importance of effective and predictable intellectual property (IP) protection, including patents, regulatory data protection, and patent term extensions as a key incentive for innovation. • The G20 members should accelerate the approval processes for diagnostics, new therapies, and treatments, as well as enable a rapid uptake of new technologies. • The G20 members should track their innovation readiness, identify enablers and barriers, and act upon them, including support for health startups.
Owner G20 members	**Timing** 2017 onwards
1.2	**Fostering Results-Focused Approaches** – The G20 members should foster a results-focused approach to healthcare systems by facilitating regulations that evaluate innovations based on their contribution to the sustainability of healthcare systems, by reducing inefficiencies in the entire system, by advancing R&D collaborations, and by offering patient-centric care while securing fast access to innovation. • The G20 members should adopt a holistic approach and address all inefficiencies in the healthcare system. • The G20 members should keep markets open to enable knowledge exchange and investment in health. • The G20 members should support multi-stakeholder dialogues and collaborations in order to address healthcare challenges efficiently.
Owner G20 members	**Timing** 2017-2018
1.3	**Improving Universal Health Coverage and Self-Care** – The G20 members should promote access to essential healthcare services to their citizens by sharing best practices, building improved healthcare policies, incentivizing private sector involvement, and empowering citizens by enabling self-care and health literacy. • The G20 members should exchange best practices with higher-, middle-, and low-income countries on how to best extend access to essential medical and rehabilitation services to the populations that require them most. • The G20 members should enhance health capacity building, more strongly cooperate on aid for health, and identify areas for joint action. • The G20 members should promote effective self-care and well-being as well as health literacy by undertaking education and awareness efforts.
Owner G20 members	**Timing** 2017 onwards

Context

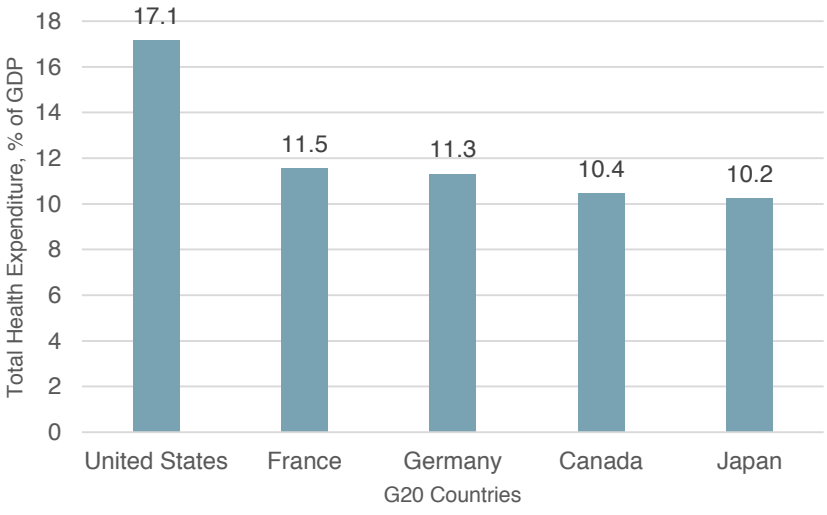
The G20 faces a multitude of health challenges, including rising demand for healthcare and social care services due to an aging population as well chronic diseases. Exhibit 2 shows the total health expenditure per capita as the sum of public and private health expenditure, which covers the most important aspects of health expenditure such as provision of health services and nutrition activities. Exhibit 3 shows the five G20 members that spent the highest share of their GDP on healthcare in 2014.

Exhibit 2 | World Health Expenditure Per Capita [USD]



Source: The World Bank, World Development Indicators (2017), accessed May 15, 2017, http://databank.worldbank.org/data/reports.aspx?source=2&series=SH.XPD.TOTL.ZS&country=#.

Exhibit 3 | Top 5 G20 Country Health Expenditure as Percentage of GDP, 2014



Source: World Bank, *World Development Indicators*, (2017), op cit.

Healthcare spending is likely to continue to grow faster than GDP,[14] posing considerable fiscal challenges for many governments. The WHO furthermore estimates a shortage of labor in healthcare services to reach 12.9 million globally by the year 2035, negatively affecting not only economies as a whole but also each individual.[15]

Innovations have not only the potential to improve health, but also to generate economic growth and to reduce the public costs of care. Improving health requires a holistic approach, i.e. focusing on innovation in medical products as well as on healthcare delivery, processes, services, as well as skills development. This includes:

- a shift in focus from acute, hospital-based care to early and accurate prevention, early detection and diagnosis, population management, community and home-based care;
- a much stronger participation of citizens in their own care process (self-management); more recognition, support and participation of health and care professionals;
- new roles, skills, and responsibilities for professionals;
- new patient pathways ensuring the cooperation among care actors and timely follow up;
- new governance models between payers, providers, and consumers of care that incentivize co-delivery of care and results;[16]
- overcoming "silo" approaches to innovation.

Innovation should be constantly measured. For example, Alzheimer's Disease International and the Global Coalition on Aging have developed a useful tool for measuring innovation in dementia care. The categories of innovation levers established therein could be used when defining, discussing, and advancing concepts of innovation (see Exhibit 4).

Exhibit 4 | Case Study: Measuring Innovation – Innovation in Dementia Care

The Dementia Innovation Readiness Index aims to clarify the barriers to and enablers of innovation and, from those learnings, identify opportunities to adopt supportive approaches across the diverse areas of need in dementia. The goal is to uncover and clarify: where innovation in dementia is currently occurring; the enablers of innovation in prevention, treatment, and care; and the barriers to innovation in prevention, treatment, and care.

The Index evaluates dementia innovation across ten categories: 1. strategy and commitment; 2. government funding; 3. education and workforce; 4. early detection and diagnosis; 5. regulatory environment; 6. access to care; 7. prevention and risk reduction; 8. business environment; 9. care standards; 10. built environment.

Source: Global Coalition on Aging and Alzheimer's Disease International, *First-Ever Dementia Innovation Readiness Index launched at ADI Conference,* accessed May 15, 2017, https://www.alz.co.uk/news/first-ever-dementia-innovation-readiness-index-launched-at-adi-conference.

[14] World Bank, *Health Expenditure* (2017), accessed May 15, 2017, http://data.worldbank.org/indicator/SH.XPD.PCAP.
[15] WHO, *Global Health Workforce Shortage to Reach 12.9 Million in Coming Decades* (2013), accessed May 15, 2017, http://www.who.int/mediacentre/news/releases/2013/health-workforce-shortage/en/.
[16] European Commission, *Blueprint Digital Transformation of Health and Care* (2016), accessed May 15, 2017, http://ec.europa.eu/research/conferences/2016/aha-summit/index.cfm?pg=blueprint.

Policy Action 1.1: Encouraging Innovation

The G20 members should value innovation in all its forms, including major and incremental advances from all sectors through market-based incentives. They should encourage the ongoing nature of research and development where, at times, small steps cumulatively lead to progress, particularly in medicine, and substantial gains for patients.

Governments should incentivize innovation through a robust and predictable regulatory framework and targeted financial support, including, for example, measures such as tax incentives for industrial research and improving funding capabilities.[17] A big impetus could furthermore be provided by increasing the speed of approval processes for new diagnostics, therapies, and treatments.

Valuing innovation also means that intellectual property rights (IPR) are sufficiently protected across borders. IPRs are central to the business model of healthcare companies because they ensure that developers can at least recover their investments from the risky and expensive R&D processes.[18] Once IPRs are no longer safeguarded, the incentives to engage in resource-intensive and risky processes are no longer given.

New innovations will also help make healthcare systems more sustainable through more efficient use of resources, for example, by early detection and accurate diagnosis for early and effective intervention. Governments should ensure rapid uptake of new diagnostic and therapeutic technologies, including innovative payment models, early-access schemes, and regulatory reviews. In order to enable new technologies and therapies, they should also consider innovative ways of how to evaluate and measure the value of innovative therapies at launch and throughout the lifecycle by collecting real world data on health outcomes. Public stakeholders should collaborate to ensure that new innovations also reach citizens.

Alongside the development of new therapies, research on known therapies offers an important and efficient means of providing new and improved treatments for the benefit of patients. In terms of their quality and licensed indications, known therapies are already well characterized regarding quality, efficacy, and safety. Side effects are generally known and well documented. As a result, the risk to patients and the economic risk for the bodies conducting the research are lower and more transparent. The potential benefits of these innovative products are of particular importance for the sustainability of healthcare systems as well as access to affordable medicines for doctors and patients.

Late stage product development requires large scale global trials that are expensive and contain significant risk. Reducing redundancies through global collaboration, that are compliant with International Health Regulations (IHR 2005), harmonization of regulatory systems and, where needed, financial incentives in case of poverty-related and neglected diseases, will help in significantly reducing the time to patients for innovative new health products. In this context, public-private product development partnerships play a key role by helping raise public, private and philanthropic funds, by scaling up research for product development, by decreasing the risk of companies in developing, and by delivering innovative and affordable health technologies.

Startups play an important role for the innovation process, as they typically find radically new ways of development. Startups in health, such as the German startup Medlanes, may well disrupt the healthcare system in the same way as other innovative concepts like AirBnB have changed the hospitality sector.[19]

[17] BDI und ZVI, *360-Grad-Check - Steuerliche Rahmenbedingungen für Forschung & Entwicklung* (2016), accessed May 15, 2017, http://bdi.eu/media/themenfelder/steuerpolitik/publikationen/20170116_Broschuere_BDI_ZVEI_360-Grad-Check.pdf.
[18] C. N. Saha und S. Bhattacharya, "Intellectual Property Rights: An Overview and Implications in Pharmaceutical Industry", *Journal of Advanced Pharmaceutical Technology & Research* (2011), 2:2, 88-93.
[19] Roland Berger, *Digital Disrupted: All Change for Healthcare* (2016), accessed May 15, 2017, https://www.rolandberger.com/publications/publication_pdf/roland_berger_digitalization_in_healthcare_final.pdf.

It is important to support startups, especially in later stages, until the technology or medicine is completely market ready. One such initiative has been put in place in France. Health Minister Marisol Touraine announced supplementary funding to health innovation programs. However, such initiatives are rare. Thus, the B20 would like to see the G20 members promoting and supporting health startups and creating an environment that encourages risk-taking.

Exhibit 5 | Case Study: Driving Innovation in Alzheimer's Treatment

Scientific innovation to address mental and neurological disorders such as Alzheimer's is extremely challenging, with therapies requiring more time to obtain regulatory approval compared with medicines for treating other diseases. These diseases alone affect more than one third of the world's population and result in nearly $1 trillion lost in economic productivity and a heavy burden on health systems, caregivers, and families. G20 members need to lay out incentives for research in mental and neurological disorders, support new research partnerships, care models, and public health campaign to address these diseases holistically.

Source: Alzheimer's Disease International, *World Alzheimer Report 2015, The Global Impact of Dementia,* accessed May 15, 2017, https://www.alz.co.uk/research/WorldAlzheimerReport2015.pdf.

Policy Action 1.2: Fostering Results-Focused Approaches

The G20 members should foster a results-focused approach to healthcare systems by facilitating regulations that evaluate innovations based on their contribution to the sustainability of healthcare systems, by reducing inefficiencies in the entire system, by advancing R&D collaborations, and by offering patient-centric care while securing fast access to innovation.

Increasing efficiency in healthcare systems requires a holistic and results-focused approach to healthcare. The International Chamber of Commerce (ICC) launched a set of principles in late 2015 to support the development of policy frameworks that enable innovation and reduce inefficiencies.[20] These include: building investor confidence, training skilled workers in an environment that promotes exchange of knowledge, opening markets to trade and investment, and ensuring appropriate intellectual property systems. Governments need long-term innovation strategies that ensure a high level of coordination and collaboration between different government ministries (industrial, economic, health, finance)[21] and cultivate effective coordination between academia and the public and private sectors.[22]

Healthcare is still an astonishingly fragmented industry. Individual players are often unaware of R&D programs of other players. Cooperation of market participants – both within and across countries – could accelerate innovation cycles and efficiency. However, collaboration is hampered by several factors, including the lack of agreed-upon standards for health data protection, concerns about a lack of evidence on cost-effectiveness, and ambiguous legal and regulatory frameworks. Greater integration of hospital, primary, community and social care services could also enable higher-value care interventions, as fragmented and underdeveloped data collection on health outcomes make it difficult to compare the value of different care interventions and prioritize decision-making across care providers. Therefore, B20 calls upon the G20 members to incentivize the cooperation of all health market players.

The interconnection of public university hospitals with private (profit and non-profit) research and development initiatives could be particularly beneficial. Public hospitals compete with private health

[20] ICC, *ICC Launches Principles to Support Innovation and Meet Global Challenges* (2015), accessed May 15, 2017, https://iccwbo.org/media-wall/news-speeches/icc-launches-principles-to-support-innovation-and-meet-global-challenges/.
[21] Charles River Associates, *Policies That Encourage Innovation in Middle-income Countries* (2012), accessed May 15, 2017, http://www.ifpma.org/wp-content/uploads/2012/01/CRA_Policies_that_encourage_innovation_in_middle-income_countries_Key_Findings_Web.pdf.
[22] Ibid.

companies as well as the government for manpower in a market with an increasing skilled labor shortage, thereby escalating costs even further. Public-private partnerships could help manage rising healthcare costs. There is already a variety of public-private partnership initiatives in place across G20 economies. However, to maximize benefits, B20 would like to see the G20 members foster cooperation of public university hospitals with private (profit and non-profit) research and development initiatives (within and across borders). The G20 members should also share best practices in this area.

Policy Action 1.3: Improving Universal Health Coverage and Self-Care

The G20 members should promote access to essential healthcare services to their citizens by sharing best practices, building improved healthcare policies, incentivizing private sector involvement, and empowering citizens by enabling self-care and health literacy.

Goal 3 of the SDGs stipulates that universal health coverage (UHC) and access to quality essential healthcare services, as well as safe and effective vaccines, therapies, and diagnostics should be available for all by 2030.[23] UHC does not mean free healthcare coverage for all healthcare interventions possible. Its aim is to enable every person to access the medical services and medicines they need without financial hardship.[24] This includes, as specified by the WHO, access to rehabilitation services that are becoming increasingly important because of the increasing prevalence of NCDs and aging populations.[25] The benefits of UHC are clear: an OECD study covering a number of OECD countries and emerging economies found that life expectancy increases as the core UHC indicators (see Exhibit 7) are improved.[26]

A 2015 WHO report evaluated global access to essential health services by assessing, among others, access to family planning, antenatal care, skilled birth attendance, child immunization, antiretroviral therapy, tuberculosis treatment, clean water, and sanitation. The WHO found that at least 400 million people lacked access to at least one or more essential services.[27] Furthermore, the report found that across 37 countries, out-of-pocket payments (direct payment made to healthcare providers by individuals) for health services tipped or pushed six percent of the population into extreme poverty.[28] The G20 members should therefore take decisive action to advance UHC globally and to assist low- and middle-income countries in increasing healthcare access to ensure sustainable development.

[23] United Nations, *SDG, Goal 3: Ensure Healthy Lives and Promote Well-Being for All at All Ages* (2015), op. cit.
[24] WHO, *Universal Health Coverage (UHC)*, Fact Sheet (2016), accessed May 15, 2017, http://www.who.int/mediacentre/factsheets/fs395/en/.
[25] WHO, *Rehabilitation 2030: A Call to Action*, Meeting Report (2017), accessed May 15, 2017, http://www.who.int/disabilities/care/Rehab2030MeetingReport_plain_text_version.pdf.
[26] OECD, *Universal Health Coverage And Health Outcomes*, Final Report (2016), accessed May 15, 2017, https://www.oecd.org/els/health-systems/Universal-Health-Coverage-and-Health-Outcomes-OECD-G7-Health-Ministerial-2016.pdf.
[27] WHO, *Universal Health Coverage (UHC)*, Fact Sheet (2016), op. cit.
[28] WHO, *Universal Health Coverage (UHC)*, Fact Sheet (2016), op. cit.

Exhibit 6 | Gender Matters

Men and women face different challenges in access to healthcare. Men's and women's biological differences as well as social roles cause different demands with regard to healthcare. While men are at higher risk of accidents and consequences of excess consumption, women are more prone to HIV and also face difficulties in access to reproductive health such as family planning, prenatal and antenatal care. UHC needs to incorporate the needs and roles of men and women to guarantee quality health access for both according to their needs.

Source: Women and Gender Equity Knowledge Network, *Final Report to the WHO Commission on Social Determinants of Health*, accessed May 15, 2017, http://www.who.int/social_determinants/resources/csdh_media/wgekn_final_report_07.pdf.

Exhibit 7 | Universal Health Coverage: The WHO's Indicators to Measure Progress to Sustainable Development Target 3.8 (UHC)

Indicator 3.8.1 – Coverage of essential health services.

- The average score of the four trace indicators of the four categories is calculated.

Reproductive, maternal, newborn, and child health	Infectious disease control	Non-communicable diseases	Service capacity and access
• Family planning coverage • Pregnancy care • Immunization coverage • Care seeking for pneumonia	• TB cases detected and treated • HIV antiretroviral therapy • Insecticide treated bed nets • Improved water and sanitation	• Non-elevated blood pressure in adults • Non-elevated blood glucose in adults • Cervical cancer screening • Non-use of Tobacco	• In-patient admission rate • Health worker density • Access to essential medicines • IHR core capacity index

Indicator 3.8.2 – Lack of financial protection.

- The proportion of the population with large household expenditures on health as a share of total household expenditure (expressed as % share).

Sources: World Health Organization (WHO), *Monitoring Sustainable Development Goals* (2017), accessed May 15, 2017, http://www.who.int/health_financing/topics/financial-protection/monitoring-sdg/en/; D. Hogan et. al., *Technical Note: Developing an Index for the Coverage of Essential Health Services* (May 2016), accessed May 15, 2017, http://www.who.int/healthinfo/universal_health_coverage/UHC_WHS2016_TechnicalNote_May2016.pdf.

Exhibit 8 | Case Study: Placing a Stronger Focus on Disabilities

The WHO recognizes disability as a global public health issue, a human rights issue and a development priority. According to the WHO's Global Disability Action Plan 2014-2021[1], people with a disability, throughout their life course, face widespread barriers in accessing health and related services, such as rehabilitation, and have worse health outcomes than people without a disability.

The WHO estimates that 1 billion people live with some form of disability, which corresponds to 15 percent of the world's population, who would benefit from one or more assistive products. With populations aging and the prevalence of non-communicable diseases rising across the world, this number will rise above 2 billion by 2050. Among those who most need assistive technology are people with a disability, older people, people with non-communicable diseases such as diabetes, cancer and stroke, people with mental health conditions and people with gradual functional decline. Furthermore, road traffic accidents, natural disasters, and conflicts contribute to increasing numbers of people with disabilities and suggest a corresponding increase in the need for mobility devices. Today, only 1 in 10 people have access to assistive products. For example: 70 million people need a wheelchair but only 5 to 15 percent have access to one. According to estimates, people needing orthoses or prostheses and related services represent 0.5 percent of the population in developing countries. The WHO

recognizes that the impact of assistive technology goes far beyond the benefits of health and well-being to individual users and their families. It also includes socioeconomic benefits, by reducing direct health and welfare costs, enabling a more productive labor force, and stimulating economic growth. Increasing access to assistive technology will also support tackling other major contributors to the global burden of disease.

Recognizing the huge and unmet global need and at the same time the high relevance of assistive technology, the WHO is coordinating the stakeholder initiative Global Cooperation on Assistive Technology (GATE). The GATE initiative aims to improve access to high-quality affordable assistive products globally. Providing practical tools, it represents a concrete step towards realizing the goals of the Convention on the Rights of Persons with Disabilities (CRPD), Universal Health Coverage (UHC), and the SDGs.[2]

Source: 1) WHO, Worldbank, *World Health Report on Disability (*Malta 2011*),* accessed May 15, 2017, http://www.who.int/disabilities/publications/en/; 2) WHO, WHO Global Disability Action Plan 2014-2021, Better Health for All People with Disability (2014), accessed May 15, 2017, http://www.who.int/disabilities/policies/actionplan/Disability_action_plan_faq.pdf?ua=1. 2) WHO, *Global Cooperation on Assistive Technology (GATE)*, accessed May 15, 2017, http://www.who.int/disabilities/technology/gate/en/.

Changes in demographics, lifestyles, patient expectations, and developments in medical progress mean that UHC is an evolving challenge. However, wherever possible, specific targets and milestones should be identified. B20 welcomes the initiative "Healthy Systems for Universal Health Coverage – A Joint Vision for Healthy Lives".[29] Accordingly, the G20 members need to set their own priorities – for some the focus will be on increasing the services available, for others the priority will be reaching underserved populations. But for all, a focus on prevention (including early diagnosis, screening etc.) and not just on treatment, is essential. Furthermore, governments should, at a minimum, provide a public safety net for the most vulnerable populations and individuals, which, where possible, avoids out-of-pocket payments through risk-pooling mechanisms. As such, G20 members should continue and expand sharing good practices on how to improve access to health, including schemes such as health cooperatives that are estimated to provide access to health to nearly 100 million households around the world.[30] The G20 members should also explore governmental and public-private initiatives promoting proactive investments that can prevent and treat disease.[31] Finally, the G20 members should promote the establishment of the International Health Partnership for Universal Health Coverage 2030 (UHC2030) as a multi-stakeholder platform to progress towards UHC.[32]

Consideration should be given to streamlining and harmonizing regulatory processes, with a focus on seeking regional solutions where possible to speed up patient access to medicines and vaccines as well as avoid duplication of efforts. Where appropriate, private health insurance as well as hybrid solutions should be employed, particularly for growing middle- and upper-income populations to release public funding for more vulnerable groups and to raise the overall level of health provision.

The G20 should also aim to improve the sustainability of healthcare systems by identifying successful healthcare financing models. The G20 should thus task the World Bank and the WHO with undertaking a review of financing frameworks for activities in healthcare systems with a goal of developing strategic recommendations on best practices. The review should assess the policy environment required for successful implementation of alternative financing models, including economic, regulatory and socio-political factors. This review would support the implementation and viability of universal healthcare coverage by identifying alternative sources of revenue collection, pooling revenue to spread risk across the population, and allocation to specific geographies or demographics.

[29] Federal Ministry for Economic Cooperation and Development, *Healthy Systems-Healthy Lives (2017)*, accessed May 15, 2017, http://www.health.bmz.de/what_we_do/hss/Healthy_Systems-Healthy_Lives/index.html.
[30] International Labour Organisation and International Co-operative Alliance, *Cooperatives and the Sustainable Development Goals* (2014), accessed May 15, 2017, http://www.ilo.org/wcmsp5/groups/public/---ed_emp/documents/publication/wcms_240640.pdf, 8.
[31] The Lancet Commission on Investing in Health, *Global Health 2035: A World Converging within a Generation,* (2013), 382, 1898-1955, accessed May 15, 2017, http://www.globalhealth2035.org/sites/default/files/report/global-health-2035.pdf.
[32] Ihp+, *Development cooperation and health (2017)*, accessed May 15, 2017, https://www.internationalhealthpartnership.net/en/about-ihp/.

To enhance healthcare access in the poorest countries, the G20 should further enable them to explore new financing mechanisms that may, inter alia, encourage tiered pricing – the concept of selling drugs and vaccines in developing countries at prices systematically lower than in industrialized countries – and voluntary licensing models – an authorization given by the patent holder to a third party to make, use, sell or import the patented article, e.g., a medicine – to ensure that the poorest of the poor in low income countries have access to the latest innovations.

The private healthcare sector plays a significant role in working towards greater access to essential medical services globally.[33] Industry, however, will only be able to flourish and contribute to increased health access if governments create a supportive regulatory framework and set the right incentives. Examples of such incentives are supply-side interventions such as social marketing, social franchising, and vouchers.[34] Social marketing of commodities, for example, involves the application of commercial marketing methods to stimulate demand for products and services that have a large value to public health.[35] The marketed products and services could be available for sale at subsidized prices in order to incentivize customers. Mechanisms like social marketing are increasingly common in low-income countries; more than 100 of these programs exist in more than 70 countries.[36] In addition, the G20 members should continue their work in decreasing risk of capital investments and facilitate investments particularly in low income countries.

Exhibit 9 | Business Sustainable Development Commission

The Business and Sustainable Development Commission was launched in January 2016 to engage the private sector to accelerate sustainable and inclusive economic growth and poverty reduction. Founded by Unilever CEO Paul Polman and former UN Deputy Secretary-General Malloch-Brown, the Commission articulates the economic case for industry to get involved in achieving the SDGs. The Commission aims to explore current and future business models and map out the new financing mechanisms required to reach the SDGs. It investigates changes in core business operations and behaviors that go beyond traditional corporate social responsibility and voluntary partnerships. Areas of research and activity include corporate tax, accountability, and water scarcity.

Source: Business Sustainable Development Commission, *Our Work* (2017), accessed May 15, 2017, http://businesscommission.org/our-work.

Furthermore, distribution systems in many developing countries are often complex and inefficient due to different roadblocks along the delivery route: the quality of and accessibility to the healthcare system, its general infrastructure, access to insurance, and government policies on import tariffs and taxes can impede private sector engagement. The G20 members should therefore address these barriers more energetically.

To tackle inequalities in health, the G20 members furthermore need to intensify their efforts in capacity building at home and abroad, i.e. the development of sustainable skills, organizational structures, resources, and commitment to health improvement. This encompasses not only providing skills and awareness, but also creating channels through which learning can be transferred into sustainable action. The G20 members need to increase the range of people, organizations, and communities who are able to address health problems, and in particular, problems that arise out of social inequity and social

[33] R. Horton and S. Clark, *The Perils and Possibilities of the Private Health Sector*, *The Lancet*, 388, (2016), 540-541.
[34] D. Montagu and C. Goodman, *Prohibit, Constrain, Encourage, or Purchase: How Should We Engage with the Private Health-care Sector?*, (2016), op. cit.; Social marketing refers to the use of commercial marketing techniques to create demand for products with a high public health value. Social franchising entails the use of franchising methods to achieve social goals by linking private health practitioners in a network to provide socially beneficial services under a common brand. In this context governments provide vouchers to users to indirectly purchase services and thus incentivizing supply of health services.
[35] D. Montagu and C. Goodman, *Prohibit, Constrain, Encourage, or Purchase: How Should We Engage with the Private Health-care Sector?*, (2016), http://dx.doi.org/10.1016/S0140-6736(16)30242-2, accessed May 15, 2017.
[36] D. Montagu and C. Goodman, *Prohibit, Constrain, Encourage, or Purchase: How Should We Engage with the Private Health-care Sector?*, (2016), op. cit.

exclusion based on gender, race, class, religion, or sexuality. Improving health in poorer countries is a shared responsibility for all G20 members. The G20 members should therefore coordinate their aid for health programs more strongly and identify areas for joint action.

Exhibit 10 | DETERMINE Consortium for Action on The Socioeconomic Determinants of Health: Capacity Building in Health

The EU-funded "DETERMINE Consortium for action on the socioeconomic determinants of health" has identified six components of health capacity building:

- raising awareness by collecting evidence on the given social health determinants and formulating suitable advocacy strategies;
- developing the information and evidence base in order to understand and analyze the dynamics of the social health inequities, and sharing this information;
- assessing the capacities within the respective organizations in order to identify the resources and structural changes required;
- developing necessary skills, which entails creating and providing knowledge and training on the social determinants of health to professionals.
- developing leadership and partnership;
- conducting policy assessments in the area of social health inequalities, and exploring how such aspects could be implemented into policy.

Source: European Portal on Action on Health Inequality, *Capacity Building*, accessed May 15, 2017, http://www.health-inequalities.eu/tools/capacity-building/.

Finally, patient self-care allows patients to take more responsibility for their health and should be encouraged by the G20 members. Patient self-care can help improve medical outcomes for individual patients and patient populations and is also expected to lower overall costs of treatment, thus having a positive effect on overall healthcare spending for G20 member states.

Exhibit 11 | Self-Care: Definition

Self-care in health refers to the activities individuals, families, and communities undertake with the intention of enhancing health, preventing disease, limiting illness, and restoring health. These activities are derived from knowledge and skills from the pool of both professional and lay experience. They are undertaken by lay people on their own behalf, either separately or in participative collaboration with professionals.

Source: WHO, *Health Education in Self-Care: Possibilities and Limitations. Report of a Scientific Consultation* (1983), accessed May 15, 2017.

B20 calls upon the G20 members to improve the health literacy of their citizens so that they can undertake preventative care, restorative care, participate in clinical research, and safely and effectively use over-the-counter medicines. By undertaking educational and awareness efforts, patients can be enabled to know about and use available resources to maintain their health and well-being individually. This includes the encouragement of health professionals to support and facilitate citizen-led responsible self-care. Additionally, the G20 members should build stronger public-private partnerships and collaborations to add to the body of evidence on self-care effectiveness and use this evidence to guide self-care related policy and practices.

Exhibit 12 | Case Studies: Positive Impact of Patient Empowerment

Just Ask Campaign, Demark: Denmark created a program to drive population-wide change in the relationship of patients and professionals. This involved mass distribution of tools supporting and prompting patients to ask more questions and overcome 'white coat silence'.

TASO, Uganda: TASO serves around 100,000 Ugandans with HIV per year through a network of 11 patient-run HIV/AIDS service centers around the country. Their 'expert clients' manage drug distribution, conduct home visits and educate other patients on better managing their condition.

Patient First Ambassador, Australia: Designed to create a step-change in patient understanding of their rights, responsibilities and ability to make informed choices, volunteer patients were recruited and trained to discuss these aspects of care with their peers on outpatient wards.

Source: APPG, *Patient Empowerment: For Better Quality, More Sustainable Health Services Globally* (2014), accessed May 15, 2017, http://www.appg-globalhealth.org.uk/reports/4556656050.

This also applies to the digital realm: the digital transformation is redefining the patient's position in healthcare, not only allowing them to better monitor their own health, but also regarding the interaction with the whole healthcare system. Although physicians remain the most important point of contact for most patients (mostly true for developed countries), digital information is bringing about a major shift in the patient's role, giving them access to an extensive network of medical information and allowing them to communicate with other patients regarding their health status and treatment options. As patients collect ever more data about themselves, most of it stored in a cloud environment, patients will no longer rely on a single and local physician, but will be able to access healthcare platforms when they have a specific medical need.[37] According to a McKinsey Digital Patient Survey in 2014, conducted in Germany, Singapore, and the United States, more than 75 percent of all patients expect to use digital services in the future.[38]

Exhibit 13 | Case Study: Diabetic Patient Self-Management

Problem: All patients need to obtain an optimal glycemic control without overstressing the healthcare system and the patient.

Innovation: A shift of the glycemic control towards the patient in combination with new portable diagnostic kits and auto inject therapies enables patients to monitor and auto-regulate the treatment without a medical intervention. The medical intervention shifted from treating the patient to monitoring the overall trend of the treatment. The education of the patient allowed a greater understanding of the sickness and of how to avoid its complications, such as coma and other acute episodes.

Benefit: The costs for the entire system are reduced as well, thanks to the fact that patients do not need to see a doctor for frequent consultation. This has an economic impact on the health system but also on the labor cost of the patient and his relatives.

Learning: Empowerment of the patient due to the knowledge transfer from the specialist to the patient leads to significant cost savings in terms of reduced hospitalization, ambulatory visits, and emergency room use.

Source: Deloitte, *How Digital Technology is Transforming Health and Social Care* (2015), accessed May 15, 2017, https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-connected-health.pdf.

[37] Roland Berger, *Digital and Disrupted: All Change for Healthcare* (2016) accessed May 15, 2017, https://www.rolandberger.com/publications/publication_pdf/roland_berger_digitalization_in_healthcare_final.pdf.
[38] Stefan Biesdorf, Florian Niedermann, *Health Care's Digital Future* (2014), accessed May 15, 2017, http://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/healthcares-digital-future.

Recommendation 2: Combating Antimicrobial Resistance (AMR)

The G20 members should combat antimicrobial resistance, including multidrug-resistant tuberculosis (MDR-TB), by incentivizing R&D of new medicines, advancing preventive measures, and promoting responsible use of antibiotics, as well as supporting capacity building in low- and middle-income countries.

Policy Actions	
2.1	**Scaling up R&D** – The G20 members should improve the conditions for developing new antimicrobials, vaccines, therapies, diagnostics, and better technologies for infection control by increasing the predictability and sustainability of R&D funding, improving the convergence of the regulatory environment across borders, and incentivizing cooperation between business and research organizations. • The G20 members should incentivize the product development of new antimicrobials, vaccines, therapies, diagnostics, and technologies for infection control through appropriate push and pull mechanisms such as development funds and launch rewards. • The G20 members should commit to support the Global Antibiotic Research and Development (GARDP) Partnership and the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X). The G20 members should work together to harmonize regulatory environments across countries to accommodate and incentivize global collaborative research and product development.
Owner G20 members, business	**Timing** 2017
2.2	**Setting Guidelines** – The G20 members should call on the World Health Organization (WHO) together with the Food and Agriculture Organization (FAO) and the World Organization for Animal Health (OIE) to devise guidelines for responsible and sustainable use of antibiotics, and to disseminate the information to all stakeholders. Guidelines are also needed to improve infection control measures and education. • The guidelines should include: appropriate use of antibiotics in hospitals, office-based care, primary care, and agriculture (including livestock and crop-based industries), which limits the use of antibiotics in quantity and point in time. This also requires rethinking preventative uses of antibiotics. • The G20 members should disseminate information about a rational use of antibiotics to prescribers, patients, and other important stakeholders. The G20 members should commit to intensify their efforts to implement the WHO's Global AMR Surveillance System (GLASS).
Owner G20, G20 members	**Timing** 2017
2.3	**Advancing Capacity Building** – The G20 members should assist low- and middle-income countries in their fight against AMR, including MDR-TB as well as other neglected diseases that may impact AMR, and support R&D capacity building in the countries that require it most. • The G20 members should foster availability of better vaccines, diagnostics, and innovative medicines which can reduce diseases caused by resistant strains and decrease the inappropriate use of antibiotics and other medicines. • Together with business, the G20 members should devise financing mechanisms that ensure access to new and existing antibiotics for those that cannot afford them. • The G20 members should focus their capacity building on AMR surveillance and support low- and middle-income countries that require help in developing surveillance systems.
Owner G20, G20 members	Timing 2017-2019

Context

Anti-infective drugs have been one of the most effective health innovations in the history of modern medicine since penicillin, the first antibiotic, was introduced in the 1940s and broadly used in the 1950s. Antimicrobials and other medicines have become a crucial part of modern life. However, the objective of universal health is threatened by the growing problem of bacterial infections becoming resistant to an increasing number of antimicrobials, including those of last resort. The rate of discovery of novel compounds, especially of antibiotics, has decreased with the last new class of antibiotics discovered in the late 1980s.[39] Nearly every antibiotic available today is a derivative of an antibiotics class discovered between the early 1900s and 1984.[40]

Only a limited number of pharmaceutical companies are still active in developing new antibiotics. The reasons for this lie in scientific, regulatory, and economic challenges. Firstly, discovering new antibiotics is difficult as bacteria are constantly evolving. Secondly, it is difficult to develop new antibiotics because of the regulatory environment, including challenges with clinical trials and complex regulatory pathways. Thirdly, the economic reality of antibacterial development is challenging. Novel antibiotics are generally undervalued by the existing systems in comparison with the benefits these antibiotics bring to society. This leads to limited returns for new antibiotics relative to other therapeutic areas and less investment in antibiotic R&D.[41]

Antimicrobial resistance is increasing rapidly. For example, a range of E.coli bacteria in China have recently developed a resistance to all antibiotics, including those of last resort.[42] Further, the common bacterial infections caused by enterobacteria in hospital settings are rising everywhere.[43] Some of these bacteria have become resistant to last-resort antibiotics and are an increasing cause of mortality in regions such as Asia.[44] Multidrug-resistant tuberculosis (MDR-TB) is a fast-spreading airborne infectious disease that poses a grave threat, being responsible for more than one-third of all AMR deaths; middle-income countries within the G20 are among those most affected.[45] Most recently, the WHO has published a list of priority pathogens for R&D of new antibiotics (see Exhibit 14 below), although the omission of MDR-TB is controversial in the health landscape amongst many G20 members and organizations.

[39] F. Walsh, *Antibiotics Resistance 'as Big a Risk as Terrorism'*, *BBC (*2013), accessed May 15, 2017, http://www.bbc.com/news/health-21737844.
[40] The Pew Charitable Trusts, *A Scientific Roadmap for Antibiotic Discovery* (2016), accessed May 15, 2017, http://www.pewtrusts.org/en/research-and-analysis/reports/2016/05/a-scientific-roadmap-for-antibiotic-discovery.
[41] J. Bérdy, *Thoughts and Facts about Antibiotics: Where We Are Now and Where We Are Heading*, *The Journal of Antibiotics*, 65 (2012), 385-395.
[42] H. Branswell, *Superbug E. Coli, Resistant to Last-Resort Antibiotic, Show Up in China*, Stat News (2017), https://www.statnews.com/2017/01/27/china-antibiotic-resistance/ accessed May 15, 2017.
[43] J. Thaden et. al. *Rising Rates of Carbapenem-Resistant Enterobacteriaceae in Community Hospitals: a Mixed-Methods Review of Epidemiology and Microbiology Practices in a Network of Community Hospitals in the Southeastern United States*, Infect Control Hosp Epidemiol, 35:8 (2014), 978-983.
[44] C.L. Ventola, *The Antibiotic Resistance Crisis*, P&T 40/4, (2015), 277-283; C-I. Kang and J-H. Song, *Antimicrobial Resistance in Asia: Current Epidemiology and Clinical Implications*, Infection & Chemotherapy 45/1, (2013), 22-31.
[45] WHO, *Antimicrobial Resistance* (2016), accessed May 15, 2017, http://www.who.int/mediacentre/factsheets/fs194/en/,; Forbes, *World TB Day: How Budget Cuts Threaten Progress In Tuberculosis Globally* (2017), accessed May 15, 2017, https://www.forbes.com/sites/judystone/2017/03/24/world-tb-day-how-budget-cuts-threaten-progress-in-tuberculosis-globally/#1b877922267e.

Exhibit 14 | New Antibiotics Required: The WHO's List of Priority Pathogens for R&D for New Antibiotics

Priority 1: Critical

- Acinetobacter baumannii, carbapenem-resistant
- Pseudomonas aeruginosa, carbapenem-resistant
- Enterobacteriaceae, carbapenem-resistant, ESBL-producing

Priority 2: High

- Enterococcus faecium, vancomycin-resistant
- Staphylococcus aureus, methicillin-resistant, vancomycin-intermediate and resistant
- Helicobacter pylori, clarithromycin-resistant
- Campylobacter spp., fluoroquinolone-resistant
- Salmonellae, fluoroquinolone-resistant
- Neisseria gonorrhoeae, cephalosporin-resistant, fluoroquinolone-resistant

Priority 3: Medium

- Streptococcus pneumoniae, penicillin-non-susceptible
- Haemophilus influenzae, ampicillin-resistant
- Shigella spp., fluoroquinolone-resistant

Source: WHO, *WHO Publishes List of Bacteria for Which New Antibiotics Are Urgently Needed* (February 27, 2017), http://www.who.int/mediacentre/news/releases/2017/bacteria-antibiotics-needed/en/, accessed May 15, 2017.

Various factors contribute to the emergence and spread of resistant microorganisms. These include irrational and self-use of antibiotics, lack of adherence to a prescribed regimen, partially inappropriate use of antibiotics in hospitals, office-based, primary care, as well as partially inappropriate use of antibiotics in livestock. Some countries use more than two-thirds of antibiotics that are medically important for humans in livestock.[46] Problems also arise due to the lack of policies and restrictions that regulate the rotation of antibiotics and infection-controls in hospitals.[47]

Several initiatives have been set up to tackle AMR around the world. In 2015, the WHO published its Global Action Plan on Antimicrobial Resistance and aims to implement it by collaborating with the Food and Agriculture Organization (FAO) and the World Organization for Animal Health (OIE).[48] The Global Action Plan has five strategic objectives: improve awareness and understanding of AMR, strengthen knowledge through research and surveillance, reduce incidence of infection, optimize the use of antimicrobial medicines, and develop the economic case for investments in R&D for new medical products. Furthermore, the WHO's Global AMR Surveillance System (GLASS) aims at strengthening knowledge. It targets comprehensive and multisector national action plans for every country to be in place by the 2017 World Health Assembly (see Exhibit 15).[49] The UN convened a high-level meeting on antimicrobial resistance in September 2016 and followed up with a pledge for an international and coordinated approach to tackle AMR.[50] Most recently, the UN convened an interagency coordination group on AMR headed by the Deputy Secretary General.[51]

[46] *The Review on Antimicrobial Resistance* (2016), accessed May 15, 2017, https://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf.
[47] *The Review on Antimicrobial Resistance* (2016), op cit.
[48] WHO, *Global Aciton Plan on Antimicrobial Resistance*, (2015), accessed May 15, 2017, http://www.wpro.who.int/entity/drug_resistance/resources/global_action_plan_eng.pdf.
[49] WHO, *Global Action Plan on Antimicrobial Resistance*, (2015), op. cit.
[50] UN, *High Level Meeting on Antimicrobial Resistance* (2016), accessed May 15, 2017, http://www.un.org/pga/71/event-latest/high-level-meeting-on-antimicrobial-resistance/.
[51] UN, *UN Announces Interagency Group to Coordinate Global Fight Against Antimicrobial Resistance* (2017), accessed May 15, 2017, http://www.un.org/apps/news/story.asp?NewsID=56365&utm_campaign=KFF-2017-Daily-GHP-Report&utm_source=hs_email&utm_medium=email&utm_content=46699193&_hsenc=p2ANqtz-9CBzgrTS08oDp2gWrwdULmeCFJCrTPmZVNxffmkNhsEpxPh4eoJoFvaQGx6jd2azcIQppleMQRvltRAa4mdskr1CJO6g&_hsmi

In 2015, under the German presidency, the G7 endorsed the WHO's Global Action Plan on Antimicrobial Resistance, outlining the One Health approach, which encompasses human and animal health, agriculture, and the environment. The G7 acknowledged the need for a holistic approach to retain the effectiveness of antimicrobial agents.[52] The G20 listed AMR as a significant global challenge at the 2016 Leaders' summit in Hangzhou, China, promising to promote prudent antibiotic use and calling on the WHO, the FAO, the OIE, and the Organization for Economic Cooperation and Development (OECD) to report back in 2017 on possible solutions to the problem, including the economic aspects.[53] AMR is part of the G20 agenda under the German G20 presidency in 2017. In early 2017, the G20 agricultural ministers acknowledged that the agricultural sector needed to contribute to containing the development and spread of antimicrobial resistance in line with the 'one health' approach. The G20 announced that its members would strive to restrict the use of antibiotics in veterinary medicine to therapeutic uses alone.[54]

Exhibit 15 | Global AMR Surveillance System (GLASS)

The goal of the Global Antimicrobial Resistance Surveillance System (GLASS) is to enable standardized, comparable and validated data on AMR to be collected, analysed and shared with countries. GLASS aims to inform decision-making, drive local, national and regional action, and provide the evidence base for action and advocacy. Its objective is:

- to foster national surveillance systems and harmonized global standards;
- to estimate the extent and burden of AMR globally by selected indicators;
- to analyze and report global data on AMR on a regular basis;
- to detect emerging resistance and its international spread;
- to inform implementation of targeted prevention and control programs; and to assess the impact of interventions.

Source: Boston Consulting Group, *Breaking Through the Wall: A Call for Concerted Action on Antibiotics Research and Development*, commissioned by the German Federal Ministry of Health (2017), accessed May 15, 2017, http://www.bundesgesundheitsministerium.de/fileadmin/Dateien/5_Publikationen/Gesundheit/Berichte/GUARD_Follow_Up_Report_Full_Report_final.pdf.

The world agrees on the significance of the challenge posed by AMR, but action plans tailored to individual countries and progress on establishing antimicrobial stewardship are still deficient. The G20 members should agree to incentivize long-term investments, either building on existing systems (e.g., reimbursement reforms) or through novel incentive models (e.g., market entry reward, transferable exclusivity, insurance license model) to strengthen R&D. Low-and middle-income countries face the greatest losses in terms of human life and economic growth due to their fragile health systems and infrastructure.[55] They require support in formulating and implementing national action plans corresponding to their capacities and capabilities. Lastly, the G20 members need to move towards actionable regulations that limit the inappropriate use of antibiotics in agriculture. The G20 community is in a strong position to drive change.

=46699193#.WM_wEfkrKUn.

[52] Federal German Government, *New Strategy to Fight Antimicrobial Resistance* (2015), accessed May 15, 2017, https://www.g7germany.de/Content/EN/Artikel/2015/05_en/2015-05-13-kabinett-dart-2020.html.

[53] European Commission, *G20 Leaders' Communique Hangzhou Summit* (2016), accessed May 15, 2017, http://europa.eu/rapid/press-release_STATEMENT-16-2967_de.htm.

[54] G20, *G20 Agriculture Ministers' Declaration 2017* (2017), accessed May 15, 2017, http://www.g20.utoronto.ca/2017/170122-agriculture-en.pdf.

[55] The Review on Antimicrobial Resistance, May 2016, op cit.

Policy Action 2.1: Scaling up R&D

The G20 members should improve the conditions for developing new antimicrobials, vaccines, therapies, diagnostics, and better technologies for infection control by increasing the predictability and sustainability of R&D funding, improving the convergence of the regulatory environment across borders, and incentivizing cooperation between business and research organizations.

New scientific approaches using genomics, proteomics, new methods for screening soil organisms, and bioinformatics can speed up the identification of new targets and the development of new therapeutic molecules, particularly against resistant microorganisms. The economic challenges related to AMR are different from the challenges encountered by other disease areas where market inefficiencies also exist. Therefore, more innovative solutions are needed to encourage industry to develop new antibiotics, vaccines, biomarkers, and other therapies.[56]

Governments should continue their efforts to stimulate research and product development investment through "push" mechanisms, such as grants, and add complementary "pull" mechanisms that reward the successful development and approval of a medicine to realize the full impact of funding (see Exhibit 16). These should be guided by Target Product Profiles (TPPs) that steer research into the direction of the greatest public health need. Such mechanisms would ensure sufficient return on investment and incentivize companies to take on the risk that comes with R&D of new antibiotics and vaccines as well as improving the predictability of demand. G20 members should also commit to support the Global Antibiotic Research and Development Partnership (GARDP), set up jointly by the WHO and the Drugs for Neglected Diseases initiative (DNDi) in May 2016, to develop new antibiotics and to promote the prudent use of antibiotics (see Exhibit 17). Other examples include the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) detailed below (see Exhibit 18), and the EU's IMI New Drugs for Bad Bugs (ND4BB) project.[57]

Exhibit 16 | Push and Pull Mechanisms

Examples for push and pull mechanisms were developed in a recent report commissioned by the German Federal Ministry of Health:

- A Global Research Fund could support academic institutions and small and medium-sized enterprises (SMEs) in their basic research in the most urgent bacterial needs. The fund would be guided by the TPPs and could be effective with a starting budget of US$ 200 million that would fund 250 additional researchers and increase existing funding for pre-clinical research by 50 percent.
- A Global Development Fund could be launched in order to support the promising drug candidates along the clinical development pipeline. Such a fund would require a yearly budget of US$ 200 million coupled with a mechanism to return the funding in the case of commercial success.

A Global Launch Reward of US$ 1 billion per commercialized product that matches a TPP would make much-needed investments in this type of R&D less risky because there is a chance that it could generate a substantial operating profit.

Source: Boston Consulting Group, *Breaking Through the Wall: A Call for Concerted Action on Antibiotics Research and Development*, commissioned by the German Federal Ministry of Health (2017), accessed May 15, 2017, http://www.bundesgesundheitsministerium.de/fileadmin/Dateien/5_Publikationen/Gesundheit/Berichte/GUARD_Follow_Up_Report_Full_Report_final.pdf.

Governments should encourage good antimicrobial stewardship by reducing the proportion of manufacturer revenue derived from antibiotic sales volume (often called "de-linked" or "partially de-

[56] B. Spellberg, *The Future of Antibiotics*, Critical Care 18:228 (2014), 3, accessed May 15, 2017, https://ccforum.biomedcentral.com/articles/10.1186/cc13948.
[57] IMI, *ND4BB - New Drugs for Bad Bugs (2017)*, accessed May 15, 2017, http://www.imi.europa.eu/content/nd4bb.

linked" models), while adequately incentivizing development, which is especially important for antibiotics that are likely to be used rarely or to be reserved for late-line use.

Furthermore, regulations such as clinical trial regulations should be harmonized as much as possible internationally. This would allow for increased cooperation in R&D for new antimicrobials.

Exhibit 17 | Global Antibiotic Research and Development Partnership (GARDP)

Jointly launched by the WHO and the Drugs for Neglected Diseases initiative (DNDi) in May 2016, the GARD Partnership seeks to develop new antibiotics to address the threat of resistant pathogens. GARD also aims at promoting the prudent use of antibiotics and ensuring that everyone who needs this treatment has access to it. GARD will work with all stakeholders, including technology companies, startups, other product development partnerships, academia, civil society, and health authorities – from countries of all income levels.

It will:

- address global public health and specific needs of low- and middle-income countries;
- target products that industry will likely not develop due to lack of profitability or other reasons;
- pilot the use of alternative incentive models delinking cost of R&D from volume-based sales and prices of antibiotics, which support conservation of and access to new antibiotics;
- ensure that new antibiotics developed by GARDP are affordable to all in need.

Source: DNDi, *Developing New Antibiotic Treatments, Promoting Responsible Use, and Ensuring Access for All*, accessed May 15, 2017, https://www.dndi.org/diseases-projects/gardp/.

Exhibit 18 | Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X)

The Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X) is a non-profit public-private partnership dedicated to protecting human health from the most serious bacterial threats by accelerating global antimicrobial innovation. It is supported by the U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA), the Wellcome Trust, the U.S. National Institute for Allergy and Infectious Diseases, Boston University, the Broad Institute of Harvard and MIT, MassBIO and CLSI. CARB-X brings key stakeholders from the government, not-for-profit, and academic sectors together to fund and support the translation of the best science for the most innovative antibacterial tools. Launched in August 2016, CARB-X has now raised US$ 455 million to be spent over the next five years on antibacterial innovation, including therapeutics (small and large molecules), diagnostics, vaccines, and other prevention technologies. The first US$ 23 million in non-dilutive grants were awarded to eleven companies in March 2017, with up to US$ 24 million in additional milestone-based awards possible. A second round of awards will be announced in July 2017, and a third in November 2017. CARB-X focuses on early start ups at proof-of-concept (hit to lead), supporting them to the end of Phase I human trials, providing grants paired with expert business and technical advisory services. All services are provided at no cost to the product developers (fullynon-dilutive).

Source: Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), *About CARB-X* (2017), accessed May 15, 2017, http://www.carb-x.org/about.

Policy Action 2.2: Setting Guidelines

The G20 members should call on the WHO together with the Food and Agriculture Organization (FAO) and the World Organization for Animal Health (OIE) to devise guidelines for responsible and sustainable use of antibiotics and to disseminate the information to all stakeholders. Guidelines are also needed to improve infection control measures and education.

The G20 should mandate the WHO, together with the FAO and the OIE, to devise guidelines for national "medicine policies", which foster a rational use of antibiotics. These should include measures aimed at regulating the inappropriate use of antibiotics in hospitals, office-based, and primary care, as well as limiting the use of antibiotics in agriculture (including livestock and crop-based industries).

Furthermore, the G20 members should agree to strengthen control policies. Existing infections can be prevented and controlled through more systematic use of existing antimicrobials, including new and existing vaccines. This includes bacterial infections in hospital settings and promotion of universal measures of hygiene and sanitation relevant to prevention of infection. Today it remains as true as ever: if fewer people get infected, fewer people will require antibiotics. Even basic sanitary measures such as regular hand washing can have a significant impact of limiting the spread of superbugs in hospitals and elsewhere.[58] These basic sanitary measures need to be expanded to and enforced in as many hospitals and healthcare facilities as possible. It is the responsibility of the G20 members to ensure that these sanitary and hygiene measures are enforced and adhered to.

AMR calls for a multisectoral response – including governments and the private sector; business and civil society; industry as well as the agricultural sector; education and labour organizations. To raise awareness, broader and more comprehensive information campaigns are necessary. These campaigns should target medical doctors, patients, and other members of society, particularly those involved in animal husbandry and industrial use of antimicrobials.

In addition, surveillance needs to be strengthened. One of the five strategic objectives of the WHO's Global Action Plan is to strengthen the evidence base through enhanced global surveillance and research. Both global and regional surveillance programs have been in place for many years (e.g. the Central Asian and Eastern European Surveillance of Antimicrobial Resistance, the European Antimicrobial Resistance Surveillance Network, and the Latin American Antimicrobial Resistance Surveillance Network). While these programs have been successful in gathering data, significant gaps remain. These gaps, together with a lack of common standards for methods, data-sharing and coordination at local, national, regional and global levels, are hampering efforts to produce meaningful data at a global level to enable comprehensive monitoring and analysis of the occurrence and trends of resistance worldwide. The G20 members should therefore commit to intensify their efforts to implement the WHO's GLASS.

Policy Action 2.3: Advancing Capacity Building

The G20 members should assist low- and middle-income countries in their fight against AMR, including MDR-TB as well as other neglected diseases that may impact AMR, and support R&D capacity building in the countries that require it most.

Low- and middle-income countries, which stand to lose the most from drug-resistant infections, are also worst-equipped to deal with them. Resources in these countries are scarce and a significant share of the affected populations does not have the resources to afford innovative medical tools. The G20

[58] B. Spellberg, *The Future of Antibiotics*, Critical Care 18:228 (2014), 3, accessed May 15, 2017, op. cit.

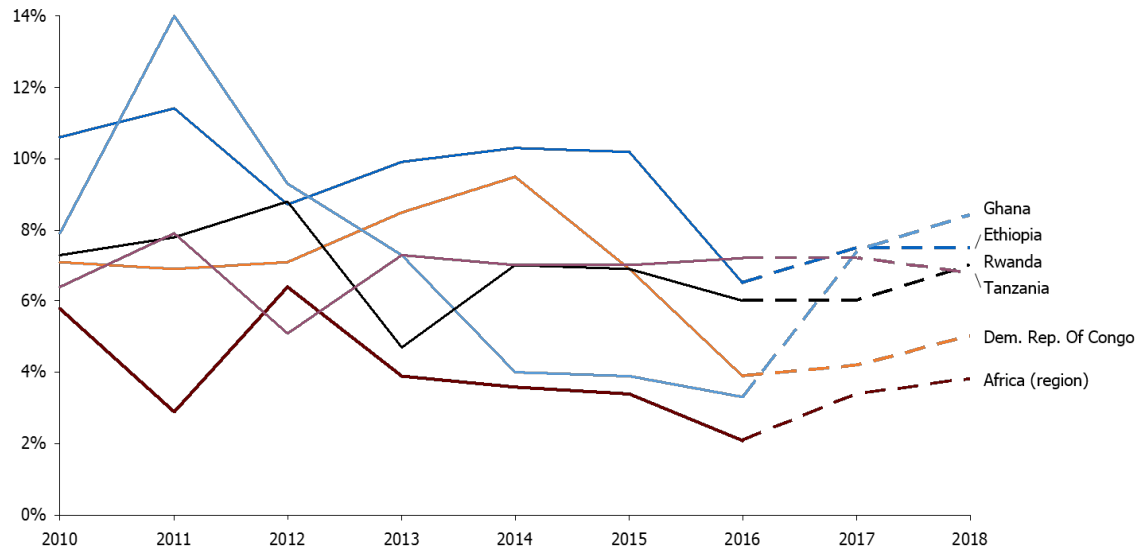
members should therefore work more strongly together with these countries to ensure patients access to effective antimicrobial products through the appropriate channels to limit the growth of resistance. The G20 members should foster availability of better vaccines, diagnostics, and innovative medicines which can reduce diseases caused by resistant strains and decrease the inappropriate use of antibiotics and other medicines.

Capacity building is required in both research and surveillance to strengthen knowledge about resistant diseases and how to tackle them.[59] Low- and middle-income countries are unlikely to have the capacities to implement the WHO's GLASS system. They will need assistance in doing so. The G20 members should thus provide assistance to these countries within their aid for health programs to. They should also coordinate their efforts more strongly.

Exhibit 19 | G20 Compact with Africa

Africa is a continent of vast opportunities, but also many challenges, including poverty, hunger, poor education, ill health, rampant unemployment and inequality, bad governance, and climate change. Just to absorb new entrants into the labor force, around 20 million jobs need to be created every year until 2035. Sub-Saharan Africa is home to a large proportion of the poorest countries in the world. In order to realize the many opportunities, but also to tackle the challenges, more investment is needed – among others in health, education, climate change mitigation, and infrastructure.

Africa Region and Top Five Fastest Growing African Countries

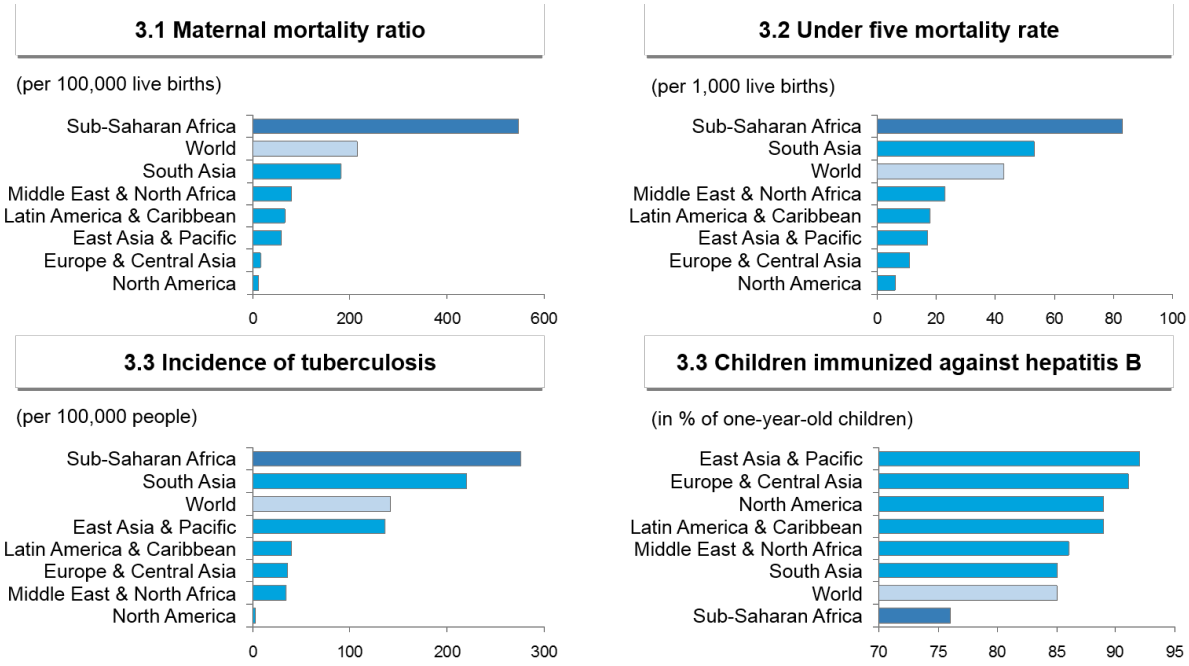


The German G20 presidency has therefore placed sustainable economic growth and development in Africa high on the agenda. The G20 Compact with Africa (CWA) Initiative aims to increase investment in Africa, in particular in infrastructure, by improving the macroeconomic, political, and financial framework conditions, in line with the African Union's (AU) Agenda 2063. The initiative is demand-driven. Compacts will be signed with individual African countries and will be tailored to the needs and interests of the respective country.

Africa struggles with a long list of serious diseases. While the continent has made progress on some diseases such as polio, there has been less progress with regard to others. The leading causes of death are HIV/AIDS, diarrheal diseases, malaria, ischemic heart disease, meningitis, tuberculosis, diabetes mellitus, neonatal sepsis and infections, cirrhosis of the liver, as well as epilepsy. Healthcare on the continent differs widely, depending on the country and also the region. In general, however, health outcomes are worse in Africa than anywhere else in the world. While technology is transforming how healthcare is delivered, giving more people better care, access to

[59] London School of Hygiene and Tropical Medicine, *AMR Surveillance in Low- and Middle-income Settings* (2016), accessed May 15, 2017, http://amr.lshtm.ac.uk/wp-content/uploads/sites/12/2016/11/AMR-Surveillance-Protocol.pdf.

health remains particularly poor for those living in rural and remote areas. According to the World Bank, sub-Saharan Africa has very low per capita health spending and slow growth in health spending compared with other regions. Many countries in Africa depend on external resources for a substantial proportion of total health expenditure. Household out-of-pocket health expenditure is very high.



Africa's health challenges require concerted action from all stakeholders. The B20 lauds G20 Germany for placing health on the agenda of this year's summit. Aiming to improve health globally must be synonymous with committing to long-term engagement and investment. Medical innovation and policy changes take years to develop and take effect. Only a sustained and long-term commitment to tackling health challenges can ensure progress. Investing in health should therefore also be considered in the Compact with Africa Initiative. Building on global and regional initiatives, the G20 should work together with Compact partners to expand access to essential healthcare services to their citizenry by sharing best practices, building improved and sustainable policies, as well as incentivizing private sector involvement.

Source: AfDB, IMF, WBG, *The G-20 Compact with Africa*, *Report March 17-18, 2017* (Baden-Baden 2017), accessed May 15, 2017, http://www.bundesfinanzministerium.de/Content/EN/Standardartikel/Topics/Featured/G20/2017-03-30-g20-compact-with-africa-report.pdf?__blob=publicationFile&v=2 ;International Monetary Fund, *IMF DataMapper,* accessed May 15, 2017, http://www.imf.org/external/datamapper/datasets.; The World Bank, *HNP Sustainable Development Goals*, accessed May 15, 2017, http://datatopics.worldbank.org/hnp/HNPSDG.

Recommendation 3: Fighting Neglected Tropical Diseases

The G20 members should fight NTDs by increasing funding for public health interventions, strengthening cooperation with governments of endemic countries and capacity building, as well as agreeing on more financial support for R&D.

Policy Actions	
3.1	**Advancing Cross-Cutting Approaches** – The G20 members should advance cross-cutting approaches to tackle NTDs as specified by the WHO's five public-health interventions to prevent, control, eliminate, and eradicate NTDs. • The G20 members should increase funding in the fight against NTDs in line with the WHO's guidance on the most effective public-health interventions in the field. • In addition, the G20 members should work with governments of NTD-endemic countries to encourage co-investment in the battle against these diseases and in capacity building. • The G20 members should facilitate and participate in multi-stakeholder partnerships, including domestic governments, which implement cross-sectoral solutions to combat NTDs.
Owner G20; G20 members	Timing 2017-2018
3.2	**Increasing Funding for Research and Product Development** – The G20 members should agree to scale up research and product development to battle NTDs. • The G20 members should increase funding for R&D for NTDs, not only in discovery, but especially in the product development phase through actors such as product development partnerships (PDPs) and support capacity building to ensure uptake. • The G20 members should work together with the business community and civil society to devise access mechanisms for new medical tools. • The G20 members should encourage R&D for new medical tools by improving the regulatory landscape, including patents and advanced market commitments where appropriate.
Owner G20 members	Timing 2017 onwards

Context

More than one billion people worldwide are affected by neglected tropical diseases every year in 149 countries, most of them in low-income countries.[60] Children are deprived of their development prospects since maternal mortality is much higher among infected women. Research suggests that the productivity of people suffering from one or more NTD decreases significantly, having a damaging effect also on the economies as a whole.[61] In addition, people living in the poorest countries are seldom affected only by one NTD. Many are infected with multiple diseases, which negatively impacts their ability to work and earn a living.[62] The disease burden of NTDs amounts to more than 22 million disability-adjusted life years and equals 0.8 percent of the global burden of disease.[63] In addition, many developing countries suffer from a double burden of neglected tropical diseases and non-communicable diseases.[64] In this

[60] WHO, *Neglected Tropical Diseases* (2017), accessed May 15, 2017, http://www.who.int/neglected_diseases/diseases/en/.
[61] E.J. Lenk et. al., *Productivity Loss Related to Neglected Tropical Diseases Eligible for Preventive Chemotherapy: A Systematic Literature Review*, *PLOS Neglected Diseases* (2016), 1-19.
[62] The Bill and Melinda Gates Foundation, *Neglected Tropical Diseases – Strategy Overview* (2017), accessed May 15, 2017, http://www.gatesfoundation.org/What-We-Do/Global-Health/Neglected-Tropical-Diseases.
[63] WHO, *Accelerating Progress on HIV, Tuberculosis, Malaria, Hepatitis and Neglected Tropical Diseases. A New Agenda for 2016 – 2030* (2016), accessed May 15, 2017, http://apps.who.int/iris/bitstream/10665/204419/1/9789241510134_eng.pdf?ua=1.
[64] A. Boutayeb, *The Double Burden of Communicable and Non-communicable Diseases in Developing Countries*, Transactions of the Royal Society of Tropical Medicine and Hygiene, 100:3, (2006), 191-1991; S.M. Islam et. al., *Non□Communicable Diseases (NCDs) in developing countries: a symposium report*, Global Health 10:81, (2014), 1-7.

context, it is even more important that high income countries start to focus on NTDs as a serious health challenge.

Exhibit 20 | Neglected Tropical Diseases (NTDs)

NTDs are a diverse group of communicable diseases that prevail in tropical and subtropical conditions in 149 countries. They affect more than one billion people, mainly populations living in poverty, without adequate sanitation and in close contact with infectious vectors and domestic animals and livestock.

The WHO prioritizes 17 NTD: Buruli ulcer, Chagas disease, Dengue and Chikungunya, Dracunculiasis (guinea-worm disease), Echinococcosis, Foodborne trematodiases, Human African trypanosomiasis (sleeping sickness), Leishmaniasis, Leprosy (Hansen's disease), Lymphatic filariasis, Onchocerciasis (river blindness), Rabies, Schistosomiasis, Soil-transmitted helminthiases, Taeniasis/Cysticercosis, Trachoma, and Yaws (Endemic treponematoses).

The WHO's roadmap for the fight against NTDs aims at the reduction or elimination of the majority of the diseases by 2020. The roadmap was published in 2012 and recommends five strategies to control, eliminate, and eradicate NTDs:[65]

- Preventative chemotherapy and other preventive treatment regimen are shown to work against several helminthiasis and trachoma.
- Disease management should be intensified for complex diseases such as Chagas disease and Buruli ulcer by improved case detection and decentralized care management.
- Vector- and host-control is crucial to tackle vector-borne NTDs.
- Veterinary medicines at the intersection of human and animal health have to be improved in order to deal with NTDs where transmission or origin involves animals.
- Safe water, sanitation, and hygiene are essential tools in tackling NTDs effectively, though 1.8 billion people around the world use a fecally contaminated source of drinking water and a further 2.4 billion people do not have access to basic sanitation facilities.[66]

The objectives can only be achieved if appropriate tools and adequate resources are made available in a well-coordinated manner. Since many of the required technologies are already available, the costs are relatively low. In addition, partnership programs encouraging civil society, industry, affected countries, and the WHO to cooperate already exist in many countries.

[65] S.M. Islam et. al., *Non□Communicable Diseases (NCDs) in Developing Countries: a Symposium Report*, Global Health, 10:81, (2014), 1-7; WHO, *Accelerating Work to Overcome the Global Impact of Neglected Tropical Diseases – A Roadmap for Implementation* (March 2012), 3-4.
[66] United Nations, *Sustainable Development Goal 6: Ensure Access to Water and Sanitation for All*, (2017), accessed May 15, 2017, http://www.un.org/sustainabledevelopment/water-and-sanitation/.

Exhibit 21 | Case Studies: Partnerships to Fight Neglected Tropical Diseases

Fighting African Sleeping Sickness: In the last ten years, more than 80 percent of reported cases of Human African Trypanosomiasis (HAT) occurred in the Democratic Republic of the Congo (DRC). In 2016 Bayer agreed with the WHO to double the support of the mobile intervention teams in DRC until 2020 and further support training of healthcare providers as well as general education and awareness. Furthermore, Bayer agreed to support surveillance and monitoring of HAT. The objective of the partnership is to support the WHO in eliminating Human African Sleeping Sickness by 2020 as outlined in the London Declaration on NTDs.[1]

Chagas Coalition and the Chagas Research Platform: Infecting approximately 5.7 million people worldwide and causing 7,000 deaths each year, Chagas disease is a serious public health burden. The Chagas Coalition and the Chagas Research Platform, set up by the DNDi to support R&D activities on Chagas disease, provides opportunities to improve access to diagnosis and treatment and facilitate research activities.[2]

Global Alliance to Eliminate Lymphatic Filariaisis (GAELF): GAELF was founded in 2000 as an initiative to tackle lymphatic filariaisis. Its mission is to bring together a diverse group of public-private health partners to support the Global Programme to Eliminate Lymphatic Filariasis by mobilizing political, financial and technical resources. Its partners are government ministries (e.g. the UK's Department for International Development), pharmaceutical companies (e.g. Merck, GlaxoSmithKline, Johnson & Johnson, Eisai, Inverness Medical Professional Diagnostics), non-governmental organizations (e.g. LEPRA), and academic institutions from around the world. [3]

Global Schistosomiasis Alliance (GSA): Schistosomiasis is a vector-borne tropical disease, spread by contact with water that contains parasitic worms. Schistosomiasis affects more than 249 million people worldwide. It is endemic in 70 developing countries, including countries in Africa, the Middle East, Asia and the Caribbean. An estimated 90 percent of the estimated schistosomiasis cases are found in sub-Saharan Africa. The GSA brings together public and private stakeholders to fight schistosomiasis, including the Bill & Melinda Gates Foundation, Merck, and USAID.[4]

STH Coalition: Soil-transmitted helminthiasis (STH), a disease caused by intestinal worms, affects the health of more than one billion people – one of every seven worldwide – and over 875 million children are at risk of infection. The STH Coalition, which brings together a diverse group of stakeholders, aims at catalyzing demand for and scale up deworming programs, preventing reinfection and reducing STH transmission, as well as supporting effective programs to accelerate impact. Partners and funders of the initiative include Children Without Worms, the Boston Consulting Group, Bill & Melinda Gates Foundation, Johnson & Johnson, and GlaxoSmithKline.[5]

Sources: 1) Health Partnerships Directory, *Fighting African Sleeping Sickness*, accessed May 15, 2017, http://partnerships.ifpma.org/partnership/fighting-african-sleeping-sickness; 2) DNDi, Chagas Clinical Research Platform, accessed May 15, 2017, https://www.dndi.org/strengthening-capacity/chagas-platform/; 3) aGlobal Alliance to Eliminate Lymphatic Filariaisis, accessed May 15, 2017, http://www.filariasis.org/partners.html; 4) Global Schistosomiasis Alliance, accessed May 15, 2017, http://eliminateschisto.org; 5) STH Coalition, *Framework for Action* (December 2014), http://www.childrenwithoutworms.org/sites/default/files/STHCoalition_FFAReport110515.pdf.

The commitments of pharmaceutical manufacturers to provide the necessary medicines free of charge came with the understanding of the cost-effectiveness of preventive chemotherapy interventions to control and eliminate NTDs. In 2012, a number of large pharmaceutical manufacturers pledged to continue or extend large medicinal donations under the London Declaration on NTDs.[67] The cumulative value of these donations of $17.8bn from 2014 to 2020 represents the greatest growing public health donation and additionally targets the most vulnerable afflicted populations in the world.[68] In 2015 alone, biopharmaceutical companies donated an estimated 2.4 billion tablets, enough for 1.5 billion treatments to prevent and treat NTDs – an increase of 11.7 percent from 2014. Between 2012 and 2014, the number

[67] Uniting to Combat NTDs, *The London Declaration* (2017), accessed May 15, 2017, http://unitingtocombatntds.org/london-declaration.
[68] Uniting to Combat NTDs, *Country Leadership and Collaboration on Neglected Tropical Diseases - Third Progress Report of The London Declaration* (2015), accessed May 15, 2017, http://unitingtocombatntds.org/sites/default/files/document/UTCNTD%20FULL%20REPORT.pdf, 5.

of people who needed treatment decreased by 230 million.[69] While progress has been made, distribution and access of available medicines needs to improve significantly in order to ensure that they reach patients in need. The G20 members should therefore strengthen the implementation of national disease programs while requesting more engagement from the national governments of affected countries.

Overall, the current rate of progress is not sufficient to reach the WHO's 2020 targets. In particular, there is an urgent need to fill the financial and human resource gap which prevents that available, donated drugs are effectively distributed. Bridging this gap will require an upgraded partnership that maximizes existing and new donor resources and increases domestic financing. Blending resources can help advance complementary goals across integrated national NTD programs. Donor support can energize and expand the reach of national programs to help achieve elimination goals. In tandem, affected countries should commit to increasing their domestic financing to support control programs and strengthen their national NTD programs.

Policy Action 3.1: Advancing Cross-cutting Approaches

The G20 members should advance cross-cutting approaches to tackle NTDs as specified by the WHO's five public-health interventions to prevent, control, eliminate, and eradicate NTDs.

The G20 should work towards placing NTDs at the forefront of global health policy, and G20 members should commit to increase funding in order to accelerate the prevention, control, elimination, and eradication of NTDs, as outlined by the WHO (see Exhibit 22).[70] Current levels of funding are insufficient to tackle the enormous burden of these diseases. Health services need to be more accessible and staffed with qualified healthcare professionals. More attention needs to be placed on delivery of medicines down the last mile. The G20 members should also work on co-financing schemes for implementation together with governments of affected countries. In addition, capacity-building is crucial to ensure uptake of medical tools once they are available.

Exhibit 22 | The WHO's Five Public-Health Interventions to Prevent, Control, Eliminate, and Eradicate NTDs

The WHO identifies five public-health interventions to prevent, control, eliminate, and eradicate NTDs:

1. preventive chemotherapy;
2. vector ecology and management;
3. veterinary public-health services;
4. provision of safe water, sanitation, and hygiene;
5. innovative and intensified disease management (IDM).

Source: WHO, *Investing to Overcome the Global Impact of Neglected Tropical Diseases, Third Report WHO Report on Neglected Tropical Diseases*, (Geneva: 2015), http://www.who.int/neglected_diseases/9789241564861/en/.

- *Preventive Chemotherapy and Transmission Control (PCT):* PCT focuses on those NTDs for which a global strategy exists and for which tools are readily available for large-scale deployment. The most prominent examples of NTDs that have been allocated to the PCT group are lymphatic filariasis, onchocerciasis, schistosomiasis, and soil-transmitted helminthiasis. The main tool is the periodic administration of efficacious, safe, and inexpensive (usually donated) drugs to entire at-risk populations.[71] It is a viable option due to donations from pharmaceutical companies through the

[69] IFPMA, *The London Declaration on NTDs*, accessed May 15, 2017, http://partnerships.ifpma.org/partnership/the-london-declaration-on-ntds.
[70] United to Combat NTDs, *The London Declaration* (2017), op. cit.
[71] WHO, *Investing to Overcome the Global Impact of Neglected Tropical Diseases- Third WHO Report on Neglected Tropical*

WHO or directly to affected countries. Since 2000, an increasing number of people have received treatment with donated drugs as preventative chemotherapy. Treatments ranged from using drugs to kill the parasite (soil-transmitted helminths, schistosomiasis) to breaking transmission and prevent new infections (onchocerciasis and lymphatic filiarisis). As more and more data becomes available, it is evident that costs vary from country to country and from district to district according to accessibility and local factors. Thus, training programs that help countries adopt global strategies need to be scaled up.[72]

- *Integrated Vector Management (IVM):* IVM is an intervention focused on controlling vector-borne diseases and the appropriate use of insecticides by using rational decision-making processes to use existing resources effectively. In this context, the WHO Pesticide Evaluation Scheme (WHOPES) has been coordinating and evaluating the use of pesticides to tackle vector-borne diseases since 1960. Additionally, the WHO founded the Vector Control Advisory Group (VCAG) in 2013 to assist the Malaria Policy Advisory Group of the Global Malaria Programme and the Strategic and Technical Advisory Group for Neglected Tropical Diseases in using new forms of vector control. More investments are needed to devise innovative forms of vector control and to expand and improve existing practises.[73]
- *Veterinary Public-health Services*: Veterinary public-health services are required to tackle zoonotic NTDs whose life-cycle includes animals. The obstacles to tackling zoonotic diseases effectively are numerous and include the misconception that the disease burden is low. Further obstacles are weak surveillance systems as well as limited resources and skills for laboratory diagnosis of endemic diseases. Increased investments are required to support the partnerships and programs initiated by the Tripartite Concept between WHO, FAO, and OIE.[74]
- *Water, Sanitation, and Hygiene (WASH)*: WASH is of upmost importance because it forms the bedrock of other interventions. At the end of 2012, an estimated 2.5 billion people around the world did not have access to improved sanitation facilities. Many NTDs thrive in environments in which access to clean and secure water, sanitation, and hygiene facilities is deficient. Dengue and other vector-borne diseases can spread in drinking water storage facilities that are not secured properly.[75] Another example is lymphatic filiarisis: the relevant vectors breed in polluted waters and poorly secured latrine facilities. Having access to clean water is also essential in order to reduce the severity of disease symptoms. It is therefore paramount that the G20 members increase their funding of WASH projects and scale up those that are already in place and have proven successful.
- *Innovative and Intensified Disease Management (IDM)*: Increased funding is required for innovative and intensified disease management, which refers to managing diseases where medicines are not available and where the disease burden is intensified.[76] The strategy behind IDM is to combine disease specific knowledge of tackling these diseases with multisector approaches such as disease surveillance, capacity building, and research. Examples of IDM include the adoption of antibiotics into the treatment regimen for Buruli Ulcer, which were previously not thought to be effective against the disease.

Diseases (2015), accessed May 15, 2017, http://www.who.int/neglected_diseases/9789241564861/en/.
[72] cf. ibid.
[73] cf. ibid.
[74] cf. ibid.
[75] cf. ibid.
[76] WHO, *Innovative and Intensified Disease Management (IDM)* (2017), accessed May 15, 2017, http://www.who.int/neglected_diseases/disease_management/Innovative_Intensified_Disease_Management/en/.

Policy Action 3.2: Increasing Funding for Research and Product Development

The G20 members should agree to scale up research and product development to battle NTDs.

The development of new vaccines, diagnostics, and therapies is essential to effectively fight a number of NTDs, but funding for R&D in this area has been decreasing for most NTDs. The Ebola crisis was the main reason the total financial support for R&D for new medical tools for NTDs did not decrease. In 2014, R&D to combat Ebola received US$ 165 million and was the only NTD whose funding increased apart from kinetoplastids (increase of US$ 16 million) and dengue (US$ 12 million).[77] All other NTDs, such as helminths and Buruli ulcer, saw R&D funding decreasing. Considering the risks of possible transmissions of dangerous disease pathogens from animals to humans ("zoonosis"), as illustrated recently by Ebola, strengthening R&D for all NTDs is essential.

While public sector funding for neglected disease R&D continued to fall in 2015, industry contributed more R&D funding for NTDs in 2015 than ever before. According to the 2016 G-Finder report, industry (multinational and smaller pharmaceutical and biotechnology corporations) contributed US$ 471 million to neglected disease R&D.[78] Of this total amount, US$ 147.6 million were spent on malaria and US$ 102 million on tuberculosis.[79] Another US$ 226 million were spent on Ebola and other African viral hemorrhagic fevers.[80] This shows the important role industry plays in fighting NTDs. However, it is also clear that the incentives for industry to act during the Ebola crisis were non-commercial. In order to be prepared for future epidemics, there have to be sustainable and predictable commercial incentives in R&D for NTDs.

Industry is already active in sharing intellectual property available for R&D for NTDs, tuberculosis, and malaria as well as through public private partnerships like the Global Health Innovative Technology Fund (GHIT). WIPO Re:Search is an initiative by the World Intellectual Property Organization (WIPO), several leading global pharmaceutical companies, and BIO Ventures for Global Health (BVGH). Together, these organizations share pharmaceutical compounds, technologies, know-how, and data on a public searchable database to facilitate new partnerships and to support those organizations currently conducting R&D in this area.[81]

[77] Policy Cures Research, *Neglected Diseases Research and Development: The Ebola Effect* (2015), accessed May 15, 2017, http://policycures.org/downloads/Y8%20GFINDER%20full%20report%20web.pdf, 4.
[78] Policy Cures Research, *Neglected Disease Research and Development: A Pivotal Moment for Global Health*, 2016, http://www.policycuresresearch.org/downloads/Y9%20GFINDER%20full%20report%20web.pdf, accessed May 15, 2017.
[79] Policy Cures Research, *Neglected Disease Research and Development: A Pivotal Moment for Global Health*, 2016, op.cit.
[80] Policy Cures Research, *Neglected Disease Research and Development: A Pivotal Moment for Global Health*, 2016, op.cit.
[81] WIPO Re:Search, *About WIPO Re:Search,* 2017, http://www.wipo.int/research/en/about/, accessed May 15, 2017.

Exhibit 23 | Case Study Global Health Innovative Technology Fund (GHIT)

The Global Health Innovative Technology Fund (GHIT Fund), headquartered in Japan, is an international public-private partnership between the Government of Japan, 16 pharmaceutical and diagnostics companies, the Bill & Melinda Gates Foundation, the Wellcome Trust, and the United Nations Development Programme. It funds scientific research and development for anti-infectives and diagnostics for diseases that primarily affect the developing world. It aims to facilitate international partnerships that bring innovation, investment, and leadership to the global fight against infectious diseases and poverty in the developing world. The GHIT Fund provides a platform that encourages global R&D partnerships for the private sector, enabling, in this case, companies in Japan to access global health information and assets that are unavailable domestically and reinforcing their commitment to global health in line with their business strategy in emerging markets.

Source: GHIT, *About the GHIT Fund* (2017), accessed May 15, 2017, https://www.ghitfund.org/about/orgnization/mission

The B20 calls upon the G20 members to increase and strengthen global R&D funding to make achieving the WHO's road map reality. This includes investments in the public research sector and for product development partnerships.

Recommendation 4: Improving Pandemic Preparedness and Response

The G20 members should support ongoing efforts to improve pandemic preparedness and response, including efforts to foster public-private partnerships in a variety of sectors.

Policy Actions	
4.1	**Promoting PPPs in Infectious Disease Research and Product Development** – The G20 members should support initiatives to accelerate R&D relating to infectious diseases. • The G20 members should provide increased financial support the Coalition for Epidemic Preparedness Innovation (CEPI), which has a strong focus on vaccines, and encourage the development of an equivalent international public-private partnership focused on diagnostics. • The G20 members should work with industry partners to develop approaches to accelerate drug approval processes through regulatory harmonization as well as to ensure adequate and flexible manufacturing capacity and stockpiling arrangements. • TheG20 members should ensure that responses to health security threats are not impeded by national legislation. The G20 members should be able to freely and safely share genetic resources and other materials needed to enable speedy development of medical interventions.
Owner G20 members	**Timing** 2017 onwards
4.2	**Promoting PPPs in Preparedness and Response** – The G20 members should support efforts to develop effective public-private partnerships for pandemic preparedness and response. • The G20 members should encourage assessments of private sector engagement in preparedness and response in Joint External Evaluations (JEE), including, but not limited to, private sector healthcare providers. JEEs should be followed up by regular cross-sectoral pandemic simulations to build awareness and improve execution and coordination of responses. • The G20 members should leverage private sector assets and capabilities for the prevention, detection, and control of infectious disease outbreaks, particularly in data management and logistics. • The G20 members should work with financial institutions to ensure maintenance of essential services during outbreaks, including access to credit, and empower local banks to offer flexible and accessible loans to businesses so that they can adapt repayment schedules to external shocks.
Owner G20 members	**Timing** 2017 onwards
4.3	**Incorporating Pandemic Risk in Macro-Economic Assessments** – The G20 members should encourage incorporating the economic risks of infectious disease outbreaks into macro-economic assessments to build greater risk awareness and encourage investment in preparedness. • The G20 members should task the IMF and World Bank to develop the capabilities to incorporate the economic risks of pandemics into assessments of countries' economic risks and prospects (e.g. the IMF's Article IV Consultations and the World Bank's Systematic Country Diagnostics). • The G20 members should encourage private sector actors, such as financial institutions, to take account of infectious disease risks in investment and other business decisions.
Owner G20 members	**Timing** 2017 onwards

Context

The number and type of infectious disease outbreaks have increased significantly over the past 30 years.[82] As global trade and travel enable humans and goods to be more and more mobile, the risk of diseases spreading beyond national borders increases.[83] Infectious diseases are often mistakenly viewed as mere health issues. However, they are potentially grave threats to countries' security as well as economic stability and well-being.[84]

Ebola, the Middle East Respiratory Syndrome (MERS), pandemic influenza, and the Zika virus have all demonstrated the extraordinary economic costs associated with infectious disease outbreaks. The World Bank estimated in 2008 that a severe flu pandemic could result in $3 trillion in global economic losses, equivalent to 4.8 percent of GDP.[85] The majority of the losses would not be caused directly by the flu virus itself, but by losses in productivity, economic output, consumer reactions, and severe labor shortages.[86]

In order to mitigate the effects of such infectious disease outbreaks, the Global Health Security Agenda (GHSA) was formed in 2014. The GHSA is a country-led, multi-sector effort to strengthen capacities for coordinated action to prevent epidemics, detect biological threats, and respond to disease outbreaks effectively and efficiently. The GHSA currently includes nearly 50 countries.[87]

Given that epidemics and pandemics can devastate economies and threaten major investments by multinationals and small businesses alike, the business sector has a strong interest in supporting disease outbreak prevention and response. This is not only out of a sense of corporate social responsibility, but also because it is good business to intervene, protecting employees, operations, and markets. An example of private sector involvement during disease outbreaks could be witnessed during the Ebola crisis: operatives from several different companies self-organized the Ebola Private Sector Mobilization Group (EPSMG), in order to provide responders with local knowledge and use their networks for vital elements needed in the response.[88]

Exhibit 24 | Gendered Approaches and Pandemic Preparedness

Women have shown to be the major victims of the Ebola virus in West Africa. Women face a particular exposure to the Ebola Virus Disease (EVD) due to their social roles as caregivers in families and communities. Among those infected are specifically those women in the most economically active age. As woman are a driving force of economic growth, the high infection rate among them impacts productivity and income generation. Pandemic preparedness and response therefore needs to consider women's specific exposure to diseases such as EVD, Zika, or HIV, thus also stabilizing productivity and economic growth.

Source: UNDP Policy Briefing, *Socio-economic Impact of the Ebola Virus Disease in Guinea, Liberia and Sierra Leone*, accessed May 15, 2017, http://www.africa.undp.org/content/dam/rba/docs/Reports/UNDP%20Policy%20note%20EN_web.pdf.

The importance of the private sector as a partner beyond the traditional donor role is becoming

[82] K.F. Smith et. al., *Global Rise in Human Infectious Disease Outbreaks*, Journal of the Royal Society Interface 10:101 (2014), 1-6.
[83] S.M. Soto, *Human Migration and Infectious Diseases*, Clinical Microbiology and Infection 15 (2009), 26-28; A.J. Tatem et. al., *Global Transport Networks and Infectious Disease Spread*, Adv Parasitol 62 (2006), 293-343.
[84] World Bank Group, *Ebola Response Fact Sheet* (2016), op. cit.
[85] World Bank Group, *Pandemics*, Overview (2015), accessed May 15, 2017, http://www.worldbank.org/en/topic/pandemics/overview.
[86] Ibid.
[87] Global Health Security Agenda, *Global Health Security Agenda* (2017), accessed May 15, 2017, https://www.ghsagenda.org/about.
[88] World Economic Forum & Boston Consulting Group, *Managing the Risk and Impact of Future Epidemics: Options for Public-Private Cooperation* (2015), accessed May 15, 2017, http://www3.weforum.org/docs/WEF_Managing_Risk_Epidemics_report_2015.pdf.

increasingly evident. Private companies have expertise and capabilities that are critical during an emergency – whether in logistics and supply chains, health, technology, data management or financial services. They also have local capacity (including equipment and personnel) and local knowledge of communities and cultures that are invaluable when time is of the essence.[89]

Responses to recent outbreaks have featured a range of innovative partnerships among businesses and civil society to complement the official response, such as the WHO R&D Blueprint.[90] However, such efforts have traditionally been ad hoc, often not well-organized, limited to healthcare entities, initiated only after the outbreak has substantially progressed, and not commensurate with the magnitude of private sector capacity or interest. Exhibit 25 illustrates a couple of examples of forward-thinking private sector engagement for disease preparedness, which should be built upon.

Harmonized regulatory environments, including mutual recognition agreements, are critical if medicines and vaccines are to be made available to patients in the quickest possible time. Research and development for new vaccines and treatments for pandemics remains a crucial part of an effective response. Examples include the EU's Innovative Medicines Initiative with its research program called "New Drugs for Bad Bugs". Push–pull mechanisms such as advanced market commitments, priority review vouchers for regulatory approval, tax credits, and public funding for clinical trials should be fully assessed and adapted to the circumstances. Certain champion countries should support market-based incentives, particularly for late stage development (phase 3), where costs dramatically increase (CEPI does not normally go beyond phase 2). Virus strains need to be shared safely and rapidly to facilitate pandemic risk assessment, the development of candidate vaccine viruses, updating of diagnostic reagents and test kits, and surveillance for resistance to antiviral medicines.

Exhibit 25 | Private Sector Engagement for Disease Preparedness

The Coalition for Epidemic Preparedness Innovations (CEPI): The initiative was conceived in response to the recent Ebola outbreak, which caused more than 11,000 deaths in West Africa over two years beginning in 2014. It is being launched in response to a cross-sectoral pandemic simulation that took place in Davos in February 2017, which was co-chaired by Jim Kim, President of the World Bank Group, and Bill Gates, Co-Chair of the Bill & Melinda Gates Foundation. CEPI will focus on shortening the time it takes to create and deliver vaccines by supporting innovative medical technologies. It will begin by targeting viruses with serious potential to cause epidemics such as MERS-CoV, Lassa, and Nipah.

Private Sector Roundtable (PSRT) of the Global Health Security Agenda (GHSA): The mission of the PSRT, which was formed in response to a call to action at the 68th World Health Assembly for industry to play a greater and coordinated role in advancing the GHSA, is to mobilize industry to help countries prevent, detect, and respond to health-related crises and strengthen systems for health security. The PSRT currently has members across the sectors of healthcare, communications, energy, logistics, and technology. The PSRT aims to generate private sector insights and utilize resources to address specific health and development risks and vulnerabilities.

Sources: World Economic Forum, *Managing the Risk and Impact of Future Epidemics* (2017), accessed May 15, 2017, https://www.weforum.org/projects/managing-the-risk-and-impact-of-future-epidemics. Global Health Council, *Global Health Council (*2017), accessed May 15, 2017, http://ghbb.globalhealth.org/briefs/global-health-security/;
David Barash, *The Time Is Now: How We Can Work Together to Address the Global Health Security Agenda* (June 2016), accessed May 15, 2017, http://www.huffingtonpost.com/david-barash/the-time-is-now-how-we-ca_b_10319716.html.

[89] Ibid.
[90] WHO, *R&D Blueprint For Action to Prevent Epidemics* (2017), accessed May 15, 2017, http://www.who.int/csr/research-and-development/blueprint/en/.

Policy Action 4.1: Promoting PPPs in Infectious Disease Research and Product Development

The G20 members should support initiatives to accelerate R&D relating to infectious diseases.

It is crucial that the world has vaccines at its disposal that are effective and accessible to mitigate social and economic damage. The G20 members should therefore support initiatives to accelerate R&D. Specifically, the G20 members should increase their financial support for initiatives such as CEPI and the Global Research Collaboration for Infectious Disease Preparedness (GLOPID-R).[91] Though CEPI has many committed supporters already, it only has half of its required budget (US$ 460 million) for its first five-year phase.[92]

Diagnostics are often neglected in the R&D landscape even though they allow for an early and rapid detection of infectious diseases in humans or animals. Early detection is critical in responding to infectious outbreaks because the response can be targeted. The G20 members should work together with industry, PDPs, foundations, and other relevant research institutions to find avenues to accelerate R&D of diagnostics for diseases with a high pandemic risk factor.

In addition, G20 governments can support pandemic preparedness by actively mitigating against legislation that impedes responses to health emergencies. G20 countries should ensure that their laws do not obstruct or restrict development of medical interventions to prevent or respond to imminent or anticipated pandemic situations. In the event of a major public health emergency, they should be able to freely and safely share genetic resources and other materials needed, including deadly pathogens, to enable speedy development of medical interventions. It is crucial that the appropriate drug approval processes are in place to allow industry and other product developers to bring their products to the market as soon as possible to tackle a major public health emergency.

Furthermore, the G20 members should work with industry to develop approaches to ensure adequate and flexible manufacturing capacity and stockpiling arrangements. In the event of an epidemic or pandemic, manufacturing capacity is crucial to produce the required amount of vaccines, therapies, and diagnostics. A delay in the distribution can slow down pandemic responses as it did, for example, during the 2009 pandemic of the H1H1 influenza A virus.[93] Stockpiling products for infectious diseases can increase speed and effectiveness of a response and should therefore be considered by G20 members.[94]

Policy Action 4.2: Promoting PPPs in Preparedness and Response

The G20 members should support efforts to develop effective public-private partnerships for pandemic preparedness and response.

The G20 members should take the lead in leveraging private sector assets and capabilities for the prevention, detection, and control of infectious disease outbreaks. This includes, among others, data analysis and management, development of medical interventions, and ‘last mile’ delivery of medical tools where infrastructure is underdeveloped.

In addition, the G20 members should encourage assessments of private sector engagement in preparedness and response in Joint External Evaluations (JEE), including, but not limited to, the private

[91] Global Research Collaboration for Infectious Disease Preparedness, *Learn About Us* (2017), accessed May 15, 2017, https://www.glopid-r.org/learn-about-us/.
[92] The Guardian, *$460m Pledged for Vaccine Initiative Aimed at Preventing Global Epidemics* (2017), accessed May 15, 2017, https://www.theguardian.com/society/2017/jan/18/460m-pledged-for-vaccine-initiative-to-prevent-global-epidemics-davos-mers-nipah-lassa.
[93] Institute of Medicine - The National Academies, *Emerging Viral Diseases: The One Health Connection: Workshop Summary* 2015, accessed May 15, 2017, https://doi.org/10.17226/18975.
[94] C. Yen et. al., „The Development of Global Vaccine Stockpiles”, *Lancet Infectious Diseases* (2015), 15:3, 340-437.

healthcare sector. JEEs are voluntary external evaluations to assess a country's national health security capacity. The aim is to prevent, detect, and quickly respond to public health threats, whatever the cause may be.[95] Countries should publish their completed assessment, as data transparency and accountability are vital to address global health threats. The private sector should also be integrated into post JEE planning, through groups like the Private Sector Round Table (PSRT) and the Pandemic Supply Chain Network (PSC) (see Exhibit 25 and 26). G20 members should furthermore devise the appropriate financing mechanisms that address any gaps found during the JEE. JEEs should be followed up by regular cross-sectoral pandemic simulations to build awareness and improve execution and coordination of responses.

Exhibit 26 | The Pandemic Supply Chain Network – A Public-Private Initiative

The Pandemic Supply Chain Network (PSC) is a public-private initiative that seeks to increase supply and logistics capacities and develop an information platform to more equitably match demand and supplies.

The PSC network was created following the World Economic Forum meeting at Davos in January 2015 where the need for coordinated, global preparedness and response to public health emergencies was expressed. The West Africa Ebola outbreak demonstrated that more focused attention was needed in the areas of supply chain logistics and public-private collaboration to enable better responses to future pandemics.

The initiative now has 15 members, including healthcare suppliers such as Henry Schein Inc., logistics companies such as UPS, and IT companies such as NEC. Public sector members include the World Food Program (WFP), WHO, UNICEF, and the World Bank.

Ongoing progress of the initiative includes:

- creating a list of essential supplies required for healthcare professionals to effectively respond to a pandemic;
- increasing the visibility of global supply, including mapping of manufacturers, stockpiles, and transport routes;
- developing guidelines for humanitarian logisticians responding to a pandemic;
- designing an information platform to help suppliers, humanitarian responders, donors, and governments coordinate supply chains in a pandemic;
- raising awareness about the importance of pandemic supply chains and public-private collaboration and identifying existing gaps via simulations.

Global health security will remain precarious without recognizing that supply chain delays seriously compromise the effectiveness of pandemic response action and that a lack of public-private sector coordination exacerbates economic disruption. The PSC network seeks to address this challenge.

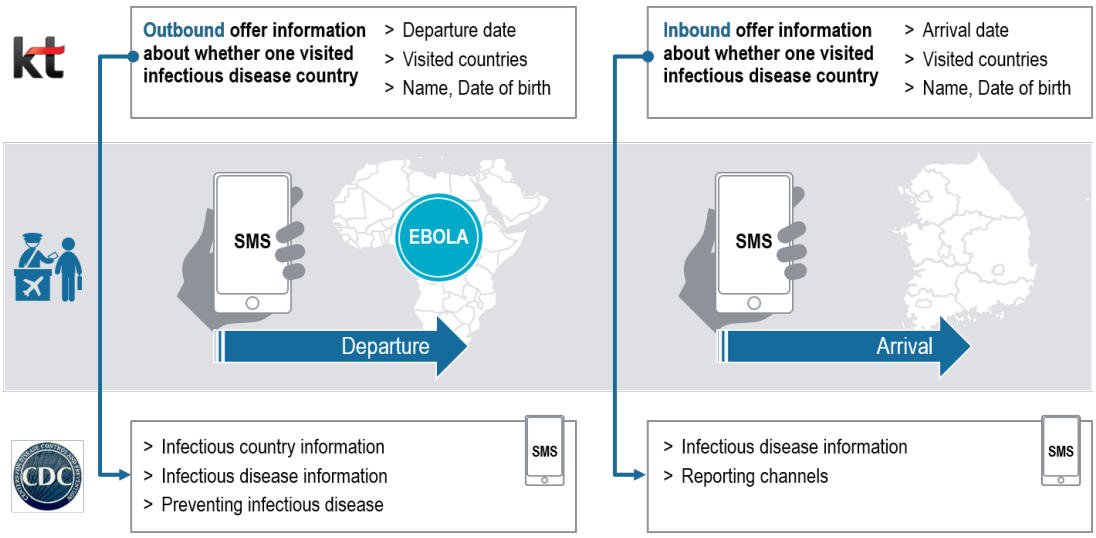
Source: World Food Programme, *Innovative Supply Chain Information Platform Will Help Prepare For The Next Pandemic* (2017), accessed May 15, 2017 https://www.wfp.org/news/news-release/innovative-supply-chain-information-platform-will-help-prepare-next-pandemic.

Information technology and communications is another area where the G20 members should seek cooperation in order to improve communication and outbreak surveillance in pandemic preparedness and response especially in rural areas (see Exhibit 27).

[95] Global Health Security Agenda, *Assessments & JEE* (2017), accessed May 15, 2017, https://www.ghsagenda.org/assessments.

Exhibit 27 | The Use of Big Data in Pandemic Preparedness and Reaction

Korea Telekom has started an initiative offering infectious disease Big Data to dedicated Centers for Disease Control. By collecting Telco's roaming information, Korea Telekom has built an effective information sharing system to its subscribers.



Source: Korea Telecom

Countries need to be prepared for the aftermath of pandemics by accelerating access to finance in order to safeguard economic stability.[96] The G20 members should work with financial institutions to ensure maintenance of essential services during outbreaks, including access to credit. Local banks should be empowered to offer more flexible and accessible loans to businesses and adapt repayment schedules to external shocks. The UN, World Bank, European Union, and African Development Bank recommend additional short- and medium-term recovery measures. In the short-term, governments should provide access to micro credits and coverage of outstanding loans. In the medium-term, cash grants for business can strengthen the capacities of micro-finance systems, including those that are community-based. Furthermore, local economic recovery programs could include direct employment support.[97] The G20 members should commit to supporting these initiatives.

In addition, the G20 members should support regular cross-sectoral simulations to improve readiness for future pandemics and to ensure effective integration with established international response institutions, policies, and procedures. The German G20 Presidency will conduct a pandemic preparedness exercise at the G20 Health Minister Meeting mid-May 2017.[98] The B20 welcomes this exercise. Such exercises should become a general feature at G20 Health Minister Meetings.

Health systems are only resilient, responsive, and responsible to the extent that they meet the needs of the communities they serve. Communities and community mechanisms play a vital role in supporting health awareness, disease identification, and reporting. They also support accountability as first line information when stock outs or delivery issues are at stake. The Ebola response, as well as the HIV and polio response, demonstrated the critical role that community ownership plays. Strengthened collaboration that draws on private sector expertise and capacities with community knowledge and

[96] Dalberg, *From Recovery to Response in the Ebola Crisis: Revitalizing Health Systems and Economies* (2015), accessed May 15, 2017, http://www.dalberg.com/wp-content/uploads/2015/04/Dalberg_Ebola_Report.pdf.
[97] UN, World Bank, European Union, African Development Bank, *Recovering from the Ebola Crisis (*2015), accessed May 15, 2017, http://www.ilo.org/wcmsp5/groups/public/---dgreports/---dcomm/---publ/documents/publication/wcms_359364.pdf.
[98] P. Osewe, *Pandemic Simulations: Preparing for the Catastrophe we Hope Will Never Happen*, (2016), accessed May 15, 2017, http://blogs.worldbank.org/health/pandemic-simulations-preparing-catastrophe-we-hope-will-never-happen.

insights will be critical to a rapid response to emerging epidemics. The G20 members should thus invest in strengthening community systems. As such, they should build on existing mechanisms and networks, e.g. community networks of people living with HIV/AIDS (PLHIV) and HIV programmes as well as polio and other vaccination distribution structures.

Policy Action 4.3: Incorporating Pandemic Risk in Macro-Economic Assessments

The G20 members should encourage incorporating the economic risks of infectious disease outbreaks into macro-economic assessments to build greater risk awareness and encourage investment in preparedness.

The G20 members should task the IMF and World Bank to develop the capabilities to incorporate the economic risks of epidemics and pandemics into overall assessments of countries' economic risks and prospects. Examples of such assessments are the IMF's Article IV Consultations and the World Bank's Systematic Country Diagnostics. The risk posed by infectious diseases to economic growth and overall stability is usually only mentioned once an outbreak has occurred, as in the example of the Ebola virus in West Africa, the Zika virus in Brazil, or HIV/AIDS in much of Africa.[99] When economic risk assessments are carried out, they are usually applied to the global risk level.

Incorporating infectious disease risk into country-level economic risk assessments would raise awareness. The G20 members should encourage private sector actors, such as financial institutions, to take account of infectious disease risks in investment and other business decisions. If private sector actors across all sectors understood more clearly what is at stake, they would also be in a better position to identify their own weaknesses. This would contribute to enabling industry to play a more effective part in epidemic preparedness and response.

[99] P. Sands et. Al., "Assessment of Economic Vulnerability to Infectious Disease Crises", May 2016, *The Lancet*, S0140-6736(16)30594-3.

Recommendation 5: Advancing Digital Health

The G20 members should endorse the use of Big Data in health by promoting translational data flows as well as protecting individual data. They should also accelerate the provision of a high performance digital health infrastructure by setting clear targets and deploying broadband and mobile connectivity.

Policy Actions	
5.1	**Facilitating Big Data** – The G20 members should endorse making use of big data in digital health by facilitating and promoting translational and cross-border data flows, while at the same time protecting patients' health data by implementing clear governance rules. • The G20 members should foster international as well as translational data exchange among all healthcare stakeholders by introducing clear governance rules. • The G20 should establish consensus for the need of data regulation and propose guidelines that apply across countries, such as the OECD Recommendation on Health Data Governance
Owner G20 members	**Timing** 2017 onwards
5.2	**Improving Digital Health Infrastructure** – The G20 members should accelerate the provision of a high performance digital health infrastructure by setting clear targets, agreeing on international standards for technical and semantical connectivity, and boosting investment in high capacity and mobile connectivity. • The G20 members should set measurable targets specific to health infrastructures in regional and national digital strategies, such as Healthcare Sector Digitization (eHealth) as well as National Broadband plans, and review them regularly. • The G20 members should boost investment in mobile network infrastructures (e.g. 5G networks), especially for rural areas in underdeveloped countries, by producing national and regional actions plans with a specific target date (e.g. 2020).
Owner G20 members	**Timing** 2018 onwards

Context

Digitalization changes the ways we live, how we communicate with each other, and how we produce goods and services.[100] There are computer chips in almost every device, be it in cars or in modern home appliances. Digital technologies are rapidly transforming industry structures and create new cooperation patterns in cross-industry and cross-sectorial networks.

For healthcare, however, the potential of digitalization has not yet been fully realized. Advancements in the digital health transformation would allow systems to become more efficient and patient-oriented with care provided increasingly remotely. Costs of healthcare could be reduced, benefiting both patients and firms. Digitalization in healthcare can enable both improved clinical and societal outcomes. Digital health applications can also help to optimize conventional treatment approaches and provide novel diagnostic techniques and forms of therapy and thus improve overall care. It creates opportunities to make greater use of real world data for insights into treatment outcomes for patients, more efficient research and development of highly effective therapeutics and medical technologies, and ultimately better informed policy decisions by regulators. Finally, Digital Health creates new market opportunities for both investors and innovator companies, thus boosting employment (see Exhibit 30).

Digital Health is a broad concept that includes many other aspects of digitalization, including information

[100] See also B20 Germany Taskforce Digitalization.

and communication technology, Big Data, and the Internet of Things (IoT) (see Exhibit 28).[101]

Exhibit 28 | Areas of Digital Health

Big Data: Big Data describes large and complex data sets for which traditional data processing software is insufficient to deal with. Big Data in health opens new possibilities in the discovery of new therapeutic approaches and technologies, as the sector is facing a quantity of data never seen before, coming from novel sources such as lifestyle data, payer data, and social media.

eHealth: eHealth can foster patients' involvement in the care process and facilitate access to healthcare. It has the potential to increase the effectiveness and efficiency of healthcare.

Internet of Things (IoT): IoT is an umbrella term for all devices that are able to connect to the internet, and thus, transmit data. These devices are often equipped with Wi-Fi or BLE (Bluetooth Low Energy) and allow for communication between machines. In health, it is also referred to as the Internet of Medical Things (IoMT) and describes medical devices and applications that connect to healthcare IT systems through online networks.

mHealth: mHealth or Mobile Health describes the broader use of mobile technology in health to improve access to information and deliver health and diagnostic services remotely. Patients seeking advice online before visiting a physician is a typical example for Mobile Health.

Telehealth: Telehealth is closely linked to eHealth and mHealth and highlights specific services that use technology to help people living more independently, for instance by using alarms and connected health monitoring devices.

Precision Medicine: Precision medicine refers to a medical approach that uses insights into health and disease to guide decisions with regard to the prediction, prevention, diagnosis, and treatment of illnesses. New tools harnessed by precision medicine include '-omics' technologies, which seek to define and explain the molecular mechanisms of the human body. Integrating advances in molecular technology into clinical practice comes with challenges and is referred to as translational gap.

Wearables: Closely related to the Internet of Things (IoT), wearables are small devices that users can wear close to their bodies, such as fitness trackers and smartwatches.

Wireless Health: Wireless Health is the combination of wireless technology with traditional medical approaches, such as diagnosis, monitoring, and illness treatment. Wireless Health is closely connected to IoMT. Wireless health differs from mHealth in that wireless health solutions will not always be mobile and mobile health solutions will not always be wirelessly enabled.

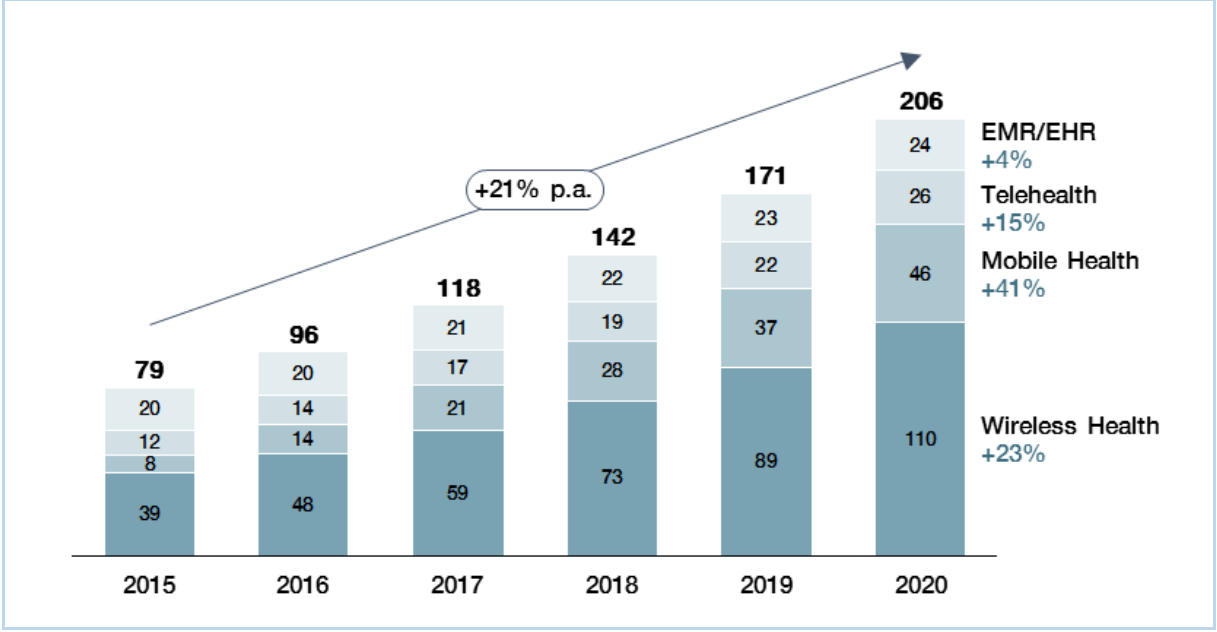
Interoperability: The ability of health information systems to work together within and across organizational boundaries in order to advance the health status of, and effective delivery of healthcare for, individuals and communities.[1]

Source: HIMSS Dictionary of Healthcare Information Technology Terms, *Acronyms and Organizations*, 3rd Edition (2013), 75.

The areas of Digital Health are evolving rapidly. For instance, in 2016, publishers of mobile health apps have brought to market 100,000 more apps, a 57 percent increase over 2015. This brings the total to 259,000 health apps globally available to consumers.[102] The largest drivers for Digital Health are mobile and wireless applications, as can be seen in Exhibit 29.

[101] European Parliament Research, *Topical Digest: Digital Health* (2016), 1.
[102] Research2Guidance, *mHealth App Developer Economics 2016*, accessed May 15, 2017, http://research2guidance.com/r2g/r2g-mHealth-App-Developer-Economics-2016.pdf.

Exhibit 29 | Digital Health Market Development 2015-2020 [USD bn]



Source: Allied Market Research, Markets and Markets, Grand Market View, Transparency Market Research, BCC Research, Roland Berger Research (2016).

The digital transformation has the potential of redefining the patient's position in healthcare, not only allowing them to better monitor their health, but also regarding the interaction with the whole healthcare system. It gives them access to an extensive network of medical information and allows them to communicate with physicians and other patients regarding their health status and treatment options. Patients will no longer rely on a single and local physician, but will be able to access healthcare platforms when they have a specific medical need – also across borders.[103] According to a McKinsey Digital Patient Survey in 2014, conducted in Germany, Singapore, and the United States, more than 75 percent of all patients expect to use digital services in the future.[104]

[103] Roland Berger, *Digital and Disrupted: All Change for Healthcare* (2016), 5, accessed May 15, 2017, https://www.rolandberger.com/publications/publication_pdf/roland_berger_digitalization_in_healthcare_final.pdf.
[104] Stefan Biesdorf, Florian Niedermann, *Health Care's Digital Future*, accessed May 15, 2017, http://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/healthcares-digital-future.

Exhibit 30 | Examples of Cost Saving Achieved through Digital Health

Jurisdiction	Application	Benefit	Economic Impact
Denmark	Extensive health information exchange (HE) within the entire health sector	Fewer GPs are seeing more patients with no complaints of being overworked: efficient data exchange facilitates elimination of unnecessary tests, saving both technical and human resources; improved decisions lead to less daily stress on staff	Reduction in costs to the healthcare system in terms of reimbursing physicians
Andalucía, Spain	Automation of medication prescriptions	Reduction in the number of drugs being prescribed	Reduction in drug related costs
Rhode Island, USA	Use of electronic health records	Improved healthcare quality, with a 44% median rate of improvement in family and children's health, 35% in woman's care, and 24% in internal medicine	Lower monthly healthcare costs, averaging between 17% and 33% less per member than those receiving care in non-participating practices
UK Whole System Demonstrator Program	Use of telehealth technology for individuals with chronic conditions	Improvement in quality of care led to a reduction of patient mortality rates by 45%	20% reduction in emergency admissions and 15% reduction in emergency department visits
Memphis, USA	Sharing patient data electronically between 12 hospital emergency rooms	Avoidance of needless admissions, CT scans and other tests after getting insights from the patients' medical histories	Participating hospitals reduced healthcare costs by US$ 2 million over 13 months
Lombardy, Italy	Extensive use of electronic health records (EHRs) and data exchange	Hospital doctors are now able to sign reports electronically and medical information is made available to physicians throughout the region; electronic processes were activated, such as eBooking procedures, eReferrals, eOrders and ePrescriptions	Return on investment from digital health increased to annual benefits of over 160 million Euros in 2012, almost 78% more than its total annual costs.

Source: World Economic Forum, *Network of Global Agenda Councils Reports 2011-2012,* (2012) accessed May 15, 2017, http://reports.weforum.org/global-agenda-council-2012/.

A 2013 McKinsey report summarized the following value paths as a consequence of Digital Health:

- **Right Living:** Patient can take greater responsibility for their own health by taking a more active role in their treatment, including disease prevention.
- **Right Caring:** Digital Health and the usage of Big Data enable physicians to provide better diagnosis and allow patients to get more timely and appropriate treatment.
- **Right Provider:** Utilizing Big Data allows for a better match between the needs of a patient and possible providers.
- **Right Value:** Digital Health enables cost-efficient treatment at highest quality.
- **Right Innovation:** Big Data helps to advance identification of new therapies and approaches to delivering care.

Source: Basel Kayyali, David Knott, Steve Van Kuiken, *The 'Big Data' Revolution in Health care. Accelerating Value and Innovation,* (2013) accessed May 15, 2017, http://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/the-big-data-revolution-in-us-health-care.

However, there has been a slow adaption of digital technologies in health, and the industry is currently risking falling further behind. As a result, there has been a lack of productivity improvement, which stands

in contrast to robust growth in others sectors of the world economy.[105] To make digital health a reality, governments have to commit financing, devise effective governance mechanisms with defined roles, and include health more strongly in national ICT frameworks.[106] Realizing that analogue-based regulations are not the ideal foundations for Digital Health, the G20 members should facilitate the development of the necessary infrastructure and provide appropriate regulatory frameworks: secure data management, facilitating global data exchange, and driving a culture of innovation. G20 governments need to shift the collective mind-set about patient data to "share, with protections," rather than "protect", and, at the same time, acknowledge that it is the patients who "own" their data, not the providers of healthcare.

Policy Action 5.1: Facilitating Big Data

The G20 members should endorse making use of big data in digital health by facilitating and promoting translational and cross-border data flows, while at the same time protecting patients' health data by implementing clear governance rules.

The positive impact of digital health is largely dependent on the availability of high quality, reliable data. The value of Big Data is fourfold. Firstly, Big Data leads to an increased understanding of diseases. It can accelerate the design of treatments by developing new pathways, thus allowing patients to get access to new effective treatments. Secondly, the use of Big Data allows the development of targeted medicines through patient stratification. Thus, patients can profit from the right treatment for their unique needs and preferences. Drug research, development, and approval processes can be made more efficient by focusing on the right target population. Furthermore, Big Data allows integrating biological, clinical and environmental information in developing predictive models, learning systems and continuous quality improvement at the individual level that facilitate identification of new disease biomarkers and subtypes. Thirdly, Big Data offers the potential for improved understanding of the benefits and risks of treatment options in a given patient population and thus enables patients, clinicians, and policy-makers to make better informed decisions regarding these options. Fourthly, Big Data allows a better integration of hospital, primary, community and social care, where information is not yet shared efficiently across service providers, and citizens and patients are often expected to integrate services themselves. Patients are often overburdened communicating complex care needs and medical histories across healthcare services, entailing higher costs. Furthermore, underdeveloped and fragmented data collection on health outcomes makes it difficult to compare the value of different care interventions and prioritize decision-making across care providers. To provide better and safer care, delivery mechanisms should be transformed to take a more person-centered approach that encompasses health and social care.

However, there are also challenges to overcome in order to fully realize the benefits of Big Data in health, including clinical, technical, legal and cultural hurdles.[107] One of these challenges is the sudden availability of vast unstructured personal data sets. It is not only technically difficult to integrate structured clinical data with unstructured data from personal devices, but there is also a great need for categorizing data. In addition, legal issues have to be addressed. This is, for example, the case when a consumer device becomes a diagnostic medical device and regulatory approval and quality insurance become an issue. Another challenge is related to handling and storing data. A lack of trust in how data is handled

[105] World Economic Forum, *Global Agenda Council Digital Health*, accessed May 15, 2017, https://www.weforum.org/reports/global-agenda-council-digital-health-2012-2014.
[106] Broadband Commission for Sustainable Development, *Digital Health: A Call for Government Leadership and Cooperation between ICT and Health* (2017), accessed May 15, 2017, http://broadbandcommission.org/Documents/publications/WorkingGroupHealthReport-2017.pdf.
[107] OECD, *Health Data Governance: Privacy, Monitoring and Research*, accessed May 15, 2017, https://www.oecd.org/health/health-systems/Health-Data-Governance-Policy-Brief.pdf.

can severely hamper the use of Big Data in Health in coming years.

Exhibit 31 | Recommendations of the B20 Germany Taskforces Digitalization and Trade & Investment on Cross-Border Data Flows

- G20 members should commit in trade agreements not to prevent the free flow of data across borders – without prejudice to clearly defined exceptions for the protection of privacy and security. Furthermore, G20 members should strengthen efforts for interoperable data protection standards, facilitate the use of the accountability principle, and pursue additional bilateral and plurilateral agreements that enable cross-border data flows in accordance with privacy and data protection requirements.
- G20 members should address cross-border data flows in their discussions on digital trade and aim for guarantees for unimpeded transfer, access, and storage of data across borders in their trade agreements. These should include appropriate safeguards for privacy and security. The G20 should instigate a WTO negotiation mandate on digital trade at the next WTO Ministerial Conference, which should inter alia address free cross-border data flows.
- The G20 should ask UNCTAD and the OECD to guide a multistakeholder dialogue – including governments as well as experts from private and public organizations – on interoperable data protection and privacy protection standards. The process should lead to the development of a framework of common guiding policy principles that increase interoperability.
- G20 members should facilitate the use of accountability-based legal instruments and pursue bi- or plurilateral agreements, such as the adequacy-based Privacy Shield, to enable cross-border data flows while safeguarding privacy requirements.
- To increase legal certainty related to cross-border data flows, G20 members should review efficiency and cooperation processes within the framework of mutual legal assistance treaties.

Sources: B20, *Digitalization for All. Future-Oriented Policies for a Globally Connected World*, April 2017, https://www.b20germany.org/fileadmin/user_upload/documents/B20/B20_Digitalization_Policy_Paper_2017.pdf.

All G20 economies are investing in health data. There are, however, significant cross-country differences in data availability and use. Some countries have already established innovative practices enabling privacy-protective data, while others are lagging behind.[108] G20 members need to engage with businesses and other relevant experts and organizations to further develop common codes, standards, and other mechanisms that enable the efficient exchange and interoperability of health data whilst protecting privacy. The OECD Recommendation on Health Data Governance sets the condition for greater harmonization of national health data governance frameworks (see Exhibit 32). G20 governments should further develop the Recommendation through active multi-stakeholder engagement and drive forward implementation. A clear specification of different data types, such as genotype, genomics, lifestyle, and environmental, are an important step and can foster translational and international data flows. The G20 members should also share best practices on digital health inducing regulations.

[108] OECD, *Health Data Governance*, accessed May 15, 2017, http://www.oecd.org/publications/health-data-governance-9789264244566-en.htm.

Exhibit 32 | OECD Recommendation on Health Data Governance

The OECD, amongst others, recommends that governments:

- establish and implement a national health data governance framework to encourage the availability and use of personal health data to serve health-related public interest purposes while promoting the protection of privacy, personal health data and data security;[…]
- engage with relevant experts and organizations to develop mechanisms consistent with the principles of this Recommendation that enable the efficient exchange and interoperability of health data whilst protecting privacy, including, where appropriate, codes, standards and the standardization of health data terminology; […]
- support transborder cooperation in the processing of personal health data for health system management, research, statistics and other health-related purposes that serve the public interest subject to safeguards consistent with the Recommendation.

Sources: OECD, *Recommendation of the OECD Council on Health Data Governance, The Next Generation of Health Reforms*, (January 2017), accessed May 15, 2017, https://www.oecd.org/health/health-systems/Recommendation-of-OECD-Council-on-Health-Data-Governance-Booklet.pdf.

Policy Action 5.2: Improving Digital Health Infrastructure

The G20 members should accelerate the provision of a high performance digital health infrastructure by setting clear targets, agreeing on international standards for technical and semantical connectivity, and boosting investment in high capacity and mobile connectivity.

Paramount for digitalization in healthcare is advanced infrastructure. The volume of mobile broadband data in members of the OECD grew by 71 percent in 2015 compared to the year before.[109] According to Cisco's Virtual Networking Index, the global internet traffic will be 92 times greater in 2020 as compared to 2015.[110] This tremendous increase in data traffic corresponds to the increase in health data traffic. A high-performing health infrastructure is required to manage the enormous amount of health data created.

Accordingly, the G20 members should extend their national digital strategies to healthcare infrastructures. To date, national digital strategies often focus on the speed of service offered, percentage of coverage, and penetration rates. Rarely do they regard infrastructure demands specific to health. Important fields of improvement concern the integration of different care providers, i.e. physicians, hospitals, facilities of rehabilitation, and other areas of health services. Particular attention should be given to mobile network infrastructures, such as 5G networks, for rural areas. The increasing penetration of mobile networks and thus, mobile phone ownership, fosters innovative development in those regions, which lack comprehensive health infrastructure. The G20 members should also agree to pay more regard to digital health in their development cooperation with less developed countries, as Digital Health and the use of Big Data can play an important role in reaching the SDGs.

Lastly, the G20 members need to focus on skills and capabilities. Staff needs to be trained in machine learning and statistics, individuals need to understand the nuances of data, and people need the technological skills required to develop and manage big-data systems. Only then will societies be able to fully realize the benefits of Big Data and Digital Health.

Personal health data is very intimate. Therefore the G20 members should devise acceptance campaigns that educate citizens about the uses of digital health systems and the security measures that are put in

[109] OECD, *OECD Broadband Portal 2017* (2017), accessed May 15, 2017, http://www.oecd.org/sti/broadband/oecdbroadbandportal.htm.
[110] Cisco, *Visual Networking Index*, accessed May 15, 2017, www.cisco.com/c/en/us/solutions/service-provider/visualnetworking-index-vni/index.html.

place to secure data.

Exhibit 33 | Case Studies: Mobile Technology Helping to Overcome the Lack of Healthcare Infrastructure in Rural Areas

Mali: Pregnant young mothers in Mali receiving help via text messages in form of information of prevention and awareness has reduced perinatal and maternal mortality rates by 30 percent.

Botswana: A mobile-enabled program has reduced government response time to malaria outbreaks from four months to just three minutes.

India: A program to monitor outbreaks of Dengue Fever with the use of mobile devices has helped to shorten reportage on disease outbreaks to central authorities and thus decreased response time for treatment.

Zambia: "Visualize No Malaria" campaign shows how digital technology (data analytics/visualization software 'Tableau') can improve malaria surveillance capacity in Zambia.

Sources: Deloitte, *How Digital Technology is Transforming Health and Social Care* (2016), accessed May 15, 2017, https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-connected-health.pdf.

Annex

Acronyms

AMR	Antimicrobial Resistance
AU	African Union
BLE	Bluetooth Low Energy
BVGH	BIO Ventures for Global Health
CEPI	Coalition for Epidemic Preparedness Innovations
CRPD	Convention on the Rights of Persons with Disabilities
CWA	Compact with Africa
DNDi	Drugs for Neglected Diseases initiative
DRC	Democratic Republic of Congo
EHR	Electronic Healthcare Record
EPSMG	Ebola Private Sector Mobilization Group
ESBL	Extended-spectrum beta-lactamases
EVD	Ebola Virus Disease
FAO	Food and Agriculture Organization
GARD	Global Antibiotic Research and Development
GATE	Global Cooperation on Assistive Technology
GDP	Gross Domestic Product
GAELF	Global Alliance to Eliminate Lymphatic Filaraisis
GHIT	Global Health Innovative Technology Fund
GHRF	Commission on a Global Health Risk Framework for the Future
GHSA	Global Health Security Agenda
GLASS	Global AMR Surveillance System
GSA	Global Schistosomiasis Alliance
HAT	Human African Trypanosomiasis
ICC	International Chamber of Commerce
IDM	Intensified Disease Management
IHR	International Health Regulations
IMF	International Monetary Fund
IoT	Internet of Things
IoMT	Internet of Medical Things
IP	Intellectual Property
IPR	Intellectual Property Rights
IVM	Integrated vector management
JEE	Joint External Evaluation
MDR-TB	Multidrug-Resistant Tuberculosis
MERS	Middle East Respiratory Syndrome
NCD	Non-communicable Diseases
NGO	Non-Governmental Organization
NTD	Neglected Tropical Diseases
OECD	Organization for Economic Cooperation and Development
OIE	World Organization for Animal Health
PCT	Preventive Chemotherapy and Transmission Control
PDP	Product Development Partnership
PLHIV	People living with HIV/AIDS
PPP	Public-Private Partnership
PSC	Pandemic Supply Chain

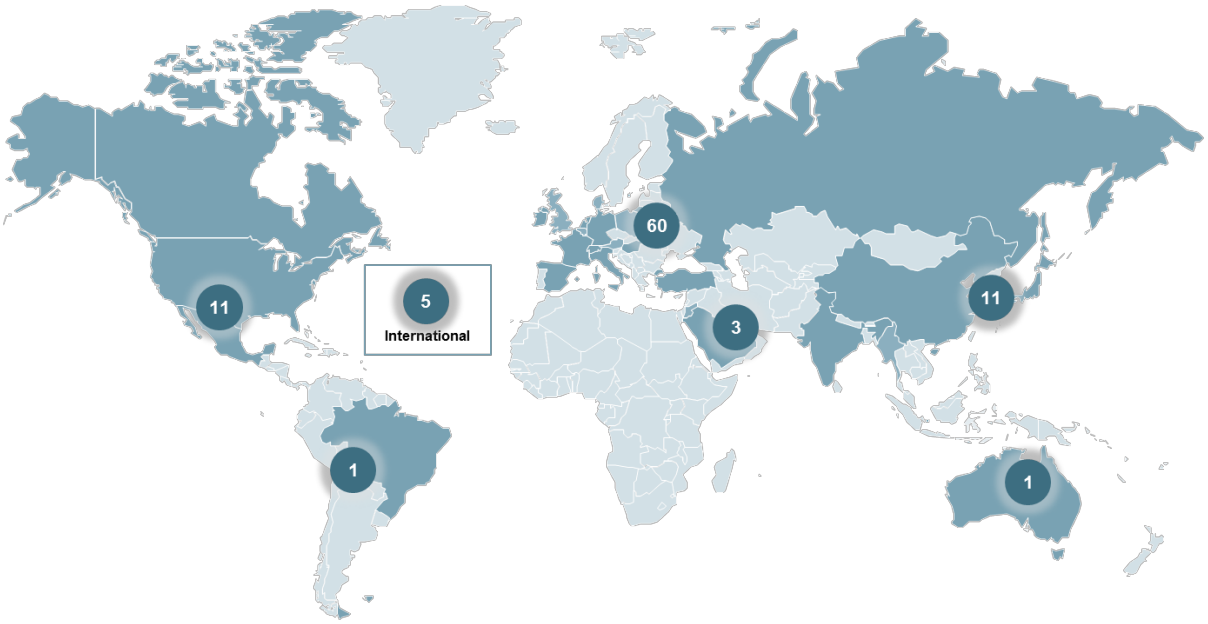
PSRT	Private Sector Roundtable
R&D	Research and Development
SDG	United Nations' (UN) Sustainable Development Goals
SME	Small and Medium Enterprise
STH	Soil-transmitted helminthiasis
TPP	Target Product Profiles
UHC	Universal Health Coverage
UN	United Nations
UNCTAD	United Nations Conference on Trade and Development
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VCAG	Vector Control Advisory Group
WASH	Water, sanitation, and hygiene
WEF	World Economic Forum
WFP	World Food Program
WIPO	World Intellectual Property Organization
WHO	World Health Organization
WHOPES	World Health Organization Pesticide Evaluation Scheme

Schedule of Taskforce Meetings

#	Date	Location	Theme
1	22 March 2017	Paris	Discussion of policy proposals in 1st policy paper draft
2	07 April 2017	Conference Call	Discussion of taskforce recommendations in 2nd policy paper draft
3	12 May 2017	Conference Call	Refinement of taskforce policy proposals in 3rd policy paper draft
4	18 May 2017	Berlin	Presentation of Policy Recommendation to G20 Health Ministers

Distribution of Members

Country	#	Country	#	Country	#	Country	#
Australia	1	India	1	South Korea	3	Total	92
Brazil	1	Italy	1	Turkey	3		
Canada	3	Japan	1	United Kingdom	3		
China	5	Mexico	1	United States	7		
France	1	Russia	1	International	5		
Germany	37	Saudi Arabia	1	Other	17		



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