HEALTHY NATIONS
SUSTAINABLE ECONOMIES

HOW INNOVATION CAN BETTER ENSURE HEALTH FOR ALL

PROFESSOR DAVID L. HEYMANN, MD

RECOMMENDATIONS TO G20 HEADS OF GOVERNMENT & MINISTERS
The health and well-being of citizens is an essential driver of inclusive economic growth. Bringing health and finance ministries together, enabling international comparison and the exchange of good country practices contributes to the sustainable financing of health systems and the development of better policies for better lives.

Francesca Colombo
Head of Health Division, OECD

In order to achieve the United Nation Sustainable Development Goals by 2030, this report presents and innovative approach of how gaps in health funding can be tackled by lifting the burden on global economies – We welcome the creation of this report for the G20 Presidency in Japan.

Mitsunari Okamoto
Member of the House of Representatives & former Parliamentary Vice – Minister of Foreign Affairs, Japan

The ancient African principle of Ubuntu, we are what we are because of others, underpins the vital importance of recognizing our interdependence and shared humanity. This is particularly true in tackling global health issues. No nation or sector public, or private, can do this on its own. This welcome report is a practical call to action. It should inform the conversation between nations, civil society, and ministries of health and finance that is vital in the delivery of cost effective and accessible solutions to global health challenges.

The Rt Hon The Lord Boateng
Member of the UK House of Lords

“If we want to tackle some of the most pressing global health challenges such as AMR and the levels of obesity, diabetes and heart-disease globally, we must ensure the engagement of a wider-group of stakeholders by also including parliamentarians more into the debates on health innovation – This report rightly highlights how diseases, that are obstacles for future economic growth, can be tackled with new and alternative financing mechanisms in health.”

Nigel Evans MP
Member of the International Development & Trade Committee
UK House of Commons
NCDs in Saudi Arabia account for 73% of deaths and this is a major challenge to our national economy. As my engagement with this Partnership dates back to the G20 presidency in Germany in 2017, I fully support and welcome the recommendations set out to G20 leaders in this report and look forward to discussing them in Saudi Arabia in 2020.”

Abdullah Aldahmash
General Director of Prince Nafif Bin Abdulaziz Health Research Center and Founder and Director of Stem Cell Unit, King Saud University

“"I recognize the potential to advance the values of the Commonwealth Charter through collaboration with the G20 Health and Development Partnership in its efforts to ensure advocacy for innovative health financing. Through Commonwealth connection and collaboration, we are able to facilitate the sharing of experience on financing universal health coverage, appreciating the need for mutual support among our member countries on efforts to accelerate universal health coverage so that the needs and priorities of all people living in them can be satisfactorily addressed.”

The Rt Hon Patricia Scotland QC
Secretary General, The Commonwealth

It is predicted that several countries in the G20 will not be able meet the United Nations Sustainable Development health goals by 2030. I endorse the calls contained within this report calling for cooperation between G20 heads of government, finance- and health ministers to actively promote partnerships and existing and innovative financing models in global health research.”

Angela Eagle MP
Former Shadow Minister, Treasury & Member of the European Statutory Instruments Committee, UK House of Commons

“"You cannot think of the world’s most pressing issues without thinking about their interrelatedness – health and climate change will affect our global economy, will affect people’s lives, especially in regions left behind. Therefore, let us broaden our horizon in thinking of innovative partnerships and let us strengthen synergies to reach the sustainable development goals. Migration is a result of war, violence and especially of terrible living conditions in the time of climate change.”

Elmar Brok
Member of the European Parliament
I would like the G20 health and finance ministers to bring about the necessary marriage between the wealth and the health of nations.

Lord Jim O’Neill
Chair, Royal Institute of International Affairs
Chatham House London

FOREWORD

In 1776, Adam Smith published *The Wealth of Nations*. This Scottish economist—though he would describe himself as a philosopher—transformed thinking about how wealth is created and what either helps or hinders wealth creation.

If Adam Smith were to return today, I believe he would be writing a follow-up to his famous treatise called *The Health of Nations*. It would argue that an unhealthy nation would never, if poor, become a sustainable and wealthy economy; and if rich in terms of GDP per capita, an unhealthy nation could become even stronger if it invested in a healthy citizenry.

I am an economist and have spent a life studying how countries—outside the golden club of those that have been accumulating wealth in one way or another over centuries—can lift themselves higher up the economic league table in order to serve their people. Good health is clearly one of the ways in which countries can more rapidly lift themselves higher, through ensuring access to quality health services.

But most health services have been set up as separate parts of the state and were not integrated into long-term economic thinking and planning. Over the years I have become more and more convinced that the care of the health of nations must migrate from the strict confines of health professionals, who are essential to delivering good health, into the mainstream deciders of the economy who provide the resources necessary: finance ministers, bankers, investment fund managers and other stewards of the nation’s wealth.

But let me stress, this concept is not about subordinating health care to national financial or economic priorities, it is about working together while the window of opportunity for good health remains open. In 2018 I co-authored a book titled *Superbugs: An Arms Race Against Bacteria* that looked at the new challenge of combating resistance of bacteria to antibiotics. Resistance was already predicted by Alexander Fleming, the discoverer of penicillin, who told his research team in the 1940s that bacteria were smart and would mutate to make themselves resistant to attacks by antibiotics, especially if the latter were dispensed too liberally.

And today most bacteria have developed resistance. Tuberculosis (TB), for example, has rapidly developed resistance to the antibiotics used to cure it. TB was the HIV/AIDS of the 19th century in Europe—who has not felt a tear in the corner of an eye when watching Mimi fade away from TB in Puccini’s opera, *La Bohème* or as they see how TB continues to ravage the poor of the world today? 10 million people are infected each year, and 1.6 million die, including 200,000 children. And resistance to antibiotics used to treat TB continues to increase, partially closing the window of opportunity to effectively treat and save lives.
At the same time, non-communicable diseases (NCDs) such as cancer, cardiovascular diseases, chronic respiratory diseases, diabetes and mental health disorders are becoming the leading cause of death and disability worldwide. It is estimated that in low- and middle-income countries (LMICs) 80% of the global NCD-related deaths occur, often because of a lack of trained healthcare professionals that limits access to care, and the failure of governments to allocate the necessary resources. Deaths from NCDs are expected to nearly double by 2030.

I would invite the G20—which includes rich, middle-income, and poorer countries, including of course the BRIC (Brazil, Russia, India and China) nations that I headlined as 21st century players 20 years ago—to make health part of their thinking. I would like the G20 health and finance ministers to bring about the necessary marriage between the wealth and the health of nations.

It is an appeal to G20 finance ministers to remove the silo walls around health care to see what can be done to make a link between the health and the wealth of our nations. If asked, many would place great value on being healthy throughout a lifetime, but societal goals are still described in terms of income, employment and economic growth. Too often, policy-making is narrowly focused on short-term GDP-based metrics, with the social and economic value of health overlooked. The biggest influences on people’s health are not only access to health facilities and hospitals but also timely access to innovative, affordable and effective drugs, vaccines, diagnostics and equipment; appropriate housing; education; and access to affordable food.

This report by the G20 Health and Development Partnership sets out to support the need to invest in human capital in terms of global health. It is a holistic approach that blends economics and health so that the wealth and the health of nations are united in a new priority for government, society and the economic actors in the rest of the century.

Lord Jim O’Neill
Chair, Royal Institute of International Affairs
Chatham House London
Health challenges must be treated with the same importance and urgency as climate change throughout the G20 and beyond.

AN OPEN LETTER TO G20 HEADS OF GOVERNMENT & FINANCE & HEALTH MINISTERS

Within year four of the implementation of the 17 United Nations Sustainable Development Goals (SDGs) covering social and economic development issues, policy-makers, the private sector, academia and non-profit organizations worldwide must realize that more urgent and coordinated actions are necessary to tackle the most pressing challenges in the 21st century.

Recent studies demonstrate that some G20 countries will fail to meet the 2030 health goals under SDG 3.

Underinvestment in measures to tackle the disease burden and improve health within the G20 is seriously impairing growth and economic performance and presents major long-term challenges for public budgets. As a matter of fact, all 17 SDGs are intertwined and better economic growth, rising quality of life, safer environments, digital transformation and better employment can only be achieved if we ensure healthy lives and promote wellbeing for all (SDG 3).

Climate change was largely left to environment ministers in the 1990s but is now quite rightly on the agenda of the G20 heads of government and that of finance ministers. G20 policy-makers must understand that the other existential threat to humanity is the spread of drug-resistant communicable diseases and the rapid increase in non-communicable diseases in society. Health challenges must be treated with the same importance and urgency as climate change throughout the G20 and beyond.

The G20 Health and Development Partnership, which emerged during the course of the German presidency of the G20 in 2017, is an advocacy organization that aims to ensure that G20 countries are coordinating their health innovation strategy to tackle the growing burden of communicable and non-communicable diseases globally. With the support of 21 leading global organizations, representing more than 1000 collaborators, we have created a unique cross-sectoral partnership that includes: The TB Alliance; Medicines for Malaria Venture (MMV); the Coalition for Epidemic Preparedness Innovations (CEPI); the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA); PATH; the Global Fund to Fight AIDS, Tuberculosis and Malaria; the Global Health Technologies Coalition (GHTC); mPedigree; Unitaid; the Global Health Innovative Technology Fund (GHIT); Novartis; African Risk Capacity (ARC); Johnson & Johnson; Bugworks; Lombard Odier (IFlFm); FIND; DMI; and Ending Pandemics, with academic support from Harvard T.H. Chan School of Public Health, Harvard Kennedy School and Columbia University.

The Partnership would like to thank the G20 presidencies of Germany and Argentina for giving health a prominent role during their presidencies in 2017 and 2018. We also welcome the creation of the Global Observatory on Health R&D and the newly established AMR Collaboration Hub created under the G20 presidency of Germany. We now welcome the Japanese G20 presidency’s tremendous efforts to make health play a central part of the G20 agenda in 2019. We also welcome the first Joint Session of Health and Finance Ministers that will be organized under the Japanese presidency.

This report aims to elevate health permanently on the agendas of finance ministers and heads of governments during the G20 presidency of Japan and will be submitted to all G20 stakeholders ahead of the G20 summit and the Joint Session of Health and Finance Ministers in June 2019. Our partners set out concrete examples of the successes that have been achieved from investment in health innovation. These examples demonstrate convincingly that through coordinated and sustained investment and partnership, significant progress can be made within the timeframe of the SDGs. This report also highlights existing and new models for innovative and blended forms of financing that have been most successful and that significantly supplement funds that are currently provided by the governments, the private sector and philanthropic organizations.

Commencing 2019, the G20 can set in motion steps to examine new ways of funding innovation in health and encourage the establishment of mechanisms that will help to fund the diagnostics, vaccines and medicines that are so urgently required globally. Investment in health innovation produces significant returns, including improvements in sustainable economic growth. Michael Bloomberg has recognized that in tackling climate change there is a need for a major new global initiative that engages with the financial services industry, including major sovereign and pension funds. Health requires a similar initiative that should include those businesses that are benefitting from globalization. The G20 Health and Development Partnership urges G20 policy-makers to carefully consider the evidence in this report and adopt its recommendations, which we believe can make a major impact on reducing the disease burden and help deliver on the SDGs to which we all signed up in September 2015.

Alan Donnelly
Convener, The G20 Health and Development Partnership, Executive Chairman, Sovereign Sustainability and Development
BACKGROUND – THE G20 HEALTH & DEVELOPMENT PARTNERSHIP

The G20 Health & Development Partnership emerged over several months of consultation and policy dialogue that started in 2016 and included a lynchpin “G20 Global Health Innovation” roundtable in Berlin in April 2017.

Following broad interest to build on the initiative, Sovereign Sustainability and Development (SSD) was created to act as the convener and secretariat of the Partnership and a Working Session was hosted in the UK Houses of Parliament in December 2017 to collectively plot a course for the Partnership. Following another event in May 2018, in the side-lines of the World Health Assembly (WHA) in Geneva, the G20 Health & Development Partnership urged G20 heads of government, health and finance ministers to incentivize innovation in health research and development and delivery. Over the course of three years building this initiative, we have broadcasted our messages to the highest political levels by engaging with policy-makers and the media to echo the common messages of our partners. Our experience was that the economic impact of the growing burden of diseases are well-recognized by health stakeholders but that decision-makers outside of the health sector have little understanding of the return on investment from public and/or private investments in addressing global health challenges. Therefore, our objective was to break the existing silos.

This report is prepared for the G20 troika of Argentina, Japan and Saudi Arabia by including Germany in its focus based on its successful presidency championing health in 2017. The case studies in this report convincingly exemplify that through coordinated, innovative and sustained investment and cross-sectoral partnership models, further significant progress can be made within the timeframe of the United Nations Sustainable Development Goals.

As the G20 will continue its focus on areas such as health emergencies, antimicrobial resistance (AMR), health systems strengthening and universal health coverage, we will seek to add value and support these areas of prioritization and drive political support. We aim to align with the WHO’s 13th General Program of Work (GPW13) by maintaining a focus on the broader innovation ecosystem. In 2019, we will organize a series of events including the launch of this report in the UK and a Health20 event in Osaka that coincides with the G20 summit and the Joint Health- and Finance Ministers’ Meeting focusing on global health innovation and innovative financing for health. We will explore further potential avenues for advocating our agenda in national and international fora in and beyond the G20.

For more information about the G20 Health & Development Partnership, please contact us.

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It presented scientific evidence to support the argument that health is critical to economic development, and that health will not automatically improve as a result of economic growth. In simple terms, the report provided evidence that demonstrates how disease is an obstacle to economic growth.

The report affirmed the vision of the then Director-General of the World Health Organization (WHO), Gro Harlem Brundtland, who had come to the organization in 1998 convinced that health must be placed at the center of sustainable development. Global health – in addition to its humanitarian goals – thus became a political and economic issue.

With this understanding, multinational and bilateral development partners seeking to improve global health broadened the range of partners they engaged with to include economists, civil society, private philanthropic organizations, industry, financial institutions and academics. The intensified period of innovation that resulted from these new partnerships changed the way in which the world does business to improve health.

It was a privilege to work under Director-General Brundtland during the five years she led WHO, when the report on macroeconomics and health was prepared and when a flow of new ideas led to the development of innovative mechanisms for ensuring better health in low- and middle-income countries.

Many of those innovations are highlighted in this report to demonstrate the benefits of inclusive partnerships that permit each partner to add its comparative advantage, underpinned by funding from philanthropic organizations and development agencies in G20 and other countries. Through these partnerships, for example, large databases of compounds held by pharmaceutical companies are being made available for screening and further research and development of drugs for infectious and tropical diseases; fiduciary principles of private banking and investment are being applied to funds that increase access to medicines and vaccines; and existing and new technologies are being better applied to a range of activities to strengthen health security.

The innovations summarized in this report have been organized under three chapters. The first chapter, titled “Research and Development to Ensure Better Health”, outlines mechanisms for increasing research and development for new or improved medicines and vaccines. The second chapter, titled “Adapting and Developing Enablers of Health Security”, highlights field studies of technologies that enhance our health security: diagnostic tests to better protect individual health; communications to increase uptake of health services; and mobile phone technologies adapted to detect counterfeit medicines and infectious disease outbreaks. The third chapter, titled “Creating an Environment to Enhance Delivery and Uptake of Innovations”, describes community-based mechanisms to increase demand for new and innovative health products and demonstrates how innovation can be accompanied by blended forms of financing to fund continued research and better ensure access to the newly developed goods to improve health.

The report ends with conclusions that are drawn from the innovations it summarizes, and from academic institutions, and provides six recommendations that if implemented have the potential to increase the health of all – those living in G20 and other high – and middle-income countries and those who live in low-income countries that depend on development assistance and support.

Professor David L. Heymann, MD
Head, Centre on Global Health Security
Chatham House

“...It is also a privilege, almost twenty years later, to work with the G20 Health and Development Partnership to prepare this report for G20 Heads of Government and health and finance ministers of the G20 – a report that shows the results of innovation in health that started at the end of the 20th century and continues today.”
CHAPTER ONE

“Less than 10% of worldwide resources devoted to health were put towards health in developing countries, where more than 90% of all preventable infectious disease deaths occurred.”

RESEARCH AND DEVELOPMENT TO ENSURE BETTER HEALTH

By the turn of the 20th century one of the major obstacles to the development of vaccines and medicines for infectious disease in developing countries had become the lack of commercial incentives.

Though the developing market was high in volume, the profit margin was low. The majority of the research-based pharmaceutical companies therefore concentrated their focus on industrialized-country markets, where they are able to recoup their research and development costs within the time limit of their patents.

By the late 1990s, studying developing country needs, the Global Forum for Health Research adopted the term “the 10/90 gap” to call attention to the fact that less than 10% of worldwide resources devoted to health were put towards health in developing countries, where more than 90% of all preventable infectious disease deaths occurred.

As understanding developed early in the 21st century (from reports such as the Sachs report on macroeconomics and health) that healthy populations lead to healthy and sustainable economies; and with funding from major philanthropic organizations such as the Bill & Melinda Gates Foundation and the Wellcome Trust and from G8 and other European government development agencies, innovation took front and center. It did so in the form of innovative public/private partnerships that linked databases and compound libraries of the research-based pharmaceutical companies to academia and other research groups, with public and private funding taking the risk.

The following innovations provide a sample of the many innovations in research and funding for the development of new medicines and vaccines that have occurred during the past 20-year period.
FACT

TB is the leading infectious cause of death in the world; each year 10 million people fall ill and 1.6 million die.

NEW AND IMPROVED TUBERCULOSIS THERAPIES FOR CHILDREN

Tuberculosis (TB) is the leading cause of death worldwide from a single infectious agent; each year 10 million people fall ill and 1.6 million die, including more than 200,000 children.

Before 2015, drugs for children with TB did not exist and health workers were required to break or crush bitter-tasting adult pills that children often refused to take and that health workers had difficulty judging the correct dose.

TB Alliance, a public-private partnership, launched STEP-TB in 2013, provided funding to a number of private pharmaceutical companies that then committed to develop less bitter and properly dosed TB treatments for children. The new child-friendly, therapeutic, dissolvable, fixed-dose combination product is now being made available through the Stop TB Partnership’s Global Drug Facility to countries around the world as well as directly from the manufacturer.

To build the investment case, TB Alliance worked with academic modelers to refine estimates of the childhood TB burden and the potential market for paediatric TB formulations. These more accurate estimates raised the previous estimate of 550,000 paediatric infections (and 200,000 deaths) each year to more than 1,000,000 infections per year, indicating a more viable market.

The partnership with Macleod’s Pharmaceuticals was essential in developing, commercializing, and registering the child-friendly formulation to treat TB. The non-governmental organization, Management Sciences for Health, working with the Global Drug Facility, supported the company through regulation and procurement, while the World Health Organization (WHO) worked with countries to ease the introduction of the new therapeutic syrup. Lupin, a second pharmaceutical company, also took up the challenge and is also developing a child-friendly therapeutic formulation.

“India and Cote d’Ivoire were the first countries to register the new drug. Working with WHO, TB Alliance, Management Sciences for Health and the Kenya Centre for Health Solutions, the government of Kenya was the first country to successfully introduce the therapeutic product into its health system nationwide. Since then more than 80 countries have procured the drug.”

Cheri Vincent
Chief, Tuberculosis Division, USAID
Some key lessons to better ensure health for all from TB Alliance’s work:

- Improved products widely available at roughly US$ 15 for full treatment, similar to the cost of previous drugs.
- Reduced risk of development of drug-resistance in children because of precise dose and better compliance.
- Better understanding of the paediatric TB burden by a strengthened process for estimation.
- More competitive market for paediatric TB therapies because two private pharmaceutical companies have developed the child-friendly TB drug.

- Increased visibility of paediatric TB in the broader child survival agenda through awareness that TB is a major challenge to child survival and related SDGs.
- Increasing diagnostic and treatment linkages with the Stop TB Partnership’s Childhood TB Working Group.
- Development of a model for future development of innovative medicines for children that has proven effectiveness and can be rolled out in those G20 neighbouring countries where childhood TB is a major problem.
“MMV shows how the market can work for the world’s poorest people”

Melinda Gates
Founder of Bill and Melinda Gates Foundation

HARNESSING GOVERNMENT AND THE PRIVATE SECTOR TO COMBAT MALARIA

Medicines for Malaria Venture (MMV) brings together researchers from the public and private sectors including pharmaceutical companies, biotechnology laboratories, universities and public research institutions from 30 countries.

The result is the assembly of the largest and most diverse pipeline of malaria drug development projects in history.

MMV was created in 1999, when resistance to known antimalarials was increasing and the pipeline for new antimalarials was virtually empty. Though new antimalarials were needed, the return on investment was too low to attract pharmaceutical research. MMV was developed to leverage donor funding, sourced through syndicated investments by governments, philanthropic organizations, international organizations and private sector funders. This funding has enabled industry, academia, contract research organizations, governments and non-governmental organizations (NGOs) to work together to discover, develop and deliver on a revitalized malaria drug pipeline.

MMV leverages the facilities, knowledge and expertise of the pharmaceutical and biotechnology industries as well as research and academic institutions, drawing on their valuable experience and resources at every stage of the drug development process.

MMV has brought forward nine quality-assured malaria medicines since 2009 aimed at addressing various medical needs of malaria patients and has worked to increase access to them and to two others transferred from DNDi. To date an estimated 1.5 million lives have been saved by these MMV-supported drugs.

“If international cooperation on malaria and indeed other diseases has received such results in 20 years, can we not apply a similar model to other global health challenges?”

Jeremy Lefroy MP
Member of Parliament, UK House of Commons
More than 100 million vials of Artesum®
[Glulin Pharmaceutical’s MMV supported injectable antimalarial] for servers malaria delivering since 2010 – saving an estimated 650,000 additional lives compared to treatment with quinine.

Over 350 million treatments of Child-friendly Coartem® Dispersible
[artemether – lumefantrine, co-developed with Novartis] distributed in over 50 countries since launch in 2009.

Over 250 Pathogen boxes
shipped free of charge to scientists round the world to boost neglected diseases drug discovery.

More than 1.5 million lives saved
by MMV – supported medicines since 2009.

1st child-friendly medicine
Approved via article 58, Pyramax Granules

1st single dose cure for relapsing Malaria
[Pyramax] approved by the US FDA and Australian TGA.

68 million Courses of SP+AQ
shipped to countries in West Africa’s Sahel region 2017 by MMV’s partner Glulin Pharmaceutical enough to Provide 18 million children with Seasonal Malaria Chemoprevention.

Treatments of child-friendly Coartem® Dispersible distributed to more than 50 countries since 2009

Of investment impact thanks to direct and in-kind support from partners

Suppository products for pre-referral management of severe malaria approved

MMV rigorously manages its research portfolios using resources flexibly and based on need. It terminates failing projects as early as possible, replacing them with better back-up compounds when warranted. It works with partners to develop and facilitate the use of innovative and life-saving interventions in the community. Rectal artesunate, for example, rapidly clears at least 90% of malaria parasites in the body of children with severe malaria and buys time to allow them to reach higher-level health facilities to receive the complete treatment with injectable artesunate or another medication approved by the World Health Organization (WHO).

MMV raises funds to finance its research portfolio and receives funds from major donors and development agencies around the world. Since its foundation, MMV has raised more than US$ 1 billion to invest in the largest-ever antimalarial drug research and development (R&D) portfolio. MMV also negotiates in-kind contributions from industry partners to maximize the impact of funds raised. It successfully de-links R&D expenditure from marketing and price, operates under a strict value-for-money approach and strives to maximize the impact of funding by maintaining low overhead expenses.

Achieving the UN and WHO targets of a 90% reduction in morbidity and mortality by 2030 will require intensified investment and effort, coupled with transformative tools and with strategies to maximize treatment effectiveness. The World Malaria Report 2018 states that, for the second year running, progress in malaria has levelled off globally, with still one young child dying of malaria every 2 minutes. The disease can infect an African child more than 10 times a year. If not treated within 24 hours of symptom onset, malaria can progress to severe illness, which often leads to death. MMV prioritizes the development of easier-to-administer and palatable child-friendly formulations, which are highly needed. This requires sustained R&D investment from the international community; antimalarials adapted to the needs of pregnant women – another population which is highly vulnerable to malaria; medications addressing special forms of the disease such as seasonal, relapsing and severe malaria; and treatments able to counter antimalarial drug resistance as a contribution to the fight against antimicrobial resistance and in support of the global health security agenda.

MMV uses its funds wisely, and as a result the estimated cost of clinical development of an MMV medicine is US$ 4.5 million per year, compared with US$ 12.5-25 million for a medicine developed by the pharmaceutical industry alone. Direct and in-kind support obtained from pharmaceutical partners more than triples the value of each dollar donated to MMV. This demonstrates how funding from G20 governments can be powerfully leveraged to drive down the cost of essential medicines, such as those to treat malaria, to affordable levels for the poorest and most vulnerable groups.
A GLOBAL INSURANCE POLICY TO DEFEND AGAINST FUTURE EPIDEMICS

In a world characterized by increasing population density, human mobility and ecological change, emerging infectious diseases pose a real and growing threat to global health security.

Epidemic diseases affect us all and they do not respect borders. If a highly contagious and lethal airborne pathogen with the characteristics of the 1918 Spanish Flu were to emerge today, it is estimated that nearly 33 million people worldwide would die in just 6 months¹. The costs of emerging infectious diseases are vast, in both human and economic terms. Recent economic work estimates that the annual global cost of moderately severe to severe pandemics is roughly $US 570 billion, or 0.7% of global income². Even small epidemics can cause tremendous economic disruption.

The global need for an organization like the Coalition for Epidemic Preparedness Innovations (CEPI) was recognized after the devastating West African Ebola epidemic, which killed more than 11,000 people and had an economic and social burden of more than $US 53 billion³. The world’s response to this crisis fell tragically short. Against this backdrop, CEPI was launched at Davos 2017 by the governments of Norway and India, the Bill & Melinda Gates Foundation, the Wellcome Trust and the World Economic Forum based on a consensus that a coordinated, international, and intergovernmental plan was needed to develop and deploy new vaccines to prevent future epidemics.

As such, CEPI was established to accelerate the development of vaccines against emerging infectious diseases and enable equitable access to these vaccines for affected populations during outbreaks. CEPI offers a unique opportunity for its investors to lead on global health security and, in partnership with other governments and international organizations, invest in a solution that protects some of the most vulnerable people in the world while helping prevent the global spread of epidemics. However, planning for emerging infectious diseases is challenging, as the research and development (R&D) is complex, lengthy and expensive. The market potential for such vaccines is limited and testing such vaccines is difficult.

1. www.idmod.org/news/node/296
Japan has highlighted the importance of pandemic preparedness and universal health coverage. I believe that CEPI will contribute to achieving them through encouraging development of vaccines.”

Yasuhisa Shiozaki
Minister of Health, Labour and Welfare, Government of Japan

There are already many actors in vaccine funding and R&D implementation, but a number of critical gaps have been identified, which CEPI has been designed to fill:

• CEPI advances vaccines against known disease threats through proof-of-concept and safety testing in humans and will establish investigational stockpiles of these vaccines before epidemics begin;

• It funds new and innovative vaccine platform technologies that can accelerate the development and manufacture of vaccines against unknown pathogens (also referred to as “Disease X”);

• CEPI will coordinate activities to improve collective response to epidemics, strengthen capacity in countries at risk and advance the regulatory science that governs product development.

To date, CEPI has secured more than US$ 750 million toward its US$ 1 billion funding target, with financial support provided by the Bill & Melinda Gates Foundation, the Wellcome Trust and G20 members such as the European Commission, and the governments of Australia, Belgium, Canada, Germany, Japan, Norway and the United Kingdom.

Since its launch, CEPI has announced three calls for proposals (CfP) inviting applicants to submit funding proposals for projects to develop specific vaccine candidates or research that can directly support vaccine development. The first call supported candidate vaccines against Lassa viruses, MERS coronavirus and Nipah virus. These were chosen from a priority list established by WHO in its R&D Blueprint for Action to Prevent Epidemics. CEPI has established nine partnership agreements to date, reflecting a potential investment of more than US$ 270 million and supporting the development of 17 vaccine candidates (against Lassa, MERS, Nipah, Marburg, influenza, respiratory syncytial virus and rabies), and has a number of additional partnerships under negotiation. CEPI has partnered with organizations such as Janssen Vaccines & Prevention B.V., Imperial College, IDT Biologika, Inovio, International AIDS Vaccine Initiative, Profectus Biosciences, Themis Bioscience, and University of Oxford. These partnership agreements represent just the start of CEPI’s product development portfolio.

The second call for proposals will advance vaccine platforms that will enable CEPI to rapidly respond to the emergence of an unknown pathogen. The third call for proposals will support vaccines against Rift Valley fever and Chikungunya viruses.

CEPI is by definition an international organization but its work requires close engagement with national scientists in the countries where the target pathogens are present. By engaging with CEPI, G20 finance and health ministries can help prevent the international spread of epidemic diseases. CEPI engages with countries where its priority pathogens are likely to emerge or re-emerge by involving national scientists in the review process of research proposals it solicits, and by establishing bilateral partnerships with national and regional research institutions. CEPI thus aims to prevent, contain and mitigate future outbreaks in low- and middle-income countries, and because of this, the world more broadly will have greater health security.

For CEPI to accelerate the development of vaccines against emerging infectious diseases, it must overcome a number of hurdles. For example, the epidemiology of CEPI’s priority pathogens is not well understood; animal models and other models for research and development are underdeveloped; and international standards for analytical tools with which to assess vaccine effectiveness have not yet been established. With financial and technical support from G20 countries, these challenges can be overcome.

Just over a year ago 193 states adopted the Sustainable Development Goals –the roadmap for the future we want. Epidemics threaten that future. They can ruin societies on a scale only matched by wars and natural disasters. They respect no borders and don’t care if we are rich or poor. Protecting the vulnerable is protecting ourselves. This is why we all must work together to be better prepared –and why my government is fully committed to ensure that CEPI achieves its mission.”

Erna Solberg
Prime Minister, Norway
**FACT**

GHIT has invested US$ 141 million in 77 projects for malaria, tuberculosis, and neglected tropical diseases.

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**NEW THINKING FROM JAPAN – FUSING PRIVATE AND PUBLIC SECTORS IN THE BATTLE FOR GLOBAL HEALTH**

The Global Health Innovative Technology Fund (GHIT) was conceived in 2011 by Japan’s pharmaceutical industry, when CEOs sought to build on Japan’s legacy of global leadership in drug development and technological innovation by linking with official development assistance for global health research and development (R&D).

The GHIT Fund invests across four research platforms (Target Research, Screening, Hit-to-Lead and Product Development) in R&D partnerships between Japanese and non-Japanese pharmaceutical companies and research institutes. This gives researchers around the world access to Japanese expertise and investment, linking it to the global pipeline.

In 2013, the initial GHIT partners committed approximately US$ 100 million over 5 years. Half came from the Japanese ministries of Foreign Affairs and Health and the other half came from Japanese pharmaceutical companies, as well as the Bill & Melinda Gates Foundation. In 2016 the Government of Japan announced an additional US$ 130 million contribution, and in 2017 GHIT secured commitments of more than US$ 200 million for its next phase of work, allowing it to increase the speed at which the most advanced of its medicines become licensed and reach the hands of those who need them most.

GHIT has invested US$ 146 million in 74 projects for malaria, tuberculosis and neglected tropical diseases. There are currently 46 active R&D projects, and eight developmental products have been tested in G20 countries including in Africa and South America. One such product is a paediatric formulation of praziquantel, a drug for schistosomiasis that causes serious illness in children and adults and that if not treated can lead to cancer.

The GHIT Fund uses private-sector standards for product development, investing heavily in management and evaluation of projects, swiftly terminating non-performers. GHIT has a “private-sector” orientation to the management of investments, but no expectation of financial return. Through its public/private partnerships, GHIT has also made possible the screening of tens of thousands of developmental drugs for potential new treatments. By serving as a matchmaker between the public and private sectors, GHIT enables all partners to capitalize on their strengths in R&D and address diseases that affect one out of seven people on earth.
Japan is a leader in global health, and GHIT is a primary example of Japan’s commitment to transforming the global health landscape with a partnership that brings together the unique resources of governments, pharmaceutical companies, and the philanthropic sector to develop products that can turn the tide against the greatest burdens of disease in low- and middle-income countries.”

Trevor Mundel
President of Global Health
Bill & Melinda Gates Foundation

“I believe that having global public–private partnerships from the very beginning has been a key factor in the GHIT Fund's success to date.”

Keizo Takemi
Member of the House of Councillors of Japan, Chairman of the Special Committee on Global Health Strategy for Japan’s Liberal Democratic Party

Photo credit: pixalbay.com
Already, innovation had played a role in the development of the World Health Organization Expanded Programmes on Immunizations in 1970. A group of scientists, health professionals, business leaders, engineers and experts in other specialties, supported by development agency funding, had developed new immunization-related products suitable for use in developing countries. These products had been inserted into immunization programs, increasing their safety and effectiveness almost overnight.

But by the 1990s another major gap had been identified in the global armamentarium to fight infectious diseases—tests for disease diagnosis that were simple to use and could clearly demonstrate the cause of disease near the bedside so that patients could be better managed. Several innovative mechanisms are having success in developing the needed tests, especially important as antibiotic overuse continues to reduce the effectiveness of our antibiotic supplies because patients are treated without accurate diagnosis. Initiatives are also being developed to increase uptake of these devices and other goods in communities, with a goal of better health for all.

And finally, globalization has brought with it risks that range from cross border trade in counterfeit medicines to spread of infections that cause major outbreaks and economic setback.

This chapter provides some examples of innovative research and development partnerships and financial mechanisms that were developed to fund global health innovations, promote more effective health seeking behaviour, improve safety against counterfeit medicines, make transport and use of vaccines safer and enhance response to existing deadly diseases and outbreaks caused by new and emerging infections. Financial mechanisms that mobilize and disburse funds necessary to continue the development of new medicines and vaccines are also described, as is a unique African fund to provide up-front funding for natural disasters and infectious disease outbreaks.
FACT

Every dollar from USAID was matched with two dollars of funding from other sources.

INNOVATIVE SYRINGES AND SMART STICKERS: SAVING LIVES & MONEY

After getting its start more than 40 years ago, PATH works in more than 70 countries to advance innovative ideas for dealing with neglected public health problems...

…with the aim of achieving the third goal of the United Nations Sustainable Development Goals (SDG 3).

PATH advises and partners with public institutions, businesses, grassroots organizations and investors to solve some of the world’s most pressing public health challenges. Products developed by PATH are intended for use in low- and middle-income countries (LMICs), where commercial markets are lacking, and PATH seeks to deploy innovative models to leverage limited donor funding and catalyse investments from the private sector.

For example, The Technologies for Health Program (HealthTech), a partnership with United States Agency for International Development (USAID), resulted in the launch of more than 20 new products uniquely designed for use in LMICs. Development of these products depended on partnerships with the private sector, and they leveraged USAID funding; every dollar from USAID was matched with two dollars of funding from other sources.

PATH received its first HealthTech award from USAID in 1987. The award aimed to support USAID’s goals of developing and introducing low-cost health products to improve maternal and child health. USAID’s decision to provide a multi-year investment across a portfolio of products was unique and a win for all parties involved.

The USAID decision to take a portfolio approach, rather than funding research on a single product, allowed PATH to shift funds between different products in the portfolio as they showed promise. It allowed technical experts to make decisions about which products showed the most promise and were worth continued investment, and it helped reduce risk to the US government by diversifying investments throughout the portfolio. An auto-disable (AD) syringe that was licensed to a private sector partner in 1990 and a vaccine vial monitor that was introduced in 1996 are just two of the dozens of products launched through HealthTech.

Both provide snapshots into the far-reaching health, policy and economic impact of the program.

Every dollar from USAID was matched with two dollars of outside funding.
The auto-disable syringe, which is now widely available at low cost, presents the lowest risk of person-to-person transmission of bloodborne pathogens.”

WHO–UNICEF–UNFPA
Joint Statement, 2003

Auto-disable needles and syringes for safer injection and a policy shift in health care

Before the advent of the AD syringe, many low-income countries faced challenges to ensure the sterilization of injection equipment after every use for the delivery of vaccines and medicines. Recognizing the negative impact of unsafe injection practices, especially in spreading diseases, PATH, with funding from HealthTech, set out to develop and patent a design for an AD syringe that automatically locks after a single injection, making it impossible to reuse.

While PATH had the scientific and technical know-how to design the technology, it partnered with Becton Dickinson and Company (BD), the world’s largest syringe manufacturer, to validate the design, support large-scale production and enable widespread distribution. The initial funding provided by HealthTech enabled PATH and BD to pursue an aggressive distribution program that led to SoloShot™, the world’s first commercially available AD syringe.

Since the launch of SoloShot™, the use of AD syringes, and other safe injection technologies, have led to safe injections and improved health outcomes. Studies have shown that transmission of bloodborne diseases caused by dirty needles has been reduced by 90 percent in programs using some form of AD syringe.

HealthTech investment in AD syringes helped to catalyse the creation of safe injection as a new technology category. It also launched a global policy shift in safe injection and improved healthcare delivery by enabling healthcare workers regardless of experience or training to safely administer injections. More than 7 billion vaccinations have been delivered using SoloShot™ in more than 40 countries.

Safer transportation for safer vaccination

The journey of a vaccine from a manufacturer in a vaccine-producing country to a rural health centre in that country, or in any other country, especially in LIMCs, may take weeks. During this journey the vaccine must be kept cold to avoid spoilage. In the past, vaccines often spoiled en route to health facilities because low temperatures were not maintained, and when unpacked they were either used or discarded by health workers who rightly assumed they had spoiled. To meet this challenge, PATH used funding from HealthTech to develop a suitable technology that could be used to monitor the exposure of vaccines to heat to permit health workers to clearly decide whether to use or discard them.

PATH partnered with small start-up company Temptime, which had the scientific and technical know-how and the intellectual property for such a technology but lacked the understanding of how the technology could be used for global health purposes. Funding from HealthTech enabled the development and validation of the technology that is known as the vaccine vial monitor (VVM), which was introduced in 1996. To date, more than 7 billion VVMs have been used, saving lives by ensuring that vaccines which could have spoiled in transit are potent and safe to use. The VVM is a tiny sticker that adheres to each vaccine vial and changes colour if temperatures during transit rise to unsafe levels. In addition to assuring health workers that the vaccine they use is unspoiled, the VVM has been estimated to save US$ 14 million each year because transport problems are signalled, and cold shipment problems rectified and because health workers no longer unnecessarily discard vaccines out of fear they have been spoiled during transport.

Partnership with the World Health Organization

Through HealthTech, PATH worked with the World Health Organization (WHO) to field test the VVM and engage the United Nations Children’s Fund (UNICEF), the GAVI Alliance (Gavi) and vaccine manufacturers to facilitate the supply of VVMs for vaccines destined for LIMC markets. Buy in from these partners assured adequate demand to keep Temptime engaged in manufacture. Today, all vaccines procured by UNICEF and Gavi must include VVMs, helping to ensure that only unspoiled, potent vaccines are administered in immunization programs.

A variety of the factors that made the PATH/USAID HealthTech program successful can be replicated to decrease the risk of investing in product development for LIMCs, and should be considered as the G20 finance ministers allocate funding for R&D.
Innovative diagnostics that ensure patients get the right treatment are essential to the fight against AMR and access to diagnostics must be a central priority to avoid the rise of drug-resistant disease. Australia invests in diagnostics to ease the challenges brought by drug resistance, especially in tuberculosis and malaria, in Southeast Asia and the Pacific. Supporting FIND is part of Australia’s commitment to the AMR response, and to the health security of our region. FIND is catalyzing diagnostic solutions, from development through to implementation, as well as championing behaviour change initiatives to preserve and protect our life-saving antibiotics.”

Peter Versegi
Australian Ambassador for Regional Health Security

RE-CATALYZING DIAGNOSTIC TEST DEVELOPMENT AND ACCESS TO SAVE LIVES AND FIGHT ANTIMICROBIAL RESISTANCE

Diagnosis is the first step on the path to treatment of infectious diseases.

Rapid and correct diagnosis ensures the use of appropriate treatment and thus increases the efficiency of healthcare spending while helping fight against antimicrobial resistance. Diagnosis is also the foundation of disease surveillance and elimination.

FIND is a product development and delivery partnership, founded in 2003 with initial support from the Bill & Melinda Gates Foundation and subsequent funding from several G20 nations. Its initial goal was to bridge development gaps for essential diagnostic tests by initiating and coordinating research and development (R&D) projects in collaboration with the international research community, the public sector and the diagnostics industry.

After a few years, it was understood that the diagnostic tests being developed needed to also be licensed by and adopted for use in low- and middle-income (LMICs) countries where the need was greatest, and that in some instances there was a need to proactively work with development partners to make them accessible through the public sector and civil society.

Copyright: FIND
FIND has therefore broadened its goals to not only identify needed diagnostic testing solutions and remove barriers to their development, but to also:

- Lead newly developed diagnostic tests through the clinical trials pathway to licensing and global policy on use and market entry.
- Support the uptake and appropriate use of diagnostics to achieve health impact.
- Improve understanding of the value of diagnostics and strengthen commitment to their funding and use.

In order to reach these goals, FIND partners with commercial companies conducting R&D on diagnostic tests, academic and research institutions, international public health organizations and non-governmental organizations, public donors, and philanthropic organizations. The organization works closely with health ministries/disease control programs in G20 countries including India and South Africa.

Through its partnerships FIND has delivered 21 diagnostic tests for diseases including tuberculosis, sleeping sickness and malaria, in some cases helping to transform the diagnostics landscape:

- Tuberculosis patients can now get diagnosis and rapid drug-susceptibility testing in only 90 minutes at a district hospital whereas this took 120 days previously and testing was only available at national reference laboratories.
- A rapid diagnostic test for sleeping sickness has helped to make eradication of the disease a reality. Previous testing relied on obtaining a tissue sample from a lymph node and examining it under the microscope, with limited accuracy.
- A quality control program for currently available rapid diagnostic tests for malaria has spurred an improvement in quality such that 96% of tests now meet World Health Organization quality standards, compared with 23% a decade ago.
- Programs to increase access to hepatitis C screening are now using newly developed rapid diagnostic tests in LMICs in Africa and Asia.

FIND continues to support the development of new diagnostic tests but it is also focusing on packaged solutions that connect the technical world of product development with the realities of access to better diagnosis for end-users. This includes helping to overcome the perpetual delays caused by fragmented regulatory procedures and lack of global policies that sometimes interfere with the best possible patient diagnosis and successful treatment.

Small and medium enterprises, especially from middle-income countries, are playing a greater role in R&D and innovation. For example, FIND works on R&D/clinical studies with partners in middle-income G20 countries including India and South Africa, as well as high-income countries including Australia, France, Germany, Japan, South Korea and the UK. G20 countries could facilitate continued innovation of diagnostic tests by increasing donor and venture capital funding to manufacturers. Even so, the willingness and financial ability to make new diagnostic tests accessible is limited in some LMICs, and G20 finance ministers could advocate for, and provide more funding for, diagnostic tests through mechanisms such as The Global Fund to fight AIDS, Tuberculosis and Malaria, and the Stop TB Partnership.
FACT
Child mortality was estimated to have decreased by 9.7% in the first year of the campaign.

MEDIA IMPACT FOR BETTER HEALTH - CREATING GOOD HEALTH BEHAVIOUR THROUGH RADIO DRAMAS

International development funding from G20 and other countries has strengthened health systems in low- and middle-income countries (LMICs), and adult and child mortality are decreasing in most communities.

To maximize impact, however, there is a need to create greater demand for the health services they offer. Lack of demand occurs either because parts of the local population do not know the services exist, or because they are not aware of the symptoms of dangerous illness in themselves or their children.

Media campaigns can provide straightforward and easily digestible information to increase demand, but many times information alone is not enough. Most people, for example, know about the need for handwashing, but few do it as often as they should. Reasons for not changing behaviour such as handwashing may be cultural or social, such as religious beliefs and local traditions. The media can be used to motivate as well as to inform.

Development Media International (DMI) was established in 2005 with initial grants from USAID and the Joseph Rowntree Charitable Trust. Its focus was on bringing a scientific precision to the creative process of mass media campaigning.

Using radio, television and mobile phones, DMI works with development partners and local media stations in G20 countries in Asia, Africa, Latin America and the Caribbean. It aims to strengthen their capacity to provide mass media campaigns aimed at changing behaviour in one of four areas:

- Maternal and child health
- Family planning
- Early child development
- Nutrition

One campaign, aimed at increasing health-seeking behaviour of women with sick children in Burkina Faso, represented the first time that mass media had been scientifically proven to change behaviours. It ran from 2012 to 2015 on seven radio stations across the country. The campaign used the DMI Saturation+ methodology, broadcasting one-minute radio dramas 10 times a day, 365 days each year, alongside daily radio phone-ins in six languages. The spots promoted health-seeking behaviours, with a particular focus on treatment seeking for malaria, pneumonia and diarrhoea by mothers of sick children.
The campaigns were evaluated for impact by the London School of Hygiene & Tropical Medicine, comparing the seven radio diffusion areas where there were campaigns (blue) to seven equivalent control areas (red).

How the campaign saved Mariéta?

Tibandiba Lankoandé lives in the village of Dakiri, in rural Burkina Faso. Three years ago, his one-year-old daughter Mariéta, fell ill and went into a coma. Despite consulting traditional healers and spending his limited resources on a number of counterfeit medicines, bought from a local market, Tibandiba was unable to cure his daughter. He became convinced that Mariéta was cursed with an illness caused by a bird flying over a sleeping child – a widespread belief among rural communities. It was only when he heard a radio message explaining to parents how to recognize the symptoms of malaria and encouraging them to seek treatment that Tibandiba realized his daughter had severe malaria. He immediately sought medical help, as advised by the campaign. Mariéta made a full recovery and is now fondly known in her village as ‘child of the radio’.

By providing support for DMI-type campaigns in LIMCs, G20 finance ministers could better ensure that the bilateral and multilateral funding spent on health system development is also optimizing health-seeking behaviours.

During the first year of the campaign approximately 2.4m people were reached and, compared with the control groups there was a:

- 56% increase in consultations for malaria.
- 39% increase in consultations for pneumonia.
- 73% increase in consultations for diarrhoea.
- 9.7% decrease in child mortality during the first year.
- approx 3000 lives saved during the 3 year campaign.
FACT

Over 1 billion products have been protected from counterfeiting, diversion and tampering

AN INNOVATIVE AFRICAN APPROACH TO COUNTERFEIT FAKE MEDICINES

Counterfeit drugs are estimated to cause more than 120,000 deaths in Africa per year because they contain too little of the active ingredient, or in some cases none at all.

A mobile phone verification service developed by mPedigree enables patients and/or distributors to text a product code on a medicine package. The code is then checked against the registry of authentic medicines, verifying in real time that the medicine is legitimate. This not only assures the patient that the medicine is safe, but also helps pharmaceutical manufacturers defend their brands and shield shopkeepers from selling ineffective counterfeits.

The company, founded in 2007 in Ghana, has since grown operations to 12 countries in Africa and Asia, including in G20 countries such as India and South Africa, working with pharmaceutical companies that produce medicines for humans and animals. mPedigree also works with producers of products that are potentially counterfeited, ranging from electrical goods to baby food, cosmetics and high-yield agriculture seeds.

Former US President Bill Clinton describes the Mobile Authentication System (MAS) in Nigeria as a “truly remarkable achievement.” The Clinton Health Access Initiative has become a core partner in MAS.

Bill Clinton
Former President of the United States
The impact of mPedigree is being closely monitored:

Over 100 million users globally

Over one billion products

mPedigree maintains a central registry of barcodes and each year more pharmaceutical and other companies participate in the verification program.

Specific country results show:

30% of all antimalarials protected are for children

Nigeria estimates that counterfeit medicine use has decreased from 30% in 2008 to 9% since the introduction of its Mobile Authentication System (MAS).

Kenya and Uganda estimate that more than 30 million seeds have been protected in one recent year.

From the start, mPedigree has maintained three interlocking project financing and management principles:

1. Zero-financing from the public sector at all stages of implementation.
2. Competitive technology development.
3. Zero-cost to end-users

Sustainability models using these principles are being developed in countries and vary based on national requirements. G20 finance ministers should clearly understand this pharmaceutical end-to-end traceability system that allows full consumer participation in the pharmaceutical quality assurance process. They should also note its potential to have a major impact on regulatory norms such as “good distribution practices” in the interconnected pharmaceutical supply chain, and that eventually it could contribute to regulatory harmonization across national borders.
A MOBILE APPLICATION FOR EARLY DETECTION OF INFECTIONS AT THE HUMAN/ANIMAL INTERFACE

The majority of newly identified infections in humans that cause sickness and death—called emerging infections—come from wild and domestic animals. The organisms that cause these human infections may or may not cause sickness in animals.

They infect humans by crossing the normal human/animal species barrier because of closer than normal contact with animals, whether these are alive, dead or have been slaughtered for food.

Early detection of these emerging “zoonotic” infections in animals, and/or in humans is essential, as they can cause severe outbreaks with high mortality and in some instances lead to pandemics. Avian influenza, Ebola and Middle East Respiratory Syndrome (MERS) are just a few of the emerging diseases that have made headlines recently.

The Participatory One Health Disease Detection (PODD) project was established in Thailand in 2014, with support from the San Francisco–based Ending Pandemics, to enable early detection of emerging human, animal and environmental health threats. PODD was developed by Chiang Mai University in Thailand, in partnership with a social-minded technologist–led, digital–native social enterprise called Opendream Co. The PODD team leverages smartphone and web applications that empower trained village volunteers and community members to report unusual disease events in livestock, wild animals and in humans. Volunteers report potential human or animal disease outbreaks as well as environmental hazards such as floods and forest fires through the PODD mobile app. These disease reports are triaged by PODD analysts and lead to a local response from public health and livestock offices. Local responders collect lab samples from the disease source and work with community members on preventative or outbreak control measures.
Lessons learned from PODD:

- PODD has trained more than 14,979 community volunteers across 27 provinces on what types of events to report and how to report through the PODD application.
- To date, 9,887 abnormal events have been reported through PODD. They include outbreaks in animals and humans, as well as environmental hazards.
- One study of the system found that 73% of confirmed poultry outbreaks were contained within the village of origin, with the remaining 27% contained within neighbouring villages before further spread.
- In one instance, an outbreak of foot and mouth disease in domestic livestock was rapidly contained. The early response is estimated to have saved the local economy approximately US$ 4 million.
- PODD serves as an example of how innovation in disease surveillance using available technologies such as mobile phones can provide greater health security, while permitting communities to participate in their own disease prevention and control. This approach has been replicated in Tanzania through Ending Pandemics’s support for the AfyaData project, led by the Southern African Centre for Infectious Disease Surveillance at Sokoine University.
- Some G20 countries have developed mobile apps for self-reporting of human diseases such influenza-like illness, and by further investing in these and additional self-reporting systems can increase national and global health security.

“PODD’s approach of engaging local communities in early detection of health threats is crucial to limiting the loss of lives and livelihoods to emerging diseases. The model developed by PODD and Ending Pandemics should be replicated in every country where humans, animals and wildlife interact with high frequency and density.”

Dr. Margaret Hamburg
Former commissioner of the U.S. Food and Drug Administration and current Foreign Secretary for the National Academy of Medicine
FACT
For each US$ 1 it spends in providing for drought relief, countries have been able to save US$ 4.40 of post disaster response costs.

INNOVATIVE FINANCING FOR NATURAL DISASTERS AND INFECTIOUS DISEASE OUTBREAKS – A PAN-AFRICAN APPROACH

The frequency and severity of natural disasters continue to rise. Extreme climate events, particularly droughts, floods, tropical cyclones and disease outbreaks and epidemics, are increasingly straining African economies and are hampering the development momentum that African countries have been recording in recent decades.

To respond to these foregoing challenges, the African Union (AU) Head of States established in 2012 the African Risk Capacity (ARC), an agency to help African countries to better plan and prepare for and respond to extreme weather events and other natural disasters. In 2014, the ARC agency launched its affiliate insurance arm, ARC Insurance Company Limited, to carry out the commercial insurance functions.

By linking early warning systems with contingency planning and supported by modern financial mechanisms (specifically insurance), ARC enables governments to provide targeted responses to disasters in a more timely, cost-effective, objective and transparent manner, thereby reducing response costs to governments and loss of livelihoods.

In only four years of its operations, the ARC Insurance Company had paid out approximately US$ 38 million to four countries, supporting more than 2.1 million people and one million livestock herds from drought-related food shortage. ARC estimates that for each US$ 1 it spends in providing drought relief, countries have been able to save US$ 4.40 in disaster response costs. G20 countries including Germany, Canada, France and the UK, are supporting ARC and recognize its value proposition and cost-effectiveness.

The cost of managing the Ebola outbreak in West Africa was highly unexpected, as it is for the ongoing Ebola crisis in Democratic Republic of Congo. The cost was of the same magnitude as the cost related to responding to droughts and other natural disasters. It is estimated by the World Bank to have been approximately US$ 32 billion, with an estimated US$ 2.2 billion lost in the gross domestic product in 2015. According to some epidemiological models, the total number of deaths due to Ebola could have been reduced by 80% if greater international support and funding had arrived two months earlier than late August 2015. Following the 2015 Ebola crisis, the African ministries of finance with the financial support of development agencies and foundations from G20 countries have noted the value and success of ARC in helping countries to better plan and prepare for and respond to natural disasters. This has prompted the ARC secretariat to develop a product to address countries’ financing needs to contain outbreaks and diseases that are common in the African continent.
The goal of the Outbreaks and Epidemics (O&E) Department of ARC’s secretariat is to incentivize countries to acknowledge outbreaks early by tying national declarations of infectious disease outbreaks to immediate financial payouts, and a pool of capital that can be rapidly deployed at the early onset of a disease outbreak has now been established. Initial funding for O&E, to stimulate other funders to join in, was provided by the Rockefeller Foundation and The Swiss Agency for Development Corporation. O&E is being piloted in Guinea and Uganda. The four infections selected for the pilot are Ebola virus disease, Marburg haemorrhagic fever, Lassa fever, and meningitis, as they have an endemic potential in more than 40 AU member states. Attention will be paid to analysing the cost effectiveness and cost-benefit ratio during this pilot phase. In addition, to contain outbreaks, Africa CDC is expanding on the O&E risk profiling to produce a tool, the Africa Epidemic Risk Index, that can be used across the continent to produce country epidemic indices.

**$1 spent through African Risk Capacity**

saves **$4.40 in post-disaster response costs**

**Expected results**

- Faster and more predictable funding
- Early action by governments to combat outbreaks and epidemics
- Catalytic funding to start country response and promote ownership
- Reduce impact of outbreaks and epidemics
The O&E Programme will eventually:

- **Facilitate** better health systems strengthening and preparedness including better surveillance mechanisms and contingency planning.
- **Establish** a pool of capital that can be rapidly deployed early after an outbreak.
- **Promote** pan-African and sub-regional solidarity and coordination.
- **Incentivise** countries to acknowledge outbreaks early.

G20 countries could contribute both technical and financial support to the O&E pilot studies and help lead African countries to stronger collective action and solidarity in the face of infectious disease outbreaks.

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“African Risk Capacity and its partners are developing solutions using sovereign risk transfer and innovative financing tools for public health emergencies that are cutting-edge, inclusive, transboundary, and pan-African. This ground-breaking program is an illustration of a complementary approach to tackle public health emergencies before they spiral out of control like we have too many times before.”

Kingsley Aboagye Gyedu
Deputy Minister of Health of Ghana
CHAPTER THREE

Innovative finance mechanisms and partnerships have been developed not only to facilitate developing country procurement of new and existing products but also to ensure the continued mobilization of the financial resources necessary for innovations.

CREATING AN ENVIRONMENT TO ENHANCE DELIVERY AND UPTAKE OF INNOVATIONS

One of the great concerns of innovators in health is how to make sure the products they have developed have maximum impact on the health of those in need. Innovations in demand creation are underway in many communities to make sure there is an understanding about when to seek health care using existing and newer technologies.

At the same time, innovative finance mechanisms and partnerships have been developed not only to facilitate developing country procurement of new and existing products but also to ensure the continued mobilization of the financial resources necessary for innovations. This chapter provides an overview of several community-based demand-creating innovations, and of many different financial mechanisms that mobilize and provide funding so that developing countries are able to provide best practice in health care.

It also provides examples of how partnerships in advocacy can justify global health financing, and mobilize the resources needed. Some of these mechanisms provide opportunities for private and corporate social investment and are increasing in demand in G20 and other countries around the world. Other mechanisms demonstrate how vaccine bonds ensure predictable and efficient funding and how innovative contracting models between governments and the biopharmaceutical industry can help contain costs and better sustain health care.
FACT

Overall, the number of deaths caused by AIDS, tuberculosis (TB) and malaria each year has been reduced by one-third since 2002.

Source: The Global Fund Results Report 2018

"We are determined to lead the fight. In 2019, for the first time, France will bring together actors in the fight against AIDS, TB and malaria with the Global Fund, which has saved 27 million lives since 2002."

Emmanuel Macron
President of France -- May 16, 2019

ACCELERATING THE END OF EPIDEMICS

The Global Fund to Fight AIDS, Tuberculosis and Malaria

In 2000, AIDS appeared to be unstoppable, devastating many countries in Africa. While antiretroviral medicines were being developed, the cost of treating millions of people looked impossible to meet. In response to that crisis, the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) was established in 2002 as a partnership organization to pool resources aimed at ending epidemics. With an innovative governance model that coordinates work by governments, civil society, the private sector and people affected by the diseases, the Global Fund succeeded in drastically reducing the price of treatment for AIDS per person from more than US$ 10,000 a year to under US$ 100 a year. The Global Fund supports programs designed and implemented by local experts and has now saved more than 27 million lives.

Overall, the number of deaths caused by AIDS, tuberculosis (TB) and malaria each year has been reduced by one-third since 2002 in countries where the Global Fund invests.

The Global Fund is geared toward capitalizing on scientific advances, innovative ideas and private sector savvy to unlock improvements in disease prevention, treatment and care. By pooling resources and engaging a diverse
set of actors, the Global Fund has scale, flexibility and leverage. Its pooled procurement mechanism has saved hundreds of millions of dollars for countries that participate. It can pivot to meet new challenges, such as the surging rates of HIV infection among adolescent girls and young women in Africa, and the threat of malaria drug resistance in the Mekong. It has incentivized a tremendous increase in domestic spending on health in countries most affected by infectious diseases, as well as strengthened supply chains.

Approximately 28% of total Global Fund grant funding is dedicated to strengthening systems of health, including supply chains, data systems, training healthcare workers, building stronger community responses and systems and promoting more integrated service delivery. The Global Fund also addresses human rights barriers to health services, due to discrimination or stigma. Having initially focused this aspect on HIV, the Global Fund now provides support to programs to reduce human rights-related barriers to services for tuberculosis and malaria as well.

Supported by strong advocacy from many partners, especially by civil society and people affected by the diseases, advocates of global health have guided governments, mostly from G20 nations, to contribute constructively to reduce the burden of AIDS, TB and malaria in countries worldwide, including in Argentina, Brazil and Mexico. Although contributions to the Global Fund have steadily increased since 2002, the Global Fund still faces a shortage of resources necessary to end the epidemics. All G20 nations should continue to invest in addressing global health priorities and increase their contributions to the Global Fund.

Results at a glance

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>People on ART for HIV</td>
<td>17.5 million</td>
</tr>
<tr>
<td>HIV tests taken</td>
<td>79.1 million</td>
</tr>
<tr>
<td>People reached with HIV prevention programs &amp; services</td>
<td>9.4 million</td>
</tr>
<tr>
<td>Global Fund grants disbursed</td>
<td>US$ 4.2 billion</td>
</tr>
<tr>
<td>Savings generated by pooled procurement</td>
<td>US$ 205 million</td>
</tr>
<tr>
<td>People with TB treated</td>
<td>102 thousand</td>
</tr>
<tr>
<td>People with drug-resistant TB on treatment</td>
<td>5 million</td>
</tr>
<tr>
<td>Mosquito nets distributed</td>
<td>197 million</td>
</tr>
<tr>
<td>Cases of malaria treated</td>
<td>108 million</td>
</tr>
</tbody>
</table>

Source: The Global Fund Results Report 2018
FACT

3 passengers are financing seasonal malaria chemoprevention for one child

ENSURING BETTER ACCESS TO HEALTH THROUGH AIR TICKET MICRO-LEVIES

Unitaid is a global health initiative that funds projects to ensure widespread adoption of cutting-edge drugs and medical technologies in low- and middle-income countries.

The goal is to bring innovative ideas to fruition in the real world, where they can help underserved populations. Unitaid’s interventions include affordable new treatments, diagnostics and prevention tools for HIV/AIDS, tuberculosis (TB) and malaria, as well as deadly HIV co-infections such as hepatitis C and human papillomavirus. A growing number of Unitaid’s projects address more than one disease—maximizing the effectiveness of health systems as a whole—and more than half of the organization’s portfolio is dedicated to the fight against antimicrobial resistance.

Unitaid, which is hosted by the World Health Organization (WHO), enables countries and key partners to scale up its interventions and realize their full potential.

During the period since Unitaid’s inception, air-ticket levies have been used by ten countries to generate funding for Unitaid: Cameroon, Chile, Congo, France, Guinea, Madagascar, Mali, Mauritius, Niger and the Republic of Korea. Since the founding of Unitaid in 2006, micro-levies on air tickets in France have provided an estimated 1.5 billion euros. In 2017 alone, micro-levies generated an estimated 210 million euros.

Early in Unitaid’s development, there was concern that the micro-levy would hinder the competitiveness of participating airlines; in France, a levy of 1 to 45 euros was added to the price of each airline ticket. But a study showed that France’s proportion of national aviation traffic actually increased 26% between 2007 and 2017.

Since its inception, Unitaid has received close to US$ 2 billion in contributions from innovative finance and another US$ 1 billion from other funders. Unitaid receives a portion of the French Financial Transaction, which generates more than 1 billion euros a year. About half of this revenue is allocated to various development organizations, including the Global Fund, Gavi, the Vaccine Alliance and Unitaid. Unitaid receives funds from G20 countries including France, the United Kingdom, Brazil and the Republic of Korea, along with donations from Norway, Spain, Chile, and the Bill & Melinda Gates Foundation.

Unitaid disburses funding to its grantees through a transparent competitive process. It first seeks promising medicines, diagnostics and prevention tools that are in final-stage development, then identifies and removes roadblocks to introducing these goods in low- and middle-income countries. In some instances, Unitaid finances their introduction as well.

Grantees include national and international civil society and non-governmental organizations and other groups working to ensure access to primary health care and scale-up.
These landmark achievements show Unitaid’s impact.
The organization:

1. Created and invested in the Medicines Patent Pool Foundation, which negotiates with industry to secure voluntary licenses for HIV medicines, enabling manufacturers of generic medicines to make them available at a lower price. The drug Tenofovir was voluntarily licensed with cost savings of US$ 195 million during 2012–2015.

2. Introduced TBxpert for diagnosis of TB, partnering with WHO and the Stop TB Partnership. Approximately 245,000 TB patients in Africa, Eastern Europe and Asia were diagnosed because TBxpert reduced the cost of test cartridges by 40%.

3. Launched the HIV Self-Testing Africa (STAR) initiative. Self-testing was readily accepted, even by high-risk groups unlikely to visit clinics or hospitals. Self-test kits can now be procured for as little as US$ 2 across 50 low- and middle-income countries. The second phase of the project involves distributing 4.2 million test kits during the coming years.

4. Provided US$ 68 million for seasonal malaria chemoprevention (SMC). The project, in partnership with the Malaria Consortium and Catholic Relief Services, provided SMC to more than six million African children. It was the world’s first effort to evaluate the effectiveness of SMC on a large scale.

An increase in G20 funding would allow Unitaid to boost its impact by introducing more innovative health solutions into the global health response and in doing so, enable multi-lateral funding partners and countries to be more effective and to do more with their resources.

FACT

IFFIm has financed more than US$ 1.3 billion for pentavalent vaccines, accelerating the vaccination of at least 80 million children.

FLEXIBLE FINANCING FOR VACCINES

Childhood vaccination saves lives, and new vaccines are being developed to prevent infections such as diarrhoeal disease, pneumonia and cancer of the cervix.

Once these vaccines have been licensed, it is essential that they will be introduced in low- and middle-income countries (LMICs) in order to save lives and help these countries reach the United Nations Sustainable Development Goals (SDGs).

Funding is not always available when there is a need to provide new vaccines to LMICs that are eligible for vaccines under Gavi, the Vaccine Alliance. To address this problem, Gavi established in 2006 the International Finance Facility for Immunisation (IFFIm).

IFFIm is based on an initial concept proposed by the United Kingdom, a G20 country. IFFIm receives long-term sovereign donor pledges and issues vaccine bonds in capital markets, permitting their conversion into immediately available cash resources.

The World Bank acts as Treasury Manager to IFFIm, which raises funds from institutional and individual investors for the highly rated vaccine bonds it issues. In aggregate this has been at a lower cost than the weighted average funding cost of its donors. IFFIm then applies donor grant payments to repay IFFIm bondholders.

IFFIm makes large volumes of funds immediately available and accelerates the availability and predictability of funds for Gavi-supported immunization programs, including the introduction of new vaccines.

IFFIm’s donors—G20 countries such as Australia, Brazil, France, Italy, South Africa and the UK as well as the Netherlands, Norway, Spain, Sweden—have pledged to contribute more than US$ 6.5 billion to IFFIm spanning more than 20 years. Brazil has recently pledged to become IFFIm’s 10th donor.

The proceeds of vaccine bonds help ensure predictable funding and more efficient operations for Gavi, which increased its spending on immunization five-fold from US$ 200 million in 2006 when IFFIm was launched to US$ 1.1 billion in 2017. It also provides predictability for countries’ vaccine programs.

To date, IFFIm has provided US$ 2.6 billion in funding to Gavi, mobilizing resources that are needed in a timely manner. As part of this, IFFIm has financed more than US$ 1.3 billion for pentavalent vaccines, accelerating the vaccination of at least 80 million children.
Since, 2006, investors in IFFIm’s vaccine bonds have joined many donor governments to significantly reduce child mortality by helping finance Gavi immunization programs around the world. They have blazed an exciting and important new trail in the area of socially responsible investing.”

Dr. Seth Berkley
CEO of Gavi, the Vaccine Alliance

US$ 6.5 billion in donor commitments

- **United Kingdom**
  - US$ 2.98 billion over 23 years
- **France**
  - US$ 1.88 billion over 20 years
- **Italy**
  - US$ 535 million over 20 years
- **Australia**
  - US$ 284 million over 20 years
- **Norway**
  - US$ 264 million over 15 years
- **Spain**
  - US$ 240 million over 20 years
- **The Netherlands**
  - US$ 181 billion over 10 years
- **Sweden**
  - US$ 38 million over 15 years
- **South Africa**
  - US$ 20 million over 20 years
- **Brazil**
  - US$ 20 million over 20 years

G20 member countries have an opportunity to pledge support for IFFIm and similar highly rated and secure mechanisms to ensure child survival and support for countries as they work towards achieving the SDGs.”
FACT
Since 2016 the ICRC have operated 139 projects in 34 countries, helping approximately 330,000 people.

RESULTS-BASED FINANCING CAN PROVIDE INNOVATION CAPITAL FOR HEALTHCARE DELIVERY

Violence during conflicts can leave people with physical disabilities, and many require physical rehabilitation and some type of brace, artificial limb or wheelchair.

However, it is estimated that a maximum of 10% of those with physical disabilities have access to the services they need. This often leads to social and economic exclusion and a heavy burden on those with disabilities, their families and their communities.

The International Committee of the Red Cross (ICRC) is the world’s largest provider of physical rehabilitation services in developing and fragile countries where conflict and violence often occur and where demand is greatest. The ICRC has delivered physical rehabilitation services in zones of conflict since 1979, and in 2016 the Physical Rehabilitation Program of the ICRC operated 139 projects in 34 countries, helping approximately 330,000 people by providing physiotherapy and mobility devices including wheelchairs, artificial limbs and braces.

Nevertheless, funding for rehabilitation has been difficult to obtain; the ICRC has embarked on a way to ensure longer-term capital to help improve the possibility of providing physical rehabilitation services in zones of conflict. This has led to a social investment program from the private sector, the Program for Humanitarian Impact Investment (PHII), also called the “Humanitarian Impact Bond.”

PHII is a private debt transaction in support of humanitarian activities that was launched by the ICRC, with support from Swiss private bank Lombard Odier, which has co-sponsored a private loan to a number of European social investors and outcome funders, including governments and private investors. The initial loan is a five-year commitment of US$ 26 million. The funds are being used by ICRC to finance the construction and operation of three physical rehabilitation centres of the ICRC in Mali, Nigeria and the Democratic Republic of Congo.

Thousands of people in need of help, and who have been deprived of this help until now, will gain access to rehabilitation and will be able to start a new life thanks to the Humanitarian Impact Bond.”

Alexander De Croo
Deputy Prime Minister and Minister of Finance, Belgium

At maturity after five years, outcome funders (the governments of Belgium, Italy, Switzerland and the United Kingdom, and la Caixa Foundation in Spain) will provide funding to the ICRC that will be used to pay back the social investors. The amount paid out will depend on the efficiency of operations in these three rehabilitation centres as measured by the ratio of how many people receive mobility devices per physical rehabilitation professional. If there has been an efficiency improvement of 80% over the baseline efficiency of other physical rehabilitation centres of the ICRC in Africa, the total return to social investors will amount to 7% per annum over the five-year investment term. If efficiency improvement has not been achieved, the social investors will not realize the full potential of their initial investment.

G20 governments, by building on the PHII mechanism of innovative results-based financing from social investors, could offer an increase in humanitarian funding where there is demonstrable improvement potential, and where outcome funders are willing to repay private sector social investors for the innovation risk they are taking on.

In order to accomplish this, the following action points are key:

01. Identify a program of strategic importance that has potential to be scaled up such as the ICRC rehabilitation centres.
02. Consider how alternative funding mechanisms could provide the capital needed.
03. Identify metrics that can track the results.
04. Enlist social investors, and funders close to the organization.
05. Recognize that such innovative financing efforts may take time to develop and perfect.

“G20 governments, by building on the PHII mechanism of innovative results-based financing from social investors, could offer an increase in humanitarian funding where there is demonstrable improvement potential, and where outcome funders are willing to repay private sector social investors for the innovation risk they are taking on.”

Peter Maurer
President, ICRC
FACT
Novartis offers a basket of fifteen medicines for US$1 per treatment per month.

LINKING HEALTH AND FINANCE TO IMPROVE HEALTH CARE FOR PEOPLE EARNING BETWEEN US$ 2 AND US$ 5 PER DAY

In 2007 Novartis launched Healthy Family programmes to improve the health of people in rural areas earning between US$ 2 and US$ 5 per day.

Novartis Family Health Programme
The programs consist of education and affordable products and health services.

The initiative was launched in India, a G20 nation, and then extended to Vietnam and Kenya. Currently it is being rolled out in additional African and Asian countries. Health educators from the communities where they grew up are supported by the Healthy Family programme to host health education meetings and explain the importance of prevention and of seeking out diagnosis and treatment from a qualified doctor or other health worker before a health condition worsens. It is important to stress that the health education we give is focused on what is most prevalent and important in those communities.

In India, they work closely with village leaders and the local Aasha (government-accredited social health activists), and with rural child center workers appointed by the government to conduct community health education. Vietnam and Kenya have adopted a similar model, with health educators from the communities where they live giving legitimacy to health messages and building trust.

Sales supervisors supported by Novartis interact with distributors, pharmacists and local doctors to ensure medicines are available in rural communities by establishing a solid distribution network for a sustainable supply, thus building future business for Novartis. The revenues generated through the sale of the Healthy Family products fund the health education activities of the Healthy Family programmes.

Funding of similar programs by other G20 pharmaceutical companies that can provide medicines for local diseases, or by the G20 directly to low-and-middle-income countries (LMICs), could increase demand for medicines and other health goods, compensating in part for low volume in markets that are considered less desirable by pharmaceutical companies. By replicating this program in other national contexts, local pharmaceutical companies as well as countries make an investment in local capacity building and provision of health education.

Such a program can be particularly powerful if combined with a deliberate attempt to strengthen community health workers to support local service delivery. The G20 can make a contribution as it would be optimal if the system would be owned domestically — potentially based on initial donor support — and companies such as Novartis would provide input and share lessons.
Since 2010 accomplishments of the Health Family Programme in India, Vietnam and Kenya include:

- 40 million patients with diagnoses and treatment
- 51 products available for six key therapeutic areas in Healthy Family portfolios
- 3 million patients with diagnoses and treatment
- 300 fold increase in medicine sales
- 522 full-time equivalent positions and contractors employed

“A healthy family is the foundation of a thriving society and a prosperous nation. Patients at the base of the pyramid earn very little, and expenditure on health puts tremendous strains on families. In the five years we have worked with Familia Nawiri, besides improving health education and services for poor communities, the program has helped educate people on health-seeking behaviors, the importance of disease prevention, early diagnosis and health prevention – all very crucial to improve health.”

Dr. Salim Ali Hussein
Community Health and Development, Ministry of Health, Kenya

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Photo credit: Novartis - “Healthy Family; Connecting business success with social progress: 10 years on the ground”

The Novartis Access Portfolio is a basket of 15 medicines for treatment of non-communicable diseases offered to governments, non-governmental organizations and other institutional customers in lower-income countries at a price of US$ 1 per treatment per month. The medicines target cardiovascular diseases, type 2 diabetes, chronic respiratory illnesses and breast cancer. If patients do not receive the drugs free from any of these sources, they have the option of purchasing them at the same price. Novartis Access is being rolled out in the public sector in Sub-Saharan Africa, Southeast Asia, Central America and Central and Eastern Europe. Ultimately, the goal is to maximize patient reach across all income levels to ensure sustainable access and sustainable business for Novartis.

In some countries Novartis Access also supports capacity building activities to strengthen the capacity of healthcare systems in preventing, diagnosing and treating non-communicable diseases (NCDs). Novartis Access in Kenya, where at least one family member has one of four non-communicable diseases, is being evaluated by Boston University to determine whether people with diseases covered by Novartis Access are more likely to have been prescribed medicines than those in a control area, and what proportion of household income was spent on prescription medicines in both areas. Evaluation continues and initial outcome results will be available sometime during 2019, while performance indicators are regularly monitored.

**Key Performance Indicators [KPIs]**

<table>
<thead>
<tr>
<th>Key Performance Indicators</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>Aggregated numbers or period-end information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of submissions / approvals for Novartis Access products</td>
<td>41 / 12</td>
<td>329 / 72</td>
<td>132 / 137</td>
<td>502 / 221</td>
</tr>
<tr>
<td>Number of new countries in which Novartis Access products are submitted</td>
<td>9</td>
<td>12</td>
<td>3</td>
<td>24</td>
</tr>
<tr>
<td>Number of monthly treatments</td>
<td>39 985</td>
<td>84 448</td>
<td>685 233</td>
<td>809 666</td>
</tr>
<tr>
<td>Number of patients reached with Novartis Access products</td>
<td>3 397</td>
<td>8 470</td>
<td>386 463</td>
<td>398 330</td>
</tr>
<tr>
<td>Number of FTEs working on Novartis Access*</td>
<td>10</td>
<td>14</td>
<td>25</td>
<td>25</td>
</tr>
</tbody>
</table>

* Externally assured

1. The patient number was calculated based on treatment delivered and the following elements: daily treatment doses, treatment duration, treatment adherence and potential treatment overlap (as it is common for NCD patients to take several drugs). The treatment adherence and treatment overlap factors are based on the assumptions from developed markets and will be revised when we gain additional insights from Novartis Access roll-out countries.

2. Full-time equivalent positions and contractors.

**Novartis Access Portfolio**

The Novartis Access Portfolio is a basket of 15 medicines for treatment of non-communicable diseases offered to governments, non-governmental organizations and other institutional customers in lower-income countries at a price of US$ 1 per treatment per month. The medicines target cardiovascular diseases, type 2 diabetes, chronic respiratory illnesses and breast cancer.

Non-communicable diseases will sooner or later overwhelm the existing health system capacities unless rapid investments are made in disease prevention and health promotion. An NCD unit is fully functional in the health ministry at federal level and we are working closely with the provinces to contain the spread of non-communicable diseases. Having access to high-quality treatment at low cost is a critical part of our work to lessen the impact of chronic diseases. Under the prime minister’s national health program, Pakistan is taking strides in providing free treatment to millions of families through both public and private health facilities. We do not believe in hollow slogans or mere campaigning. We believe in delivering to the masses.”

Saira Afzal Tarar
Federal minister for national health services, regulations and coordination, Pakistan
FACT

The private sector has a crucial role to play in addressing critical healthcare challenges.

THE RESEARCH-BASED BIOPHARMACEUTICAL INDUSTRY PARTNERS WITH OTHERS TO CATALYZE TRANSFORMATIONAL CHANGE, FOCUSING ON OVERCOMING BARRIERS TO ACCESSING QUALITY HEALTHCARE.

Access Accelerated: Better access to vaccines, medicines, and training for non-communicable disease control.

Access Accelerated was launched at the World Economic Forum in January 2017 with a goal of helping countries reduce premature deaths from NCDs by one-third by 2030, thus increasing their likelihood of achieving Goal 3.4 of the United Nations Sustainable Development Goals (SDGs).

Access Accelerated projects include men, women and children depending on the health challenge being addressed. Each project is unique. Projects vary from corporate foundation funding to countries and civil society as they increase awareness of the risk factors for non-communicable diseases; to pricing agreements based on ability of populations to pay, and training of health workers in prevention and patient management for a range of health challenges from obstetric fistulas and breast cancer to infant and child mortality. Many of the programs also include vaccine and drug donations that are either short term, to kickstart prevention and treatment, or long term, to sustain access.

THE RESEARCH-BASED BIOPHARMACEUTICAL INDUSTRY PARTNERS WITH OTHERS TO CATALYZE TRANSFORMATIONAL CHANGE, FOCUSING ON OVERCOMING BARRIERS TO ACCESSING QUALITY HEALTHCARE.

Access Accelerated brings together a group of biopharmaceutical companies with a common vision of working with lower- and middle-income countries (LMICs) towards a future where no one dies prematurely from non-communicable diseases (NCDs), and all people living with risk have access to appropriate treatment, prevention and care.

Access Accelerated is facilitated by a secretariat at the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). For the first time, more than 20 biopharmaceutical companies have come together to bring their global reach and local expertise in partnerships with governments, civil society, multilateral and non-governmental organizations to support multi-sectorial dialogue and drive on-the-ground implementation and action plans to address NCDs. They work in a variety of ways and with a variety of populations with five principal partners: the World Bank, the Union for International Cancer Control, the NCD Alliance, PATH and the World Heart Federation.
The private sector has a crucial role to play in addressing drug-resistant superbugs globally. It is encouraging to see commitment and concrete examples of progress from 36 companies, but much more needs to be done within the private sector to help address this complex challenge. We must continue to make the case for action and work across all sectors, countries and professions if we are to have any chance of success.”

Professor Dame Sally Davies
The Chief Medical Officer (CMO) for England and the co-convener of the United Nations Inter-Agency Coordination Group on Antimicrobial Resistance
FACT
Since the polio vaccine was introduced has eliminated polio paralysis and resulted in an estimated $180 billion saved in treatment costs.

FACT
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TACKLING THE UNFASHIONABLE DISEASES: HOW US$ 1 CAN BE INCREASED EIGHTFOLD TO US$ 8

The Global Health Technologies Coalition (GHTC), housed at PATH, is a group of more than 30 non-profit organizations, academic institutions and aligned businesses working to advance policies and investment to accelerate the creation of new drugs, vaccines, diagnostics and other health technologies.

GHTC targets critical global health challenges such as HIV/AIDS, malaria, tuberculosis (TB), and other neglected diseases and conditions including new and emerging infections.

First established in 2007, GHTC serves as the collective voice for the global health research and development (R&D) community. The focus of GHTC is on policy solutions and investment to address the lack of commercial market incentives to drive private sector product development for GHTC target diseases, and for other diseases that have epidemic potential because they primarily affect people in low and middle-income countries (LMICs).

Ongoing need
Lack of essential health technologies

- No HIV/AIDS vaccine
- TB treatment lasts 6-30 months, TB vaccine almost 100 years old
- No suitable treatments for Chagas, leishmaniasis

214 million
Women have unmet need for modern family planning

1 billion
People affected by neglected diseases globally

6 million
Annual deaths worldwide from neglected diseases

Copyright: GHTC - Policy Cures Research Return on Innovation Report.
US investments in global health R&D create jobs and economic growth

200,000 new US jobs
$33 billion in economic output


The GHTC case for investing in global health R&D

Globally, approximately 1%-2% of health research funding is directed towards GHTC target diseases and conditions even though they continue to cause high mortality and a negative impact on the economies of LMICs, where markets are unreliable. Financial investment from the G20 countries is essential to jumpstart such research from discovery through product development. G20 funding can incentivize the private sector or philanthropic donors to participate, as they would perceive a lower financial risk.

GHTC and other advocates have galvanized political will and policy-maker support by documenting the tangible and measurable returns from investing in global health R&D — both in terms of life-saving technologies generated and the domestic returns to investing nations, including job creation, economic growth and improved health security. Though much of GHTC’s research focuses on the impact of US government investment, the core findings of the work remain applicable to other nations and contexts.

Public investment in global health R&D is effective in catalyzing the creation of new drugs, vaccines, diagnostics, and other tools to address poverty-related and neglected diseases (PRNDs) and health conditions. US government support for global health R&D has helped advance 42 new global health technologies since 2000, including eleven new products for malaria, ten for TB, and one for HIV/AIDS. In addition, it has helped move promising products into late-stage development including more than 100 vaccines, drugs and diagnostics for neglected diseases; 11 products for Ebola and other viral haemorrhagic fevers; and 14 novel technologies to improve reproductive health.

Public investment in global health R&D is a win-win as measured by economic outcomes

US government investments in global health R&D have resulted in significant direct returns for the domestic economy. Approximately US 89 cents of every US government dollar spent on global health R&D is invested in the US. That means that between 2007 and 2015, US government investments in global health R&D injected US$ 12 billion into the US economy, creating 200,000 new jobs and resulting in US$ 33 billion in increased economic output.

US investments in global health R&D also leverage private sector investment. Every US$ 1 the National Institutes of Health spends on basic research is projected to generate an additional US$ 8.38 in industry investment over the next eight years. By 2023, the US government’s 2015 investment in global health basic research alone will spur an estimated US$ 4 billion in additional investment that would not have happened otherwise.

In addition to concrete economic returns through job creation and economic growth, global health R&D provides new and/or more affordable products to prevent and treat infections, and thus can reduce treatment costs and productivity losses in the US and globally. The US$ 26 million investment in polio vaccine R&D in the 1950s has eliminated polio paralysis in all but two countries as of January 2019, putting polio on track to be the second human infection to be eradicated. Use of the polio vaccine in the US since it was introduced has eliminated polio paralysis and resulted in an estimated US$ 180 billion saved in treatment costs. Introduction and scaling of MenAfriVac (referenced in the section on PATH) has prevented an estimated 400,000 deaths in sub-Saharan Africa since its introduction and is predicted to have saved US$ 9 billion in treatment costs by 2020.

More opportunities exist for cost savings and increased economic productivity. For example, Chagas disease, previously restricted to Latin America, has emerged in the US and infected up to 300,000 people. Because technologies to diagnose and treat Chagas are inadequate, the US now spends an estimated US$ 900 million annually on sub-optimal treatments. Better products for diagnosis and treatment of Chagas disease are needed both in the US and in Latin America. They would save lives and decrease the negative economic impact caused by Chagas disease.
US investments in global health R&D leverage private sector funding

Each dollar the NIH invests in basic research

$1

Leverages an additional industry investment of

$8.38

US investments in global health R&D promote cost-savings

A $26 million investment in polio vaccine R&D in the 1950s has

saved $180 billion in treatment costs in the United States alone

It cost $50 million to develop menAfriVac — a low-cost meningitis A vaccine

By 2020, it is predicted to have

saved $9 billion in meningitis A treatment cost

Large-scale disease pandemics could cost the global economy more than

$60 billion a year

An R&D investment of $1 billion per year could deliver the tools needed to protect against these outbreaks

“

I was a big believer in the merits of health research, partly because it’s simply the right thing to do… But from a fiscal standpoint you really can bend the cost curve [by investing in research]… We also have to look at these things from a broader perspective than just dollars and cents, and look at what the benefits yielded to the American people are—and beyond that, to humanity… To me, this is one of the easiest cases in government to make. Cutting [health research] is penny wise and pound foolish. You hurt your ability to deal with disease in your country — and disease is enormously expensive not just for individuals but society in general.”

Tom Cole
Member of the U.S. House of Representatives from Oklahoma’s 4th district
Chairman of the House Appropriations Subcommittee on Labor, Health and Human Services, US Congress
FACT

MDR-TB is predicted to cost the global economy approximately US$ 17 trillion over the next 35 years if it is left unchecked.

ENABLING A WORLD FREE FROM THE BURDEN OF TB

Tuberculosis (TB) is one of the leading causes of death worldwide, and multidrug-resistant TB (MDR-TB) in particular is a major global health security threat.

The Challenge

It is airborne, and each person carrying the disease could infect up to 10-15 other people in a single year if they are not treated. MDR-TB affects more than half a million people in a single year across the globe. Only about one in three people with this condition are diagnosed and one in four are treated. Even with treatment, almost half of people who catch MDR-TB die. It drives families and communities into poverty, and it is predicted to cost the global economy approximately US$ 17 trillion over the next 35 years if it is left unchecked.

Our response

In 2002, Johnson & Johnson (J&J) scientists identified the first targeted TB medicine with a novel mechanism of action in more than 40 years, bedaquiline (SIRTURO®). Since bedaquiline was approved by the U.S. Food and Drug Administration in 2012 for MDR-TB, J&J has invested significant resources to deliver more than 82,000 courses of this treatment to patients in 114 countries.

J&J works with all partners to provide a comprehensive framework that ensures bedaquiline is available and affordable for all MDR-TB patients in need. J&J has partnered with the Global Drug Facility and its procurement agent, IDA Foundation, to ensure access to bedaquiline in more than 130 countries. Additionally, J&J is supporting high-burden countries to train thousands of health workers and modernize TB treatment, ensuring appropriate use and stewardship of bedaquiline.

In 2018, J&J announced a comprehensive 10-year initiative in support of the United Nations Sustainable Development Goals target of ending TB 2030. With the goal of saving an estimated 1.8 million lives and preventing 12 million new TB infections in the next decade, J&J will work with partners to improve detection of undiagnosed cases of TB, broaden access to its novel medicine for MDR-TB and accelerate research & development to discover next-generation TB treatments.
Medicines Alone Are Not Enough to Combat MDR-TB
We also work towards creating an enabling environment for delivery of new innovations.

Now is the Time to Invest in MDR-TB
Recognized as a serious global health threat, MDR-TB is already predicted to be on track to become the most prevalent form of TB in some countries if we fail to make bold commitments and take swift action. However, with larger and more effective investment in the right tools and approaches, we can control the disease. We need innovation in medicines, diagnostics, access and delivery. And we need to look beyond siloed financing and sectoral barriers to build innovative partnerships putting TB patients, their families and their communities at the center of our efforts.

Closing the estimated US$ 67 billion funding gap needed for TB programs and research and development (R&D) for new tools in 2016–2020 could achieve:9

- 8.4 million fewer TB cases
- 1.4 million fewer TB deaths
- 181 billion US$ productivity gains
- 5.3 billion US$ reduction in treatment costs
- 27–85 return per dollar invested

About J&J Global Public Health
Charting a bold new, self-sustainable approach, J&J Global Public Health is the first fully dedicated organization within a healthcare company that combines R&D, novel access programs and approaches, in-country operations, advocacy and the power of multi-sectoral partnerships to ensure that innovative treatments and technologies are available, affordable and accessible for the world’s most underserved populations. Good health is the cornerstone of sustainable development. When people are healthy, they can go to school, take care of their families and contribute productively to their economies – in short, entire communities and nations thrive.

CONCLUSIONS AND RECOMMENDATIONS

Throughout history there have been discoveries that have opened the door to a whole series of follow-on innovations that have improved the quality of human life. Take for example the creation of the electric dynamo by Michael Faraday in the early 19th century.

It not only demonstrated that a moving magnet inside a coil of copper wire could generate electric current but also led to a series of innovations during the following century that range from the incandescent light bulb to the hand-held communication devices and electric vehicles of today.

Other discoveries have catalysed innovation in the same way. Discoveries about human physiology and immunology, and about how infectious organisms cause human disease and death are good examples. The innovations that followed during the centuries after these discoveries have had an impact that can be measured today in longer and healthier lives.

But differences in access to these innovations have always existed. Market forces and government engagement have not been great enough to ensure that these goods are made accessible when and where they are needed most. Nor have they been strong enough to ensure the pipeline of new products better suited for those countries where the need is greatest.

The global community had, in many ways, comfortably relegated the research and development of new products to the pharmaceutical and health technology industry, and the responsibility of ensuring access to international and multilateral organizations. The G20 and other like-minded governments, civil society, academic institutions and others, advocated for change.

A convergence of several factors in the late 20th century, however, has changed the paradigm and contributed to a series of new and exciting innovations in health that could not have been imagined just 30 years ago. The factors that converged were in part stimulated by an international commission and report on macroeconomics and health in 2001 that clearly showed, with supporting evidence, that investment in making populations healthy could lead to more rapid and sustainable economic development than could economic development unaccompanied by concerns for human health.

Once assimilated by leaders of the G8 and other like-minded countries, and by international health agencies, this message led to the creation of partnerships that brought together development agencies, philanthropic organizations, civil society, academic and financial institutions and other public and private sector groups including industry and the multinational organizations.

Though many of these partners had previously been antagonistic and unwilling to work together, either because of a perception of conflict of interest or other ideological differences, they agreed—with support from G8, and then G20
governments and others— to innovate and work towards a common goal of levelling out the inequalities in health among the world’s population.

This report outlines some of the innovations that have resulted from these partnerships. They include changes in the way new drugs, vaccines and diagnostic tests are developed and provided to the market. They also include new applications of existing technologies (some present for decades) that provide for greater individual and collective health security. And finally, they include financial mechanisms that help ensure access to new innovations in countries. Together they are contributing to a reduction in health inequality in countries around the world, and more healthy lives for all.

Recent reports from Harvard and Columbia Universities, associate academic members of the G20 Health and Development Partnership, emphasize that health and well-being remain core requirements to fulfilling human potential in any sector. Yet, as they point out, there is a dramatic shortfall in current resources needed to achieve sustained progress in health to meet Goal 3 of the United Nations Sustainable Development Goals (SDG 3).

While infectious diseases are a major health risk in the lower-income countries, the burden of non-communicable diseases—largely preventable—is also increasing.

Non-communicable diseases in industrialized countries are estimated to cost the equivalent of a 10% tax on of gross domestic product (GDP), and spending on them is estimated to account for almost 60% of current health spending, approximately US$ 2,400 per person every year.

Estimates from the World Health Organization suggest that annual investment of up to US$ 371 billion is required in lower- and middle-income countries to achieve the SDG 3. While up to 85% of necessary investment to achieve SDG 3 may be met with domestic resources in higher-income countries, in lower-income countries—arguably the countries for whom SDG 3 progress is most critical—annual shortfalls of up to US$ 54 billion are estimated to occur.


References:
Academics from the Harvard School of Public Health and Harvard Kennedy School point out that current government health spending by G20 countries has been benchmarked against the minimum investment of 5% of GDP, termed the Chatham House Goal. They further point out that by 2040, one (3%) of 34 low-income countries, and an estimated 36 (37%) of 98 middle-income countries will reach this Chatham House Goal of government health spending.

In order to do so they will require additional financial support from sources such as the G20 and other government development agencies and the development banks.

The economic argument for continuing to invest in better health remains the same as that demonstrated by the 2001 Sachs report on macroeconomics and health: healthier populations are more productive, which leads to greater economic productivity. And there are many potential partners to continue to invest in innovations for better health. Richard Feiner from Columbia University points out that from 2013 to 2015, seven foundations provided more than US$ 100 million each in health-related giving: The Bill & Melinda Gates Foundation, Susan Thompson Buffett Foundation, CIFF, The Wellcome Trust, Bloomberg Philanthropies, The Carlos Slim Foundation and The Hewlett Foundation.

These foundations as well as high-net-worth philanthropists and family charities, are looking for partnerships with governments, donor countries, multilateral agencies and development banks. Their interests vary but often focus on making investments in social entrepreneurs and civil society organizations that work to advance global health. They understand that such investments complement and de-risk G20 global health investments in innovative mechanisms for research and development, and at the same time help increase access to health services. Pharmaceutical companies are also looking for partnership and innovative contracting models are being developed.

15 Richard Feiner (Program in Non-profit Management, Columbia University)
16 See above
As the G20 continues to gain understanding of the importance of healthy populations in the quest for sustainable development and as the UN SDG deadlines approach, the stage is now set, and opportunities exist for even greater innovation. G20 Heads of Government together with Ministers of Finance and Health can help increase the momentum of innovation in global health by:

1. Placing health at the center of sustainable economic development, and recognizing that economic development alone is not a guarantee that health inequalities will be decreased;

2. Scoping the health technology horizon for gaps that need to be filled in order to lessen inequalities in health and to fulfill SDG3 commitments;

3. Recognizing the importance of actively promoting existing and innovative financing models for global health research (R&D), together with upscaling successful partnerships and delivery mechanisms during the Japan G20 presidency, with the engagement of those who benefitted most from globalisation including the financial services industry in creating new health-related financial instruments;

4. Including foundations, philanthropies and businesses/the pharmaceutical industry together with product development partnerships (PDPs) that all have shared-values as actors in the G20 health dialogue and decision-making process;

5. Continuing to engage with governments globally to promote the health of their populations using a mix of traditional, national and international funding together with resources generated by new innovations in health financing;

6. Creating a high-level panel following the 2019 G20 Joint Session of Health and Finance Ministers, in collaboration with the OECD and the World Bank to fully implement these recommendations, with the intention of establishing new long-term ways of funding innovation in health. These concrete proposals will be presented during the G20 presidency of Saudi Arabia in 2020.
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"A healthy nation becomes a wealthy nation. Economic policy-makers and finance ministers should factor in new thinking on public-private partnerships to combat the continuing scourge of TB, malaria and epidemics like Ebola virus as well as the non-communicable diseases or conditions from cancer to Alzheimers, even obesity, which cost so much in terms of economic performance to poor and rich nations alike."

Professor Sir Christopher Pissarides
Regius Professor of Economics at the London School of Economics, Nobel Laureate for Economics

"Good economic management and better health outcomes are linked global priorities and at national level finance and health ministries should be working hand in hand as the wealth of the nation depends on the health of the nation."

Bernard Kouchner
A doctor and former Health and Foreign Minister of France
Founder of Médecins Sans Frontières, MSF International

"We need optimized budget, empowerment and a clear signal from the States that research, science and technology are the fundament of our wealth. I appreciate this very important Health Initiative within the G20 Partnership. Cooperation is the only way to solve global issues and to shape the future of better living together."

Paul Ruebig
Member of the European Parliament

"We at Johnson & Johnson believe that humanity’s best days are ahead of us, not behind us. This report is a timely appeal to G20 leaders to elevate innovation – in health and health financing – permanently on the agenda for finance ministers and heads of government. This is an important first step to ensure health is an integrated part of G20 discussions on the management of global economic solutions."

Zeger Vercouteren
Vice President Government Affairs and Policy
Europe, Middle East & Africa (EMEA), Johnson & Johnson

"As Chairman of the Global Ambassadors’ Panel of the G20 Health and Development Partnership, I would like to warmly welcome and strongly support the efforts of this initiative in raising the salience of the impact of some of the worlds’ deadliest diseases on the agendas of the G20 heads of government, finance and health ministers."

The Rt Hon, the Lord Jack Cunningham of Felling
Member of the House of Lords

"I highly appreciate the efforts provided for compiling this important report. I am sure that the report will make significant contribution to the welfare of the international community."

Hitoshi Tanaka
Chairman, Institute for International Strategy, the Japan Research Institute, Ltd.
OUR PARTNERS