

Institute on Science for Global Policy (ISGP) Emerging and Persistent Infectious Diseases (EPID) Proposal for EPID Phase 2

Introduction

According to the World Health Organization (WHO), approximately 14 million people globally die each year from infectious diseases (i.e., one-fourth of total annual deaths). While the majority of these deaths occur in less wealthy countries, globalization and increased ease of travel have accelerated the speed within which infectious diseases are transmitted across the world. Moreover, in many wealthier countries, infectious diseases that were previously believed to be under control — such as tuberculosis, measles, and whooping cough — have returned at alarming rates. In all world sectors, infectious disease morbidity severely compromises not only the health of populations, but also impacts economic productivity and social stability.

Great strides have been made over the past decade to draw attention to the importance of controlling infectious diseases (e.g., by UN Millennium Project Task Force on AIDS, Malaria, TB, Other Major Diseases, and Access to Essential Medicines; the World Health Organization [WHO] infectious disease programs; the Bill & Melinda Gates Foundation projects on malaria and neglected infectious diseases). However, it is clear that significantly more work remains to be done worldwide before infectious diseases can be viewed as effectively managed. Bridging the gap between the scientific and technological options currently available, and domestic and international policies in place, remains an imperative if efforts to understand, prevent, and mitigate infectious diseases are to be successful.

The ISGP Model

The ISGP is a non-profit organization that does NOT express, advocate, or promote any specific policy position, but rather facilitates the communication of credible scientific and technological options to those who make and/or significantly influence domestic and international policies, both in government and the private sector. The ISGP functions primarily with financial support from governmental agencies.

Given that many of the most significant geopolitical policy and security issues facing all sectors in the increasingly global societies of the 21st century are directly connected with the remarkably rapid and profound science and technology (S&T) accomplishments of our time, it is critical that governmental and societal decision makers are well informed about the global advances in S&T. Such dialogues are a crucial step towards ensuring that policies are formulated and implemented based on credible scientific knowledge.

The ISGP seeks to assist governmental agencies and departments and the private sector in obtaining the realistic net assessments needed to balance commitments of resources devoted to the strategic, anticipatory analysis of emerging global S&T with those resources needed to address urgent security issues and topics that promote prosperity and social stability. The ISGP format supports an ongoing Science and Technology Review, Integration, and Verification (STRIV) model designed to identify rapidly changing global S&T advances. The review, integration, and verification of S&T information is achieved by the ISGP through extensive interviews with subject-matter experts worldwide that are used, in part, for structuring an up-to-date Strategic Roadmap

describing a series of ISGP conferences that are convened over a multi-year period.

ISGP programs are conducted using a unique format composed of six distinct, complementary activities:

1. Interviews and correspondence are conducted with globally recognized subject-matter experts to obtain their views of: (i) the current realities that accurately characterize the S&T topic, (ii) the scientifically credible opportunities and challenges available to effectively meet governmental and societal needs, and (iii) the policy issues (advantages and risks) associated with these S&T options that societies must consider.
2. The viewpoints that are provided during the interview process are used by the ISGP to prepare a Strategic Roadmap describing a series of conferences, which are comprised of extensive critical debates and policy caucuses between an international group of highly credible and influential scientists and policy makers. The resultant Strategic Roadmap is shared with the participating governments, societal organizations, and private sector companies prior to its implementation. Each invitation-only ISGP conference in a given series focuses on a specific aspect (e.g., surveillance) of the S&T topic (e.g., EPID) identified within the process of preparing the Strategic Roadmap as a priority issue.
3. A series of ISGP invitation-only conferences are convened. Several (typically 8) distinguished scientists are invited by the ISGP to prepare concise (3 pages) policy position papers. During the conference, each paper is debated for 90 minutes (5 minutes are allocated at the outset to the author to summarize his/her points). The invitation-only audience is comprised of policy makers and subject-matter experts from governments, philanthropic and nongovernmental organizations, and the private sector, identified by the ISGP to participate in the critical debates and caucuses. To promote candid debate, each ISGP conference is convened in a “not-for-attribution” (Chatham House Rule) environment. After the debates are completed, caucuses are held to identify areas of consensus and actionable next steps to be considered in the formulation and implementation of new domestic and international policies.
4. Areas of consensus and actionable next steps are identified based on the views of presenters and participants during each conference.
5. “Not-for-attribution” summaries of each critical debate and caucus are prepared by the ISGP staff. Together with the eight policy position papers, these debate summaries, areas of consensus, and actionable next steps are published in a book prepared by the ISGP and made available publicly.
6. Although the ISGP expresses no opinions or engages in no advocacy concerning the topics addressed at ISGP conference, it does prepare and participate in briefings to governmental agencies and departments, societal organizations, and private sector stakeholders when invited to do so. Such briefings are designed to accurately represent the views expressed by those participating in the debates and caucuses and focus on the areas of consensus and actionable next steps emerging from ISGP conferences.

ISGP Program: Emerging and Persistent Infectious Diseases (EPID)

ISGP programs function in direct support of United States government agencies and their respective international counterparts support initiatives designed to remain knowledgeable about

rapidly developing S&T. The ISGP developed the Emerging and Persistent Infectious Diseases (EPID) program to address the challenges of incorporating credible scientific understanding into the process of effective policy making, both domestically and internationally. As part of this program, four invitation-only conferences were convened between 2009 and 2011 that examined the central issues associated with EPID, and those aspects of Food Safety and Security (FSS) and Synthetic Biology (SB) related to infectious diseases: *Global Perspectives* (December 2009; Tucson, Arizona, U.S.), *Surveillance* (October 2010; Warrenton, Virginia, U.S.), *Prevention* (June 2011; San Diego, California, U.S.), and *Mitigation* (October 2011; Edinburgh, Scotland, U.K.). A fifth conference that focuses on the *Societal and Economic Context* associated with EPID will be convened July 8-11, 2012 at George Mason University in Fairfax, Virginia, U.S.

The success of the ISGP's EPID program is evidenced by the broad engagement by many U.S. governmental agencies and departments that have participated in recent ISGP conferences, including the Office of Science and Technology Policy (OSTP), the Congress, Department of Health and Human Services (HHS), Department of Agriculture (USDA), Department of Homeland Security (DHS), Department of Defense (DOD), the Department of State (DOS), and various parts of the U.S. intelligence community have participated in recent ISGP conferences. These individuals from the U.S. have been joined by their international counterparts including representatives from the U.K. Italy, Canada, Japan, Singapore, France, Germany, Mexico, and Denmark. Participants in ISGP conferences routinely represent not only a wide range of governments, but an international cross section of the NGO, academic, and private sector industrial communities. During the first phase of the EPID program, about 250 individuals, representing approximately 20 international governments and organizations, have actively participated in ISGP conferences. Approximately 50% of these individuals have participated in multiple ISGP conferences.

In addition, feedback from former participants has highlighted great enthusiasm for the EPID program and its exceptionally productive format of critical debates and caucuses. There has been significant support for EPID as a programmatic focal point for diverse reasons including finding effective approaches for (i) addressing the increasing global infectious disease burden, (ii) strengthening and expanding the cross-sector and inter-disciplinary communication among the governmental, NGO, academic, industrial, veterinary health, biodefense, pharmaceutical, and food communities, and (iii) keeping pace with the constantly changing scientific landscape emerging from increasingly global research efforts concerning the molecular basis for infectious diseases. All of these issues, as well as others, require the dynamic and candid discussions, debates, and caucuses that characterize ISGP programs and conferences.

EPID 2: Proposal Specifics

Strong interest has been expressed from within the policy, scientific, and private sector communities in continuing the EPID program at the ISGP into a new, second phase. Such a Phase 2 EPID program would address a variety of scientific and policy issues that have yet to be adequately addressed. The ISGP format, based on the four activities described above, would be used in Phase 2 EPID.

The ISGP proposes to launch the Phase 2 EPID programs by focusing on at least some, if not all, the following six topics:

1. Antimicrobial Resistance

Antimicrobial resistance has recently been recognized as a critical priority, as illustrated by WHO's statement that, "antimicrobial resistance is a global problem that needs urgent action." Since the 1940s, antibiotics and antimicrobial agents have been used to treat infectious diseases, greatly reducing illness and death among patients. However, due to the widespread overuse, misuse, and underuse (i.e., incompleteness of treatment) of such drugs, infectious organisms that antibiotics are designed to kill have adapted to them, making drugs less effective, or in some cases, not effective at all. While some microorganisms have developed resistance to a single antimicrobial agent or classes, other strains are multi-drug resistant (MDR). While it is known that antimicrobial resistance leads to unnecessary deaths and rising health care costs, according to WHO, resistance is only recently being considered a societal and economic issue and therefore, there is a need to better understand these relationships. Additionally, there are growing concerns that severe declines in antimicrobial drug development during the past decade will further complicate efforts to control drug resistance. While we do not yet fully understand the extent to which deficiencies in new drugs will impact levels of future disease morbidity and mortality, the escalation of "superbugs" that have a limited number of treatment options indicates that new challenges are on the horizon.

2. Infectious Diseases and Genomics: Balancing Innovation and Security

The genomic revolution has produced new opportunities to alter the landscape of infectious disease control (e.g., reductions in morbidity/mortality; limiting the transmissibility of disease vectors). These laboratory-based research efforts exemplify many of the most advanced and exciting aspects of scientific inquiry and have elicited great interest within the research community. There are many reasons to suggest that this frontier area of genomic research may lead to a wide range of potentially beneficial outcomes. It is also recognized that the capabilities to pursue such research are increasingly available worldwide. However, it is also clear — with recent events associated with the genetically modified H5N1 influenza virus experiment conducted at the University of Wisconsin, Madison and at Erasmus University being the most obvious example — that there are mounting concerns regarding the potential for this information to be used for nefarious activities as well. A very fine border, which lies between aggressively pursuing these types of genomic advances in the research laboratory and determining how to properly disseminate the resulting information, has rapidly emerged as a major policy issue in many societies. The ISGP program would examine these issues from a broad international perspective that reflects diverse governmental and societal priorities and goals. It is likely that differences between governments and societies will help define what effective national and international policies might be needed to foster innovative research while protecting all parties from nefarious activities.

3. Zoonoses

Animals represent the largest reservoir for infectious diseases. The majority of emerging infectious diseases in humans today are zoonotic in origin (i.e., spread to humans by animals). More than 60% of all human pathogens are zoonotic and have represented 75% of all emerging pathogens during the past decade. HIV/AIDS, SARS, chikungunya, and nipah virus are zoonotic diseases that were generally unheard of prior to 1980, but are now commonly recognized as significant threats to human health. Yet, there is a vast gap in understanding current diseases of animals. Predicting the changes and conditions for change in this disease reservoir is a complex scientific challenge. While new methods for prediction are being developed and implemented (e.g., syndromic surveillance), the ability to accurately predict the emergence of new diseases that will cross the animal-human species barrier remains unclear. Moreover, animal farming increases the risk of contracting a zoonotic disease, primarily by bringing humans in close contact with animals and their waste. The risks posed by proximity

are exacerbated when unsanitary meat processing conditions are used, as is often the case in resource-poor parts of the world. Further, the extensive use of antimicrobials in animal farming is spawning resistances that can cross the species barrier, making zoonotic diseases more challenging to treat in both animals and humans.

4. Environmental Changes

Scientific understanding of how changes in natural and man-made environments affect the emergence and spread of infectious diseases is at best limited, and often contradictory. As the effect of human induced environmental changes (urbanization, the availability of water and food resources, deforestation, changes in ocean chemistry, and the frequency and severity of natural disasters) becomes clearer, it is expected that we will increasingly encounter an array of infectious diseases that have greater impact on human health. By obtaining an in-depth understanding of the relationship between environmental conditions and human health, policy makers are better positioned to make fully informed choices. While it has long been recognized that many infectious diseases dynamics are intimately related to climate (e.g., malaria), the scale and diversity of the climate disruptions now occurring and anticipated has redefined the climate change/disease debate. For example, water, both in excess and scarcity, is closely tied to many infectious diseases (e.g., cholera and polio). It is evident that the global water supply, already taxed by rising populations, faces extreme threats from changes in precipitation patterns thought to be part of climate change. As the environment alters the infectious disease patterns we have historically experienced, existing health infrastructures will be challenged in new ways. Health systems unable to manage the burden of existing infectious disease will be the least able to protect their citizens from those disease outbreaks connected to global climate change. We do not yet understand in detail how the range of anticipated environmental disruptions will affect infectious diseases, but it appears clear that environmental changes will play a major role in influencing the severity and spread of disease worldwide.

5. Neglected Tropical Diseases

Neglected tropical diseases (NTDs), a group of approximately 17 diseases that persist in less wealthy regions of the world, are endemic in more than 75% of the world's countries. It is evident that although NTDs most acutely impact poorer areas, wealthier regions are recognizing that these infectious diseases can both be imported and impact their own economic wellbeing (e.g., by limiting trading partners, reducing debt repayments, and increasing the need for foreign aid). While preventive measures or medical treatments exist for some NTDs, many of these therapies are not universally available in poorer areas. WHO estimates that "millions of people require preventive chemotherapy, a public-health intervention for the treatment of NTDs." Awareness of the need to combat NTDs has grown in recent years, as illustrated by WHO's first meeting of global partners to discuss the issue in 2007. More recently, in early 2012, a consortium of 13 pharmaceutical companies, the U.S., U.K., and U.A.E. governments, the Bill & Melinda Gates Foundation, the World Bank, and other global health organizations announced a coordinated effort to accelerate progress toward eliminating or controlling 10 NTDs by the end of the decade. The most effective approaches for moving forward in the effort to combat NTDs (e.g., identifying infrastructure overlaps, possibilities for utilizing new methodological approaches such as synthetic biology or molecular epidemiology, and avenues for enhancing research progress) still must be determined.

6. The Societal and Economic Context

Modern societies all possess social and economic interests, many of which are greatly impacted by the health of their populations. For example, infectious diseases have been demonstrated to impact social relationships (e.g., changes in family dynamics stemming from

the orphaning of vast numbers of children in areas where HIV/AIDS is endemic) and economic productivity (e.g., the financial impact of airport closures during the SARS epidemic). As we gain better control of some diseases (e.g., polio) and are faced with new challenges (e.g., SARS), the social and economic landscape of infectious diseases constantly changes. Therefore, there is a significant need to evaluate, and re-evaluate, both the social and economic dimensions of emerging and persistent infectious diseases. By maintaining an up-to-date understanding of these issues, policymakers will be better situated to protect the populations they serve.

The **EPID Phase 2** conference series would follow the ISGP format described above including (i) extensive international interviews, (ii) updated and expanded strategic road mapping, (iii) organization and convening a series of conferences at U.S. and international venues, and (iv) briefings based on specific invitations.