IQT Roundtable: Capabilities Required for Pandemic Response – August 2021

Introduction

On August 12, 2021, In-Q-Tel (IQT) convened a virtual Roundtable meeting to examine the technologies used to respond to the Covid-19 pandemic and other epidemics, to discuss what needed capabilities were missing from the Covid response, and how these critical needs might be addressed. Roundtable participants included experts drawn from several United States government (USG) agencies, academia, private-sector technology companies, and members of the IQT/B.Next team [see Roundtable Participants pg. 14]. The meeting was conducted on a not-for-attribution basis.

For over two decades, increasingly frequent and consequential outbreaks of infectious disease have demonstrated that we are living in an "age of epidemics". It is urgent that nations become more adept, individually and collectively, at controlling disease outbreaks. While improving global preparedness requires changes in national, institutional, and individual behaviors, many of the capabilities required to respond to lethal, fast-moving epidemics are technologies which can be realized through collaboration among governments, universities and private companies.

Our collective struggle against Covid-19 has demonstrated that technologies, ranging from diagnostic tests and vaccines to personal protective equipment and contact tracing apps, are essential to the task of quenching pandemics. Yet, with a few exceptions, analyses of how technologies might enable critical pandemic management functions, and the strategies required to make such technologies widely available for this—or the next—pandemic, remain the exception, not the rule.

Background

In-Q-Tel (IQT) is a not-for-profit, non-governmental organization founded in 1999 to ensure that the CIA and the broader United States national security community have access to innovative technologies. Since the 1990s, small, innovative start-up companies, typically funded by venture capital, have become the major source of technology innovation across multiple fields, including biomedicine. IQT acts as a strategic venture investor and technology accelerator to identify, adapt, and deliver innovative technology solutions to support the missions of the U.S. national security agencies. Over 20+ years, IQT has made over 550 investments, more than half of which have resulted in government agencies adopting new technologies.

The IQT B.Next team focuses on the intersection of national security and biotech, life sciences, and healthcare. Over the past several years, B.Next has invested in start-up companies delivering core capabilities needed to respond to the threats posed by infectious disease outbreaks. Several of these companies are engaged in the response to the Covid-19 pandemic. What we have learned over the years, as exemplified by the current crisis, is that in order to effect the kind of response required in an emergency, investment in technological solutions must be made to ensure that these solutions are commercially sustainable so as to be available when they are needed. It is not enough to simply be "innovative" – we require solutions that are in place ahead of any emerging crisis if we are to ensure the best possible outcomes in support of the economic, health and national security of the US and our global partners.

The Roundtable discussion focused on three questions intended to explore each of the *functional capabilities* (described in the technology architecture below) needed to prepare for and respond to the emergence of a fast-moving, potentially lethal infectious disease outbreak:

- *What technologies have been critical to successful pandemic response – for Covid-19 and other outbreaks?*
- *What capabilities are needed but missing from the technology architecture or are not entirely realized by existing technologies?*
- *What additional capabilities should the federal government and private sector invest in and develop to improve pandemic response?*

To help organize the discussion, we relied on a conceptual framework known as a *technology architecture.* Technology architectures are used by IQT, as well as by some commercial firms, to enable understanding of the key capabilities and core technological components of complex systems. The density and complexity of existing technologies, as well as the ways in which technologies can combine to create new capabilities, make it challenging to think clearly or share thoughts about complex technological systems. Technology architectures provide a sharable and visible representation of a complex technology space or problem and are useful in understanding what technologies must be assembled and combined to realize a specific capability. Technology architectures are *tools* to help us think clearly about technological systems. They are rarely comprehensive, and they evolve as available technologies expand and our understanding of the problem deepens.

B.Next developed a Biodefense Technology Architecture to identify the capabilities and technologies required to rapidly identify, characterize and respond to infectious disease epidemics [see Figure 1]. The technology architecture identified four broad categories of functional capabilities needed to achieve effective response:

- pathogen detection, diagnosis, characterization and attribution of origin
- protection of those who are healthy
- treatment of the infected
- data collection, cleaning, aggregation, analysis and communication.

IQT/B.Next has been making investments in companies developing technologies that could deliver the capabilities identified by this tech architecture.

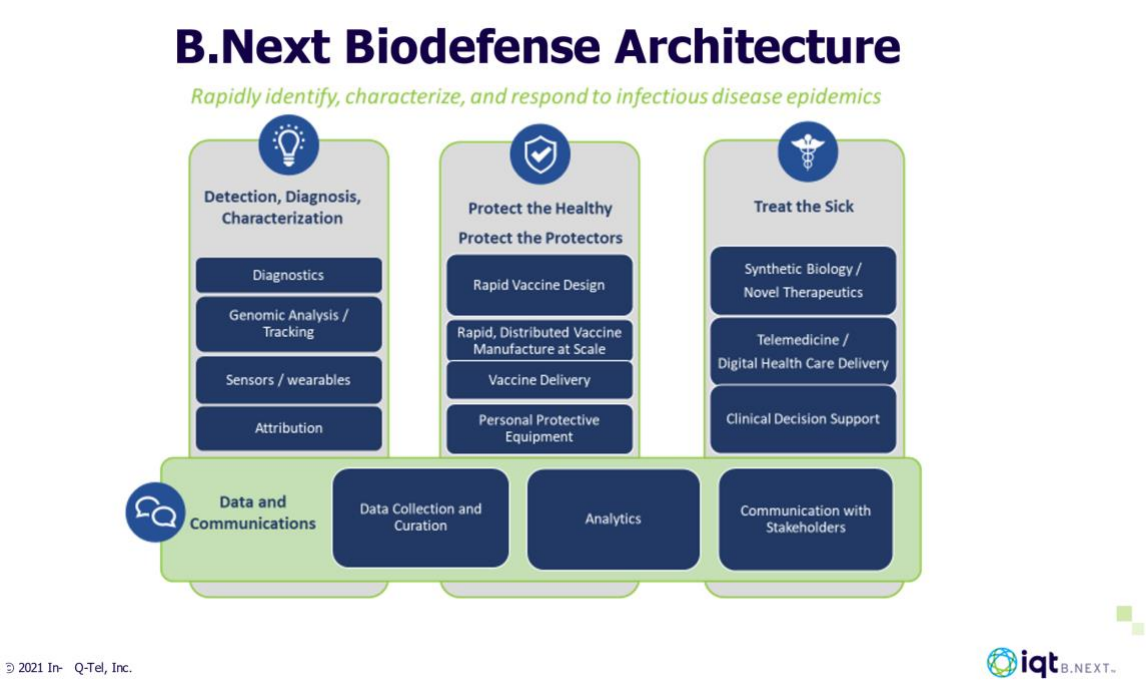

Figure 1. B.Next Biodefense Architecture

The Roundtable discussion was structured to allow participants to reflect upon each of the first three broad top-level functional capabilities, and on the technologies that might help achieve them. As we have witnessed throughout the Covid-19 response, data and communication capabilities are essential to realizing all other capabilities, but often inadequate in practice. This fourth key capability is very challenging, and of great interest to IQT, but because of time limitations, we elected not to include it in the Roundtable discussion; we intend to address this topic in a future roundtable.

A summary of these key capabilities B.Next identified as being critical to pandemic response follows, along with the Roundtable participants' comments and discussion highlights.

Roundtable Discussion

Capability 1: Pathogen detection, diagnosis, characterization, attribution

B.Next Rationale

- *Diagnostic tests are critical to effective epidemic response. Effective diagnostic capabilities must include tests that are accurate, widely available, provide rapid results,*

can scale to population levels, and can be used without elaborate equipment and specialized personnel.

- *As the demand for testing can exceed supply, testing strategies should be thoughtfully designed to leverage the different types of diagnostic tests available, considering turnaround time, cost, availability, and performance (i.e., sensitivity, specificity) in the context of the individual and/or population being tested.*
- *Without such tests readily available in a response:*
    - *It is almost impossible to attain situational awareness, to know if the epidemic is getting worse or where and how it is spreading.*
    - *It is virtually impossible to assess the efficacy of interventions, including the use of therapeutics, vaccines, and non-pharmaceutical initiatives.*
    - *Diagnostic technologies that can assess population health status—such as monitoring wastewater from college dorms or neighborhoods for evidence of infection—may provide visibility into the prevalence of disease in a local population, until testing of individuals becomes possible.*
- *Pathogen characterization must include genetic sequencing throughout the duration of the outbreak to track the geographic spread and genetic evolution of the virus.*
- *The development of experimentally validated protocols, technologies, and procedures for determining attribution deserves more attention. Standardized practices for ascertaining whether an outbreak is a natural occurrence (e.g. the result of an animal pathogen "spill over" to humans), or due to a deliberate attack, and consensus procedures for investigating the origins of outbreaks, are needed.*

Discussion

The discussion emphasized the importance of **developing diagnostic test platforms which are not limited to identifying single pathogens only. These platforms must be able to rapidly adapt to enable detection of many pathogens, including a novel, newly emergent pathogen, in order to be able to assist in rapid outbreak recognition and improved disease characterization**. The likelihood of outbreaks featuring novel infectious agents, and the possibility that deliberate attacks might employ engineered agents underline the importance of creating diagnostic platforms that could be rapidly adapted to detect unexpected pathogens.

Although PCR-based diagnostics are both sensitive and specific to the nucleic acid sequences for which they are designed, they are expensive, require specialized equipment and skills, and have proven difficult to scale to population levels, as both the 2015 West African Ebola outbreak and the Covid-19 pandemic have demonstrated. CRISPR-based diagnostics are among several newer technologies that are capable of rapid design, could be manufactured at scale relatively cheaply, and deployed as point-of-use diagnostics. CRISPR-based diagnostic technologies can generate highly sensitive, specific, and mass-producible tests that, in contrast to PCR tests, are as easy to use as home pregnancy tests. However, they are not sufficiently commercialized to date to play a major role in Covid-19 response.

Another **desirable characteristic of next-generation diagnostics would include the ability to determine an individual's degree of infectivity (perhaps as denoted by viral burden)**, thereby enhancing the ability to predict who is likely to transmit disease. A related point was the need for more technologies and scientific inquiry focused on understanding disease transmission, especially in health care settings. Also needed are more scientifically validated principles for protecting people from infection, which is critical to epidemic management. In particular, the lack of scientific precision in our understanding of how best to protect health care workers, and the use of "broad brush strokes" to guide personal protection have often proven inadequate. Failures to protect front line workers in particular engender fear and suspicion.

Finally, it was recognized that to understand the extent and movement of disease within communities, traditional clinical diagnostic tests are not sufficient. **Achieving situational awareness during dynamic epidemics requires collection and integration of information from multiple sources and sensors, including wearables and other technologies.** Such data could be used by individuals to guide decisions regarding personal protection and safety or, if aggregated at the population or community level, could help inform public health interventions. [See December 2019 IQT/B.Next Roundtable Meeting summary regarding the use of digital health technologies during large scale epidemics, and a July 2021 blogpost on the use of digital health tools to support national security needs]. It would also be desirable to enable public health authorities to access results of tests performed by individuals, schools, companies, etc., to ensure accurate situational awareness of community infection levels.

Capability 2: Protecting the Healthy

B.Next Rationale

- *Preventing disease transmission is key to controlling pandemics. History has shown that vaccines are the most effective and efficient means of protecting people from infectious disease.*
- *A key goal of epidemic management is the capability to rapidly design, test and manufacture vaccines at scale. Before the Covid-19 pandemic, the time needed to design, develop, test and manufacture new vaccines has ranged from four years (mumps vaccine) to several decades (the as yet unrequited quest for HIV/AIDS vaccines). The Covid-19 vaccines—especially those employing next-generation platforms such as mRNA—have established a "new normal" for the speed of vaccine development (at least for those pathogens that are amenable to vaccine prophylaxis). At least 200 vaccines against Covid-19, using many different vaccine platforms, began development during the pandemic and at least 50 reached clinical trials.*

Discussion

Participants strongly supported the need for rapid vaccine design and manufacturing capabilities and acknowledged the extraordinary achievement of Operation Warp Speed in producing Covid-19 vaccines within a year of first sequencing the virus. Participants particularly emphasized the

importance of being able to **manufacture vaccines at the large scales required to counter fast-moving outbreaks and global pandemics**. The existing shortfalls in global vaccine manufacture are due to a range of challenges, including lack of manufacturing capacity, supply chain limitations such as materials for vaccine adjuvants or delivery formulations (such as lipid nanoparticles), and skilled personnel.

It was noted that the highly successful vaccines against Covid-19 benefitted from decades of research on the biology of coronaviruses (provoked by the 2003 SARS outbreak), and a government commitment to develop mRNA vaccine technologies (supported by DARPA and BARDA, and spurred on by the 2015 West African Ebola outbreak). As one participant said, "We knew A LOT about coronaviruses and A LOT about mRNA vaccines." Next time, we might not be so lucky, and may confront a virus we know little about. The importance of R&D funding at a company's early stage of development was emphasized as critical to supporting the "innovation pipeline". Over the course of the discussion, participants commented on the **need for more support for mission-driven basic research in several key areas: including understanding the biology of a broader range of potentially pandemic viruses; the mechanisms of transmission to and among humans; and the immunological correlates of protection (the specific molecular signature of a person whose immune system is able to protect against infection); as well as the need for technologies that can rapidly determine such correlates of infection to replace the slow and laborious methods currently in use.** These points emphasized the iterative nature of basic research and technology development, as well as the need for "mission-driven" research.

Finally, participants noted the **importance of applying environmental and engineering controls to reduce the burden of infectious particles in the environment**. This topic area picked up on discussion related to the need to better understand the science of aerosol and droplet transmission risks. As society addresses issues related to managing shared spaces, technologies that reduce the burden and risk of transmission will be increasingly important. Development of airborne isolation capabilities are needed to maintain healthcare facility and other critical infrastructure functionalities, including the ability to occupy transportation hubs and other areas of mass gathering, in addition to workspaces and office complexes.

Capability 3: Treating the Sick

B.Next Rationale

- *Maintaining the function of the health care delivery system, especially hospitals, is a central element of effective pandemic response. Patients suffering from acute illnesses and injuries must be able to receive necessary care, in addition to those sickened as a result of the pandemic.*
- *Assuring the "load balancing" of patient distribution to hospitals is critically important in order for the health care system to be able to maintain the highest standard of care delivery possible. This requires significant improvements to situational awareness capabilities.*

- *Throughout the Covid-19 pandemic, telemedicine and telehealth have expanded significantly to enable patients to access medical expertise without visiting clinics or hospitals.*
- *Remote patient monitoring solutions were used during several clinical trials of Covid-19 vaccine candidates.*
- *Electronic health records, in their current state of deployment, are incapable of supporting the complexities related to pandemic response, and need to be completely revamped.*

Discussion

The participants' commentary focused on the importance of **developing and implementing "systems of care" to inform and guide the overarching medical management of large scale public health emergencies (e.g. comprehensive approaches akin to those developed for trauma care, cardiac care, stroke care, etc.)**. Such efforts, in conjunction with new technologies, are especially needed to maintain critical medical services and improve health care outcomes in the context of high volumes of acutely ill patients., Better technologies, such as widely accessible telemedicine services, deployment of wearables and remote sensors, and newer forms of AI-powered or AI-augmented telehealth are also needed to care for less severely ill people without burdening stressed health care facilities.

Barriers to access to medical care were of particular concern. The pandemic has served to accelerate the use of telehealth and telemedicine services, but it has also revealed that some areas of the country are "technology deserts"—displaying gaps in the availability of internet connectivity and shortages of key types of domain expertise, including nurses and respiratory therapists. Clinician participants emphasized that Covid survivors need persistent access to health care, after hospital discharge or acute illness and perhaps for long periods in the case of "long" Covid.

One approach to improving accessibility of vaccines would be to transition to new methods of countermeasure delivery. Microneedle patches, sublingual, or oral delivery technologies are available, but the small innovative companies which developed such technologies struggle to scale up manufacturing and to partner with large pharmaceutical firms during crises. Technologies for self-delivery of viscous countermeasures, such as monoclonal antibodies, are already available for chronic immune diseases. Monoclonal antibodies are also effective in preventing severe Covid, if given soon after the onset of symptoms. However, hospitals have struggled to deliver these medicines intravenously in outpatient settings.

Participants involved in clinical care noted that **during an emergency, when time and resources are scarce, it is especially difficult to validate or implement new tools and technologies.** It is possible that technologies can divert scarce resources or cause harm if not appropriately vetted. This was arguably the case with recommendations made at the height of the first surge regarding the mechanical ventilation of patients using airway circuit splitters, in the participants' view. But the need to innovate during crises requires that more robust validation and implementation

strategies be developed, including ways to speed the regulatory process without compromising standards.

Priorities for Pandemic Response: Capabilities needed to confront new and unexpected pathogens

In the concluding section of the meeting, the expert group was asked to address the following questions:

- *What capabilities should be prioritized over the next 2-3 years? What ought to be considered over a longer horizon?*
- *How should the innovation pipeline be structured and incentivized in order to move beyond "innovation" towards implementation?*

A few overarching themes stood out in the discussion during this final section of the meeting, concepts and ideas that the B.Next team supports in full. In the near future, the world is likely to face more infectious disease outbreaks, including outbreaks of newly emergent pathogens and/or the possibility of deliberate attacks using uniquely engineered viruses. It is critically important that response capabilities are agile enough to address the unexpected.

Early Detection

The ability to conduct diagnostic testing at scale and over long periods in order to better differentiate the infected from the non-infected, as well as degree of infectivity, is critical to pandemic management. Accurate, affordable, and accessible diagnostic platforms appropriate to different settings—hospitals, doctors offices and at home—are crucial to situational awareness and to pandemic control. The availability of diagnostic platforms that can be rapidly designed to identify new pathogens and manufactured at scale should be developed commercially. Market barriers to the introduction of novel diagnostic approaches should be examined and addressed, possibly including rethinking the role of centralized testing in US healthcare.

Finding ways to standardize, aggregate, and analyze the results of diverse diagnostic tests from multiple test sites so that public health authorities can assemble a real-time understanding of disease distribution, prevalence, and forecasting regarding large outbreaks is of great importance.

Protect the Healthy and Treat the Sick

The federal government and the private sector should jointly pursue the development of multiple vaccine platforms and therapeutic strategies in order to assure control of the Covid-19 pandemic, and in anticipation of future infectious disease outbreaks including epidemics of newly emergent or engineered pathogens. In this area too, there is a need for both mission-driven basic research

and technology development. It was suggested that the immunological "correlates of protection" for families of viruses with pandemic potential should be intensively studied, to aid more rapid vaccine development, if needed.

Multiple vaccine platforms, which could address a range of virus families, could be established, tested, and used to produce relatively small amounts of vaccines, with the capability to rapidly scale manufacturing during crises. It is possible that R&D efforts could create vaccines and therapeutics against conserved targets found across a virus family (e.g., a pan-coronavirus vaccine or therapeutic). Such countermeasures could not only address emerging variants but also new viruses in the family. The potential for advances in vaccine manufacturing should also be investigated.

Utilizing biomanufacturing capabilities to ensure the domestic production of key components within the supply chains for diagnostics, vaccines, and therapeutics was noted as a promising, potentially powerful, cross-cutting capability that could help build an independent and secure supply chain. While some components and manufacturing processes may be specific to a particular diagnostic, vaccine, and/or therapeutic, there are others which may be extensible – such as PCR reagents (for PCR-based diagnostics), nucleic acid manufacturing (for nucleic acid-based vaccines), etc. Synthetic biology-based approaches might also be employed to minimize supply chain dependencies. For example, CRISPR-based assays are less dependent on supply chain issues because Cas enzymes and CrRNAs can be produced using synthetic biology methods very quickly and at scale.

Mission-driven basic research is an essential component of technology innovation

Two areas of mission-driven research in need of more attention were highlighted during the discussion. First, shortcomings in the scientific understanding of respiratory pathogen transmission, as well as related issues pertaining to the development of better protective equipment, were highlighted as near term priorities. Infection control decision-making should be based on a fuller understanding of the dynamics related to aerosol and droplet particle movement. It is also important to recognize that the nature of health care delivery is changing rapidly. Increasingly, health care is shifting to outpatient settings, or is being delivered in the home via telemedicine services or phone apps. Better information about how to adapt infection control practices to these arenas is needed.

The second area in need of urgent scientific inquiry highlighted by the participants was the need to gain a better scientific understanding of the human immune system response to infection. Given the broad physiological implications of "cytokine storm" and autoimmune dysfunctions, more precise insights into these phenomena will significantly benefit the quest for effective therapeutics, vaccines and other countermeasures in future pandemics.

Effective Response to Future Pandemics Requires Imagination and Aggressive Efforts Now

The COVID-19 pandemic has served as a "forcing function", driving adoption of innovative technologies such as telemedicine, smart phone diagnostic applications, and the first large scale manufacture and use of mRNA vaccine technologies. But these technologies mostly existed before the pandemic and their use during Covid, though vital, represented incremental technological progress rather than radical improvements.

The Covid-19 pandemic did not, for example, catalyze the use of technologies such as microneedle patches, sublingual delivery systems, etc. that might have allowed self-administration of vaccines without needles or syringes. Such delivery technologies might have increased vaccine uptake and relieved some of the burden on medical and public health systems. These technologies already exist commercially, but the small companies producing them found it challenging to gain attention or scale up during the crisis.

The design, testing and manufacture of effective mRNA vaccines within one year of the virus being sequenced by Operation Warp Speed "set a new normal" and demonstrated the importance of putting multiple efforts and solutions into play simultaneously. Such a strategic approach to innovation demands significant resources on a scale only governments can muster. The expertise and willingness to make difficult decisions, prioritize what is important, and remove bureaucratic restrictions are also essential. But only the private sector has the talent and capacity develop and manufacture medical countermeasures.

It remains unclear what will happen to the more than 100 Covid-19 vaccine candidates still completing clinical trials. Market forces alone are unlikely to promote novel vaccines beyond those which have already gained regulatory approval. Yet it is possible that some of these pipeline vaccines could prove essential in the next pandemic.

Still to be realized – or even imagined in detail – is the essential goal of making and distributing enough vaccine for the world's population. In the present era of global trade and travel, a national approach to pandemic control is doomed to failure. Clearly, an enormous increase in the Covid vaccine manufacturing capacity is needed. How to do this efficiently and in a manner that enables governments and industry to mount rapid responses to emergent pathogens in this age of epidemics is an urgent priority.

Effective detection, management and resolution of infectious disease epidemics requires a societal-wide response. The Covid-19 pandemic should provoke a critical review of the authorities, processes and resources that were brought to bear against this ferocious virus which has done so much damage. But we should also consider how we might make better use of technologies to save lives and halt disease transmission. If we remain reliant on conventional technological approaches, or allow market forces to set the pace of adopting new technologies, we will miss the opportunities to create the capabilities we need to respond rapidly to coming outbreaks – and to quench them before they become pandemics.

Conclusion

Natural outbreaks of infectious disease are increasingly common and increasingly impactful. All evidence indicates that this trend will continue and likely intensify. In addition, continuing advances in molecular biology will continue to make the engineering of viruses easier, increasing the likelihood that bad actors will attempt to create and release an engineered pathogen. Moreover, better preparedness cannot consist of stockpiling ever larger supplies of antimicrobial therapies, diagnostics, and vaccines, because we cannot know what pathogens will cause outbreaks before they occur. Even if we could predict the organisms that will cause outbreaks, we cannot predict the timing of outbreaks. The cost of discarding and replenishing expired countermeasures sufficient to treat the US population between outbreaks makes stockpiling drugs and vaccines prohibitively expensive.

However, the same advances in molecular and synthetic biology that might enable deliberate misuse have the potential to transform our ability to prepare and respond to emerging outbreaks. We have witnessed how fast vaccines can be developed, when the need is great. For testing, we similarly need to continue investing in and developing next-generation diagnostic tests (e.g., CRISPR-based), which could enable fast, affordable, and sensitive point of care tests which can be rapidly adapted to detect a novel pathogen. Investment in domestic biomanufacturing of nucleic acids will be critical for the engineering and manufacture of both new, synthetic biology-based vaccines, which can now be rapidly designed upon the sequencing of a novel viral pathogen, and CRISPR-based diagnostics. And research on the feasibility of proactively developing vaccines and therapeutics against entire families of viruses (such as coronaviruses) could provide a critical “jump-start” against some emergent pathogens from families with higher likelihoods of spillover.

A “systems approach” to biodefense and pandemic response is of crucial importance to the health security and national security of the nation and the world at large. And while we continue to recognize the critical need to develop systems of care that are responsive to the surge demands resulting from a pandemic event (or from any “all-hazards” mass casualty generating event), there are key capabilities that must be achieved in order to effect a cogent, timely, cost-effective, and successful response. We must reconsider what the innovation pipeline in health care delivery, biotech, biopharma, and engineered biology looks like going forward. We require a commercially sustainable approach to such solutions. Our technological innovations must be marketable and commercially viable, so that they are available when they are needed.

And in anticipation of future discussion, we also must be capable of achieving the creation of a national platform for de-identified data sharing that can be used to support both the early detection of sentinel events, as well as help manage the allocation of key resources over time as a crisis unfolds.

In summary, we suggest that the nation—through public and private sector collaboration—adopt the following goals, many of which we have discussed throughout this report:

Mission-focused science goals:

- Better understand immunity to expand the families of pathogens that can be addressed by vaccines and improve our ability to demodulate immune overreaction
- Better understand the biology and physics of disease transmission, including aerosol biology, so that behavioral guidance and the correct selection and use of protective equipment can be implemented faster

Technology goals:

- Utilize vaccine formulations that minimize or eliminate the need for refrigerated storage, and transition all delivery by needle and syringe to needle-free methods (microneedle-embedded, jet injectors, sublingual, oral, intranasal, etc.)
- Transition from culture- and PCR-dependent pathogen detection and diagnosis to point-of-care methods that are as sensitive and specific, including, but not limited to sequencing and CRISPR-based biochemistries that are quickly adaptable to a novel pathogen, inexpensive to manufacture at scale, and easy to use
- Stockpile key ingredients/materials to support these goals, rather than finished goods (such as bulk nucleotides, adjuvants, certain fine chemicals, etc.)
- Continue developing sensors that make buildings of the future capable of detecting airborne pathogens (and the protocols for acting upon those data: air re-routing, decontamination, work schedule modifications, etc.)
- Advance the practice of, and access to anonymized data for artificial intelligence applications, so that electronic health records can be used effectively in detecting outbreaks and developing countermeasures
- Develop medical devices with sensors that can self-regulate to patient physiology (i.e. mechanical ventilators that adjust to blood gas levels; IV-pumps that deliver titrated medications based on hemodynamic parameters)

Business innovation goals:

- Meet the above science and technology goals within the framework of healthcare business transformation, so that markets for essential technologies ensure their survival and further development during times between outbreaks
- Start conceiving, developing, and marketing health technologies with outpatient administration in mind from the outset

Public policy / engagement goals:

- Communicate advances in support of the above goals to the public on an ongoing basis to establish credibility between outbreaks
- Engage communities with proven expertise (such as Silicon Valley) to improve best practices in getting the public to adopt new technologies
- Recognize that behavioral and cultural changes, along with vaccines, are a line of defense ahead of protective equipment

- Facilitate better public health research utilizing electronic health record data

The opportunity to improve the quality of preparedness and response begins with the ability of government to incentivize the private sector to contribute to the development of these key capabilities. Developing disruptive, innovative technologies that are focused on building the foundational elements needed for improvements in health care delivery, as well as those related to biotech and engineered biology, will lead the way toward an improved response in the next pandemic. As was noted on multiple occasions throughout the meeting, our ability to observe, orient, decide, and act with respect to a public health emergency has been broken at a national scale. Let's use this experience to generate the improvements needed to move beyond simple observation of the problem at hand and take charge to make bold decisions and act decisively to save lives, reduce suffering and improve the health and security of the nation.

Roundtable – Participants

JJ Ben-Joseph is a Data Scientist at IQT Labs who works in the confluence of biosecurity and artificial intelligence, advises startups, and contributes to technical projects. He has a computer science degree from Johns Hopkins and previously worked for the National Security Agency.

Nathan Bergin is the B.Next intern at IQT this summer, focusing on innovation systems and biodefense strategies. After IQT, he will join Deloitte Consulting as a Strategy Analyst in the Government and Public Services Practice. He holds a Bachelor of Science in Foreign Service from Georgetown University with a concentration in biotechnology and global health.

Jane Bigham, MPH is a Senior Health Policy Advisor for the Senate Committee on Health, Education, Labor, and Pensions Majority Staff (Senator Murray, D-WA). She previously worked at the Centers for Disease Control and Prevention and at the Carter Center. She holds an MPH from Emory University and a B.A. in Psychology and Spanish from Agnes Scott College.

Luciana Borio, MD is a senior fellow for global health at the Council on Foreign Relations (CFR) and a venture partner at Arch, a venture capital firm that provides seed/early-stage venture capital for technology firms in information technology, life sciences, and physical sciences. Dr. Borio specializes in biodefense, emerging infectious diseases, medical product development, and complex public health emergencies. She previously held positions on the National Security Council and as a Vice President at IQT.

Joe Buccina is a Director of Intelligence Community Support and B.Next Operations. He focuses on customer engagement, team operations, and bioinformatics. Before joining the B.Next team, he was an IQT program manager, a public sector consultant, and a biosurveillance analyst at a startup.

Eugene Chiu is a Senior Partner on In-Q-Tel's Investments Team, leading IQT's investments in healthcare and life sciences ventures with IQT's B.Next team. He has also been responsible for a number of IQT investments in the areas of quantum computing, advanced analytics, and artificial intelligence. Prior to IQT, Eugene co-founded and led business development, marketing, and commercial operations at multiple venture-backed companies. Eugene earned his A.B. in Biochemical Sciences from Harvard College, Master's in Health Sciences and Technology from MIT, and MBA from Harvard Business School.

David H. Donabedian, Ph.D. is a Venture Partner at Longwood Fund, Startup CEO of Longwood-founded ImmuneID, and was the founding CEO of Longwood-founded Axial Therapeutics, a biotechnology company focused on the gut-brain axis. Prior to joining Longwood, Dr. Donabedian held various leadership roles at biopharmaceutical companies including AbbVie (NASDAQ: ABBV) and GlaxoSmithKline (NYSE: GSK). Dr. Donabedian holds a B.A. in Chemistry from St. Anselm College, a Ph.D. in Polymer Chemistry from the University of Massachusetts Lowell, and an MBA from the University of North Carolina.

Asha M. George, DrPH (invited) is the Executive Director of the Bipartisan Commission on Biodefense. She served on the Biden-Harris Transition Team and as a subcommittee staff director and senior professional staff for the US House of Representatives Committee on Homeland Security. She is a public health and national security expert.

Dylan George, Ph.D. is a Vice President at Ginkgo Bioworks where he is helping to develop improved biosecurity, surveillance, analytics, and capabilities to better engineer organisms. Prior to Ginkgo, Dr. George was a Vice President at In-Q-Tel (IQT) and held various positions in the United States Federal government (DoD, HHS, OSTP) where he developed analytics, promoted authorities, coordinated budgets, and enabled policies for better pandemic response and preparedness capabilities.

Peter Haaland, Ph.D. is a freelance applied scientist and inventor solving transdisciplinary problems by way of IARPA, DARPA, the USAF, early-stage VC, and diverse advisory activities in government and industry.

Dan Hanfling, MD is a Vice President on the Technical Staff at In-Q-Tel and a practicing emergency physician with expertise in operational emergency medicine. Prior to coming to In-Q-Tel he spent four years at HHS/ASPR, and before that led healthcare emergency management efforts for the Inova Health System (Falls Church, VA). He currently co-chairs the National Academy of Medicine's Forum on Medical and Public Health Preparedness.

Matthew Hepburn, MD is the Director of COVID Vaccine Development for the HHS-DoD Countermeasures Acceleration Group (formerly known as Operation Warp Speed). Prior to this he served as the Joint Project Lead for Enabling Biotechnologies for the Joint Program Office for Chemical, Biological, Radiological and Nuclear Defense (DoD), was a Program Manager at DARPA (2013-2019), and served as the Director of Medical Preparedness on the White House National Security Staff (2010-2013).

Amy Jenkins, Ph.D. joined DARPA as a Program Manager in June 2019. Her interests include the development of platforms for combatting infectious disease threats as well as novel manufacturing methods to enable rapid response. Prior to joining DARPA as a PM, Dr. Jenkins was a Senior Scientist at Gryphon Schafer where she contributed to development of programs targeting infectious disease threats within BTO. Prior to supporting DARPA, Dr. Jenkins studied the virulence factors of, and antibodies targeting, multi-drug resistant bacterial pathogens at MedImmune. She also served as a National Research Council Postdoctoral Fellow at the United State Army Medical Research Institute of Infectious Diseases where she studied virulence mechanisms of biodefense pathogens. She received her Doctor of Philosophy degree in Chemistry and Chemical Biology from Cornell University and her Bachelor of Science in Chemistry and Biomolecular Science from Clarkson University.

Robert Kadlec, MD is the former Assistant Secretary for Preparedness and Response at the Department of Health and Human Services and a member of Senator Richard Burr's (R-NC) staff.

He spent more than 20 years as a career officer and physician in the United States Air Force before retiring as a Colonel. Over the course of his career, he has held senior positions in the White House, the U.S. Senate, and the Department of Defense. He holds a bachelor's degree from the United States Air Force Academy, Doctorate of Medicine and Masters of Tropical Medicine and Hygiene from the Uniformed Services University of the Health Sciences, and Master's degree in National Security Studies from Georgetown University.

Kathryn Kosuda, **Ph.D.** is co-founder and CSO at Vaxess Technologies, a life science company focused on improving the efficacy and accessibility of vaccines using MIMIX™, a novel stabilization and skin delivery platform. Kathryn holds a PhD in Physical Chemistry from Northwestern University, did her postdoctoral research in the Department of Chemistry & Chemical Biology at Harvard, and began her career in pharmaceutical R&D at Merck Research Laboratories.

James Lawler, MD, **MPH** is Executive Director for International Programs and Innovation for the Global Center for Health Security at at the University of Nebraska Medical Center. He is also an Associate Professor of Medicine in Infectious Disease and Deputy Medical Director for the Nebraska Biocontainment Unit. Before joining the UNMC team in November 2017, he served 21 years in the US Navy Medical Corps. Dr. Lawler's work has spanned a broad array of research, policy, and field activities related to emerging and high-consequence infectious diseases, medical and public health preparedness, pandemic and outbreak response, and global health. Dr. Lawler served in national policy positions in both the White House Homeland Security Council Biodefense Office and the National Security Council Resilience Directorate spanning two administrations.

James Lim is a Summer Investment Associate at In-Q-Tel, focusing on the biotechnology/healthcare and enterprise technology sectors. He is a fourth-year JD/MBA candidate at Harvard Business School and Harvard Law School, and holds a B.A. in Economics from Harvard College.

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Kevin O'Connell, Ph.D. is Vice President and Technical Co-Lead for B.Next, the IQT technology practice focused on life sciences and the intersection of biotechnology, healthcare, and national security. Prior to joining IQT, he was a researcher and principal investigator with the U.S. Army Edgewood Chemical Biological Center for 10 years, where he focused on pathogen detection and

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Tara O'Toole, MD, MPH was Executive VP and Senior Fellow at IQT since 2014 and is now an IQT Sr. Fellow. She served as Under Secretary of Science and Technology at the Department of Homeland Security from 2009-14 and Assistant Secretary of Energy from1993-97. She was a founding member and Director of the organization now known as the Johns Hopkins Center for Health Security and professor of medicine and public health for the previous decade.

Sandeep Patel, Ph.D, is the Director of BARDA's Division of Research, Innovation, and Ventures (DRIVe). Prior to DRIVe, he founded KidneyX and PreventionX at the Department of Health and Human Services. He holds a Ph.D. from Georgia Tech and a B.S. from Washington University in St. Louis.

Martijn Rasser is a senior fellow and director of the Technology and National Security Program at the Center for a New American Security (CNAS). Prior to joining CNAS, he was an executive at an AI startup and a hedge fund. He is a former CIA officer.

Lewis Rubinson, MD, PhD is the Chief Medical Officer of Morristown Medical Center (MMC) within the Atlantic Health System (AHS). Dr. Rubinson is a critical care physician and the physician executive lead for the COVID-19 response at MMC, which was one of the early impacted referral hospitals. At the peak of the COVID-19 surge in the of Spring 2020, MMC had 20 COVID-19 inpatient units with more than 300 inpatients and more than 100 persons requiring mechanical ventilation. MMC has cared for nearly 3500 hospitalized persons with COVID-19 and AHS for nearly 8500 hospitalized patients. AHS has administered thousands of doses of monoclonal abs, hundreds of thousands of vaccination doses, enrolled 100s of patients in therapeutic trials and has implemented numerous testing platforms for COVID-19/ SARS-CoV-2.

Patrick Rose, Ph.D. is the Program Manager for the Department of Defense Bioindustrial Manufacturing Innovation Institute: BioMADE. In this role, he represents the government in a public-private partnership to address the spectrum of manufacturing challenges associated with biomanufacturing of non-medical products. He also serves as Science Director for Synthetic Biology at the U.S. Office of Naval Research Global in London, United Kingdom. In his position, Dr. Rose is responsible for maintaining a global network throughout the synthetic biology community and provides general technology awareness to the US Navy.

Sarah Sewall Ph.D. is the Executive Vice President for Policy at In-Q-Tel. From 2014-2017, she served as Under Secretary of State for Civilian Security, Democracy and Human Rights. During the Clinton Administration, she served as the inaugural Deputy Assistant Secretary of Defense for Peacekeeping. Dr. Sewall taught at Harvard for over a decade, where she directed the Carr Center for Human Rights Policy and worked closely with the U.S. military to advance civilian protection in war.

Inder Singh is the founder and CEO of Kinsa. With a network of 2.5M households, 5% of US elementary schools, and numerous enterprises that use Kinsa's illness insights tools, Kinsa helps families, communities and the system predict, prepare for, and prevent the spread of infectious illness. Kinsa built its early warning system for spreading infectious illness from the bottoms up: by first re-imagining the thermometer into a two-way communication channel to the newly sick and leveraging it collect the "missing ingredient" data—for example, real-time symptom onset, and intra-family transmission rates—and delivering outbreak insights back to these families, school communities and enterprises. Prior to founding Kinsa, Inder served as the Executive Vice President of the Clinton Health Access Initiative. He holds 3 graduate degrees from Harvard and MIT and is a proud University of Michigan alum.

Alexander Titus Ph.D. is currently the Head of Public Sector Healthcare and Life Sciences Strategy at Google Cloud as well as an Adjunct Assistant Professor of Biotechnology at the University of New Hampshire and the founder of Bioeconomy.XYZ. Prior to Google, Titus was the head of biotechnology strategy at the Department of Defense, leading the team developing the modernization roadmap for the department. Titus is also a genomic data scientist by training with a PhD in Quantitative Biomedical Sciences from Dartmouth College and a BS and BA in biochemistry and biology (respectively) from the University of Puget Sound.

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John Zicker is Data Science Vice President at Kinsa. He was previously Chief Data Scientist and conDati, CEO at Amplion, COO at Vree Health, and has experience as a founder and leader of multiple start-ups. He holds a MSEE in Biomedical Engineering from the University of Wisconsin-Madison and a BSEE from the University of California-Davis.