CRITICAL NATIONAL NEED IDEA:

Universal Protection Against Biological Threats

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In contrast to the trends toward personalized medicine and ever more specific treatments for disease and contamination, the question might be asked whether it would be possible to devise and develop a broader-based protection against current and, more importantly, new and unknown microbes simultaneously? While prevention is the ideal, is there a means for umbrella protection from unknown biothreats, such as emerging pathogens, microbicide-resistant infections, new pandemics, or bioterrorism? Or, to ask the question another way, before identification and characterization of an infectious agent can be made, is it still possible to protect populations without knowing the specifics of the pathogen?

From a public health perspective, protection against infection is becoming of increasing concern, with new threats arising more frequently as urbanization and globalization expose more people to more diverse microbes. From growing antibiotic resistance comes strains of "superbugs" that do not respond well to currently available drugs. According to the Centers for Disease Control and Prevention (CDC), healthcare-acquired infections (HAI) are now estimated to be at nearly 2 million annually, with approximately 100 thousand deaths [1], and their incidence is steadily climbing in the community at large [2] [3]; the death rate from these superbugs may be even higher than deaths from HIV at this point [4]. According to the World Health Organization (WHO) and the UK's Foresight Programme, more than 30 new diseases have been identified in as many years, many of viral origin, and new infectious agents will continue to emerge[5] [6].

The expectation of another pandemic is a matter of when, not if, by common consensus. While a great deal of research is being done on potential agents such as avian influenza, and advances are being made, there is no assurance that the next pandemic will come from the possible sources currently being studied. The growing concentration and cohabitation of people, animals, and crops can facilitate the rise of new infections and contamination. Increasing global travel, migration, and commerce can accelerate the spread of such infections at rates previously inconceivable. Changes in environmental conditions, as well as antimicrobial treatments, may also drive genetic recombinations that create new mutations in microbes that are injurious to human health and endeavors. The combination of a growing burden of disease from HAI spreading into the community and the emergence of new infections could already stress the public health system; the introduction of a pandemic on top of that could be devastating.

It should also be noted that new infectious threats are not limited to humans: livestock or crops could also be ravaged by emerging or re-emerging diseases. According to the WHO, since the 2003 outbreaks of the highly pathogenic avian influenza virus in Asia, the subsequent death or destruction of over 150 million birds has yet to control the disease [7]. A virulent new strain of stem rust could seriously reduce wheat and barley harvests in many parts of the world [8]. Thus, even if these diseases did not directly affect human health, they could have a major impact on agriculture, food supply, and commerce.

And there is the threat of bioterrorism, where biological agents could be deliberately introduced to debilitate entire populations. The anthrax attacks in late 2001 raised awareness of what havoc could be wreaked, prompting efforts by a variety of agencies including DHS, DoD, CDC, NIH, and FDA, as well as industry and foreign governments to plan measures to collectively counter such risks.

The loss of life can be significant, the costs to handle these risks can be huge, and the broader economic impact can be even greater; there could also be a significant effect on morale and confidence of the nation, particularly if known protective mechanisms were to prove insufficient. The Spanish influenza pandemic of 1918-1919 was estimated to have caused on the order of 50 million deaths [9]. The CDC estimates that HAI adds nearly $20 billion annually in additional healthcare costs [10]; Medicare has announced that it will not pay for HAI-related costs [11]. The Canadian government calculated that in 2003 the impact of SARS on that country alone was $945 million in healthcare costs, and over $500 million in economic costs [12]. The World Bank estimates that a pandemic could cost the global economy on the order of $3 trillion in losses [13].

To a significant extent, current practice in research and development trends towards detection, identification, characterization, and treatment largely of specific pathogens or classes of pathogens. Such work is necessary, to most efficaciously deal with known threats. The challenge, however, is that no one knows what new microbes or infectious agents will arise, nor when; it is clearly a diverse, dynamic, and evolving phenomenon that cannot easily be predicted. These newly emerging or re-emerging diseases may furthermore spread rapidly, making it difficult to do the research quickly enough to characterize and act against any previously unknown threat.

An alternative approach could be to reframe the question another way: even before identification and characterization of a pathogen can be made, would it be possible to protect populations without knowing the specifics of the infectious agent? Would it be possible to develop blanket bioprotective technologies that would be safe for humans and yet effective against bacteria, viruses, fungi, and other microbes?

This is a significantly different model for studying protection against biological threats because it does not follow the traditional "vertical" approach of homing in on a specific organism, but instead would require taking a more "horizontal" perspective of what might be common across microbial threats that could be utilized to create mechanisms to protect against a broad range of infectious agents without knowing, or necessarily really caring, what their specific characteristics are, as a first line of defense against any biohazard. Taking such an approach might stimulate thinking about solutions along the lines of

- New barrier technologies: such as materials or processes that would prevent any contact with potential pathogens. Examples might include the Department of Homeland Security's multi-threat glove project for first responders, or advances in hazmat suits.
- New neutralization technologies: materials or processes that might bind or otherwise interact with potential biohazards and render them ineffective, such as by filtering or precipitating them out, or binding them so that they can no longer act. Water purification technologies might be an example.
- New microbicidal technologies: new forms of disinfection or other biocidal mechanisms could be developed, that would be safer to animals and humans. An example here might be the use of silver as a biocide, which has been growing in popularity.
- New sociological or behavioral policies: thorough hand-washing has been demonstrated to significantly reduce the risk of cross-contamination, but there may be additional behavioral modifications or interventions that could facilitate protection against the spread of infection.

Asking a question differently—in this case, what would it take to create a blanket bioprotection against a broad range of known and unknown microbial threats?--can often stimulate new thinking, and view challenges from a fresh perspective. In this case, by taking the question out of the biomedical realm, there may be an opportunity to stimulate new developments in systems biology, materials science, nanotechnology, and chemistry.

The need is palpable, to protect populations from unknown biological threats. Several organizations identify public health threats as a major concern; but each looks at, and funds research on, the problem with its own focus. The National Strategy for Homeland Security recognizes naturally occurring infectious disease as a significant and ongoing hazard, in addition to man-made health threats from biological weapons, and seeks countermeasures including prevention [14]. The National Strategy for Combating Terrorism identifies protecting food supplies, water, and public health against terrorist attack as a priority [15]. The recently signed American Recovery and Reinvestment Act includes funds for research to improve surveillance of emerging, enhanced, and advanced biological threats [16]. Recent projects of the Institute of Medicine have included researching reusable face masks for use during an influenza pandemic, studying the prevention and control of viral hepatitis infections in the US, and the forum on microbial threats [17]; and in conjunction with the National Research Council, understanding the transmission and surveillance of zoonotic diseases [18]. The National Institutes of Health and the Department of Defense do research on bioterrorism agents; much of the research on protection and prevention seems to be in the area of vaccines. One of the CDC's strategic imperatives is public health research to monitor and prepare for emerging health threats. The EPA's mandate includes protection of the water supply from microbial contaminants. Despite all of these activities, it does not seem that any of them is considering the possibility of broad-spectrum protection and prevention *per se*.

Is it possible to protect against a large range of microbes without knowing what they are or how they act? In order to shift the mindset, the question needs to be asked simply, but capable of spanning multiple uses and applications. There is also the necessity of developing standards across applications for what would be considered sufficiently protective, measuring the effectiveness and, importantly, monitoring for signs of loss of protection. This is an ambitious, overarching goal, and not readily addressable by current policies or funding mechanisms. While progress has been made in funding cross-disciplinary research, much research still follows traditional lines. Government funding, while supportive of basic research, tends to follow the priorities of the agencies doing the funding. Industry funding, which focuses more on applied research and development, tends to be constrained by the more specific needs of the businesses.

Asking to find mechanisms that protect populations from viruses, bacteria, fungi, and other microbes simultaneously may encourage a different approach to the problem. TIP funding may afford the opportunity to reframe this question to address a bigger picture, articulate a broader yet still definable issue, and provide appropriate resources to address the problem of umbrella protection from multiple biothreats, from different perspectives, because it could explicitly look across applications and uses. Clearly, if the possibility of a pandemic or similar public health crisis is only a matter of time, then it is essential to accelerate finding ways to deal with such an eventuality before it becomes a catastrophic situation. Without such an emphasis and intervention, current funding mechanisms are highly unlikely to encourage any paradigm shift. With TIP funding articulating a different question, however, new technologies currently under research may find novel applications that would dramatically increase public health protection, without first requiring the specifics of what one doesn't know about the potential pathogens.

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