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SB7.0 BIOSECURITY FELLOWSHIP

REFLECTIONS FROM FELLOWS

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SB7.0 Fellowship Reflections

Addy Linan Segura - Ministry of Innovation Science and Technology, Mexico

In Spanish there is only one word that describes both biosecurity and biosafety, it is: “bioseguridad”. We encompass two concepts into one. The first day of the fellowship in Singapore helped me realize that there are two sides of the same coin, and we were missing one. In Mexico when we speak biosecurity we refer to general issues of good laboratory practices, avoiding contamination of the crop fields and avoiding contamination of pathogens from laboratory to human health. We do not talk about the ease of use of these technologies with a potential for terrorist attacks. Therefore, we lack a strategy to act, in case we suddenly find ourselves immersed in such unwanted situations.

I wanted to start this essay with the latter reflection, because I left Singapore with the idea that we have not established clear standardized measures on biosafety and biosecurity. On one side some biosecurity experts forecast imminent attacks, on the other side some scientist feel that the benefits of science outweigh potential security risks. Thirdly, some developing countries are not even considering biosecurity a true possibility. Anyways, I still felt the collision of opinions happening between two adversary points: nature-borne versus mankind. In my opinion, both groups have different enemies in mind. Biosecurity experts think of preventing wrongdoing-human acts, and scientists fear nature-borne pathogens. In true remarks, both concepts pose big threats, but when discussing to reach a middle ground, is it true that these two positions overlap? Is it really one or the other?

The closest, most recent event that Mexico suffered related to a biosecurity threat was the H1N1 virus in 2009. Certainly the whole country found itself with no other better solution than a mere recommendation of washing hands and limiting social interaction. We might as well have travelled 100 years back in time and done no better. And besides, I know that Mexico wasn’t the only country implementing those simple measures; developing countries were in similar positions. As long as we didn’t have a vaccine available, we were super vulnerable. What happened with all the other technologies and innovations around health and prevention? Haven’t we improved in 100 years? The answer is that of course we have. But what happened? Why were we seeing the vaccine as the only possible solution?

It is unacceptable that in case of a nature-borne or bioterrorist event we do not have a better system in place. A good approach in targeting biosecurity policies should be focusing on enhancing international collaboration. Let me explain more clearly. Sharing samples of virus between countries is a bureaucratic hassle, even in the middle of an outbreak. We also need every available mind tackling the puzzle. Virologists, microbiologists and related experts shouldn’t be our only go-to solutions; it is important to consider other areas of expertise. For example, immunology studies in other fields that may strengthen the health of populations before they get infected, so they become less prone to developing acute symptoms and reducing mortality rates. Special means should be developed for special circumstances and these have to be globally agreed and practiced.

A week after coming back to Mexico I organized a meeting among my peers in government to discuss the future of synthetic biology and biosecurity, and I included both pros and cons of the technology as well as raising the questions of policies. I also published an article on the subject for a general reader which is more distant from these subjects. In both activities I received comments where people and peers were amazed by how fast technology in this area is advancing and how they were also worried about all the challenges we face because of it. In our country our main concern still lingers in enhancing the adoption of the technology, because we are still far behind from the current developments.

Attending to SB7.0 was an invaluable opportunity for understanding the state of the art of Synthetic Biology, something that I don't have available inside my country. Personally, I was impressed by the number of Asian countries participating in the development of this discipline, and realized that Latin America's scarce presence worried me. But also it made me more conscious of the importance of sharing my experience and promoting good science. Making connections is also part of the first steps to enhance collaboration. So I had the fortune of meeting people who had a wide diversity of profiles, whom are not only in research but also transform knowledge into tangible actions: entrepreneurs from different parts of the world, researchers acquiring knowledge in different areas and futurologists.

Finally, the whole event helped me realize that synthetic biology is not as far away as I thought it was, and attending the event helped indirectly to raise awareness on this subject among my peers in government where for the first time we had a meeting exclusively on biosecurity and biotechnology.

Aditya Kunjapur – Harvard, George Church Laboratory, United States

Synthetic biologists are developing a myriad of tools, methods, and organisms that make biology easier to engineer and that apply new biological solutions to diverse societal problems spanning industries like energy and healthcare. Although the general advancement of the field of biological engineering could foster technologies with dual use implications, the Synthetic Biology 7.0 (SB7.0) Biosecurity Fellows program provided a level of specificity about these risks that would be difficult to learn about and discuss elsewhere. Through engagement with experts and through community building with a diverse set of young practitioners spanning synthetic biology and biodefense, the Biosecurity Fellows program provided me with invaluable knowledge and contacts that will influence the type of science that I practice for the rest of my career.

Given my technical background, I was aware of the current capabilities of synthetic biology and some of the U.S. federal agency stakeholders before the conference began. However, I was relatively new to the history of biological misuse over the course of human history, including the recent Soviet biological weapons program and the South African project during apartheid. Before the program, my intuitive sense of how to perform a risk assessment relied mainly on whether I thought something I was constructing could be deliberately misused by a rogue actor. During the program, I realized both that there was important historical context for potential state actors and that the ramifications of accidental

misuse or release was also a necessary consideration. In some ways this is ironic given that my current technical work focuses on synthetic biocontainment, which is a strategy designed to prevent proliferation outside of controlled contexts. Yet it is still very different as an engineer to construct a containment mechanism for an industrial biomanufacturing strain than to consider what may happen if a more dangerous strain evaded the containment strategy and escaped into the natural environment. The biosafety framework for preparedness in the event of accidental release or natural disease outbreaks presented me with a new perspective on how to view risk stemming from synthetic biology.

Besides the knowledge I acquired, I was really pleased to meet thoughtful individuals who have an incredibly high tolerance for stress given their perpetual focus on existential risks for humanity. Two of these contacts, Nicholas Evans and Andrew Snyder-Beattie, were particularly interested in my work and were also particularly witty. They and several other Fellows came from backgrounds more oriented towards the intersections of ethics and philosophy with technology. That is a fascinating set of topics that I wish my science colleagues, specifically the academic research enterprise at large, would encourage us scientists to spend more time dwelling on. In fact, one of the takeaways that I gathered from the Biosecurity plenary was that the system for scientists could use more driving force for biosecurity, and that there are two levels within the system that are especially influential: the funding agencies (like DARPA/IARPA) and the top journals (like Cell/Nature/Science). If these entities chose to prioritize biosecurity research and made that preference widely evident, then such research would naturally follow.

As a scientist/engineer, I am reluctant to speculate on what kinds of new regulation or practices should be implemented, even after the Fellows program. I prefer to focus on what more should be done in terms of innovative technological solutions, such as engineered countermeasures. I liked that my colleagues in the program seemed to validate my interest in developing additional countermeasures, whether it be for biocontainment or for counteracting biosynthetic production of illicit substances. Overall, I definitely think the latter and other types of research (such as the poxvirus synthesis, which I am not a fan of) require careful regulation in order to protect the reputation of the entire synthetic biology community and prevent any loss of human lives. I can speak to how research closer to what I practice ought to be regulated, and that is one reason why I look forward to staying in touch with other Fellows.

András Sándor – University of Oxford, United Kingdom

The SB7.0 conference was – as expected – a nexus of synthetic biology, biosecurity and bio-policy. A vibrant event with a remarkable lineup of speakers, SB7.0 delivered a great glimpse into the forefront of the field, and the Biosecurity Fellowship augmented and extended this programme with several panel talks and discussions focused on the biosecurity and biosafety aspects of synthetic biology. Many interesting ideas were raised by the Fellows to improve global or local biosafety and introducing policies

directly relevant to these questions. Below I will briefly discuss my take on some of these and reflect on what I gained from SB7.0 and the Biosecurity Fellowship personally.

Public understanding of synthetic biology, biosafety threats and general principles are severely lacking as noted by several Fellows. As such, a broad educational campaign aimed at the general public would be of great value, to improve understanding of this field, as a preventative measure (in case of a legitimate threat) and finally as a way to raise political capital to implement further policies (for example, to provide support for the creation of an international body as outlined below). Such a campaign would need to use modern tools for outreach, including social media (i.e., microtargeting), which has been shown in recent political campaigns (the 2017 US and 2018 British and French elections) to be the most significant force multipliers for marketing and delivering a message.

A second important idea raised multiple times throughout the Fellowship was the creation of a governing body that would oversee international biosecurity questions, issues and threats. This would be a preventative measure – to prepare before such a crisis would arise – and ideally a reactive organisation as well, that would be directly involved in tackling an already active threat. The necessity of an organisation promoting international cooperation is clear: it is the nature of biological threats (both natural and engineered) that arbitrary national borders are not respected by them, and as such, emerging biosecurity threats must be combatted on an international level and prevention and preparation should be done on the same scale as well. Such a governing body could be (depending on international support) formed from a smaller nucleus of nations (e.g.: G7, European Union, etc.) or it could be a more inclusive group (e.g.: acting as a suborganisation of the United Nations). However, as mentioned above, while a purely top-down approach (i.e.: creation of such an umbrella-organisation) might be viable, it could be augmented by popular support. Finally, preparation for biosecurity threats need to combine theoretical and practical approaches, and implement “war-games” and live practices including a broad range of actors (emergency personnel, field scientists, policy-makers and politicians, etc.).

One final idea mentioned during the course of the Fellowship was the introduction of mandatory screening of sequenced and synthesised genetic materials to flag dangerous genes. This idea was raised as a potential response to the host of issues unveiled by the reconstitution of the horsepox virus by Dr. David Evans. However, I am personally ambiguous about the benefits of such a policy: defining what genes are screened for would be a difficult question (and would be most likely either a very limited list restricted to a handful of the most dangerous toxins and viral components, or such a broad list that most common sequencing projects would trigger it).

I would like to take this opportunity to once again thank the organisers of the Fellowship for their effort and the chance to attend SB7.0 – if not for the Fellowship, I certainly wouldn’t have attended and would have missed out on this event. I believe that early career scientists can gain the most from such an experience, and this is why focusing on gathering together a group of future leaders from synthetic biology was a great initiative. Interacting and networking with my peers, global leaders, prominent PIs

and postdocs, NGOs, researchers from the industry and policymakers from all over the world really deepened my understanding of this field, gave me a growing appreciation and interest for several projects (such as the amazing SC2.0 – Synthetic Yeast project) and opened new doors. During the course of my under- and postgraduate studies, we were often told that a degree in Genetics can be used for many careers outside of academia, but only after meeting with such a wide variety of people at SB7.0 do I really understand the scope of possibilities.

Anne Meyer – Delft University of Technology, Netherlands

I thoroughly enjoyed my time as a SB7.0 Biosecurity Fellow at the SB7.0 Conference in Singapore, and I am grateful that I was given the opportunity to take part in it. As a research scientist and educator, I have put a great deal of thought into the practical aspects of biosecurity, such as how best to engineer a kill switch into a genetically modified organism, or which new biological functions could potentially cause medical risks when introduced into a laboratory organism. However, the Biosecurity Fellow program really opened my eyes to how many other areas of biosecurity exist and are crucially important to society. It was truly enlightening to get a glimpse into the often poorly-motivated logic underlying the various classes of biosafety classifications. I also appreciated the chance to reframe the way I approach the synthetic biology literature, to take a step back and contemplate whether the gain in scientific knowledge would truly outweigh the risks involved in endeavors such as resurrecting extinct viruses. I was fascinated to learn that high-profile biosecurity events such as the recent anthrax scare can lead to many more research groups working with risky viruses and bacteria, which can be eventually more dangerous than the original terrorism-related threat. Finally, as a bacteriologist, I was glad to finally get a chance to figure out how gene drives really work, straight from the pioneering experts.

Even weeks after the conference has ended, I find myself frequently thinking about the work of David Evans to synthesize the smallpox-related horsepox virus, and the interactions we had with him as a group during the fellowship program. While Evans was speaking to our group, few or no questions were asked of him to justify the scientific motivation for his research, and whether that motivation could outweigh the potential risk of disseminating his results. Only after leaving the conference did I learn that no scientific journal has agreed to publish this work, presumably for reasons of biosafety. The experience has really made me reflect upon the way that scientists normalize their own field, even when the implications of specific experiments creep far beyond the bounds of normality. When teaching my lecture course about synthetic biology, I have adopted the approach that biosafety considerations should be integrated into each course where they apply, rather than being condensed into a single, separate course of their own, which could give the message that biosafety and biological practice can and should be separate fields. Now my recent experience with the horsepox issue has led me to think that a similar approach should be adopted for scientific conferences. Perhaps pairing lectures such as Evans's during the SB7.0 conference with another speaker who could lead a discussion about the implications of such research could help to wake up the critical faculties of the audience and remind

them that they should engage with the societal implications of new research as well as with its scientific implications.

As a scientific researcher engaged with bioengineered microorganisms to perform tricks inside the laboratory, I will likely not be able to use the knowledge gained as a Biosecurity Fellow directly in my own research. However, I have many students who are not interested in climbing further up the academic ladder after graduation, and I think that I have learned a lot about different types of policy-related positions that I could discuss with them as future career paths, which could be of special interest to scientists from a bioengineering background. Additionally, as my career advances and I am able to take on more administrative roles within my university and field, I truly believe that my new knowledge and outlook will be invaluable in helping to guide the future of synthetic biology research and discussions.

Ari Dwijayanti – Imperial College London, United Kingdom

The rapid growing synthetic biology development and movement enable humans to reprogram biological systems rapidly. As a consequence, this emerging technology has been framed as dual use: can produce good and bad things. Biosecurity has an important role in controlling the development of this technology especially for preventing misuse of this technology.

Regarding the biosecurity risk and assessment, there should be a specific biosecurity risk and assessment for synthetic biology that may be different from the one for the natural pathogen. Although, with the development of synthetic biology nowadays, it is almost possible to recreate pathogens that have similar properties as the natural one. Moreover, it is difficult to distinguish natural and man-made pathogens. With the remarkable progress in XNA biology, probably someday the synthesized nucleic acid for synthetic biology purposes can be replaced by XNA materials. These XNA substances still function in the biological system but can be distinguished from the natural one. Therefore, identification and tracking of the misused synthetic biology could be done better and faster in the future.

There are different approaches that could be done for different targets to implement the biosecurity practices and policy. In the level of government, there should be a routine active dialogue between public policy makers and practitioners to update the biosecurity regulations in their countries. As the development of the synthetic biology movement in several countries is different, the developed and developing countries have their own biosecurity policies. The developed countries have more advanced biosecurity policies to prevent the harmful effect of synthetic biology development. On the other side, since the developing countries are vulnerable to the synthetic biology product and technology there is a need to establish the biosecurity strategies that should be adjusted to their home countries. Bilateral and international partnerships in biosecurity could be an excellent initiative to overcome this issue and tackle global biosecurity issues.

Since ideally, the academia and industries laboratory have a standard biosecurity regulation within the particular institution, a regular training and workshop would be one of the alternatives in disseminating the biosecurity issue. I could think that one good example for the biosecurity training in the level of undergrad and high school student is safety and human practice in the iGEM. Some of the practices through this program not only have assured that the students doing synthetic biology work safely but also raised public awareness about synthetic biology and biosecurity. However, the regulation of biosecurity and biosecurity practice for the public movement such as DIY community still has remaining questions.

From the SB7.0 Biosecurity Fellowship Program, I learned a lot about the biosecurity practices from academia and industries perspectives as well as the biosecurity policies that have been implemented by government from several countries. As they have the different level in controlling biosecurity, it was really interesting to understand their perspectives toward the biosecurity issues. The discussion with the biosecurity fellows during this event also has pointed out the different biosecurity regulation and practices from their home countries and institutions. Furthermore, the networking I obtained through this program will be very useful to my future career. This program has changed my perspectives and awareness about biosecurity issues and triggered myself to be keen about biosecurity policies in my home country, Indonesia. Overall, the SB7.0 Biosecurity Fellowship has been an excellent initiative program that accommodates the leaders from different backgrounds across the globe to share and discuss the recent issues and strategy in biosecurity. I hope that there will be continuity of this program in the near future.

Baojun Wang – University of Edinburgh, Scotland

As a selected SB7.0 Biosecurity Fellow, sponsored by the Johns Hopkins Center for Health Security and the BioBricks Foundation, I attended the SB7.0 meeting together with an accompanied full Biosecurity Fellowship event schedule. In summary, I enjoyed very much the meeting and the exclusive fellowship associated activities over the 4 days at NUS, Singapore. Herein I would like to share my experience below and thank the sponsors for the excellent opportunity to enable me to join this important event in the synthetic biology field.

First I would like to point out that arranging the biosecurity fellowship event concurrently with a highly related international meeting is very attractive to many potential attendees and has certainly increased the profile and enthusiasm for this fellowship, since I would not be similarly motivated to apply for this fellowship if it was a separate standalone event. Hence, as a recommendation for the organizers, it would be great to hold such event in a similar way in the future to attract attendees with both an interest in biosecurity and biosafety, and synthetic biology research.

In addition to the exciting meeting talks and social events, the organizers have arranged several workshops for our biosecurity fellows that have invited high profiles synthetic biology researchers and

related biosecurity and biosafety government agents both internationally and locally. Their views and extensive experience pertinent to biosecurity and synthetic biology were very helpful for us to understand the present state-of-the-art on such a topic in the field. I particularly enjoyed some question quizzes in some speakers' slides that we designed to test fellow attendees' knowledge on related biosecurity and biosafety issues, from which I noted that a lot of the selected fellows actually did not have a deep and full knowledge in biology/synthetic biology to evaluate a specific situation on biosecurity. This might be due to a lot of the fellows not having practical research experience in a biology or synthetic biology labs even though they work in related posts in their individual institutions. This alarmed me since my personal experience with our own host institutional biosafety people was not satisfying due to their limited knowledge on some research topic on pathogens and sometimes overstated/lengthy risk assessment which lead to severe delay and interruption of our funded research work agenda. Hence I think the experience and qualification of the people who are performing biosecurity and biosafety support and checks are highly important to contributing a mutually beneficial and supportive relationship between the two sides – researchers and regulators. Otherwise, either the research progress would be severely delayed or affected or there would likely exist some underground research activities that make researchers less motivated to discuss/share with biosecurity and biosafety regulators. Finally, I enjoyed a trip to the US embassy in Singapore during which we had a deep discussion and view exchange with related military experts in biosecurity and biosafety in addition to being a good excuse to escape the routine meeting agenda.

My own interest in biosecurity stems from my research and public engagement experience. For example, we have been working on developing portable synthetic whole cell-based biosensors for detecting environmental toxins and pathogens. For such synthetic biology-enabled sensors to be put into field application, the biosecurity of such sensors is an important factor to be taken into account during the research and development stage before entering the final market entry regulation process. Moreover, I am working on another project that aims to engineer broad spectrum bacteriophages to selectively kill diarrhea-causing gut pathogens for infants in developing countries. For such living organism-based therapeutics to be functional for treating human disease, the biosafety of the engineered phages will be extremely important in addition to their efficacy. Hence we have to take the biosecurity and biocontainment factors into account for the project design and development, to avoid/minimize any potential controversies from our society. On the other hand, I have been regularly involved in public engagement events such as contributing to the Royal Society Summer Science Exhibition. With my colleagues we held a week-long public exhibition on synthetic biology concept and its potential impact on our society at the Royal Society of London in 2007 that attracted lots of public attention and interest. One frequent question to us is the biosafety of these engineered microorganisms, which we have to explain to help clear out such public concern. In summary, it is certain that I will need to continue to address such issues both in my research and engagement with the public since synthetic biology is still at an early stage with lots of potential barriers or pitfalls ahead.

Being awarded with the SB7.0 biosecurity fellowship, it benefitted me by enabling my attendance at SB7.0 conference to learn and interact with the leaders and peers who share the same interest in biosecurity and synthetic biology, and to contribute to the discussion and formulation of new strategies and research plans on such topics with my own thoughts to accelerate the maturity and fast and heathy growing of synthetic biology. I subsequently helped disseminate the information and ethos resulted from this meeting to my colleagues and peers in my own institute. Hopefully it at large benefitted the synbio and biotechnology field that still faces critical challenges to address the biosafety and GMO concerns in our scientific communities and societies.

Brett Edwards – University of Bath, United Kingdom

The field of Synthetic Biology has been increasingly central to my thinking about preventing the hostile use of biotechnology over coming decades. In one sense, technological innovation stemming from this field continues to produce both opportunities and challenges for preventing and mitigating the effects of biological weapon use. At another level, the field has become a test-bed for experiments in pro-active and pre-emptive approaches to governance. Experiments in biosecurity governance reflect a sustained personal commitment by a number of individuals to ensure that real, as well as misplaced, security concerns do not damage the field or broader society. Such work has come in the context of anxieties about the field which emerged in the post 9/11 environment. Initiatives directed at establishing screening standards in the gene-synthesis industry, the embedding of biosecurity and biosafety training in the iGEM programme, as well as pro-active engagement with national level technology assessment and regulatory review all stand testament to the work in this area. Such initiatives set an example for other fields- they also mean that awareness of security issues among synthetic biology practitioners exceeds other fields.

We must remember, however, that while the field of Synthetic Biology is international - its history and identity is US centric. This has had impacts on how the field's security discussions have been framed within this community. This is something which scientists such as Drew Endy have also tried to push back against as part of broader attempts to shape the way in which the field is commercialised. However, there remains predominant framing assumptions which have served to narrow security discussions. This might lead to missed opportunities for positive and collaborative international action, and is something which may be worth remedying.

For example, there has been a preoccupation with traditional threats to US homeland security: terrorism and WMDs. In addition, the prominent approach to defining the scope of security concerns primarily reflect pre-existing approaches to governance. The logic which prevails is incremental local level review of research and technology that might be directly misapplied- such discussion has also prioritised the discussion of the misuse potential of pathogens and toxins. The dominance of this framing within discussion and assessment may have had many subtle impacts on our collective field of

vision. From my perspective there are three dimensions along which discussion needs to be opened up in order to give adequate attention to broader concerns about militarization of biotechnology by states.

1. We need to think beyond pathogens and toxins;
2. We need to think about trends in warfare that open up possibilities for new types of offensive exploitation of biotechnology; and
3. We need to think beyond the Synthetic Biology and build links with other communities trying to shepherd their own fields.

What next for our biosecurity community? Innovation biosecurity is a broad and diverse problem space, which relates tangentially to a wide range of policy areas. Not least, public health and development-practitioners in these fields caution against allowing misuse concerns to distract from, or undermine attempts to bring, greater and more equalitarian benefits to communities around the world. However, it is clear that the history of weaponry points to the need for greater and specific attention to the issue of militarization- this does not need to be adversarial (military investment is inevitable and it also had brought great positive advances) but there is a need to identify broader principles of assessment and dialogue that should be drawn on in this area. This community might be well placed to ignite that conversation. Furthermore, it is also clear that much of this work would not sit at odds with the ethos of public health and development. Action in this area is not just thinking about control, but also critical engagement with existing investment priorities and practices globally.

With this in mind, I hope that this community can work to build broader dialogue about global governance in this area going forward, and build upon existing work in this space. This is something I will be open to collaboration on in the future.

Daniel Martin-Alarcon – Recently Open Philanthropy Project, United States

Opinions on synthetic biology and biosecurity seem to fall on a certain spectrum that stretches between two edge views. At one end stands an enthusiastic scientist focused on all the benefits that SynBio can bring to the world in the short term. She's eager to provide the world with more sustainable food, energy, materials, etc., and to cure the world of tropical diseases while we're at it. She's a responsible person used to routine biosafety precautions, and would of course want to conduct research that was similarly careful not to have negative unintended effects on the environment or the public. She is skittish about biosecurity, because drawing too much attention to biosecurity sounds like a very effective way to make the general public (and government regulators) think of bioengineering as a dangerous activity that must be resisted or heavily regulated. The march of progress, not to mention the enormous benefits of the work that we hope to do, could easily become less important in the public's mind than nonspecific fears about vague dangers, real or otherwise.

At the other end of the spectrum, there is another scientist that worries about too many of her colleagues jumping excitedly into research without thinking of the implications. In the past, curiosity-driven work has often veered straight into territory where the potential for accident or misuse is very significant, and the scientists involved haven't always as careful as we'd like them to be. Will the risk become greater as technology advances? Will we fail to properly manage technology that we already have? She worries not only about the damage that we could do to the world directly, but also the damage we could do to science itself. Nuclear energy never lived up to the excitement it once enjoyed, because a few accidents tarnished its image in the eyes of regulators and the public. Genetic engineering of crops is arguably stuck in the same situation without anything bad even having happened. If we're not careful, what could happen to gene drives or gene editing or anything else in the synthetic biology pipeline?

These two perspectives are complementary. More importantly, a few areas of practice and policy are important according to both points of view. One such area is risk analysis. Do we really understand the expected cost of various risks in the context of biosecurity? What about the costs of not developing our best solutions to existing problems? Could one, for example, calculate the order-of-magnitude expected cost, in human lives, of gene drives going awry versus sticking to non-genetic means of combatting tropical diseases? What is the probability and actuarial cost of various natural epidemic and pandemic scenarios that we could be fighting better? The risks with the lowest probability would of course be the least predictable, but how much can be said with reasonable certainty about that tail-end of the probability distribution? And how much can be said about the bulk of the distribution? Computational modeling of biosecurity risks and scenarios is both a useful academic exercise and also the starting point for practical policy prescriptions.

My greatest takeaway from the Biosecurity Fellowship was a much better intuitive understanding for the sort of work that people are doing within biosecurity. I have a clearer picture of where it happens, what sort of institutions carry it out, and how it informs institutional decisions. I also feel that I've connected with just about everyone who is doing important work in the area or expects to carry out that sort of work soon in their careers. It's very valuable to know exactly where the biosecurity jobs actually are, and what they look like. As a result of the conversations I had during this conference, I also have a better understanding of the two viewpoints that I described earlier. Furthermore, I am now planning to seek out career opportunities for understanding and managing risk. I suspect that this area is both interesting and underexploited, and that the implications of better risk management would be important even beyond the context of biosecurity. The perspective and connections established during this program have been the starting point for this decision. Hopefully this effort will add on to the responsible excitement in our field, and that we will indeed advance towards the bright future that we are working so hard to design.

Danielle Fields – Gryphon Scientific, United States

Biosecurity is inevitably a key consideration as synthetic biology develops and its tools become more sophisticated and more democratized. Fields designed to expand engineering capacity or reduce knowledge barriers are dual-use by nature, and a field aiming to make biology engineerable is no exception. Appropriate biosecurity policies and practices should be established and implemented in order to shape the growth of synthetic biology in a way that maximizes the benefit-to-risk ratio. These policies and practices should aim to minimize the chance of accidental or intentional harm arising from synthetic biology while supporting the great capacity of synthetic biology for beneficial applications and enabling maximal scientific and technological advancement.

New members of the synthetic biology community should be encouraged to explore the exciting possibilities enabled by synthetic biology while simultaneously emphasizing the importance of responsible innovation. This practice has been carried out well by the International Genetically Engineered Machine (iGEM) competition, in which undergraduate bioengineers are encouraged to think beyond the experiment and consider the safety, security, and societal implications of their work. Similar approaches should be incorporated at other entry points into the field of synthetic biology. While technological achievement and dissemination of new knowledge are hugely important, the potential downsides of new technical and scientific tools should not be dismissed. Pursuit of new scientific avenues should be accompanied by consideration of both the positive and negative consequences and, if the perils are significant, formation of strategies to mitigate risk. Development of these risk-mitigation strategies for new research areas is a responsibility of policymakers as well as the researchers themselves.

Multiple stakeholder groups – including scientists and engineers in academia and industry, policymakers, and the general public – have diverse and important viewpoints on responsible implementation of new technologies. All of these perspectives should be considered in the development of a well-balanced, prudent, and reasonable set of biosecurity policies. Additionally, biosecurity practices and policies should be adaptable in order to account for the dynamic nature of biological risk. Technology (namely, synthetic biology) is always evolving and can change in unpredictable ways, and a robust biosecurity platform should have the flexibility to keep pace.

I found the SB7.0 Biosecurity Fellowship to be an invaluable experience. I had the opportunity to hear about exciting developments and interesting perspectives from leaders in the field, as part of the main conference as well as fellowship events. Some fellowship talks and events that particularly stood out to me were: Piers Millett's discussion of post-taxonomic risk assessment, which underscored the importance of adaptive biosecurity policies; Matt Watson's review of the history of biological attacks, which emphasized the harm that can arise from the misuse of biology; and a panel at the U.S. Embassy in Singapore, in which we heard from officials working on numerous facets of biosecurity. Beyond the scheduled events, some of the most valuable parts of this experience were the impromptu discussions I had while staying after speaker events to talk directly with experts or meeting up with the other

biosecurity fellows outside the conference center for some thought-provoking discussions about the intersection of synthetic biology and biosecurity. This was a great opportunity to meet many other people sharing my interest in biosecurity issues relating to synthetic biology, and I look forward to continuing my discussions with the other fellows via email, over coffee (for those in my geographic area), and at future events.

The opportunity to attend SB7.0 as part of this program provided me with great information, inspiration for new ideas, and a more refined understanding of the state of the art in synthetic biology as well as the biosecurity needs of the field. This experience has been highly relevant to my work as an analyst at Gryphon Scientific, a scientific consulting firm whose projects support federal policymaking. My first few hours back were spent enthusiastically typing up pages of notes and emails to incorporate knowledge gained at SB7.0 into current and future projects. The SB7.0 Biosecurity Fellowship was a truly unique and valuable experience, adding to my knowledge of synthetic biology and biosecurity and introducing me to many talented people with similar interests, and will shape my work for many projects to come.

Dona Sleiman – Pasteur Institute, France

When I wrote my cover letter in order to be a recipient of the biosecurity fellowship, my goal was to benefit from a renewed awareness of the current debate on “good laboratory practices,” which are instrumental for scientists who are constantly working to ensure the safety of their environment. This conference made me think of the issue of biosecurity in new ways. For me scientists should always have the best intentions. The idea that findings aiming to advance our knowledge or enhance our world would be used to spread diseases or pose a threat was admittedly something I never thought about enough before. Attending SB7.0 and biosecurity fellowship sessions made me raise several questions:

- Is it true that now, with all advancement made in science, we are more aware of our impact as scientists, and we have the means to evaluate the modifications we do (say on a bacterium, a cow or a corn) as Randal J. Kirk said?
- The fact that Christina Smolke is synthesizing morphine analogs with yeast, made me wonder how this production will be regulated by governments.
- I realize that society should have something to say about the work of the scientist, and bridges of communications should be constructed between scientists and society. Scientists are often portrayed negatively and their work is often viewed with undue suspicion in mainstream press and culture in ways that sometimes amount to fear propaganda. Should we limit the free existence of DNA sequence because some terrorists could take advantage of that and as a result delay the progress of “good science”?
- The question raised by Alexandra Daisy Ginsberg, of what constitutes good science, is something that I’d like to reflect on further in my work.

- When I heard Ryan Phelan talking about preserving species, I wondered if we should do that. What about survival of the fittest? And doesn't this prompt us to think about how this may apply to humans?
- In the security session, it was mentioned that "Nature is the worst bioterrorist." Sometimes it is very intuitive to figure out the misuse of the innovation as in case of the opium biosynthesis or recreating viruses from scratch, in other times the danger is more vicious to apprehend.

With these ideas and questions in mind, and building on a new awareness gained from discussions with organizers, SB7.0 speakers and participants. I can say that this experience has marked a turning point in my career as a scientist. Since then I have been thinking about the numerous possibilities and challenges in the biosecurity field. I think the most capable professionals to be invested in this mission are the scientists themselves. For this reason, I have decided to raise awareness about biosecurity among students aiming for a carrier in research. And that's why I will try to design courses for Master and PhD students about biosecurity. Another point raised in the conference which I would like to emphasize here is the almost complete absence of scientists in the political decision-making sphere. For the next biosecurity conference, are we going to go beyond the subject of bioterrorism in order to tackle questions like bio-engineering on human embryo or GMOs? Finally, I would like to thank all the organizers for all the time and effort they expended in order to pull together such a successful conference. I'm also grateful to be part of such a diverse group of brilliant scientists who brought so much insight into our discussion. I'm truly fortunate to have been part of it.

Eric van der Helm – Technical University of Denmark

Last month, the SB7.0 conference attracted around 800 synthetic biology experts from all around the world to Singapore. I was attending as part of the SB7.0 biosecurity fellowship, together with 30 other early-career synthetic biologists and biosecurity researchers. The main goal of the conference was to start a dialogue on biosecurity policies geared specifically towards synthetic biology.

As Matt Watson from the Johns Hopkins Center for Health Security points out on his blog, the likely earliest account of biological warfare was the one describing the 1346 attack on the Black Sea port of Caffa from an obscure memoire written in Latin. A lot has changed since then, and biosecurity is now subject of the mainstream media — as exemplified by the recently published *Wired* article "The Pentagon ponders the threat of synthetic bioweapons."

Defining biosafety and biosecurity

It is important to first get the scope right; terms like *biosecurity* and *biosafety* are sometimes used interchangeably, but there is a meaningful difference. In a nutshell, *'Biosafety protects people from germs - biosecurity protects germs from people'*, as simplified during an UN meeting.

- Biosafety refers to the protection of humans and the facilities that deal with biological agents and waste: this has also traditionally encompassed GMO regulations.
- Biosecurity is the protection of biological agents that could be intentionally misused

Although the meanings of biosafety and biosecurity are often somewhat interchangeable in the remainder of this discussion, I focus on biosecurity as this mainly involves the human component of policy making.

During the conference, Gigi Gronvall from the Center for Health Security illustrated a prime example of biosecurity from a 2010 WHO report on the *Variola* virus, the smallpox pathogen: *"nobody anticipated that […] advances in genome sequencing and gene synthesis would render substantial portions of [Variola virus] accessible to anyone with an internet connection and access to a DNA synthesizer. That "anyone" could even be a well-intentioned researcher, unfamiliar with smallpox and lacking an appreciation of the special rules that govern access to [Variola virus] genes."*

The take home lesson? What might not look like a security issue now, may soon become a threat!

Biorisks are likely terrorism or nation-state driven

What are the most likely sources that pose a biorisk? According to Crystal Watson, the following risks demand scrutiny:

- Natural occurring strains (e.g., the recent Ebola outbreak)
- Accidental release (e.g. the 1979 accidental release of anthrax spores by the Sverdlovsk-19a military research facility in the USSR)
- Terrorism (e.g., the 2001 anthrax-spore contaminated letters in the US)
- State bioweapons (e.g., the US biological warfare program ultimately renounced by President Nixon)

From a biosecurity perspective, it is interesting to note which of these risks are most imminent. The same authors recently published a perspective in *Science* that describes the actors and organizations that pose a bioweapons threat. It describes the results of a Delphi study of 59 experts with backgrounds broadly ranging from biological and non-biological sciences, medicine, public health, and national security to political science, foreign policy and international affairs, economics, history, and law.

Although the results varied considerably, terrorism was rated as the most likely source of biothreats because of *the "rapid technological advances in the biosciences, ease of acquiring pathogens, democratization of bioscience knowledge, information about a nonstate actors' intent, and the demonstration of the chaos surrounding the Ebola epidemic in West Africa in 2014."* Another likely

biorisk source would be a nation-state actor because of the *"technological complexities of developing a bioweapon, the difficulty in obtaining pathogens, and ethical and/or cultural barriers to using biological weapons."*

According to the expert panel, some threats are particularly likely to impact society:

- biological toxins (e.g., ricin, botulinum toxin)
- spore-forming bacteria (e.g., *Bacillus anthracis*, which causes anthrax)
- non–spore-forming bacteria (e.g., *Yersinia pestis*, which causes plague)
- viruses (e.g., *Variola* virus, which causes smallpox)

This list essentially covers everything that has been weaponized — only fungi, prions, and synthetic pathogens were not predicted to become weaponized in the next decade.

Now that the threats are defined: how to counteract them? One of the safeguards that has been put in place is the Australia Group, *"an informal forum of countries which, through the harmonisation of export controls, seeks to ensure that exports do not contribute to the development of chemical or biological weapons."* This organization seeks to develop international norms and procedures to strengthen export controls in service of chemical and biological nonproliferation aims. However, as Piers Millett from biosecu.re pointed out, these tools do not on their own adequately address our current needs for properly assessing and managing risks. For example, under the Australia agreement you need an export license to export the Ebola virus itself or a sample of prepped Ebola RNA. But you do not need one if you just want to download the sequence of the genome. In other words, access restriction in an inadequate biosecurity failsafe.

Why resurrect the extinct horsepox virus?

Biosecurity is directly related to the challenge posed by the dual use of research: it both creates a risk while providing insights to mitigate that risk. A particularly illustrative example is the recent synthesis of the horsepox virus, which is from the same viral genus as smallpox, but is apparently extinct in nature. Last year, the lab of virologist David Evans at the University of Alberta in Canada reconstituted the horsepox virus. Synthesizing and cloning together almost 200 kb of DNA is not exceptionally challenging today, but it just hadn't been attempted before for this family of viruses.

But *why* did Evans and his team set out to synthesize the horsepox virus in the first place? There were several motivating objectives:

1. the development of a new smallpox vaccine;
2. the potential use of the horsepox virus as a carrier to target tumors; and
3. a proof-of-concept for synthesizing extinct viruses using 'mail-order DNA.'

Evans broadly defended his actions in a recent *Science* article: *"Have I increased the risk by showing how to do this? I don't know. Maybe yes. But the reality is that the risk was always there. The world just needs to accept the fact that you can do this and now we have to figure out what is the best strategy for dealing with that."* Tom Inglesby from the Center for Health Security reasoned that the proof-of-concept argument does not justify the research as *"creating new risks to show that these risks are real is the wrong path."*

How well can the horsepox synthesis study be misused? Evans notes that his group did *"provide sufficient details so that someone knowledgeable could follow what we did, but not a detailed recipe."* Unfortunately, there are no international regulations that control this kind of research. And many scholars argue it is now time to start discussing this on a global level.

Paul Keim from Northern Arizona University has proposed a permit system for researchers who want to recreate an extinct virus. And Nicholas Evans from the University of Massachusetts suggests that the WHO create a sharing mechanism that obliges any member state to inform the organization when a researcher plans to synthesize viruses related to smallpox. Both options are well-intentioned. However, anyone can already order a second-hand DNA synthesizer on eBay and countless pathogenic DNA sequences are readily available, so these proposals do not contribute significantly to biosecurity. But, while these rules would increase the amount of red-tape for researchers, they would also contribute to the development of norms and cultural expectations around acceptable practice of the life sciences. The bottom line, which is not novel but very much worth restating, is that scientists should constantly be aware of what they create as well as any associated risks.

The future of synthetic biology and biosecurity

Synthetic biology has only been recently recognized as a mature subject in the context of biological risk assessment — and the core focus has been infectious diseases. The main idea, to build resilience and a readiness to respond, was reiterated by several speakers at the SB7.0 conference. For example, Reshma Shetty, co-founder of Ginkgo Bioworks, explained that in cybersecurity, we didn't really think a lot about security issues until computers were already ubiquitous. In the case of biosecurity, we're already dependent on biology (with respect to food, health, etc.) but we still have an opportunity to develop biosecurity strategies before synthetic biology is ubiquitous. There is still an opportunity to act now and put norms and practices in place because the community is still relatively small.

Another remark from Shetty was also on point: *"We are getting better at engineering biology, so that also means that we can use this technology to engineer preventative or response mechanisms."* For example, we used to stockpile countermeasures such as vaccines. With biotechnological advances, it is now possible to move to a rapid-response model, in which we can couple the detection of threats as they emerge via public health initiatives and then develop custom countermeasures using in part synthetic biology approaches. Shetty envisioned that foundries — with next-generation sequencing and synthesis capabilities — are going to play a key role in such rapid responses. Governments should be

prepared to support and enable such foundries to rapidly manufacture vaccines for smallpox or any other communicable disease, on-demand. While it is not clear that the details of these processes and the countermeasures themselves can be made public and still maintain their effectiveness, the communication and decision-making processes should be transparent.

Elizabeth Cameron, Senior Director for Global Biological Policy and Programs at the Nuclear Threat Initiative, similarly warned that *"if scientists are not taking care of biosecurity now, other people will start taking care of it, and they most likely will start preventing researchers from doing good science."* A shrewd starting point for this development was noted by Matt Watson: *"one reason we as a species survived the Cold War was that nuclear scientists—on both sides of the Iron Curtain—went into government and advised policymakers about the nature of the threat they faced. It's imperative for our collective security that biologists do the same."*

In other words, it is time to start having these serious discussions about imminently needed biosecurity measures during events or conferences such as SB7.0.

Frank Akpoviri – National University of Malaysia

I am delighted to have attended SB7.0, my maiden participation in the SB conference series. Trained principally in law, my involvement with SB started four years ago. I barely imagined then that I would sooner than later actively participate in its conferences. During SB7.0, my abstract, written and rewritten many times over, was thankfully accepted for poster presentation. That presentation illuminated the relevance of access and benefit-sharing under the Convention on Biological Diversity to digital sequences, and alerted synthetic biologists to benefit-sharing obligations that may accompany their research. In "Revolution 2 Part 1", I shared my SB7.0 experiences, and outlined future expectations.

The general sessions, including Sc2, acquainted me with current SB research and applications, and their socio-economic and legal aspects. Presentations by Maria Mercedes De Roca, "Revolution 2 Part 2" (Risk Assessment), Linda Kahl, "Learning By Sharing", as well as Jeff Boeke and colleagues, "Synthetic Yeast Project", concerned aspects of my current work. The last two featured open source solutions to the widely decried static inefficiency of patents, and related directly to my doctoral research investigating the role of intellectual property (IP) and open innovation in SB. They did not cover, unfortunately, the biosecurity aspect of open source, and its apparent incompatibility with domestic laws and IP policies purporting to vest institutions with ownership of IP developed by academics during employment.

Another valuable experience from SB7.0 was the opportunity to network with other participants I could not otherwise have met. I had conversations with speakers, exhibitors and colleagues during lunch breaks, SB7.0 Next Generation Leadership gathering, and SB7.0 Gala Night. At those events, I met SB7.0 speaker, Femi Olurunniji, and SynBioBeta's founder, John Cumbers. John, Femi and I are working on the

possibility of extending SynBioBeta's news coverage and introductory SB courses to Africa. Femi and I will publish a newsletter on SynBioBeta's website reviewing SB in Africa and measures necessary to progress it there.

The SB7.0 biosecurity fellowship program also left a memorable impression. Recent terror attacks worldwide made this a thoughtful addition to the SB7.0 agenda. I listened to experts relate their views on biosecurity, and availed of further networking opportunities. I am in collaboration with co-fellows, Yong-Bee Lim and Yvonne Nygard, to publish a paper on biosecurity. Broadly defined, biosecurity is the perceived threat to health and security from infectious diseases arising from experimental accidents, natural causes, or malicious uses of SB, as well as preventive and emergency measures against such events.

Our discussions underscored conflicting perspectives, and government inertia on the issue, particularly dual-use concerns. For some, open source ethos, sequence availability, deskilling of SB, unfettered research dissemination, gene synthesis services, and diffusion of virus synthesis technologies would enable terrorists, misguided professionals, and governments to develop bioweapons. But others counter that many freely accessible sequences are poorly characterized, and arranging sequences into genomes for weaponization demands sophisticated infrastructure, tacit knowledge and collaboration found only among elite scientists.

In my reflection, rising terror attacks and difficulty of combating terrorists, once firmly rooted, advise against excessive theoretical, complacent debates in biosecurity. Previous terror attacks in the U.S. and Japan involving biological and chemical agents unveil the deeply malevolent ambitions of terrorists. Their limited success yet, and claimed difficulty of bioweapons development, do not eliminate the prospect of spectacular breakthroughs, especially given SB's permissive techniques. For example, for all its potency and feared biosecurity implications, CRISPR-Cas 9 is fast, simple and cheap. Unsurprisingly, Manhattan Project leader, Oppenheimer, agreed that "there's no physics proof that you can't make the atomic bomb in your bathtub."

Even conceding that bioweapons development is complex, recreation of deadly viruses by scientists exploiting online sequence information and gene synthesis services, as well as earlier GE-based state bioweapons programs, suggests the risk of SB abuse by disgruntled professionals and governments. Importantly, bioweapons are more discreet and diffuse than conventional ones, and once acquired, terrorists could repeatedly deploy them, with greater lethality in untreatable cases like smallpox, if vaccine-resistant. Unpredictability in biological systems, evident from the mousepox experiment, shows that "bioerrors" by professionals, and especially novices, including poor containment, could also threaten biosecurity.

Accordingly, what follows outlines areas for policy development and implementation. Current domestic and international legal frameworks concerning biosecurity, including Select Agents list, NIH, WHO and Australia Group Guidelines, Cartagena Protocol, BWC, CWC, and UNSCR 1540 should be reviewed

against the pervasiveness and synthesis of sequences, multiplicity of SB practitioners and other novelties, to maximize oversight over actors and activities threatening biosecurity.

Biosecurity awareness among regions, SB students, practitioners, policymakers, and law enforcement personnel, is needed. Greater geographical, disciplinary and sectoral representation in biosecurity dialogues could enhance information exchange and capacity to identify dangerous activities, address cultural and legal variations, and mobilize best ideas for biosecurity governance. Training programs for future leaders in biosecurity should be encouraged to help guide policies. To achieve all this, government leadership is necessary.

Although DIYs may foster SB awareness and participation, policy should focus on their activities, as many are unfamiliar with and, therefore, unlikely to observe biosecurity laws and procedures. The EU model of government oversight and licensing, coupled with outreach programs, could help keep track of these geographically dispersed groups, including their activities, and prevent unintentionally or maliciously dangerous experiments.

SB professionals should abide by precautionary principles and a culture of responsibility, encouraged by governments and funders alerting them to biosecurity issues in their work, and possibility of abuse. Scientists should receive formal guidance where planned experiments present concerns. Likewise, guidelines developed by public and private, multidisciplinary actors, are essential to screen research results before publication.

Despite industry self-governance, governments should strengthen gene screening standards and ensure compliance, both for public assurance and legitimacy of gene companies. “Best Match,” Select Agents list, schism over automated and human screening, as well as possible extension of screening to oligonucleotides, should be revisited. Additionally, procedures are needed directing gene companies on steps to take and government agencies to contact, where screening raises suspicions. To avoid cost, time and effort in repeated searches, gene companies should maintain databases of suspicious results from previous screening.

Emergency preparedness is salient. Biological and physical containment measures are imperfect, and biological agents abusable. The 2016 comprehensive review of UNSCR 1540 implementation highlighted far less spending on prevention and emergency preparedness than biosecurity threat levels. Risk research gets under 1% of government funding for SB. Increased investments would enable investigations into the likely impacts of SB organisms, and techniques like gene drives. Equally, reinforcement of monitoring and alert systems, as well as partnerships among government, funders, and nonprofit emergency human services agencies, would facilitate organized and efficient service delivery during emergencies. Of course, biosecurity policies should integrate SB’s beneficial development.

Overall, my SB7.0 and SB7.0 biosecurity fellowship experiences were rewarding. They provided fruitful networking opportunities and useful information for my work, in addition to strengthening my interest

in new research areas. My desire now is for greater involvement in future conferences, and biosecurity studies. The BBF, SynBioBeta, Center for Health Security, SynCTI and Open Philanthropy Project deserve commendation for a successful conference, and the opportunity to attend.

Jennifer Weisman – Gates Foundation, United States

On the role of biosecurity in the field of synthetic biology:

Having worked at DARPA and the Pentagon for the past four years, I was previously aware of the stigma that can surround research funded by the DoD. Many individuals, and likely populations, frequently suspect an underlying offensive goal to research that is solicited for defensive, protective solutions to current challenges. Despite the numerous technological advances that defense spending has enabled for everyday life outside the defense context, the support of basic research by defense agencies is sometimes viewed with caution or open distrust. Even so, I was still surprised and found it informative to hear first-hand accounts of this kind of distrust, particularly from international students.

The field of synthetic biology is developing rapidly and the landscape of advances are inherently dual use in nature. I applaud the SB7.0 planning committee for creating a biosecurity session, as I believe we can no longer consider the one without the other. Stewardship, responsible research, and early education are imperative as we train the next generation that will carry these advances in further, and I was happy to hear these sentiments throughout the meeting.

I've frequently thought about the roles that different funding entities can and should play, given the stigmas. I've not seen public dialogs on this topic, and I wonder if it would be worthwhile. The BWC was largely left out of the biosecurity discussions at SB7.0, perhaps due to the uncertainty that the last review meeting left. I think we need a strong BWC or next iteration that would also include the products of synthetic biology. I'd like to see a move toward biosecurity protections that focus less on the agent or more on the end effects to humans, animals, the environment, and agriculture.

On my personal experience participating in the program:

The SB7.0 Biosecurity Fellowship experience was perfectly timed at a turning point in my career. I had just wrapped up at the Department of Defense Office of Net Assessment in anticipation of transitioning to the Bill and Melinda Gates Foundation, but had not yet started in my new role. As I prepared to step into my new role in global health, I began to consider if and how the biosecurity and global health communities could benefit from a focused effort at working together. In addition to understanding the current state of the art in synthetic biology advancements for health and biomedical applications, I was deeply interested in the policy proceedings of SB7.0. But most importantly, I hoped to broaden my biosecurity network and discuss my interests at the intersection of biosecurity and global health with colleagues and experts. The SB7.0 Biosecurity Fellowship more than delivered. I had excellent

conversations with old and new colleagues during the conference breaks, and the additional sessions included enlightening conversations. I made many new contacts that will be invaluable in the future.

On what will change for me going forward:

I am now in my second week as Chief of Staff for Global Health at the Gates Foundation, and I am already beginning to probe my interest area to see what kind of receptivity there may be. It will take some time to understand the internal landscape, and may ultimately be deemed inappropriate due to stigma and mission focus. But I feel supported that it is a worthwhile endeavor to pursue given the feedback I received from colleagues at SB7.0.

Karen Weynberg – University of Queensland, Australia

With the increasing interest in synthetic biology, a strong awareness of and strategic thought surrounding biosecurity are more pertinent than ever. Although the potential for biosecurity risks and the issue of 'dual use' should be kept in perspective, there is still a real possibility that a potentially catastrophic situation could arise from misuse and/or abuse of synthetic biology capabilities. Personally, being based in Australia where biosecurity is given paramount importance, it's reassuring to note tight border controls and restrictions on transport of biological material are key practices to ensure better biosecurity nationally. Planning and implementation are important components of good biosecurity measures. Detailed response strategies to potential emergency situations and international biosecurity management plans are essential. An international multilateral convention on biosecurity issues and concerns is of significant importance and great efforts should be taken to ensure strong international agreement and co-operation on biosecurity matters. Policymakers need to be kept up-to-date on developments in the area of synthetic biology to ensure relevant policies are in place and to avoid playing 'catch-up' as the research field expands and progresses. Biosecurity policies and practices are best grounded in science.

Prevention of negative outcomes is most definitely the best approach to biosecurity issues that may arise. If preventative measures do not succeed, then mitigation and containment best practice are the next best approaches, although such measures must be well-planned in advance and executed well. Multi-disciplinary consultation will help to ensure the best outcomes and will also help to base policies on accurate and appropriate assumptions around biosecurity. It would not be desirable to have such limiting controls and restrictions based on biosecurity concerns that legitimate scientific research is adversely affected.

Initially, I attended the SB7.0 conference with a very conventional scientific research background and outlook. Being exposed to a range of synthetic biology researchers, as well as biosecurity experts, philosophers, policymakers and other practitioners in this field, my awareness increased hugely on the biosecurity aspect of the research conducted in this area. I learned a great deal from these other

disciplines and the professional researchers who are immersed in this area. The visit to the US embassy was also very informative.

I gained an enormous amount of information about the issues surrounding biosecurity and international relations on the topic. Through attending presentations and engaging in conversations held at the meeting, the geopolitical landscape was revealed to me on a scale I have never experienced previously. I am now far more aware of issues and potential risks pertaining to biosecurity but feel I have a better understanding of the reality and likelihood of these risks being realised.

I enjoyed meeting a diverse set of researchers and experts in this field via the Biosecurity fellows program and the SB7.0 conference. It was refreshing and informative to meet so many international peers and colleagues with such diversity in expertise and backgrounds. Noteworthy encounters included some very interesting in-depth conversations with, for example, Professor David Evans and his post-doctoral researcher Dr. Ryan Noyce. It was very insightful to learn about their synthesis of the horsepox virus first-hand. Their insights and thoughts in response to the aftermath of their experimental research and findings were also very enlightening. It was extremely beneficial to converse with and learn from researchers from a wide range of international institutes. I learned a great deal on the need for technical expertise in policymaking and issues surrounding global governance from attending relevant presentations and holding conversations with biosecurity experts, including Dr. Piers Millett and Dr. Brett Edwards. Their shared knowledge helped to widen my outlook and reflect on my own research in a new light.

I am much more alert to and aware of the security issues that surround science, in particular synthetic biology, and the potential for misuse and abuse of this research area. Safe working practices have always been of great importance in my work but this is even more acutely so, following this conference. I will also be following far more closely future developments in this area. I thank the organisers of the Biosecurity Fellows program at SB7.0 for affording me this opportunity and for the invaluable experience I received.

Kyeong Rok Choi – Korea Advanced Institute of Science and Technology

The global action for biosecurity has been motivated by ‘good purposes’ such as to protect mankind and the biosphere from accidental pandemics and bioterrorism. Current imperfect policies for biosecurity, however, may only impede efficient development in bio research for human and the biosphere. Nowadays, regulations on living modified organisms (LMOs) and biosecurity focuses on preventing unauthorized transfer of dangerous organisms and their genetic materials and unregulated release of such materials to the wild habitats. While such regulations aim at preventing spread of dangerous species and strains, our current knowledge on classification of so-called ‘dangerous organisms’ and ‘safe organisms’ is unclear. As mentioned in one of the biosecurity fellowship sessions, for example, some of the *Bacillus anthracis* strains are unable to produce anthrax toxin while some of the Bacillus cereus

strains do, in opposite to the general impression that B. cereus is not as dangerous as *B. anthracis*. The imperfect criterion and following preventive regulations on 'dangerous organisms' are refraining researchers from accessing valuable bioresources. In addition, such regulations not only prohibit the use of thought-to-be dangerous organisms but also access to useful genes harbored by the organisms, recalling the old-fashioned black-and-white logics on 'the goods' and 'the bads'. In reality, many of the toxic effects arise from single toxin genes while other genes possess no role in toxicity at all. Still many more toxicity of the dangerous organisms are expressed from a combined set of different genes while each individual gene is powerless to induce the toxicity. One with venom is likely to possess the antivenom, as an old wisdom goes. There may be a good solution for detoxification in the dangerous organisms itself, for example. Of course the government accepts the request on approving the use of such gene or organisms labeled as 'dangerous' or re-examining the level of danger of such organisms, but only after receiving a thick pile of documents prepared by researchers busy conducting research for the world. Reconstitution is necessary for current biosecurity policies and regulations.

Too many cooks spoil the stew, and it has been observed in the world biosecurity trend. Movements and ideas closely related to biosecurity are colliding everywhere. For example, societies belonging to biosecurity struggles to block the flow of genes and engineered organisms from laboratories to the biosphere while the society are enthusiastic for reviving extinct animals with advanced synthetic biology techniques or releasing genetically modified mosquitos to quit spread of malaria. On the other side, the society is afraid of releasing LMOs to the wildlife claiming the prevention of biodiversity while the inflow of novel genes and their function indeed enriches biodiversity as being observed and reported nowadays. Current policies and trends in biosecurity has been too much affected by the general public's interest. While diversity is always important, we need an ultimate goal set and proper guidelines to achieve an important target.

The issues described above will drive me to consider a better solution and spread ideas on biosecurity throughout the societies I belong to through active discussions. The efforts of the biosecurity societies will establish a safe and ideal environment for the up-coming age of bioindustry only through active discussion and cooperation among researchers, policy makers, and the remainder of the society.

Lucia de Souza – Cutting Edge Solutions, Switzerland

Following many years the GMO debate and seeing how several countries did not yet adopt agricultural applications due to overstated risks, disproportionate regulations, vandalisms, etc., it is always important to keep in mind that when we are trying to manage the risks, including those of misuse, of a technology we are not at the same time inadvertently obstructing reaping the benefits of research and development. In the case of Synthetic Biology, we are again in front of many potential benefits for society in the most diverse fields; we also see groups of activists that have being fighting against biotech crops, like ETC, Third World Network, ENSEER, etc., calling and taking action for highly restrictive measures and even bans on Synbio research and applications. The fellowship brought back to mind the

reality that with such a highly promising technological advancement, as SynBio, new risks of accidents and even misuse emerge. The potential regrettable outcomes are not as risky to the exaggerated proportions defended by the activist groups, but we do need to carefully consider realistic risks to find reasonable ways to ensure that the technology is used for good. Reminding and raising awareness of potential misuse is essential.

The recent publication on bringing back the possibly extinct horsepox virus through synthetic biology with an apparently modest cost of 100k brings back some questions on Dual Use Research of Concern. Though not a health threat for humans, the research was justified as aiming to develop a better vaccine by a top-level lab and with the 100k cost announced probably will not suffice for making a pathogen as it does not cover lab infrastructure, etc. It reminds us that it is possible to manipulate DNA/living organisms in ways that was previously impossible or extremely difficult and puts in focus the questions whether the existing regulations, monitoring systems, and especially international collaboration systems (including agreements, guidelines, standards, communication, etc.) are adequate. In addition to the question on what can be done to contribute to a better biosafety and biosecurity level. As with any complex topic, action at different points, levels and areas are important, such as:

- Building capacity and Awareness/Education/Proper Training/biosafety & biosecurity lab manuals/codes of conduct/ethics/communication/guidelines/proportionate regulation/international agreements – e.g. perhaps focus on specific uses/products of synbio that are potentially risky. An over-stringent and sometimes prohibitive scenario like it is for GMOs (especially GM crops) would be detrimental.
- Strengthening of monitoring, reporting and surveillance–needed at different levels, e.g., for those who synthesize DNA (owners of DNA synthesizers/companies that sell DNA sequences) and those using them; learning from lab/transport accidents; communication including publications; etc.
- Maybe among the most important activities would be strengthening international collaboration. At the international level, there are some possibilities to build on existing initiatives. Synthetic biology is being discussed under the CBD (Convention of Biodiversity) and one of the aspects on biotechnology, the Cartagena Protocol on Biosafety has a roster of biosafety experts at the biosafety clearing house. This hasn't been well developed and used yet, but the idea is good as it should provide advice and other support for risk assessment to developing countries to make informed decisions. A similar roster of experts could, if appropriately developed, also be useful for SynBio. There's also the International Federation of Biosafety Associations and the national biosafety associations that could play a role in helping to meet some of the goals of biosafety/biosecurity. I also hope that our group stays connected and that the workshop was the start of fruitful collaborations and exchanges.

Overall, I learned a great deal about different applications of SynBio during the SB7 in addition to thoughts and threats on biosecurity. I also realised that I have a lot more to learn about it, for instance, the Biological Weapons Convention and its developments. I very much liked the sharing of publications, while I am still going through the articles, I hope there'll be continuous sharing of publications of

interest. I hope the Slack channel that was set will turn into a wealthy exchange of information, ideas, experiences, etc. I am also giving feedback and initiating discussions within my networks about some of the topics we discussed. I am very glad I participated in the fellowship and thankful for those that organized and provided the opportunity.

Michael Montague – Independent Biosecurity Consultant, United States

The SB7.0 Biosecurity Fellowship was a valuable experience to me in two almost independent ways. Most directly, it was an opportunity to immerse myself in the world of synthetic biology again after leaving it professionally, to become a biosecurity consultant, some 5 years ago. Also, the biosecurity fellowship ITSELF, quite independent to any relevance to synthetic biology or the SB7.0 conference, was an extremely valuable experience as a consequence of the amazingly talented and diverse people who participated, both from the Johns Hopkins Center for Health Security, and as fellows. As such, my comments on the experience will be divided into those concerning the host convention, and the fellowship itself.

Reflections on SB7.0

One of the things I noticed at SB7.0 was how small a group can now be and yet still achieve things that used to take very large research groups. As one measure of this, I saw at least half a dozen posters that described the introduction of a synthetic pathway of genes for the production of some molecule of interest into a bacteria or yeast, followed by the optimization of carbon flow through the metabolism of the organism to maximize that molecule's production. Twenty years ago a huge team at Dupont did just that for the production, by E. coli, of 1,3-propanediol in what was, in hindsight, one of the first synthetic biology projects. Conversely, the average number of authors on these posters at SB7.0 was just four. On a related note, we had the opportunity to speak with Dr. Evans whose lab, in Canada, recently synthesized the genome of horsepox virus, and successfully made live virus from it. Dr. Evans's lab is not a huge organization, and while they have the backing of a pharmaceutical company behind them, they did not have to spend bank-breaking amounts of money or time to achieve this feat. We hear about the "democratization" and "deskilling" of biotechnology, but it is a remarkable thing to see directly.

Another observation that I took away from SB7.0 is how quickly the field of synthetic biology is growing and commercializing. Almost every single presentation by scientific groups ended in words to the effect of: "And We're Hiring!" One imagines that this is what Silicon Valley felt like in the early 1970's... dozens of different booming ideas that haven't quite yet begun to transform the world. Ten years ago, Synthetic Biology, particularly in the synthetic genomics space, was a largely academic undertaking supported, with a few notable exceptions, almost exclusively by government grants of one shape or another. Now, corporate involvement toward leveraging synthetic biology toward products is much more apparent. When taken together with the trend of democratization, one can project that we will likely see a period of entrepreneurship and biotechnological product innovation starting up in people's

garages, and as the outgrowth of hobbies, and pet projects, and directed by the visions and efforts of small groups or individuals in the years to come in much the same way as we did with the computer revolution. There is a real danger, that in an over-zealous effort to protect ourselves from misuses of biotechnology, that we will sabotage the creation of the products and companies that may come out of such small entrepreneurial efforts.

An acknowledgement of that danger was implicit in a phrase that was often repeated in the conference, and not just among the biosecurity fellows: “Shaping Normative Practices”. The desire by many who used this phrase was to, in essence, create a culture or set of community norms such that researchers and entrepreneurs in the biotechnology field would, without the need for more heavy handed regulation, avoid dangerous experiments or directions of research all on their own. The field of biosecurity, as a whole, is petrified of regulators. This fear is justified when one sees how quickly the technology is moving, and yet of slowly regulations are updated. A regulation or policy that might seem reasonable and just common sense given the limitations of biotechnological capabilities today might become useless or even self-defeating with the evolution of those capabilities in the future, and such radical paradigm shifts of biotechnology are happening on a yearly or even monthly basis! Biotechnology is embryonic, with its ultimate form and applications still uncertain, and the correct regulatory approach that will work without crushing it, to say nothing of specific individual regulations, is equally undeveloped. Concordantly, the shape of the biosecurity problems that exist at the intersection of policy and biotechnology are equally uncertain.

Reflections on The Biosecurity Fellowship

It is this embryonic quality to the biosecurity problem space that Biosecurity Fellowship so valuably addressed through the simple expedient of putting so many different people connected to the issues in diverse ways into the same room and inviting them to have conversations that were both structured with invited speakers and unstructured amongst themselves. The fellows were an extremely talented and impressive group of people from many professional backgrounds, and many nations. Consequently, it was the unstructured conversations with the other fellows that I found to be the most productive as it let me challenge my own perspective against sometimes radically different ideas of people who had put significant critical thinking into biosecurity issues themselves. That diversity of perspectives is critical to building an understanding of the emerging biosecurity problem space. The defining limitations and structural elements of modern biological warfare, bioterrorism, health policy, and emerging diseases are largely unknown because the technologies and sciences that will eventually define them are still under development. One of the consequences of this is that the boundaries of just what disciplines and knowledge bases will and must be included in a complete comprehension of biosecurity is still fuzzy. There is no way to know if expertise in plant genetics, or financial tracking and intelligence, or encryption, or any number of other fields may end up being relevant or even central to the field in the long run.

I believe that there is value in a recurring biosecurity fellowship associated with a third party conference, modeled off of the SB7.0 biosecurity fellowship. Further, I believe that given the embryonic nature of the biosecurity field, that such future fellowships would benefit from doubling down on the idea that only through a diverse interdisciplinary approach can we prepare for the as yet unknown challenges of biosecurity. The way I propose to do that is to send a small biosecurity fellowship group to NON-BIOLOGY professional and academic conferences in areas that may have some synergies. (Synergistic areas that suggest themselves include, but are by no means limited to: Financial and Banking Security, as many of the problems associated with tracking unethical uses of biotechnology materials are very similar to those of tracking illicit flows of money; Cyber-Security, since one arena that biosecurity is concerned about is shadow-warfare which happens in the cyber front all the time; Nanotechnology, since it is an example of life-like qualities being engineered into matter with potentially dangerous consequences; and 3D Printing, as this is a field that is in many ways ahead of biology in the consequences and opportunities of democratization). As I imagine it, the biosecurity fellows who would be sent to these conferences on related fields would be there not just to listen and see what lessons might be derived from these other fields, but also to speak and be ambassadors to these other communities expressing the state of the biosecurity problem to outsiders and thus inviting new perspectives into the field of biosecurity... perspectives that might just let us foresee and prepare for possible dangers before they develop.

Michelle Rozo – Henry Jackson Foundation, AAAS Congressional Fellow, United States

It is the sign of a good meeting that I am still bringing it up with colleagues, friends, and family a month after its close. It is a testimony to the multitude of synthetic biology applications, which were reflected in SB7.0's diverse seminars and panel discussions. I have delighted listeners with stories of conservationists working to revive currently extinct species and designers making a "scat-alog" to demonstrate the potential applications of chromogenic E. coli. It is also timely as the SB7.0 discussion around the de novo synthesis of horsepox has recently expanded to the mainstream media. This work in particular exemplifies that there is a role for biosecurity in the field of synthetic biology and will hopefully stimulate public discourse on appropriate practices and policies. In order to be comprehensive, these practices should address multiple levels: from the individual scientists to international policymakers.

At the individual level, every scientist should have a framework that assists in identifying potential biosafety and biosecurity implications of his or her work. I appreciated learning about the iGEM standard that requires participants to do just that: specific forms address the potential risks of their project and what they are doing to mitigate those risks. I would venture a wager that most practicing scientists have not considered the risks of their research. I would suggest the number further decreases if you remove those that are working with select agents or toxins. Scientist should assist in developing

such an assessment tool and then use said tool to consider the risks of their work at periodic intervals throughout their projects, and implement mitigation strategies where necessary.

At the community level, synthetic biology has acknowledged the biosecurity implications of the field – after all, biosecurity has had a designated session at the meeting since SB2.0. However, the community as a whole should embrace biosecurity by developing and implementing appropriate regulations for itself. Scientists are somewhat rightfully distrustful of regulations, yet the best way to develop regulations that they agree with is to begin to develop them themselves. For example, journal and grant reviewers could require applicants submit a safety and security assessment that discloses DURC research. Institutions could require the same of its scientists and provide the same oversight regardless of funding source. Additionally, the synthetic biology community needs to research technologies to counter the potential threats of synthetic biology – can we make sure all gene drives have molecular ID tags and fail-safe mechanisms like 'kill-switches'? What ID strategies can we use to identify if gene drives have off-target effects once released into nature? How will we detect GOF bacteria or viruses if they bypass traditional detection machinery? Can we strengthen public health infrastructure to do just that?

At the government level, regulations and norms need to be developed not just at the national but at the international level. Clearly, any negative outcomes of DURC would have the ability to spread beyond individual countries and their artificial boundaries. As such, there need to be high-level international dialogues to discuss advances in synthetic biology and to develop norms and regulations for such work. Synthetic biology may make the best case for updating the select agent list and requirements; indeed, the horsepox synthesis project was performed within the bounds of all Canadian regulations; the same would held true were it performed in the United States. An international standard needs to be developed that encompasses not only DURC but also research that produces knowledge that can be used to produced DURC. Personally, I have developed connections with a variety of scientists, ethicists, and policy makers as a result of SB7.0. The unique make-up of the cohort allowed for robust discussions and the maturation of the concept of biosecurity past the focus on public health and epidemiology. I hope these connections will be long-lasting, and that the progression of the relationship between biosecurity and synthetic biology will allow for future meetings and discussions.

Nicholas Evans – University of Massachusetts, Lowell, United States

The SB7.0 conference was an exercise in plural and conflicting values. Its guiding questions and talking—SB7.0 – Revolution, 2; Revolution, Too; Diversity with Harmony; and All People and the Planet —stood in relief to a spirit of corporate self-interest that, from the first keynote located financial return and entrepreneurship as the central goals to which many at the meeting subscribed. This makes for a strange landscape in which the biosecurity community must act.

The market for biological and biotechnological goods, services, and processes (e.g. Carlson, 2016) and their contribution to national and global economies is one of synthetic biology's purported benefits.

Randal J Kirk, CEO of Intrexon and SB7.0's principal sponsor, put these economic gains front and center at the conference's keynote. Kirk's message: biotechnology is a tool for making people rich.

Speaking to scientists, policymakers, funders, and biosecurity professionals at SB7.0, many expressed concern about Kirk's presentation as a tone-setting exercise at the conference. Particular attention was paid to Kirk's enthusiasm toward the use of synthetic biology to refine natural gas released through hydraulic fracturing into higher-order (and thus more profitable) petrochemicals; hardly a novel or world changing ambition, and indeed one that maintains the status quo of our fossil-fuel dependent world. But Kirk's message, if gregarious, is hardly unique. The International Genetically Engineered Machine Competition (iGEM) is now party a fundraising exercise for competitors, sees keynotes by SynBioBeta (functioning as a synthetic biology industry association), and lauds post-competition achievements of former competitors in the form of startup capital raised (e.g. Ginkgo Bioworks). So-called "startup culture" is as much a part of synbio as it is information technology.

This is neither a repudiation of synthetic biology, nor a wholesale dismissal of the role of capital in our society. Rather, it is a sketch of an important, and arguably dominant strain in synthetic biology against which biosecurity may one day have to contend. Biosecurity is hardly incompatible with the bioeconomy, but their incentives and norms may conflict at important junctures.

This conflict arises because the fundamental value of market economies lies in maximizing consumer preferences. The bioeconomy will certainly promote human health and wellbeing, but only insofar as there is a profit to be made. Making the tools of biology cheaper and easier to use may create greater access to the benefits of biotechnologies in communities that might otherwise not be able to participate or compete in existing markets for energy, medicine, or advanced agriculture. However, it is not clear that consumer preferences are tailored towards biosecurity. Biosafety may be valued if continuing debates about genetically modified organisms and drug safety are any indication. But having preferences for products that enhance or cultivate biosecurity requires an understanding of those risks, and weighing the long-term benefits of secure life sciences against the proximate, or even immediate benefits promised by technology in the short term.

Moreover, markets are distorted by externalities that affect other parties without changing the market price of a certain good. Biosecurity, absent regulation, will almost certainly be an externality for many (if not most) players in the bioeconomy. Only when biosecurity concerns are a) large enough to threaten the continued existence of a firm (but not large enough that they exceed the limited liability a firm may have), and b) likely enough that they present a risk that might plausibly arise within a firm's operating horizon, is self-governance likely to proceed (Lipsitch et al., 2016). Given that biosecurity concerns are often high consequence and low probability, it is unlikely that many firms within the bioeconomy will organically promote biosecurity. Indeed, given the role of synthetic biology competitiveness as a national strategy (Gronvall, 2015), there may be little appetite at all for any biosecurity strategy that impedes the bioeconomy, no matter the risks.

This problem has parallels in the tech industry. Consider Uber, a ride-sharing program driving taxi companies out of business before price-gouging their users; pursuing predatory loan schemes with drivers; flaunting federal civil rights statutes; and creating technological means to avoid state officials in jurisdictions in which the company operates illegally. The company is now moving into autonomous vehicles. Given the firm's existing lack of concern for anything but the shortest path to maximal profit, we have no reason to believe their self-driving vehicles will be secure from remote intrusion or surveillance absent regulation. Attempts to regulate the tech industry in any way, however, have been unsuccessful, owing to the lack of political will, and apathy on the part of users. Even the open-source software landscape, in which the ability to access the source code of a program is meant to improve stability, lacks incentives to pursue security (Evans, 2015).

Leaders in the field, as SB7.0's themes demonstrated, see synthetic biology as a vehicle for radical change. Yet the capture of synbio by capital reinforces nothing but the status quo. Given what that status quo did with the relatively benign powers of 20th century science and technology, I have a deep concern for the evolution of the field moving forward.

With that in mind, the Fellowship is an opportunity to push back on this culture. It is vital that biosecurity professionals from government, NGOs, academia, and private industry push back on existing culture of synthetic biology. The friends and colleagues I've made are invaluable, and I have already seen a new set of interesting projects develop from this interaction. SB7.0 was a remarkable experience, and I hope we can recreate this atmosphere in SB8.0 (whenever that is).

In the future, I think the fellowship program would benefit from three things: closer integration with the conference organizers and schedule, better mechanisms to interact with the scientific attendees, and separate times to present work to one another and discuss the themes of the conference. To the latter, a common strategy for conferences with a distinct sub-discipline is to host a workshop in advance of the conference. Such a workshop would enable us to meet and get to know each other early (I only met some of my fellow fellows on the last day!), and prepare for the conference together.

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Geoffrey Otim – Uganda Virus Research Institute

I would like to start by giving a million appreciation to BioBricks Foundation and Johns Hopkins Center for Health Security for the fellowship award they granted to me to go and attend the SB7 Synthetic Biology conference in Singapore. I would also like to thank these individuals who dedicated their time, sleepless nights, and efforts that made the Biosecurity program a success: Brian Schulz of BioBricks Foundation, Prof. Drew Endy of Standford University, Crystal Watson of the Center for Health Security, and Elizabeth Cameron, to mention but a few.

Three possible biosecurity practices and policies that could help in minimizing the risks of synthetic biology research to the population and environment are:

1. Synthetic biology should be subject to institutional review and oversight since some aspects of this field pose biosecurity risks;
2. Oversight of dual use research should extend beyond the boundaries of life sciences and academia; and
3. Outreach and education strategies should be developed that address dual use research issues and engage the research community that are most likely to undertake work under the umbrella of synthetic biology.

Suggested good approaches to implementing biosecurity practices/policies are;

1. Creating a competent authority structure that facilitates biosecurity as a holistic concept;
2. Improving national biosecurity capability resulting from increasing interdependence of competent authorities and convergence of biosecurity issues;
3. Restructuring of competent authorities as expressions of improved biosecurity capability;
4. Improving global biosecurity capability resulting from increasing interdependence of countries and convergence of biosecurity issues;
5. Ensuring national food chain biosecurity; and
6. Creating linkages between international bodies that are enhancing development of international biosecurity standards.

During the SB7 Conference and Biosecurity Fellows sessions in Singapore, I learned many things about Biosecurity issues, policies and approaches and the Biosecurity briefing at the US Embassy, Singapore.

From the conference presentations, I took more interest on Dr. Akbari Omar's presentation about the use of gene drives in the control of malaria. This could be the best solution to control mosquitoes and prevent malaria in endemic African regions. I'm following him up for possible collaboration. Other

presentations that I took interest in are use of biosensor technology, Biofuel, iGEM Competition, to mention but a few.

I'm really so grateful and pleased to mention that I made great and memorable connections with top experts and key players in synthetic biology research and industry. I made several one on one interaction and links with the following influential and resourceful people: Prof. Drew Endy of Standford University, Prof. Mathew Chang & SynCITI, Prof. Paul Freemont of Imperial College, Kate Wildauer CEO SynBioBeta, Kim De Mora of iGEM, Dr. Elizabeth Cameron of NTI, Crystal Watson of the Center for Health Security, Brian Schulz of BioBricks Foundation, Prof. Lionel Clarke Co-chair, UK Synthetic Biology Leadership Council, Omar Akbari Assistant Professor of Entomology - University of California, Riverside and many other PhD and Post-Doctoral researchers.

I'm glad to inform the Synthetic Biology network that with the knowledge and passion I developed for synthetic biology during the SB7 Conference in Singapore and the advice that I received from the experts that I interacted with during the conference, I was able to come back to my home country, Uganda, and implement ideas that they gave me.

Makerere University took up positively my idea of establishing a Center for Synthetic Biology Research and Education at Makerere University, School of Biosecurity, Biotechnology and Laboratory sciences. The University has assigned to me four Doctors, PhD Holders with relevant experience to help in the crystallization, setting up, and successful implementation of this program at the University.

I will be very glad to collaborate with Universities, Industries, Institutions and researchers across the globe with interest in supporting the development of Synthetic biology research in Africa.

With all these words, I would like to once again thank a million times BioBricks Foundation and the Johns Hopkins Center for Health Security for the Biosecurity Fellowship award that they granted to me, which has set a high pace for me in this field of synthetic biology and I look forward to more support and collaboration.

Pranjali Vishwakarma – Biosafety Support Unit, India

The need for biosecurity practices/policies for Synthetic Biology:

- Synthetic biology could be associated with aspects related to biosafety, bioterror and even biological weapons. Clearly one can imagine that this technology can be misused for bad intentions to create pathogenic viruses and bacteria to be used in terror and war.
- Regulation of synthetic biology and more prominent, organisms created by genome editing, has emerged as an area of conflicting viewpoints.

- There are considerable international efforts through the Convention of Biological Diversity (CBD) to collectively define and clarify the regulatory status of synthetic biology and organisms and products created thereof.
- The case-by-case and step-by-step approach recommended in risk assessment of genetically modified organisms (GMOs) is highly relevant to synthetic organisms and therefore, much of the current unanswered question are not connected to specific products, but to general observations of the individual approaches to synthetic biology (i.e. top-down, bottom-up processes).
- Requirements for molecular data, description of modification, environmental impact, toxicity and allergenicity are all relevant steps in assessment of synthetic organisms intended for deliberate release.

Good approaches to implementing biosecurity practices/policies:

- Development of information, guidance and a decision support framework to determine potential environmental impacts of synthetic biology.
- The decision framework may consider inclusion of prevention base governance, quantification and/or testing of environmental Impact.
- The decision-making framework may include protocol and tools those are globally accepted and globally harmonised to support biosecurity.

Experience gained from Biosecurity Fellowship and attending the SB7.0 meeting:

During the meeting fellows discussed an urge to take a precautionary approach, and to establish effective measures to regulate the environmental release of any organism, components or products resulting from synthetic biology. The SB7.0 talks reflected future of the worldwide research and development in synthetic biology. In parallel discussion of biosecurity and biosafety issues related to research and development aided to overlook the likelihood of environmental risk that may occur due to release of synthetic biology material in environment. The spread of biotechnology and genetic engineering has added novel dimensions to both bioweapons and bioterrorism. Synthetic biology technology is largely available legitimately and is being actively researched to sharpen its thrust. Its potential for good can easily be distorted by unethical manipulation. This fellowship bought the need of involvement of regulators, members of civil society and industry representatives. There is need to characterize the different roles played by stakeholders in the analysis of risk posed by synthetic biology. Possible means for participation and/or consultation is required for global biosecurity due to emerging trends in synthetic biology. With emerging technologies ethics has got a more prominent role.

Synthetic biology has made gene technology more accessible for not trained scientists, with the cost of increased susceptibility for potential dual use. Dual use technologies have the potential to produce both desired and malicious products.

The potential to generate new pathogens by synthetic biology has raised concern both with regard to how to screen for such purposes, how to train scientists within ethics to how one can constrain publication of scientific progress and understanding that can be used in bioterrorism purposes. In general, all scientific activity should strive for openness and transparency, also research that may have dual uses as for example bioterrorism since such research increases our understanding of unexpected findings and provides a basis for how to increase defense against the same pathogens.

The Biosecurity fellowship meeting consisted of morning and evening sessions in parallel to SB7.0 conference, each preceded by opening remarks delivered by selected participants. These remarks, in turn, set the stage for subsequent group dialogue. Broadly, topics of discussion included perspectives on biosecurity and biosafety in view of synthetic biology research and developments.

With the goals of expanding knowledge regarding high consequence issues related to biological threats due to synthetic biology I exchanged view with participants. Group dialogues among participants mainly focused on technological capabilities required to address unknown biological threats, approaches to biological threat characterization, the future of the select agent list, science preparedness and biosecurity engagement, and deliberate threats due to synthetic biology. In brief, I discussed policy related issues for biosecurity and synthetic biology risk assessment framework with Crystal Watson, Matthew Watson, Gigi Kwik Gronvall, Christina D. Smolke, Drew Endy, Addy Linan Segura, Megan J Palmer, and Maria Mercedes and all other Biosecurity fellows.

Changes in work based on you lessons from biosecurity in Singapore:

The most striking thing which I learned was that the whole world is facing same problem of regulatory verses scientist understanding. The next thing I learned is that we have to have a consensus on biosecurity related issues.

Ryan Noyce – University of Alberta, Canada

The SB7.0 meeting and Biosecurity Fellowship program were, for the most part, a positive experience for me. As someone who is relatively new to the field of synthetic biology, the meeting was somewhat overwhelming, in a good way. The new technologies and advancements in synthetic biology were astonishing. From digitizing mp3 files into DNA to building synthetic cells to be used in medical, biofuels, materials and food industries. It seems like this field is only limited by one's imagination to think of new projects to tackle using synthetic biology.

With regards to human and animal health, this could bring about both positive and negative consequences. It would clearly be beneficial for societies to figure out ways to protect our food chain supply from diseases by creating better antibiotics and vaccines against agricultural pathogens, or by

making our food sources more resistant to such assaults. At the same time, however, we should also be cognizant of the potential risks these new species may have on existing species.

Although it seems like there are a number of organizations/groups that are focused on the creation of policies associated with biosecurity/biosafety, dissemination of this information to individuals/organizations seems to be a roadblock in the field. It is clear to me that there needs to be an international strategy with stakeholders from across the globe to address these issues. I also think that more opportunities for both academic scientists and policy makers to engage in discussions, similar to what happened during the Biosecurity Fellowship program, would greatly help.

One of the things that really stuck out in my mind while listening to Dr. Reshma Shetty from Ginkgo speak, was her comment that we need to transition away from a stockpile mentality as this leads us to become more vulnerable. I think that this is where synthetic biology could play a major role in R&D. By developing the tools to rapidly diagnose diseases in the field and effectively respond to threats, then we continually stay one step ahead of any potential threats. It also wouldn't necessarily matter what new threats would come our way, as we would have strong infrastructure and tools in place to quickly identify and respond to them in a controlled manner.

The Biosecurity Fellowship was a great opportunity for me to network with a group of individuals from diverse backgrounds ranging from academic scientists, policy makers, and biosecurity experts. As a basic biological scientist, I found it particularly helpful to not only engage in meaningful conversations with others regarding biosecurity, but to set up collaborations with individuals on these topics. I believe that this type of collaboration will be very helpful in getting me to think about biosecurity issues in my own research and how best to proceed in this area with future scientific projects.

If there was one comment I had on the fellowship program, was the very American-centric view that was presented to the fellows. I realize that this is a consequence of the organizations involved in organizing this fellowship program. I feel that it would be important in future meetings, however, to invite biosecurity experts from a number of countries, so that fellows can gain valuable insight in how various countries run these sorts of programs.

Overall, I thought that this fellowship program was a very positive experience. Biosecurity is not something that I learned a lot about during my academic career. These discussions were very helpful. When tackling my own research projects, I now have more resources at my disposal in order to carry out innovative research in a safe and meaningful way. The field of synthetic biology is moving forward at a rapid pace. It will be very important to have biosafety and biosecurity policies in place that won't hinder innovation. Instead, these policies will help researchers carry out their research safely.

Tiara Jones – In-Q-Tel, United States

Diversity with harmony was a key theme of the SB7.0 conference with respect to biodiversity, interdisciplinary expertise, and sharing and learning through an open community. This theme is also applicable to the discussion and implementation of biosecurity in the field of synthetic biology. The complexity of biodiversity is analogous to synthetic biology and an important characteristic to consider when implementing biosecurity practices. Implementing biosecurity regulations without context can often result in opposition because it has the potential to limit innovative solutions to solve global issues. Understanding the environment and interactions that are required to redesign natural biological systems will allow for a thorough assessment of potential risks. Given the popular modular approach in synthetic biology projects to reuse and design parts in various configurations, it is important to evaluate the impact and feasibility of systematic approaches and parts-based designs separately. This approach will enable policy makers to understand the complexity of synthetic biology and discredit the perspective that one-size-fits-all.

Biosecurity as it pertains to synthetic biology is not limited to just protecting humans and animals but also the economy and industry. With that said, it is important to leverage the expertise of scientists, engineers, economists, ethicists, and anthropologists to ensure adequate policies and procedures are put in place to prevent harmful outcomes and ensure a successful pathway for synthetic biology solutions. Understanding these various perspectives can reduce assumptions and highlight areas of opportunities and potential harm to sectors that affect us globally. Communicating a balance narrative of the pros and cons of synthetic biology can change the negative view on biosecurity and encourage an open sharing and learning mentality. As a result, synthetic biologists may be more prone to join the conversation, be transparent about their work, and reach out for education on security protocols.

Maintaining situational awareness is imperative because there will be non-state actors who have ill intentions. Encrypted digital signatures for attribution, proprietary parts and biomaterials to prevent the production of harmful or controlled materials, and a central international database for engineered sequences with cautionary alerts are a few examples that can strengthen our bio surveillance efforts. In addition, conferences like SB7.0 are essential to highlight the advancements in technology and the level of effort required to produce harmful materials so biosecurity policies and procedures are not lagging behind.

The SB7.0 conference and biosecurity fellowship have encouraged me to remain knowledgeable on the technological advancements in synthetic biology in order to evaluate how they align with current biosecurity practices and how those practices need to change to support future capabilities. I am grateful for the opportunity to have met such a prestigious group of professionals in the biosecurity fellowship. This was my first experience to engage with an international audience in the field of synthetic biology and I now have a better appreciation for the challenges they face in their countries to not only conduct synthetic biology but also manage infectious disease outbreaks. The discussions on dual-use research concerns, the challenges of managing pandemics vs. bioterror events, and the future

of push-button technologies will inform the projects I propose back to my team on how we can continue to engage with industry, government and academia. I look forward to utilizing the Slack channel to solicit feedback on future projects and brainstorming how we can communicate the benefits of an effective biosecurity strategy.

Yensi Flores – Cork Cancer Research Center, GloDx, Ireland

The scope for synthetic biology has expanded in the last decade, to a point in which its potentials can impact positively or negatively a large segment of the population within a short period. With this in mind, we should promote policies that don't hinder the advance of this field toward the much-needed positive outcomes, while preventing its non-intended misuse.

Promoting a global awareness of biosafety and biosecurity research ethics can have a more positive impact than restrictive use policies. Therefore, priorities should be set for the wide-spread adoption of biosecurity research practices, as a corner stone for ethical research. Their routine adherence should be reflected in the design, execution and presentation of any experiment in the field, and their adoption taught since early stages of a career, in the science curricula of secondary schools. The adherence to this practice should be encouraged by funding bodies, academia and peer reviewed journals.

Among these, (1) the inclusion of biological containment measures of genetically modified organisms, regardless of their purpose. Such as using organisms that are not able to live outside the lab, by reducing their fitness or making them dependent to a lab substance. (2) The adequate disposal of reagents, organisms and consumables and other biosafety measures. (3) Limiting the use of high virulence organisms to specialized labs. (4) Limiting the reproduction of an organism that will be trialed in the fields or released for commercialization – especially in the case of crops.

Above these, the synthetic biology community should create a network for fast response of emerging diseases. These organisms can arise anywhere, and more likely spread in geographical regions without access to technology. Currently, the human invasion and destruction of natural habitats for wild species, coupled with the high mobility of our population, has increased the risks for epidemics. We need to build a network for surveillance and response against these threats. This can be more easily achieved through community response of organized collaborations and the use of the most advanced tools and methods. This approach will also be helpful in the case of intended misuse of this technology.

In my perspective, restrictive and prohibiting measures for this field won't stop the intended misuse of this technology. Developing a bioterrorism threat from scratch requires high investment in time and resources and this will continue to be so, relative to other type of weapons or already existent organisms. If anyone is willing to invest in developing these threats, they will do so, even if restrictive measures are in place. Our focus as a community should be in building our capabilities for a fast

response against any threat. This in the form of surveillance, fast-detection, and response (vaccines, treatments, gene drive annulment organisms, predators or toxins for a target GMO).

Through the fellowship programme I became aware of my responsibility to promote biosecurity. As an ethical researcher, I use best practices for biosecurity, however, this topic is so relevant to us, that we need to be active in spreading knowledge to raise awareness in biosecurity and help to make the adoption of best biosecurity practices universally adopted.

Although the programme of the fellowship was focused on intentional threats in biosecurity, the conference included biosecurity in a broader context, such as food safety, ecological risks and loss of biodiversity and the risks that this carry to our planet and population. With these lectures, I realized how applying synthetic biology can be exploited to solve many of our current problems and help prevent catastrophes. In addition, I was updated with current methods and the significant advance in commercialization of synthetic biology made by brilliant start-ups.

I enjoyed the Biosecurity Fellowship reception, as the smaller group allowed us to interact more and make conversation. I enjoyed meeting all the fellows and learning about their experience. I also enjoyed the conversations with our lecturers and other conference attendees. The connections made through my participation in this fellowship are multiple, so I am thankful with the opportunity.

Yong-Bee Lim – George Mason University, United States

As one of the fortunate individuals selected for the SB7.0 Biosecurity Fellowship, I and 32 other talented, multidisciplinary fellows had the privilege to attend the SB7.0 conference hosted in Singapore. With more than 100 plenary speakers, as well as practitioners and policymakers from more than 30 different countries, this event leveraged its incredible diversity of people, topics, and perspectives to facilitate conversations to not only help exchange ideas, but to help build a unified vision of a better world through synthetic biology. As a means of facilitating these conversations among biosecurity fellows and conference attendees alike, Megan Palmer of Stanford and SynBioLeap presented four prompts to be considered, with each prompt corresponding with a particular day in the conference:

1. Day 1: #ilike – What would you like to have or know about that you currently lack?
2. Day 2: #iwish – What do you wish was true that isn't now true?
3. Day 3: #iwonder – What could you do to help others?
4. Day 4: #iwill – What will you do to help others?

As a luddite that prefers not to use Twitter, I did not participate in this exercise through social media. However, as a self-reflection paper that will be distributed through the internet seems like a good alternative, I will use Megan's structure to not only relay my thoughts and experiences, but hopefully allow for a dialogue between biosecurity experts and life science researchers and innovators.

#ilike the passion we all share in building a better world through synthetic biology

As a non-technical individual focused on biosecurity, biosafety, and the governance of emerging biotechnologies, it has often been difficult for me to have feelings of unsuppressed joy about any technology. These feelings come from being inundated in a field where the disruptive aspects and dual-use considerations of a technology are often considered before the beneficial aspects. People often speak of wearing rose-colored glasses, but in this context, I believe that I have become accustomed to wearing “storm cloud gray”-colored glasses.

However, the enthusiasm of the technical conference attendees and fellows that I met about the advancements in synthetic biology was infectious. Whether Christina Smolke was talking about leveraging yeast to produce opioids to address medical access inequities, Kate Adamala was discussing synthetic cells as an alternative for research purposes, or Dorothee Krafft explained how her lab was seeking to synthesize a simple cell with alternate building blocks, their passion for their work came through. This allowed me the rare opportunity to enjoy the possibilities of these new avenues of innovation.

Furthermore, as I took advantage of having many discussions with technical people on my areas of interest and my thoughts on biosecurity, it became apparent that my passion for biosecurity was equally as infectious. People were genuinely interested in understanding how and why the technologies they were working on may have unintended consequences, and became actively interested in ways to head off unwanted consequences. From these interactions, it became apparent that we all share a common passion: building a better world through synthetic biology.

#iwish they really had not confiscated my beef jerky

Before you think I have lost my mind, I promise there is a point to this. One of my favorite Chinese treats that I purchased in Singapore is bak kwa, which is a salty-sweet dried meat product that is similar to jerky. As the brand that I enjoy is not available in the United States, I always make sure to pick some up from overseas before I come back to the U.S.

I have had mixed results with U.S. Customs with bak kwa. Unfortunately, my trip back from SB7.0 required an agriculture check of the jerky I had brought back. It should be noted that the brand is a multinational corporation that operates in most of Asia, has a highly industrialized process involving the cooking, preservation, and vacuum-sealing of the product, and adheres to strict food safety laws. Despite my attempts to relay all of this information to the agent, my protestations fell on deaf ears: the customs agent ruled that the bak kwa would be confiscated based on the product type (animal product) and origin of purchase (Singapore). I had gambled and lost.

#iwonder if experiences like my Customs experience exist in the biosecurity and life science research contexts?

That one-sided dialogue with the customs agent made me wonder about other areas where such dialogue might be occurring. Despite the passion and the desire to build a better world that we all appeared to share at SB7.0, that type of one-sided dialogue seemed to exist between the biosecurity and practitioner communities, ultimately resulting in crosstalk without resolution. This phenomenon could be seen on a number of occasions.

At one extreme, practitioners of the life sciences seemed to view the biosecurity community, as a whole, to be obstructive. Feedback like this could be heard during the biosecurity fellows' visit to the U.S. embassy in Singapore, where one of the scientists on the panel perceived biosecurity measures as creating undue burden through unreasonable amounts of bureaucratic paperwork, as well as being a vehicle to "have their toys taken away." Frustration was also expressed in conversations I had with practitioners about how policy for technology is often made by those that have no technology background. Perhaps the greatest testament of all to this viewpoint was one that didn't require words: a significant exodus of conference attendees at the start of the biosecurity panel.

At the other extreme, biosecurity experts appear to view the practitioner community as irresponsible and myopic in regard to the benefits that can be reaped from the life sciences. I personally will admit to some concern in learning that many practitioners had undergone no formal bioethics training during their schooling. Furthermore, very few presentations at SB7.0 highlighted any of the negative ramifications of their research. For those that did, the negative ramifications were never considered salient enough to cease, or even pause, ongoing research; the benefits, without question, always outweighed the risks.

#iwill work to bridge the existing gaps between biosecurity experts and life science practitioners

Despite the perceived extant animosity between biosecurity experts and life science practitioners that I witnessed at SB7.0, my individual experiences with technical biosecurity fellows and conference attendees leave me hopeful about bridging the gaps between these two communities. Half of this issue will be addressed through a top-down approach by the entire community by rethinking the current, antagonistic paradigm of biosecurity and life science research; Beth Cameron challenged this current paradigm by asking questions such as what life sciences governance should look like for everyone involved, as well as questioning if biosecurity could also accelerate innovation. However, the other half of this issue will be addressed through a bottom-up approach by individuals engaging in active, open lines of communication with other individuals: technical individuals having their views heard by non-technical people, and vice versa. Therefore, with the great opportunity that the SB7.0 Biosecurity Fellowship has provided me by connecting me with individuals from all over the world, as well as building on the shared community goal of building a better world through synthetic biology, I will work to bridge the existing gaps between biosecurity experts and life science practitioners through active engagement, collaboration, and outreach with the global community.

Yvonne Nygard – Chalmers University of Technology, Sweden

The Biosecurity Fellowship was a great opportunity for me to learn more about this topic and most importantly about its importance. The SB 7.0 conference is a good platform where different synthetic biology communities meet and interact. The Biosecurity fellowship was a unique opportunity to meet people working with policies concerning biosecurity and to reflect on this in a broader sense. It's so easy to get caught up in your own box, only collaborating with people from similar surroundings and getting to interact with people working directly on synthetic biology, while never entering a lab was very interesting. The balance between science and security as well as practices for how to assess risks raised a good discussion among the fellows. The panel discussions with scientists working with so-called dual-use research of concern was very interesting and highlighted the need for communication and standards for biosecurity practices.

Involving scientist to work together with external policy makers in deciding on practices for biosecurity is of great importance. Guidelines for ensuring biosecurity are needed for establishing a framework of accepted practices. We as researchers need to be convinced that what we are doing is safe on a technological but also environmental and societal level. It is our task to communicate with the public and policy makers and to ensure that generally accepted biosecurity practices are formed and followed. We need to include biosecurity as a part of all our research and outreach activities, in order not to miss out on opportunities for progress. In order to ensure biosecurity, we need to understand risks, educate all stakeholders and also enforce legislation on new technologies. Outreach activities designed to help form the general opinion are needed for the acceptance of novel technologies.

Acts such as the Global Health Security Agenda (GHSA) Biosafety and Biosecurity Action Package, where a large number of countries commit to a common agenda for insuring biosecurity are crucial. Knowledge spread is ever so fast and also physical biosecurity risks see no boarders. Countries where synthetic biology is less developed may benefit greatly from policies developed in countries with more experience and practice. National biosecurity practices should be aligned with international ones and the emphasis should be on an open dialogue and transparent assessment. Standardized procedures assist to ensure biosecurity but also help tremendously should an incident compromising biosecurity happen. Overall, the fact that technologies are developing so fast and policy making takes some time is a considerable risk for ensuring biosecurity. Policies and general practices for ensuring safety and security nonetheless applies to all fast-developing technologies and not only synthetic biology. It would be interesting to know how the discussions related to policies for ensuring cybersecurity or safe practices for developing artificial intelligence and virtual realities differ from discussions on ensuring biosecurity.

I do think it is important for everyone working in the field of synthetic biology or even biotechnology to be aware of issues related to biosecurity. Biosafety is emphasized in everyday lab work and when deciding on practices for this, but biosecurity is typically not broadly discussed. Therefore, I have with my research group now discussed biosecurity and I have at my university taken initiative to include biosecurity in the mandatory ethics course that our undergraduates follow. The information and

material I was given during the Biosecurity Fellowship has been most useful for me when planning the teaching. The connections to other fellows made were also most useful as I can ask for advice and materials. With a few fellows, we have actively followed up on discussions over mail and now consider writing a joint paper.

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