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Paths to Biosafety and Biosecurity Sustainability: A Message from the MENA Region

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FOR the past decade, governments seeking biological *security* have trained personnel and secured pathogens and laboratories at home and abroad; internationally they have often included biological *safety* training to help make the security medicine go down. Some have lumped biosafety and biosecurity activities under the concept of "bio-risk management." Much of the training and many of the upgrades to labs have been helpful in making workplaces safer and some of the activities may have enhanced security. Hundreds of millions of dollars have

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been spent globally, but in many cases, neither the real increase in security nor the sustainability of the upgrades or training is known. Importantly, security in biology differs from that in a nuclear or chemical enterprise—biological materials are ubiquitous in nature. For some, invisible quantities could initiate an outbreak or epidemic and we lack real-time tools to identify or quantify the microbes or to know they are passing through transportation systems. Furthermore, unlike the case of the global nuclear and specialized chemical enterprise, many biological experts exist in nearly every country around the globe. Until very recently, the Middle East and North Africa (MENA) region was a low priority for funding. The increased socio-political turbulence in the region during the last several years has driven a heightened awareness globally of its implications for safety and security.

While biosafety and biosecurity are real challenges, addressing them in the MENA region is a complicated endeavor because of the diversity of cultures, socio-economic statuses, and dialects and languages[1]; the recent widespread socio-political unrest; and the reality that some countries in the region had offensive biological weapons programs in recent history. While other regions in the world share some of these issues, none is currently experiencing all of these risk factors at once and with such intensity. The concentration of all of these issues in the MENA region, coupled with its rich history as a leader in science, presents a number of challenges to those seeking to address biosafety and biosecurity. In some countries, certain types of research (e.g., on infectious diseases) are receiving inadequate emphasis; in others, the necessary scientific infrastructure is missing; and in others still, science is advancing apace and farther along than its neighbors. The biosafety and biosecurity needs of each of these countries differ and yet the approaches often resemble those in other regions of the world, which affects the overall utility and local buy-in of those efforts. A small group of leaders of the biological sciences community in the MENA region has recently been discussing the way ahead for a safe, secure, and sustainable life sciences enterprise with the goal of identifying biosafety and biosecurity approaches in the midst of ongoing unrest and conflict in the region.[2], [3], [4]

Biosafety is a long-understood, appreciated, and necessary component of biological research and clinical laboratory practice. Its purpose is to protect scientists and the public from unintentional exposure to pathogens and toxins. Advances in infectious disease laboratory safety have progressed nicely over the past fifty years. Biosafety concepts and practices—integrating facilities, equipment, and procedures—have been developed, tested, codified, and globally accepted. Full application is limited more often by the unavailability of resources than by knowledge of the standards or the will to employ them. Serious scientists everywhere, particularly those who work with dangerous infectious pathogens, understand and appreciate the importance of diligent adherence to the principles of laboratory safety. These fundamentals are integrated into the culture of the best and most productive laboratories around the world. A good measure of the effectiveness of laboratory biosafety programs can be found in the logs of

occupational safety offices in these labs. The extent of the risk and scientists' success in reducing it can be measured there. Effective biosafety practices are also the foundation of laboratory biosecurity activities.

Biosecurity is a much younger practice. Lab security includes everything from the now widespread risk assessment and management training, to physical protection and accountability of organisms, to psychological evaluation and law enforcement investigation of scientists and laboratory workers to determine possible malicious intent or even predilections toward carelessness. The purpose of biosecurity is to prevent the loss, theft, misuse, diversion, or intentional release of pathogens and toxins. Numerous security upgrades have been mandated and implemented since the 2001 anthrax mailings in the United States. It is easy for regulators to mandate security measures following an incident, but difficult to really evaluate either the security they provide or their impact on the scientific enterprise. Understanding exactly what is needed and what works to make labs and populations more secure is difficult because of the rarity of malevolent acts.

There is a huge global disparity in resources available for the life sciences and public health enterprise, let alone resources dedicated to securing it. There are regions of the globe where gathering food and firewood for the day is a fulltime job. Even a simple security fence built around a laboratory in those regions might not be sustainable. In such places, concerns about deliberate misuse truly pale in the face of the daily and life-long fight for survival from malaria, AIDS, tuberculosis, and parasitism. In other regions, where agricultural economies exist, the relevant fight may be to control plant and animal pests and pathogens. In yet other places, wealthy communities have the luxury of being concerned about production of industrial materials, energy generated from biotechnologies, or even environmental preservation. Safety and security perceptions and needs vary across all of these settings, as does sustainability of the programs put in place to implement them. Every region of the world is different; significant diversity also exists within the MENA region.

For years, global aid programs focused on public health: malaria, soil and water parasitism, tuberculosis, insect borne viruses, and later HIV/AIDS. Many of these legitimate public health programs had the additional virtue of building trust between individuals and national governments. After the anthrax attacks of 2001, priorities changed. First, governments enacted new security-motivated laws domestically. Soon thereafter, they began introducing security and safety programs internationally, most notably in countries considered threats or potential sources of microbial materials for biological terrorism; such efforts were eventually undertaken in the MENA region. Many of the domestic and international improvements have been positive, particularly when they didn't impede the local life sciences enterprise or slow collaboration more than they contributed to security. That balance isn't always easy and not all of the efforts have continued, particularly when an outside country introduced its own model of biosafety and biosecurity to

another. To achieve sustainability, new policies, procedures, and activities must be affordable and effective, after a benefactor is gone, and individuals, organizations, and governments must appreciate the real value of the new programs. In short, the programs must be practical and affordable.

Even when recipients take possession of the ideas, technologies, and training, some new programs have proven of limited utility if not integrated into the local life sciences enterprises. Programs have failed sometimes because the model was inappropriate for the resource base of the region or because it seemed unimportant in the local environment. Examples of resource imbalance include unreliable electricity, interrupted Internet access, lack of funds to maintain state-of-the-art facilities or equipment, lack of trained staff, and lack of awareness by and support from governments. Any enterprise, to be effective, must be built on a framework appropriate for the goals of the enterprise and the region. Depending to a great extent on the resources and political climate, the framework on which a life sciences enterprise is built will include, to varying degrees, human resources, technologies, finance, patent law, marketing, management, and safety and security programs tailored to the needs of the enterprise.

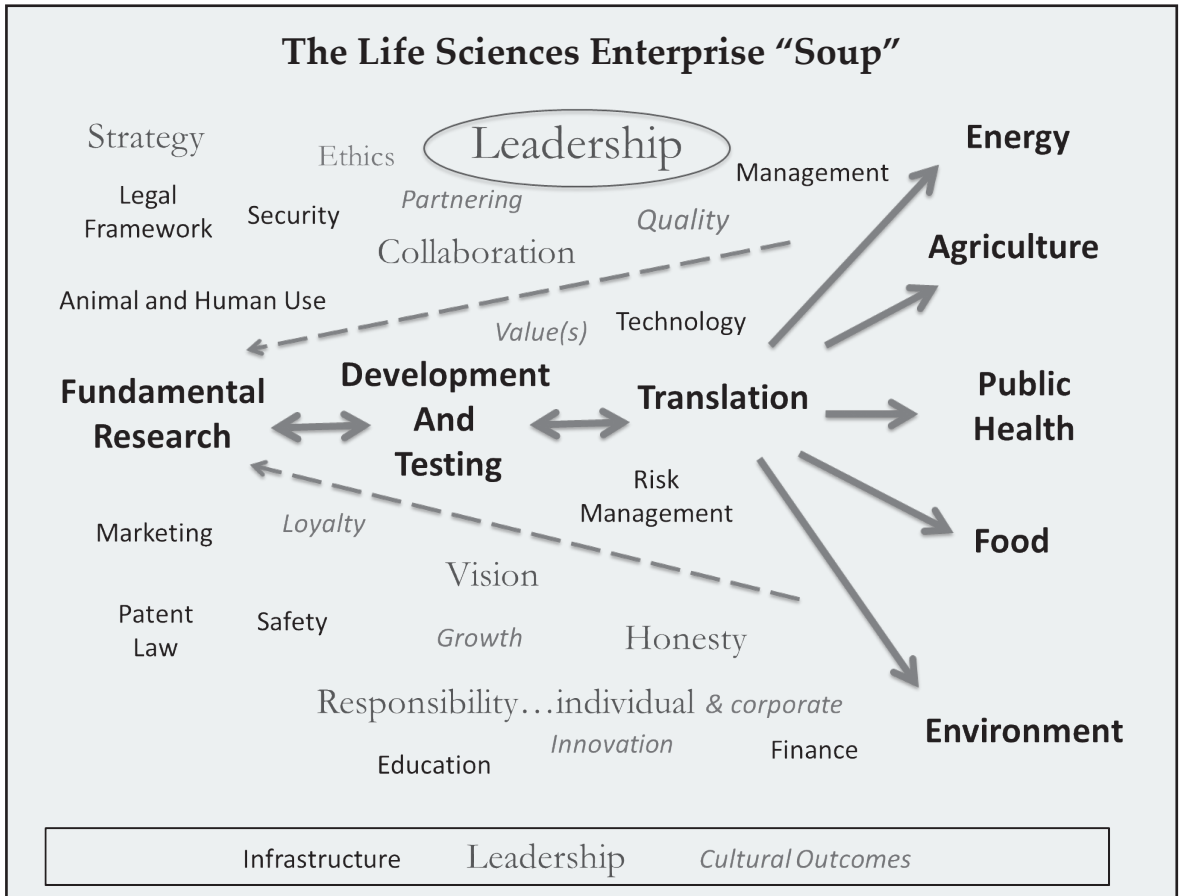
The most successful research or applied health programs typically have excellent leadership that possesses authority commensurate with responsibility. The best laboratory leaders bring with them strategy, vision, honesty, ethics, a collaborative spirit, and an appreciation and support for the integration of appropriate safety and security principles and programs into the everyday research or clinical environment. Ethics education is currently being used locally in parts of the region to help students and practicing scientists with this integration. The Center for Excellence in Biosafety, Biosecurity and Biotechnology at the Royal Scientific Society of Jordan (RSS) will offer graduate courses in this area to students from a variety of scientific disciplines. The Hashemite University in Zarqa, Jordan, has recently introduced a new course in bioethics for students in the faculties of medicine, dentistry, nursing, pharmacy, and science. The Biotechnology Industry Organization, the leading trade association in the biotechnology industry, has created an active bioethics committee, adopting a Statement of Ethical Principles in order to ensure biotechnology is not abused and is used for the betterment of humankind.

At the laboratory level, this integration of principles into the thinking of a large network of clinical laboratories can be described as the "3Cs of Biosecurity": Codes of Ethics, Codes of Conduct, and Codes of Practice. These terms serve as mental hooks onto which scientists and staff of the United Arab Emirates' Ministry of Health federal clinical laboratory system can hang principles related to responsible individual and corporate practice; principles that eventually form a protective matrix across and throughout the enterprise.

In Morocco, biosafety and biosecurity capacity building started in 2004 at the Tétouan University with the implementation of a masters degree curriculum

entitled "CBRN [Chemical, Biological, Radiological, and Nuclear] Security" in which a full module on these topics is now taught. In another example, the Moroccan Biosafety Association, in its first training course on biological risk management, engaged leaders from national universities and military and civilian laboratories in a discussion on: 1) how advances in life sciences could be used to the benefit of mankind and not as a means of destruction; 2) how the scientific community could avoid manipulating highly dangerous pathogens while supporting important research aimed at curing serious diseases; and 3) how the scientific community might balance security and freedom of researchers to advance scientific knowledge. Enlightened leaders also bring their own sense of personal responsibility regarding science and technology. When such leaders are given the opportunity to lead, organizations develop a culture of quality, value, loyalty, partnering, innovation, growth, and corporate responsibility. Communities of trust spring from such organizations and global networks result when scientist-to-scientist relationships of trust develop between the communities.

The real purpose of the biological enterprise is not safety or security; it might be public health, food production, energy, agriculture, or environmental protection—all for the good of the populations of the region in which the enterprise exists. The



The "Soup Slide," which was developed spontaneously during discussion at the MENA region meetings. Biological safety and security must be part of the "soup" of our life sciences enterprises.

finance, technology, and management are all critical components in the enterprise but not meant to stand alone either. They must be part of a system, as they are not sustainable outside the system. As in other regions, sustainability of biosafety and biosecurity programs is not achievable without careful integration and high-level management support in the MENA region.

Therefore, it is time to move beyond "check-box engagements," characterized by meetings, lectures, certifications, and training programs to integrated systems approaches where right-sized, relevant biosafety and biosecurity capabilities and knowledge are an important component. Having regulations, a fence around the laboratory and a certificate on the wall, is not enough; and a too heavy security overlay may even run counter to the intended purpose. Safety and security are only as good as the culture of an organization. The culture is only as healthy as the people and the leadership. A holistic approach is required within each country, within the region, and within the assistance programs. Only when safety and security become ingredients in the life sciences enterprise "soup" will they be both effective and sustainable.

A major challenge to integrating the knowledge of responsible life sciences research into the broader enterprise in the MENA region has been the limited access to Arabic training materials and up-to-date information on biosafety and biotechnology developments. The International Council for the Life Sciences (a U.S.-based nonprofit) in collaboration with the RSS and the Biosafety and Biosecurity International Consortium (a network of concerned individuals from twenty-two countries) with financial support from the Nuclear Threat Initiative, is undertaking the translation into Arabic of the biosafety and biorisk management guidelines of the World Health Organization and the U.S. Centers for Disease Control and Prevention's *Biosafety in Microbiological and Biomedical Laboratories*. However, the development of Arabic language training materials and curriculum in a way that presents the principles that underly biosafety and biosecurity to enable the development of locally feasible, low-cost approaches (not simply application of Western approaches) in MENA countries is also needed. With funding from the Islamic Development Bank in Jeddah, Saudi Arabia, RSS is developing an Arabic-language training curriculum for biosafety and biosecurity which is tailored to the needs of the region.

In many cases, the recipients and even the government funded implementers of engagement programs understand that leading with security is counterproductive. However, as one former high-level implementer observed, "a photo of a fence around a laboratory is something [a legislator] understands." Even nongovernmental organizations must often emphasize biosecurity in their proposals to obtain government funding for this important work. Only when senior government leaders understand that biosecurity is much different than nuclear security and that global communities of trust in biology are enormously powerful forces for global

security broadly—and global public health—will both security and productivity thrive in the life sciences enterprise.

While scientists have learned to titrate safety precautions and practices to the risk, they can also measure the benefits of the precautions. Biological security incidents are very rare but have potential for great harm. Scientists can measure the security activities, but not their effectiveness. Scientists will never remove all the risk, but working together globally they can make the most of safety, security and productivity when everyone realizes that biosafety and biosecurity programs are only really effective when they are thoroughly mixed as "immune enhancing vegetables into the life sciences soup." SD

Endnotes

1. English is widely spoken in the Middle East and French is widely spoken in North Africa, but the first language is Arabic in the whole region.
2. This perspective is derived from meetings in Morocco and Jordan, conducted by the Center for Science, Technology and Security Policy Studies with the American Association for the Advancement of Science (AAAS, publisher of *Science & Diplomacy*).
3. This material is made possible in part by support from the Project on Advanced Systems and Concepts for Countering Weapons of Mass Destruction (PASCC), Center on Contemporary Conflict, (U.S.) Naval Postgraduate School, under Grant No. N00244-12-1-0039. PASCC is supported by the Defense Threat Reduction Agency.
4. For a more comprehensive review, see *Scientific Engagement in the Broader Middle East and North Africa* (AAAS Center for Science, Technology and Security Policy, 2013, http://www.aaas.org/cstsp/files/AAAS_MENA-Cooperation-Report_2013.pdf).