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Effective Practices in Addressing Bio-Risks in the Area of Research & Development: A Perspective from MENA Region.

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Introduction



Biological Threats

- 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 "*Biorisk Management*".



Biorisk Management

- To manage biological risks, there is a need to:
 - promote a "culture of responsibility in the life sciences",
 - introduce effective oversight measures, biosafety and biosecurity training programs, and voluntary or mandatory guidelines to ensure that powerful biotechnologies such as synthetic biology are employed in a safe and secure manner, and
 - devise prudent measures to prevent misuse without impeding legitimate research or curtailing beneficial applications.



Biological Threats

• Much of the training and many of the upgrades to labs have been helpful in making workplaces safer; some of the activities may have enhanced security.

Hundreds of millions of dollars have been spent globally but in many cases, neither the real increase in *security* nor the *sustainability* of the upgrades or training is known.



The Dynamic Nature of Biological Threats

- Security in biology differs from that in a nuclear or chemical enterprise:
 - The biological materials are ubiquitous in nature; for some, invisible quantities could initiate an outbreak or epidemic.
 - Real-time tools to identify or quantify the microbes or to know they are passing through our transportation systems are lacking.
 - Many biological experts exist in nearly every country around the globe.



The Dynamic Nature of Biological Threats

- 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.



The Dynamic Nature of Biological Threats

 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 Middle East and North Africa (MENA) region



The Dynamic Nature of Biological Threats

- Until recently, the 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.
- 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.



The Start,,,

- 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 nations.
- 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.



What is Needed?

- 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 their 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.



What is Needed?

- 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 lifesciences 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.



The Way Forward,,,

- Any program, 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 and the country.



Measures to Advance Biosafety and Biosecurity

- 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.



Measures to Advance Biosafety and Biosecurity

- At the laboratory level, this integration of principles into the thinking of a large network of clinical laboratories is 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 researchers can hang principles related to <u>responsible individual</u> and <u>corporate practice</u>;
 - principles that eventually form a protective matrix across and throughout the enterprise and country.



Measures to Advance Biosafety and Biosecurity

- 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.



Measures to Advance Biosafety and Biosecurity

- The real purpose of the 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 finance, the technology or the management are all critical components in the enterprise but not meant to stand-alone either; <u>they must be part of a system</u>, as they are not *sustainable* outside the system.
- In the MENA region sustainability of biosafety and biosecurity programs is not achievable without careful integration and high-level management support.



The Soup Recipe,,,

- Therefore, we believe it's 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, 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 (Figure 1).

Figure 1: The "Soup Slide" developed spontaneously during discussion at the MENA region meetings.







Conclusions

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



Main Reference

 Paths to Biosafety and Biosecurity Sustainability: A Message from the MENA Region. By Anwar Nasim, Nisreen DaifAllah AL-Hmoud, Sabah Al Momin, Najat Rashid, Khalid R. Temsamani, Kavita Berger, David R. Franz. AAAS Science and Diplomacy. November, 2013



