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Meeting Summary: Centre on Global Health Security

Safe and Secure Biomaterials: Matching Resources to Reality

May 2012

INTRODUCTION

On 17 May 2012, the Centre on Global Health Security and International Security at Chatham House hosted an international conference on **'Safe and Secure Biomaterials; Matching Resources to Reality'**, bringing together representatives of governments, health protection agencies, medical experts, architects, engineers, and biosafety and biosecurity experts.

The objectives of the meeting were to consider the current Western biosafety and biosecurity standards for the safe control of hazardous biological materials; understand the needs of developing countries through case histories; consider innovative solutions; and explore whether and how practices can be improved with limited resources, while still meeting standards and not inhibiting necessary diagnostic and surveillance activities. This meeting was not held under the Chatham House Rule.

Background

The international regulation of biological weapons is an area of considerable public and political concern, not least for the current UK Parliament. Before the 9/11 terrorist attacks, biosafety and biosecurity was haphazard worldwide: there was little control over, for example, foreign students seeking to develop pathogens or scientists carrying specimens around the world in a plastic bag.

Since then, several countries have introduced effective counter-terrorism legislation, which in the UK was provided in the Anti-Terrorism, Crime and Security Act 2001. Public concern for safe and secure biomaterials has also risen, particularly after the accidental release of smallpox from a UK university laboratory, and there is current controversy over whether scientific research on inducing variation in flu viruses should be published, due to the risk of terrorists acquiring such knowledge.

The regulation of biomaterials constitutes the two related communities of biosafety and biosecurity:

- Biosafety – preventing the **accidental** release of biological agents and toxins, or unintended exposure.

- Biosecurity – preventing the **intentional** release of biological agents and toxins through loss, theft, misuse or diversion, as well as its unauthorised access, retention or transfer.

Such prevention is often achieved through highly secure physical containment of biological threat agents, including new buildings, new high-tech security systems and personnel training. However, these measures are associated with high costs that are unlikely to be met by developing nations with poor resources, health infrastructure and regulatory capacity – for example, cross-country assessment of laboratories and cabinet certifications in the Asia-Pacific region have uncovered serious failings, such as 'home-made' HEPA filters, inadequate maintenance and power supplies, reversed air flows, and fake branding of supposedly proprietary equipment. In addition, some biological agents that could be used for biological attacks, such as anthrax, are endemic in some areas, which means a determined malefactor could acquire and culture such pathogens with little risk of discovery.

The priority therefore is to help developing countries build the infrastructure necessary for effective biological safety and security systems. The key is to move towards information- and knowledge-sharing that reflects the principles of risk assessment, is appropriate to local circumstances and resources, and makes allowances for lower-resource environments without compromising effectiveness.

SUMMARY OF DISCUSSION

Technological innovations

It was agreed that it is important **not to be seduced into 'high-tech' solutions where simple ones would serve as effectively**. Over-engineered solutions are often unsuitable for developing countries, and can also encourage a 'tick-box' approach that may undermine intelligent assessment of risk. A good system should be simple; be straightforward to introduce, run and maintain; achieve a safer (as opposed to 'safe') state focused on protecting people and preventing further infection; and use locally available and sustainable resources.

Moreover, those who specify facilities and equipment need to have a **better understanding of what drives costs**. Simplified design, pre-fabrication and engaging technicians all provide opportunities for cost savings; in contrast, it makes no sense to insist on labour-saving measures when labour is relatively cheap in most developing countries. In particular, one must take into account the full-life costs over 40 years (running costs, maintenance and spare parts, environmental impact, etc.), not just initial capital investment.

It was argued that **innovation, not cheapness *per se*, should be the driving force** in the development of biosecurity standards. Examples of such innovations from current practice, as well as potential areas for future investigation, included:

Innovations in technology

- Removal of computerised key-card access controls for interlocking doors, which are vulnerable to power outages in inconsistent electricity supply.
- Replace electronic proximity controls on taps with elbow paddles, which are just as effective.
- Use pre-packed test kits to eliminate the need to send samples to a laboratory.
- Install cheaper and better air-handling solutions.
- Use generic or pre-fabricated equipment for reduced cost and greater reliability.
- Use informatics and robotics, e.g. a sealed box containing a robot for level 4 work.
- Use modular and mobile equipment to deal with emergency outbreak situations, e.g. 'flexible isolator in a box', though there is a danger this could fall into the wrong hands.

- Continue to explore research techniques that do not require whole pathogens.

Innovations in building design

- Minimise plant installation and maintenance costs in the design, as land may be relatively cheap in developing countries.
- Use an inexpensive and sustainable prototype, which draws on internationally accepted good practice and can be customised as necessary, e.g. adapting filter systems for differing levels of dust and humidity. Such an approach was successfully applied in Tanzania, where use of repeatable construction techniques allowed 23 laboratories to be built over a 3 year period; the accompanying strengthening of the local economy and extended training after handover ensured sustainability.
- Include incinerators (or other disposal technology) in the plan to minimise risk from transporting waste material elsewhere.
- Pre-fabricate isolators externally for cabinet refits (typically every 5 years for science projects), which can be plugged into a standard building design as the building itself can last for 40 years.
- Adapt existing systems, as this can achieve significant results with small investment. For example, pro bono engineering work by design firm Arup created a low-cost isolation unit in Sierra Leone, using natural ventilation and photovoltaic power.
- Encourage more energy-efficient laboratories, using climate change and fuel costs as a justification.

The need to **involve the end users of technology** in the development process was discussed, as well as the **role of the private sector** in better facilitating such innovations in a fast-moving field. Issues remain, such as national export controls that significantly hamper procurement of equipment.

Effective biorisk management

While much attention is given to hardware and construction, safety does not necessarily require heavy capital investment. It is as important to **ensure proper biorisk management** – risk perception, assessment and control – and in turn, **training for effective knowledge transfer**.

Risk perception

Public perceptions of risk in the West are sometimes distorted because the media often focus on improbable events, or because of governments'

impossible expectation of zero risk. The result can be excessive concern ('health and safety gone too far'), and a one-way ratchet on rigid regulatory standards that make it politically difficult to justify anything other than a strategy that seeks maximum risk reduction. There is thus a need to have a **clear doctrine on what risk is and to work on relative risk reduction, not absolute risk**.

Risk assessment

A **nationally based risk assessment, with global management tools and innovative scientific and technical system designs at its core**, is essential. A well-designed operational protocol (e.g. Standard Operating Procedures) and documentation, as well as the hardware and point-of-care diagnostics, should be developed with epidemiologists and existing surveillance systems, to be in line with local needs or availability. More thought is also needed on what certification is really for, and how frequently and to what depth it should be applied.

Risk management and control

The current lack of evidential basis for controls creates uncertainty, which in turn can lead to 'over-design', excess costs and preservation of outdated or irrelevant practices. More effort is needed to **build an evidence base for a scientific risk-based approach**. There is also need to **standardise** nomenclature and definitions for control level designations, as well as to **establish clear outcome specifications for different situations**, such as for endemic pathogens. Furthermore, biosafety and biosecurity are often not addressed together – for example, in the transport, handling and segregation of specimen and waste, or in the issue of secure access control (security) vs. safe emergency procedure (safety).

A locally led model

A recurring theme in the discussion was the need to **move away from a 'one size fits all' approach to one of national ownership, local relevance and sustainability** – there is no point in specifying high-tech, high-maintenance equipment if it cannot be maintained. Several factors were identified to facilitate such change.

National capacity building

Different countries have different needs – for example, the wide geographical and cultural diversity in Pakistan make it difficult to have a centralised, nationally coordinated system. There is thus a need to **shift away from**

externally imposed, top-down expert solutions, toward a more flexible prototype model that engages with local people and resources and encourages technology transfer. Successful examples of prototype models were drawn from the 'Nissen Hut' facilities, and the Canadian approach that focuses on outcomes sought from control rather than detailed methods. To achieve such a shift, revision of the ACDP guidelines, as well as changing the attitudes of policy-makers and top managers to overcome government inertia, were suggested.

A particular mention went to Afghanistan, where weak government institutions, regulations and enforcement make it difficult to ensure proper certification of equipment or operating procedures. In addition, lack of an investigative journalism culture that could apply pressure, and lack of incentive or means for self-reflection, means the country is accustomed to rote-learning. Cultural and behavioural change is thus the first priority to encourage flexible and innovative thinking in Afghanistan. It was argued that a more hands-on approach by foreign armed forces, and private sector involvement, might be some solutions.

Flexible funding

Development partners often place artificial constraints on funding that may not be in line with local needs – for example, they are often reluctant to fund infrastructure or consumables even when they are the most needed. The short-term nature of project funding (often 3 years) also does not support long-term development projects or effective training. **Recipient countries must be able to tell development partners what they need in order to respond to local reality**, and potentially make multilateral agreements for consecutive funding. Avoidance of language such as 'donor/recipient' and 'demand-side' may also be helpful.

Flexible standards

There was much discussion on the level of acceptable variation in standards. The UK and other leading countries will not ostensibly reduce standards, so there will necessarily be variation around the world; in any case, the upward creep in standards in developed countries is not generally supported by evidence and it would be unwise to export the unrealistic expectations for zero risk, and the corresponding risk-averse, damaging blame culture, to developing countries. A single uniform international standard would also be inappropriate, given the different countries and pathogens.

On the other hand, it may be unethical to have lower-quality or higher-risk thresholds in developing countries for the sake of cost. In addition, having high-containment laboratories with current technology is also a matter of prestige for many developing countries, such that a degree of inefficient expenditure on such facilities is inevitable. It was suggested that it might be best to **avoid presenting this as a matter of costs and standards altogether, and to focus on securing incremental improvement**. For this, **better real-time information sharing** may be key: equipment, building design and personnel/protocol solutions should be benchmarked and made available to developing nations, to ensure effective and sustainable knowledge transfer.

CONCLUSION

Change will not be easy, but two observations suggest that it is not impossible. First, the International Health Regulations in 2005 have changed government attitudes to the reporting of potential infectious disease outbreaks, which was previously thought to be stigmatising and economically damaging. Second, on-going discussions on medicine and vaccine regulation suggest that a more flexible, country-specific approach is possible in other fields.

A vision does exist on minimum global standards, which are based on performance-based regulation and sustainability. What now prevents us from achieving this vision is a lack of global coordination, and confusion over who can take responsibility for such an action plan. Leading international organizations such as WHO, FAO and OIE should come together to define appropriate roles and responsibilities to address this issue.

Key recommendations

- Complex technology is not necessary. A simple but innovative approach, with an intelligent understanding of costs, is more effective, such as use of pre-fabricated equipment or flexible prototype models.
- Proper biorisk management is essential, including intelligent perception of risk and systematic, evidence-based and standardised risk assessment procedures.
- Solutions must be sustainable and locally relevant. For this, there needs to be ownership by national policy-makers, engagement of local staff, knowledge transfer through training, and flexible funding from development partners.
- It may be more helpful to consider progress in terms of incremental improvements, rather than of costs or standards.
- Greater private sector involvement might facilitate technological and management solutions where a country may lack capacity.