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Models of Scientific and Technological Review for the Biological and Toxin Weapons Convention: A Conceptual Analysis

Abstract

Science and technology (S&T) review is key to anticipating developments in the life sciences that may benefit, or run contrary to the aims of the Biological and Toxin Weapons Convention (BTWC). It serves both as a mechanism for preparing against novel biological threats, and identifying the best opportunities for developing and sharing the life sciences to the fullest extent. In the age of rapidly advancing biotechnology, S&T review needs to be wide ranging, involve a diverse set of inputs, and be transparent about its methods and data. Here, the features of four models of S&T review in terms of their capacity to respond to the challenge of the life sciences are outlined: standing advisory boards; ad hoc working groups; peer review; and wikis. We then identify a hybrid model that is suitably broad, diverse, and transparent.

Keywords

Biological weapons; science and technology review; dual-use; nonproliferation; transparency

Introduction

A persistent issue for the governance of biotechnology is the anticipation and regulation of novel threats to biosecurity. Of particular concern are so-called "dual-use" scientific and technological developments that have the capacity to both help, and harm human health and security.[1] In the domain of biological weapons, this dilemma manifests in difficulties predicting which novel technologies will enable (or hinder) the development of biological weapons, or generate novel bioweapons about which we are unaware.

The prediction and tracking of biological technologies that may pose the risk of misuse has thus been a significant challenge for governments and international organizations. This paper enters into the field by examining possible avenues for reviewing science and technology (S&T) advances in the context of the Biological and Toxin Weapons Convention. It further seeks to provide a normative analysis of the role of S&T, in terms of what function it ought to fill in the context of the BTWC.

First, a preliminary justification for "S&T review" is given in the context of the BTWC, and the current state of the Convention is described as an entry point into an analysis of models of review. Four models of S&T review are considered with implications for the Convention, and how these might inform the design of an S&T review mechanism that satisfies the technical and political needs of the BTWC. In the discussion, the possibility of external, independent reviews is considered in two senses: a) a stopgap for the BTWC; b) on its own merits.

S&T Review in the BTWC

The basis of consideration of science and technology (S&T) in the BWC is explicit in the Convention itself. Article XII of the Convention, which covers the first review conference, notes that "such review shall take into account any new scientific and technological developments relevant to the Convention." Since 1979 States and non-government organizations (NGOs, often referred to as "civil society" in BTWC parlance) have proposed the explicit, periodic review of S&T developments with implications for the convention including:[2]

a. Advances in the life sciences pose novel ways for the creation biological weapons and toxins, and novel misuses of life sciences and their derivative technologies by state and non-state actors;[3]
b. The potential to engineer truly novel biological weapons means it is not possible to infer what S&T developments are important to the BTWC from existing agents and technologies;[4]
c. Convergent science and technology—prototypically of biology and chemistry, but increasingly including, neuroscience, information technology, and nanotechnology—could lead to unexpected and rapid advancements with capacity for misuse;
d. Reductions in barriers to access in biology entail that ostensibly beneficial civilian research may entail a "dual-use dilemma" in which one and the same piece of science or technology can be used to help or harm humanity.[5]

States parties, from these statements through to the most recent Meeting of Experts, frequently agree that reviewing the progress of S&T is an important part of the life of the BTWC. What form review ought to take, however, is not specified in the text of the Convention, and States—and civil society—disagree as to what kind of mechanism ought to be developed to review S&T for its impact on the convention. This is not the place to rehearse, in sequence, the statements made by States Parties and civil society. The Harvard Sussex Program, in advance of the Seventh Review Conference, completed this work in 2011.[6] Rather, I will proceed from this point of analysis in describing current work in the context of the Convention.

At the Seventh Review Conference, States Parties to the Convention again acknowledged the need for a more systematic means of addressing the prospect of reviewing developments in the field of science and technology related to the Convention. To this effect, the Conference decided that the 2012-15 intersessional program would include a Standing Agenda Item on the review of developments in the field of science and technology related to the Convention. This Item resulted in, *inter alia,* background papers by the BTWC Implementation Support Unit,[7] and

working papers by the United Kingdom of Great Britain and Northern Island,[8] the Russian Federation,[9] United States of America,[10] China,[11] European Union,[12] Australia,[13] South Africa,[14] Switzerland,[15] and the Islamic Republic of Iran.[16] The civil society community surrounding the Convention contributed to this discussion through statements, side events, and in the academic and policy literature.

The Eighth Review Conference of the states parties to the BTWC in 2016 included a review of the operation of the Convention taking into account, *inter alia*,

i. New scientific and technological developments relevant to the Convention, taking into account the relevant decision of this Conference regarding the review of developments in the field of science and technology related to the Convention;
ii. The progress made by states parties on the implementation of the Convention;
iii. Progress made by the states parties on the implementation of decisions and recommendations agreed upon at the Seventh Review Conference, taking into account, as appropriate, decisions and recommendations reached at previous review conferences.[17]

Despite these stated goals, the meeting's outcomes are considered to be a missed opportunity to advance measures to strengthen the legally binding accord that bans development, acquisition, and production of biological agents and toxins.[18] This is true of S&T review as much as anything else. Countries including United States, Russia, Iran, Norway, Switzerland, and the United Kingdom proposed the formation of scientific and technical bodies to assess rapid advances in S&T, but none were taken up by the Committee as a Whole or passed in the Final Document. There were also a number of proposals from members of the Nonaligned Movement (NAM) to review international cooperation and assistance activities related to the use of microorganisms and toxins for peaceful purposes.

S&T returned as an explicit point of discussion through the 2017 MSP, which sought to bring consensus on moving forward with a new intersessional program forgone

at the Eighth Review Conference. The format for this 2018-2020 intersessional program consisted of five contiguous MX per year, of which MX2 was specifically related to S&T review. The 2018 MX2, on 9-10 August, addressed the specific topic of genome editing, taking into consideration other issues including but not limited to biological risk assessment and management, and the development of a model code of conduct for biological scientists.

A broad consensus thus exists between states and among civil society that S&T review is both an important component of the convention, and a central part of upholding the prohibitory norm against the development and use of biological weapon. However, opinions diverge on the precise nature of those reviews, how they ought to be conducted, and their role on informing the evolution of the convention. This lack of consensus, however, offer and opportunity to think creatively about S&T review modalities. We can consider the strengths and weaknesses of reviews within the sphere of the BTWC and other international frameworks, as well as those S&T review or "S&T review-like" mechanisms that perform similar functions beyond the realm of disarmament and arms control. Before doing so, however, an understanding of contemporary motivations for S&T reviews is required.

The Peril and Promise of the Emerging Life Sciences

The life sciences are evolving rapidly, promising to aid in the detection, response, and mitigation of naturally occurring and intentionally caused biological threats. There are, however, also developments that may enable state or non-state actors, or individuals in the use of biological weapons, both in their capacity to cause mass harm (as WMDs) and in more limited engagements as nonlethal or incapacitating agents, weapons of small-scale terror and—potentially—as precision weapons. The states parties have expressed a desire that an S&T review process should identify both kinds of development. In addition to developments that are specifically of concern as immediate violations of the Convention, two kinds of S&T development arguably should be subject to a review mechanism, due to their potential to produce outcomes contrary to the Convention.

S&T contrary to the Convention

Dual-use research and technology

Ostensibly peaceful or permissible (i.e. defensive) S&T developments that could be misused possess so-called "dual-use potential." Not all S&T described as dual-use necessary falls under the purview of the BTWC, i.e. dual-use in the sciences arguably arose through the nuclear sciences, and has also been associated with nanotechnology and cybersecurity issues.[19] However, given the preponderance of debate in the twenty-first century has concerned the life sciences, I will use "dual-use" here to refer to exclusively to life sciences research or otherwise with implications for the BTWC. The paradigm case of dual-use in the life sciences, in which Australian researchers developed a recombinant strain of the mousepox virus that killed 100% of immunologically naïve and vaccinated mice, and 60% of genetically resistant mice[20]—a technique that could be replicated in human-transmissible orthopox viruses, such as smallpox—was understood to have future potential implications for the BTWC, though its creators argued that due to the peaceful purposes of the research it was not in contravention of the Convention.[21]

The central concern of the mousepox study was that the basic technique could be (and allegedly was)[22] directly applied to a human-infectious orthopox virus, creating a potentially devastating biological weapon. Other dual-use research and technology may be less direct in its implications. In 2014 scientists engineered a recombinant strain of *Saccharomyces cerevisiae* yeast that produced S-reticuline, a precursor to morphine and related opioids.[23] This kind of innovation is a component of a larger push in synthetic biology to utilize recombinant organisms as platforms to generate biochemical agents for use in medicine, agriculture, or energy production.[24] The same technology could, however, in principle be modified to manufacture biological agents for hostile purposes. It may be some time, however, before the potential for misuse is significant.

A challenge for S&T reviews lies in tracking the development of dual-use technologies of concern, and determining the balance benefits and risk these developments entail. For example, national and international summits on the use

and misuse of CRISPR-Cas9 and other gene editing technologies have recently occurred; the US Director of National Security recently identified gene editing as a national security challenge on par with chemical and nuclear weapons proliferation.[25] The 2018 MX2 focused heavily on the emergence of gene editing as a security risk, noting that to date, outstanding technical issues have rendered both the beneficial and malevolent uses of gene editing technologies. The sustained analysis of such an issue, particularly at the level of the BTWC, can be time consuming an expensive, but may also represent a security threat if not subject to careful monitoring.

Convergent technologies

Developments of disparate S&T (e.g., neuroscience, nanotechnology, information technology, synthetic biology) so-called "convergent technologies"—may affect the BTWC in unexpected ways. Convergent technologies are difficult to identify because they do not involve the misuse of biotechnology in isolation. For example, advances in neuroscience have enabled the design and manufacture potent bio-chemical agents that can affect the brain, producing physiological and behavioral changes in humans. These have the potential to be exploited for a variety of lethal and non-lethal hostile purposes, including but not limited to warfare, terrorism, law enforcement, riot control, interrogation, and counterinsurgency. Agents under consideration for use as nonlethal weapons include opioids, benzodiazepines, alpha2 adrenoreceptor agonists, and neuroleptic anesthetics.[26]

Convergence highlights the role civil society plays in developments that may be contrary to the convention. Some collaborations are explicit, such as those between civil scientists and intelligence agencies in research on the role of psychogenic compounds in behavior modification and interrogation, made famous by the US Central Intelligence Agency's MK ULTRA program.[27] But some are unwitting: civil medicine and agriculture have frequently informed military developments in chemical warfare; in biology, the development of aerobiology in the 1930s is an example of civil work that was coopted by military interests.[28] This interaction has

implications for S&T review in the BTWC: a robust review mechanism must be sensitive to changes in the civil scientific landscape.

Convergence and dual-use technologies are independent concepts. What counts as convergent, and what as dual-use, is not easily distinguishable, but a general rule is that dual-use concerns a multiplicity of uses from a single piece of S&T, while convergence denotes a particular use arising from a multiplicity of S&T developments. S&T may be dual-use, convergent, both, or neither.

Of the potential adverse effects on the BTWC, dual-use and convergent technologies pose the most significant challenge to the BTWC. While individual studies of concern might be identifiable[29] the potential of dual-use and converging technologies is in part a matter of institutional capacities to use or misuse research.[30] S&T reviews thus serve to identify trends in the life sciences, medicine, and healthcare that underpin the dual-use of biology and its implications for the Convention.

S&T with benefits to the Convention

The two kinds of research the SAI for the 2012-2015 intersessional process noted might benefit the Convention—disease surveillance, diagnosis and mitigation; and measures for strengthening national biological risk management—are themselves convergent technologies. Disease surveillance, for example, relies heavily on non-microbiological S&T: information technology, organizational and implementation science, psychology, human factors research, and materials science. Tests must be produced, stored, and utilized in sufficient quantities to detect patterns in disease incidence. This, in turn, has to be accompanied by sufficient political will to design health systems that can detect emerging infectious diseases early.[31]

This diversity highlights the broad benefits to be produced by a detailed review of S&T. In identifying the broad context in which S&T development that benefit the convention might emerge, it provides States and NGOs with a nuanced view on opportunities and challenges to strengthen and share in the prevention and defense against biological agents. Moreover, identifying institutional challenges to promoting S&T of benefit to the convention can inform the larger network of disciplines (including medicine, public health, and the medical social sciences and

humanities) about the challenges to countering microbial threats, whatever their source.

Normative Models for S&T Review

It is desirable that S&T review identifies traditional developments contrary to the BTWC, as well as unexpected dual-use or convergent technologies. This review process should identify developments and their implications in support of the Convention, particularly in areas of health and biosafety. A review mechanism should be responsive to the rapid evolution of the modern life sciences, and possess desirable qualities for an S&T review mechanism.

Here, I consider four broad models: i) standing advisory committees, ii) ad hoc working groups, iii) peer-review, and iv) wikis (Table 1). Three broad dimensions characterize these models. The *technical elements* of a review concern the depth and breadth of analysis. The *structural* features of a review concern the degree to which it is responsive to change, representative of a diverse range of data and stakeholders, and, can accommodate issues of greater or lesser scope or timescale. The *procedural* elements concern the degree to which a review is transparent and accountable in terms of its data sources, analysis, and underlying assumptions. The following models of review all involve tradeoffs between these different elements in the pursuit of their goals.

This analysis is a normative analysis: comparing the values promoted by the various elements, we can come to conclusions about what ought to be done when thinking about different models for S&T review moving forward. This comes with a methodological turn that may not be familiar to some readers, so I describe it here for the sake of clarity. I begin with an analysis that is agnostic about—that is, does not discount the relevance of, but sets aside— concerns about political feasibility. I then move into views about feasibility, in particular acceptability to States Parties, and to cost in the final discussion.

In addition to the theoretic reasons for this methodology, beginning with feasibility considerations limits our analysis in two important ways. The first is that NGOs have been heavily involved in S&T reviews both within the proceedings of the

Convention, and beyond it. The Verification Research, Training and Information Centre (VERTIC), for example, have noted that civil society involvement in S&T review in a manner that assists States Parties in adapting to the challenges of the Convention is valuable even in the absence of State agreement to a particular S&T review mechanism.[32] So thinking about review modalities solely, primarily, or even first in terms of the question "what can states accept" is conceptually and empirically narrow.

A similar narrowness would apply in terms of cost. First, even where the costs of the following review mechanisms have a well-determined floor, their ceiling is often determined by the level of ambitiousness of the mechanism in question. Given the BTWC has received submissions on the structure of S&T review from a variety of parties, and with a variety of ambitiousness, it makes little sense to begin with cost. Moreover, while getting States Parties to pay their dues is a challenge for the BTWC, a number of States Parties at the 2017 MSP noted in the general debate that the costs of the BTWC are modest compared to other international frameworks. So cost is in part a corollary of state acceptability, and—as above—is thus a weak starting point.

Standing Advisory Committees

Standing advisory committees, also known as scientific advisory panels[33] or scientific advisory boards,[34] are perhaps the most commonplace suggestions for S&T review in the context of the BTWC. An example of such a group is the Organization for the Prohibition of Chemical Weapons' Scientific Advisory Board (SAB), whose 25 members assess and report to the Director-General developments in scientific and technological fields relevant to the Convention.[35] A direct transplant of the SAB as candidate for an S&T review mechanism has been posed by the Russian Federation in the most recent intersessional process.[36] Even if this option is not considered, however, the SAB nonetheless can provide guidance as an example of effective S&T review in the context of international conventions.[37]

Standing advisory committees are advantageous because they can be explicitly set up with representation in mind, and agreed to ahead of time. In the case, for

example, of the OPCW SAB, the membership is set in terms of representation of the states parties to that Convention. In the case of the US National Science Advisory Board for Biosecurity, membership is set according to an inclusive, but nonexhaustive list of fields of endeavor from which members are drawn.

Advisory committees are costly to the degree that committees are active. In cases where small committees meet in predetermined, institutionally run venues that serve other roles, overheads for committees may be relatively small. These costs can balloon, however, depending on the costs of bringing members and other stakeholders together. One estimate of an InterAcademy Partnership meeting in Beijing was $250,000-$300,000 (2010 USD).[38] As above, however, this need not be a limit on the development of an advisory committee.

Membership of standing advisory boards can change relative to the needs of the committee. The SAB members, according to their bylaws, may serve a maximum of two three-year terms. Board members of a scientific advisory board may also, in principle, be rotated out as the conceptual landscape on which they advise changes. When combined with *ad hoc* groups (see below), advisory committees can be relatively powerful in providing advice on S&T developments.

The central weakness of a scientific advisory committee is that the breadth of inquiry required of it determines its size. Large advisory bodies can be unwieldy and expensive to run. *Ad hoc* groups may be created, or subcommittees appointed for special topics, but this extra complexity may compromise the chief advantages of a standing committee structure: representation, and an institutional memory.

Typically, committee advice is consensus-based. This is useful for providing legitimacy to decisions, but can run roughshod over complex or emerging issues about which there is no reasonable consensus viewpoint to take. For rapidly developing issues, this can result in watered-down reports that lack the power to provide sufficient nuance to guide decision-making.

Because of the consensus nature of advisory committees, the terms of analysis and the data used may not be fully transparent. This means that other bodies may come

to different conclusions using the same data, or different conclusions in virtue of having used different data in the same way—all without knowing that this is the case. In debating controversial issues such as the potential misuse of emerging S&T, it is ideal if all parties can at least agree on the relevant data to be included in review, even if analysis methods and conclusions are the subject of debate.

Working group models

Open ended working groups (OEWGs) involve a similar premise to advisory committee models, but are formed to address a specific area of interest. Unlike advisory committees, however, they are typically more fluid in their structure, both in terms of their membership and the task for which they are created. OEWGs have been suggested within the context of the BTWC for the purpose of, for example, discussing compliance issues.[39] In 2016, Graham Pearson suggested further that an Open-Ended Experts on Science and Technology Working Group (OEESTWG) could include both States Parties willing to participate, and members of the expert academic and scientific community.[40]

This idea is reminiscent of a broad range of other situational, or *ad hoc* groups that are created in national and international fora to examine emerging issues in science and technology. The United States' National Academies of Science committee structure deals with emerging issues under their remit as requested by the larger US policymaking sphere—these committees are largely for the express purpose of examining one issue. Other groups such as the InterAcademy Partnership, the European Academies Science Advisory Council, and Australian National Health and Medical Research Council assign working or *ad hoc* groups to issues of significance, including biosecurity and biosafety.

The central advantage of working group models are their responsiveness. This makes them relatively cheap to run, and flexible to plan in light of emerging changes. Flexibility comes at the cost of consistency in analysis between committees, and a lack of institutional memory over time. Moreover, by only forming for a single issue at a single time, their analysis may quickly lose its relevance in rapidly moving fields.

A challenge for OEWGs or other working groups is twofold. On the one hand, creating *ad hoc* groups could be laborious if consensus is required for each group, or if side-constraints such as geographical representation limit the selection of members in an otherwise narrow field of candidates. S&T review should reflect the consensus of the states parties, but deciding, say, on a series of review topics at each Review Conference could potentially be unwieldy, and also act as a bottleneck around new issues that arise in the Intersessional Process—undermining the chief advantage of *ad hoc* groups, which is sensitivity to change.

On the other hand, working groups that do not rely on representation may become dominated by stakeholders that have the resources to engage with such a group. This is a concern for political feasibility, of course, but might also represent a threat to the validity of the conclusions that such a group could reach. In particular, what constitutes a threat or benefit may change by region or country. Such a problem is surmountable (e.g. by arranging for support of national involvement by some States Parties by better resourced nations), but is worth bearing in mind in coming to decisions about the form of a particular review mechanism.

Peer-review

SABs and OEWGs are the typical fare of BTWC recommendations, but other review modalities exist beyond them. S&T reviews may be research in their own right, and thus submitted to peers within a community for comment and validation before publication. In the broadest terms, peer-review is the standard model for reviewing evidence in academic research. This is to be distinguished between the peer-review model of confidence building championed, *inter alia,* by France at recent meetings of the states parties to the BTWC, which is "the systematic examination and assessment of the performance of a State by other States, with the ultimate goal of helping the reviewed State improve its policy making, adopt best practices, and comply with established standards and principles."[41]

The systematic review, now ubiquitous in medicine and health policy, is a highly specialized form of S&T review. The related health-care technology assessment framework is dominant in providing advice to policymakers on the efficacy, safety,

and cost-effectiveness of therapeutics and medical devices. A paradigm example of this method of review is the Cochrane Collaboration, a non-governmental organization that organizes the systematic review of medical research.

Not all S&T reviews conducted in this way are subject to the formal review mechanisms common to academic journals, but are part of a broader class of inquiry into science and technology using systematic, scholarly methods. A recent attempt by Gryphon Scientific to systematically examine the risks and benefits associated with gain-of-function studies involving the creation of novel, pandemic forms of influenza, severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS) coronaviruses is a testament to the systematic treatment of biosecurity issues.[42] While Gryphon's work did not undergo formal, double-blinded peer review, it did undergo significant peer commentary before release in draft form, and revision in response to public comment.

In the context of emerging S&T, the depth of peer-reviewed research of the kind the Gryphon risk and benefit analysis represents would be useful in mapping the trajectory of emerging technology, and examining the sensitivity of developments to institutional and political change. The data for this, and the analysis, moreover, would be available for scrutiny by stakeholders and decision makers.

The key tradeoff in a peer review mechanism is one of incentive. Unless commissioned by external bodies (which can be expensive), these reviews are typically researcher-initiated. This means that unless there is a compelling professional reason to pursue such a review, interest may be low among researchers whose expertise is necessary to complete such reviews. Moreover, once a review is complete, there may be little incentive to update a review (unless further benefits are provided to the researchers). Given the additional logistics that may be required to not only review available science and technology, but provide an analysis of that technology in terms of its implications for the BTWC—a task to which bench scientists may not be ideally suited, requiring additional collaborators—this inertia could pose a serious barrier to peer-reviewed research that contributes to an S&T review process.

Peer review, moreover, is a costly process in terms of the time of the reviewer. The Gryphon report on a subset of experiments covering three viruses exceeded 900 pages—many journals struggle to find reviewers for papers that are 5-10 pages long. This cost may be alleviated by opening comment to the public, at a potential tradeoff to level of expertise or the depth of criticism, depending on the demographics of the respondents.

Wikis

Wikis are websites that allow large numbers of users to collaborate on the structure and content of documents. It allows for changes to be tracked, edited, or rejected, and for discussion about proposed changes to pages. Wikipedia is the paradigmatic example of the wiki. In 2008, Jez Littlewood posed a civil society wiki to collect and develop proposals for the 2011 Seventh Review Conference to the BTWC.[43]

A central advantage of wikis is they are incredibly adaptive to change. For example, the "United Kingdom European Union membership referendum, 2016" Wikipedia article—which only describes the referendum, not the post-referendum political process—was updated *thousands* of times in the week of the referendum. Sporting events and national elections are often updated on a minute-by-minute basis.

Changes to a wiki are transparent, and many wikis maintain forums for the purpose of justifying and contesting changes. As online documents, moreover, wikis are not subject to the economies of scale that the other models for review are—wikis can have, in principle, hundreds if not thousands of collaborators. This is ideal, all other things being equal, in the context of diverse life sciences communities.

Information in a wiki is subject to rapid change, and even total revision, without notice. While it is possible to track changes to a wiki, these are often done through separate pages of change logs, which means that small but significant changes will go unnoticed unless a user has the wherewithal to monitor changes carefully.

Wikis are also subject to vandalism, propaganda, disinformation, and misinformation. In Wikipedia, subjects such as national elections and vaccinations have been vandalized for political reasons. These incidents often lead to the need to

"lock" wikis, preventing them from being modified. This represents a barrier to engagement with potentially valuable stakeholders.

Reliability is an issue for open databases that are open to change by large groups of unverified or pseudonymous individuals. Inertia is also an issue, as volunteers typically provide information. This is a greater issue than with peer-review mechanisms, as incentives (e.g. funding streams, professional norms) that promote topics of importance are absent in wikis.

Hybrid Models

S&T review can and often do incorporate different aspects of different models in pursuit of its aims. McLeish and Trapp, for example, note that an interaction between the diplomatic/policy and scientific community that speaks to hybrid work. The CWC's SAB requested from the International Union of Pure and Applied Chemistry (IUPAC) to support an S&T review for the First CWC Review Conference.[44] This brings together advisory and working group models: the SAB retained their authority, but the IUPAC was able to develop recommendations that ultimately resulted in an SAB report at the First Review Conference, and a repeat report at the Second Review Conference.

Review modalities are thus not mutually exclusive, and should not be treated as such. Each modality leaves room for the combination of some or all elements of the others to address issues of feasibility, desirability, and cost. It is to these considerations we now turn.

Discussion

Whose Review?

One of the significant questions raised by the above methods is the role of the States Parties in a review mechanism. The typical role imagined for the States Parties is as the conveners or ultimate responsible parties for a review. In some cases, this role is more or less self-evident: an SAB-like advisory committee would be governed by the States parties, and may require representation based on world region. This involves states parties by ensuring membership – or membership of regional partners – in the operation of S&T review.

A central concern here is arguably legitimacy of process and outcome. Given the international scope of a review mechanism, and the security implications of the discussions in an SAB, representation—and states parties involvement in general—provides legitimacy to a diplomatically sensitive process. Legitimacy is a *pro tanto* requirement for any S&T review, and we typically view this in terms of a formal international process governed by States parties.

Legitimacy *qua* States Parties involvement, however, might not be required in two important cases. The first is if the above conception of legitimacy is contested. The life sciences have a strong relationship with government through, for example, funding sources. The relationship between the contemporary life sciences and national security, however, is different to that of chemistry or physics: life scientists have not given up their autonomy in the same ways that other scientists have in the pursuit of national security aims.[45] We might think nongovernmental stakeholders will treat transparent of processes and methods outside of a State controlled mechanism as legitimate in a way a State-controlled process can't be.

The outcome of the Eighth Review Conference provides another reason to not treat states parties involvement as a strict requirement for S&T review. The Eighth Review Conference resulted in a failure to secure a comprehensive, continuing S&T review mechanism beyond the Review Conference—which occur infrequently enough that most agree it is insufficient as a sole point of review. It also failed, unlike other Review Conferences, to secure an intercessional program of work to advance the Convention, with the exception of a meeting of the states parties in December 2017. Given this failure, we might think that a legitimate *qua* state run S&T review mechanism is, if not impossible, a poor bet.

In the absence of sufficient political will, it may fall to civil society to continue the work of developing a robust S&T review mechanism while continuing to campaign for an explicit, frequent mechanism within the BTWC. It is widely understood that the states parties were unable to reach a consensus on S&T review in the most recent BTWC Intersessional Period and resulting Review Conference. The reasons for this are, in part, a lack of consensus on what such a process ought to look like,

but are importantly because of a breakdown between the states parties that is broader than the issue of S&T review. Given this, a civil society group might plausibly begin the work of S&T review independent of the States with an eye to being incorporated into a State process in the event that the aims of the Convention are advanced, or work in parallel with an official BTWC process at a later time.

A hybrid model could operate both with the States Parties, or with the states parties role replaced with an international steering group drawn from interested and/or representative members from civil society. VERTIC has suggested a "Scientific and Technical Advisers' Network" as a mechanism to collate, review, and disseminate information on S&T developments with implications for the convention, and how those developments might be addressed in international arenas, national regulations, administrative undertakings, or new legislation.[46] While this network intimates that such a network would function within the BTWC framework (for example, through a member of the ISU with scientific training), nothing about the structure of such a network—which arguably resembles a hybrid of working group and peer-review models—requires States Parties oversight.

If civic society were placed with the burden of directing S&T review, independent States Parties agreement, acceptability to states would become less important. Producing information that is actionable by states would still be vital, and the process and makeup of S&T review would need to consider legitimacy concerns when providing information or advice. But the precise makeup of S&T review could be could become less dependent on the specific political goals of states within the context of the BTWC.

Costs

Cost where will depend on the level at which governance of a civil society S&T project would require central administration and coordination. This coordination could be in principle very thin, utilizing existing civil society actors that provide S&T reviews to collate information. This would conceivably also alleviate concerns about direct costs, given that civil society is strongly engaged in behavior that could be

leveraged into a review mechanism, and—particularly with the rise of groups concerned about so-called "global catastrophic risks"—may grow over the coming years.

In the absence of States Parties support, civil society actors may struggle with costs. While states may certainly have financial limits, or lack political incentives to contribute to S&T review, the relative burden on civil society actors is undoubtedly greater due to fewer resources. As above, costs in the $250,000 USD range have been identified as a challenge for some S&T reviews. This might be burdensome for states, but could be prohibitive for civil society actors.

Continual Review: An Illustrative Hybrid Model

S&T review to address rapidly changing, dual-use, or convergent technologies needs to be responsive and flexible, account of uncertainty, and be sensitive to change. They need to present information in a way that allows the states parties to interrogate particular S&T as needed, and respond to analyses through the Convention and its implementation. This speaks to a high degree of transparency about the data used, and tools of analysis in reviewing S&T.

Each of the above models have differing degrees of flexibility, and trade off against this flexibility for a range of other features. These features—representation and institutional memory, to name two—are valuable in their own right. Weighing these against the technical demands of S&T review will inform the structure of a review mechanism.

An example of a potential hybrid model is a "Continual Review Committee" governed by steering committee representative of the states parties and expertise in science, technology, and policy. The steering committee would set out guidelines on the *structure* of S&T reviews, provide a list of review topics for consideration in coordination the states parties recommendations, administer the review of submitted S&T reviews, and update the Meeting of states parties on findings of those reviews.

The states parties would set out the committee's roster and mandate. The committee, ideally, would be supported by the Implementation Support Unit (ISU). While this would require a modest expansion of the ISU, a steering committee maintained by the states parties, would retain an impartial, international position, and leverage the existing infrastructure in the BTWC to efficiently allocate reviews. This would serve the dual function of generating buy-in from member states, while reassuring States concerned about the potential for discriminatory practices in the context of the BTWC that their voices and views on S&T Review will be represented.

Reviews themselves could be commissioned, or provided by independent researcher groups and organizations. The steering committee would confirm that reviews meet established guidelines, and coordinate review of submissions by other researchers, State Parties, or other important groups. Reviews may be specific technical areas (e.g. synthetic biology, neuroscience, cybersecurity), but also on larger trends affecting S&T—civil-military interactions, emerging challenges in armed conflict, and so on. State-proposed reviews covering specific implications for nations or geographical regions would also be useful, highlighting the unique challenges the misuse of biological technologies can present.

The *review of these reviews* could be accomplished in two separate ways. The first would be through a model of conventional peer-review, utilizing a roster of independent expert reviewers nominated from a representative pool of expertise and regions. Draft reviews could also be open to wide-ranging public commentary. Both options could, alternately, be pursued at different stage of development of reviews.

Reviews, primary data (where possible) and methodological notes could be maintained on an open-access website. This would serve as a centralized platform for other researchers to interrogate the S&T reviews for their own purposes. Depending on the fine structure of this process, reviews could be considered as published material with their own DOI to incentivize the submission of reviews as contributions to the career publications of researchers.

Interested parties could update or contest reports, or provide significant reanalysis short of a complete review by submitting addenda to the steering committee. Those addenda would be reviewed, and uploaded in a format that made them easily accessible to readers of the initial reviews. These addenda would assist in keeping reviews responsive to developments in S&T.

The steering committee would provide an annual report to the states parties on a) the state of S&T with implications for the Convention, and b) the overall state of the review process, and emerging issues in need of review. The states parties could then respond to topics and issues in need of addressing by the steering committee.

Benefits

This hybrid model would be responsive to S&T both contrary to and benefiting the BTWC. The degree to which it is responsive depends on the degree of scrutiny required of submissions; responsiveness trades off against security and trustworthiness in some cases. This could be adjusted to an agreeable intermediate point between standing committees and wikis at the wishes of the states parties.

By codifying the analysis in reviews, the steering committee can render S&T review transparent to external stakeholders, and consistent between reviews. As analysis methods change, the steering committee can solicit reanalysis of existing S&T reviews. The explicit nature of analysis methods serves as a component of the institutional memory implicit to the review process. Other methods, such as staggering the replacement of members of the steering committee, would also preserve the institutional memory of the mechanism.

By collating data online, reviews be transparent and be subject to critical review by States, NGOs, and other stakeholders. There may be a case for some information restriction—for example, classified documents, individual testimony—but in general S&T review using open information sources should remain open. Open data will also assist related projects in public health or medicine that might benefit the Convention.

Existing methods for determining the representation of the steering committee can be utilized. In the April Preparatory Committee Meeting for the Eighth Review Conference, for example, Russia suggested a review committee comprised of members of the Non-Aligned Movement and Other State members, Western Group members, and Eastern European Group members.[47] This schema could be used and tailored to the needs of the states parties. Representation of reviewers could also be ensured, as could the translation of reviews and data into a representative range of languages, to avoid (as is often the case in peer-review groups such as the Cochrane Collection) limiting reviews to geographic and professional areas that are dominated by one language group.

The ultimate benefit of this hybrid model is that it leverages global expertise that already exists in government bodies, professional organizations, NGOs, and civil society groups whose activities cover the BTWC. Several excellent reviews of specific S&T developments exist,[48] but these are typically static, one-off reviews. By coordinating and commissioning reviews, and aligning them with professional norms, there is an incentive to contribute to the review of S&T.

Challenges

The hybrid model faces a series of challenges best represented as tradeoffs between desirable outcomes. First and foremost are the costs of maintaining a permanent steering committee. The majority of this would be remuneration for committee members and infrastructure support for maintaining the information dissemination of the website.

A tradeoff may arise between the range of stakeholders that inform S&T review, and the integrity of data. In wikis, stakeholder contribution is prior to data integrity—rather than regulate submission, the standing model is to correct errors in data as they emerge. This, however, is a laborious exercise—and, given the forum the BTWC represents, may inhere risks of misinformation transmitting to reports.

Two solutions could be applied: one for full submissions, the other for addenda. Peer review submissions present a barrier to entry because they are 1) expensive in the sense that creating a full review is a time and resource-intensive task; 2) they

must pass peer review. Both limit the range of groups that submit by demanding a certain level of rigor for reviews. This need not, depending on the methodology, be a demand for a certain *quantity* of evidence, as identifying gaps in information is important for future S&T review.

Addenda are, by design, smaller submissions designed to provide periodic updates to sections of a review. They may still need to pass review, but require fewer resources to compile. Strategies for dealing with these may vary from a permissive and broad-spectrum comment policy; to those capped by number of words or figures addenda are permitted; to pre-submission inquiries to the steering committee.

Conclusions

S&T review is an important dimension of maintaining the norm against biological weapons in an era of rapid scientific change. Building a review mechanism given the unique properties of the life sciences and related fields needs to consider the question of what the aims of S&T review look like in practice. In general, S&T review should be

1. Responsive to change;
2. Representative of a wide range of data sources and stakeholder perspectives;
3. Transparent and accountable regarding its data, analysis, and assumptions;
4. When considering reviews coordinated by the States Parties, acceptable to States (including but not limited to the cost of the review).

Here, we have provided a hybrid model for review that leverages the advantages of existing models, and attempts to accommodate some of the challenges faced by S&T review in the emerging life sciences.

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