 doi:10.20944/preprints202204.0051.v1

Article

BWC Assurance: Increasing Certainty in BWC Compliance

Matthew P. Shearer[1,2*], Christina Potter[1,2], Rachel A. Vahey[1,2], Nancy D. Connell[3] and Gigi Kwik Gronvall[1,2]

[1] Johns Hopkins Center for Health Security
[2] Department of Environmental Health and Engineering, Bloomberg School of Public Health, Johns Hopkins University
[3] Department of Medicine, Rutgers New Jersey Medical School
*Corresponding author: Matthew P. Shearer (mshearer@jhu.edu)

Abstract: Following the 2001 end to negotiations on a legally binding protocol, Biological and Toxin Weapons Convention (BWC) states parties (SPs) developed entrenched positions about the necessity of a verification regime, hindering progress on treaty aims. This study aimed to facilitate dialogue on verification-related issues outside the context of those positions, using the term "assurance" to represent the degree of certainty that SPs are meeting their treaty obligations. From August 2020-July 2021, 36 interviews were conducted—16 SPs' delegations and 20 subject matter experts, representing 20 countries—and interview content was analyzed utilizing a mixed methods approach, including quantitative metrics on qualitative interview content. Interviewees' views on verification, compliance, and related concepts varied widely. Efforts by SPs to achieve common understanding on these topics could facilitate concrete progress in these important areas. While no single mechanism is sufficient to achieve verification or assess compliance, packages of mechanisms could increase assurance. There was general support for implementing assurance mechanisms, even in the absence of a comprehensive, legally binding protocol or verification regime, even among SPs for which that is the primary goal. Avenues to increase assurance among BWC stakeholders merit further discussion in the Intersessional Programme following the 9th BWC Review Conference.

Keywords: Biological and Toxin Weapons Convention; Biological Weapons Convention; BWC; biological weapons; verification; nonproliferation; nonproliferation policy; arms control; disarmament; weapons of mass destruction; WMD; biology

1. Introduction

When the Biological and Toxin Weapons Convention (BWC) entered into force in 1975, it became the first multilateral disarmament treaty to prohibit an entire class of weapons [1]. As such, it served as an example for subsequent WMD arms control, disarmament, and nonproliferation treaties, but it stands out due to the absence of an implementation framework or a system to verify compliance with treaty obligations. Other nonproliferation treaties (e.g., Chemical Weapons Convention, Treaty on the Non-Proliferation of Nuclear Weapons) have established systems and activities to implement treaty provisions and verify compliance [2,3,4] BWC states parties (SPs) pursued efforts for years to strengthen the treaty through some kind of compliance mechanism, including through VEREX and the Ad Hoc Group, but formal efforts to identify appropriate mechanisms, frameworks, and capacities stalled in 2001 when the United States withdrew its support of the Ad Hoc Group's efforts to negotiate a legally binding treaty protocol, including verification. Since that time, many SPs have repeated calls for such a protocol, but in the absence of consensus support, no progress has been made toward a comprehensive treaty implementation and verification system or many other treaty aims.

This study originated with the observation that SPs and other BWC experts use similar terms but often with different meanings, and this is particularly true for the term "verification." For example, at a side event hosted by the United States at the 2018 Meet-

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 7 April 2022 doi:10.20944/preprints202204.0051.v1

ings of Experts (MXs) on the feasibility of BWC verification [5] panelists presented the US position that the nature of biological research made it impossible to provide evidence that all biological activities in a country comply with BWC obligations or, conversely, impossible to identify and inspect all ongoing biological activities to assess their compliance. In contrast, many SPs and experts contend that verification serves to provide greater transparency and certainty regarding SPs' biological activities rather than definitive proof of compliance. Other common terms with multiple interpretations include "confidence," often associated with BWC Confidence-Building Measures (CBMs), and "strengthen," used frequently but inconsistently in terms of improving the BWC. This study aims to bring clarity to BWC discussions on these complex issues and support efforts to increase certainty regarding SPs' biological activities.

2. Assurance

Following the collapse of the Ad Hoc Group and BWC protocol negotiations in 2001, the issue of verification became even more contentious and politically charged. SPs developed entrenched positions regarding a legally binding protocol and verification, with the majority expressing explicit support and the United States largely standing alone in public opposition. The practical and political connotations associated with the term "verification" and its narrow but varying definitions make it difficult to hold substantive debate on issues related to BWC compliance. This study was designed with two principal aims. The first was to examine how SPs and other stakeholders understand verification and related concepts. While it was highly unlikely that this study would identify consensus definitions, documenting the diversity of perspectives on these important and complex topics could shed light on barriers to constructive debate. The second aim was to identify mechanisms, including activities and information, that could provide increased certainty regarding SPs' adherence to their BWC obligations, particularly those that merit further debate in the Intersessional Programme (ISP) following the 9th Review Conference.

The term "assurance" was selected as the basis for this study to frame the discussions outside the narrow context of contentious terms like "verification" and "confidence." This is not the first use of the term [6] but assurance has not historically been a major topic in BWC discussions. By focusing on a relatively uncommon term, this study endeavored to facilitate constructive dialogue on verification-related concepts without limiting the conversations to specific definitions or connotations. To encourage broad discussion of these concepts and mitigate the risk of getting mired in similar challenges faced with terms like "verification" and "confidence," the researchers did not assign an explicit definition for "assurance." Rather, it was described broadly as the degree of certainty that SPs are acting in accordance with their BWC obligations. In addition to assurance-related concepts, the study addressed mechanisms that could increase that degree of certainty. Framing the conversations outside the context of a comprehensive, legally binding protocol or verification regime helped maintain focus on the relative merits and limitations of—and the degree of support for—the mechanisms themselves. The researchers also raised the possibility of implementing assurance mechanisms outside of a comprehensive verification system to gauge interest in an incremental approach to assurance [7].

Notably, both the United States and Russian Federation[1] included the term "assurance" in their national statements during the 2020 Meeting of States Parties (MSP) [2,] [8,9] It is inappropriate to speculate on the degree to which the interviews with representatives from these delegations influenced their use of this term; however, its inclusion in a national statement or working paper by two of the three BWC depository states for the first time since at least the 8th Review Conference (2016) could signal interest in alterna-

[1] Unofficial English translation.

[2] Postponed to 2021 due to the COVID-19 pandemic.

 doi:10.20944/preprints202204.0051.v1

tive means to increasing certainty regarding SPs' compliance. In this context, dialogue on assurance is intended to occur in parallel with, not as a substitute for, debate on a legally binding protocol, verification, and related concepts. With the 9th Review Conference scheduled for 2022, SPs have the opportunity to define the scope of formal debate on BWC issues for the next 5 years. This article presents findings that address the diversity in how verification, compliance, and related concepts are understood in the context of the BWC as well as prospective assurance mechanisms that merit further debate, which can provide valuable insights as SPs consider the format and topics for the next ISP.

3. Methodology

3.1. Interviews

From August 2020-July 2021, a series of 36 semi-structured, virtual interviews were conducted with key informants representing a variety of perspectives on the BWC, including individuals affiliated with BWC delegations and independent SMEs. SMEs included individuals affiliated with academic institutions and other civil society organizations, the BWC Implementation Support Unit (ISU) and other nonproliferation organizations (e.g., Organisation for the Prohibition of Chemical Weapons [OPCW]), and former BWC delegation members who provided their individual perspective. Prospective interviewees were identified based on relevant expertise and institutional affiliations, including participation in BWC and other nonproliferation meetings, utilizing purposive sampling with a view to including diverse geographic, political, and demographic perspectives.

The interview guide (Supplement) was developed based on results of an informal literature review, including historical accounts of the BWC protocol negotiations and research and commentary on BWC verification and other WMD nonproliferation regimes, and the researchers' personal experience related to BWC proceedings, statements, and debate. The first portion of each interview focused on definitions of five key concepts and vocabulary under the umbrella of assurance—"verification," "compliance," "confidence," "monitoring," and "strengthen"—asking the interviewees how they define or understand these terms in the context of the BWC. Focusing on these terms enabled the researchers to characterize how stakeholders approach these issues and provided a foundation for the second half of the interview. The second portion focused on how to increase assurance, including specific assurance mechanisms; historical changes and trends in the BWC, including technological advancements and geopolitical shifts; and the relationship between BWC verification and other nonproliferation regimes. While the interview guide included core questions and topics, interviewees were allowed to direct the conversation based on their individual experiences and priorities. All interviews were conducted on a not-for-attribution basis to promote candor and transparency. Multiple members of the research team took detailed notes during each interview, and audio was recorded—with interviewees' consent—to supplement interview notes.

3.2. Mixed Methods Analysis

A mixed methods approach was employed to analyze interview content, systematically and rigorously documenting the landscape of perceptions associated with BWC assurance—and related concepts—and assurance mechanisms. The analysis was conducted in three stages: qualitative coding of interview notes using NVivo qualitative coding software (Release 1.5.1), quantitative analysis to identify priority topics, and targeted thematic analysis of coded interview notes. While quantitative analysis was used to identify priority themes, the methodology was not designed to yield quantitative results, such as the prevalence of specific perspectives among BWC delegations or SMEs.

3.2.1. Codebook Development and Thematic Coding

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 7 April 2022 doi:10.20944/preprints202204.0051.v1

The research team developed the initial thematic coding framework during the second half of the interview process. Team members collaboratively added themes based on topics discussed during previous interviews, and additional themes were added as they emerged in the remaining interviews. At the end of the interview process, the researchers collectively reviewed interview notes to identify remaining themes and organized the themes into a hierarchy to facilitate coding efforts.

All notes from a given interview were assigned to a single coder, and interviews were distributed evenly among the coding team. Three team members conducted all coding. The coders piloted the coding framework on a subset of interviews and reviewed the results to add, edit, and reorganize codes in the final framework (Supplement) before conducting the final coding on all interviews. As new themes emerged during the coding process, new codes were added to the framework, and the coders reviewed completed interviews using the new codes. The final coding framework included higher-level, topic-focused categories such as terminology and definitions; data collection, reporting, analysis, and sharing; site visits and expertise engagement; national implementation; BWC articles; dialogue and diplomacy; funding; actors; real-world examples; and historical changes. Additional categories—including qualifiers, feasibility, sentiment, and motivations or outcomes—helped document perceptions related to other topics. Each interview was also classified by interviewee type (i.e., SP, SME). All coding was reviewed by at least one team member for quality assurance, and coding discrepancies and concerns were discussed and resolved by consensus among the coders. Interview note text could be assigned multiple codes (i.e., co-coded reference), which provided the opportunity to identify potential associations between those codes.

3.2.2. Quantitative Metrics

Quantitative data helped identify priorities for the final thematic analysis. Using NVivo and Microsoft Excel, quantitative metrics were generated for all codes in the framework regarding the frequency with which they were discussed. These metrics included the number of coding references (i.e., individual chunks of coded text) corresponding to each code and the number of interviews in which each code was discussed, and quantitative metrics were generated for both individual codes and co-coded pairs (i.e., two codes assigned to the same text). Group-specific metrics for SP and SME interviews were also generated to identify themes discussed more often in one group than the other, which could signal differences in how SMEs and SPs prioritize certain topics. To account for different numbers of SP and SME interviews, the metrics were weighted inversely by the relative proportion of interviews in each group. Priority themes identified through quantitative analysis included individual codes and co-coded pairs present in at least 10 interviews and those with a difference in weighted interview frequency of 5 or greater between SPs and SMEs.

3.2.3. Qualitative Analysis

For the final thematic analysis, a detailed review was conducted of the coded text corresponding to priority codes. Priority codes included those identified through quantitative analysis as well as a subset identified *a priori* related to topics of interest during past BWC-related meetings and literature, based on the researchers' expertise and observations, and statements that stood out during the interviews. This *a priori* list of themes enabled the researchers to identify important comments that were not prevalent across numerous interviews.

The Johns Hopkins University Bloomberg School of Public Health Institutional Review Board determined that this study did not constitute human subjects research (IRB00011207).

4. Findings

4.1. Interviews & Quantitative Analysis

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 7 April 2022 doi:10.20944/preprints202204.0051.v1

A total of 36 interviews were conducted: 16 with individuals who work on or with BWC delegations (SPs) and 20 with SMEs (Table 1), representing 20 countries across 6 continents as well as all 3 BWC Regional Groups (Figure 1). One interviewee invited to represent a SP elected to participate in her/his individual capacity, but s/he was able to provide insight into how that delegation thinks about these important topics. One SME requested not to be listed as a participant, and one SP declined to be recorded. To promote geographic and political diversity, invitations were sent to more than 90 e-mail addresses, corresponding to individuals and diplomatic missions in more than 30 countries as well as multiple UN offices. Thematic coding was performed on 93 sets of interview notes, resulting in 10,307 total coding references and 23,819 co-coded references. Of the 219 codes in the final coding framework, 134 were addressed in at least 10 interviews, as well as 109 co-coded pairs (Supplement).

Table 1. Interview participants, affiliations, and countries. One participant declined to be listed.

Name	Organization	Country/Location
Dr. Patrick Boyle	Head of Codebase, Ginkgo Bioworks	United States
Dr. Gerald Epstein	Distinguished Fellow, Center for the Study of Weapons of Mass Destruction, National Defense University	United States
Daniel Feakes	Chief, BWC Implementation Support Unit	Switzerland
Dr. Jonathan Forman	Science and Technology Advisor, National Security Directorate, Pacific Northwest National Laboratory	United States
Ljupčo Gjorgjinski	Senior Fellow, DiploFoundation & Senior Advisor for Multilateral Affairs, Ministry of Foreign Affairs	North Macedonia
Dr. Chandre Gould	Senior Research Fellow, Justice and Violence Prevention Programme, Institute for Security Studies	South Africa
Dr. Richard Guthrie	Coordinating Editor, *CBW Events*	United Kingdom
Ruth Hill	Counsellor, Delegation of Australia to the Conference on Disarmament	Australia
H.E. Yann Hwang	Ambassador & Permanent Representative of France to the Conference on Disarmament; Chief of BWC Delegation	France
Usman Jadoon	Director General (United Nations), Ministry of Foreign Affairs	Pakistan
Dr. Gunnar Jeremias	Head, Interdisciplinary Research Group for the Analysis of Biological Risks, Carl Friedrich von Weizsäcker Center for Science and Peace Research, University of Hamburg	Germany
Col. Dr. Rame Khasawneh	Royal Medical Services, Jordan Armed Forces	Jordan
Dr. Serhiy Komisarenko	Presidium Member, National Academy of Sciences of Ukraine & Director, Palladin Institute of Biochemistry	Ukraine
Dr. Alex Lampalzer	Deputy Chief & Political Affairs Officer, BWC Implementation Support Unit	Switzerland
Dr. Filippa Lentzos	Co-Director, Centre for Science and Security Studies, King's College London	United Kingdom
Alexander Lisenkov	Expert, Department of Arms Control and Nonproliferation, Ministry for Foreign Affairs	Russian Federation
Dr. Jez Littlewood	Policy Analyst, Government of Alberta	Canada
Lyu Xiaodong	Deputy Director, Nonproliferation Division, Arms Control and Disarmament Department, Ministry of Foreign Affairs	China
Dr. Irma Makalinao	Professor and Coordinator, Chemical, Biological Radiological Nuclear Health Security, Department of Pharmacology and Toxicology, College of Medicine, University of the Philippines Manila	Philippines

 doi:10.20944/preprints202204.0051.v1

Dr. Anastasia Malygina	Associate Professor, Strategic and Arms Control Studies Master's Degree Program, St. Petersburg State University	Russian Federation
Alonso Francisco Martínez Ruiz	Counselor, Permanent Mission of Mexico to the United Nations in Geneva	Mexico
Dr. Caitríona McLeish	Arms Control and Disarmament Research Unit, Foreign Commonwealth and Development Office	United Kingdom
Kathryn Millett	Director, Biosecure Ltd.	United Kingdom
Dr. Piers Millett	Vice President for Responsibility, iGEM Foundation & Senior Research Fellow, Future of Humanity Institute, University of Oxford	United Kingdom
Lorena Mohr	Division for Chemical and Biological Weapons Issues, Federal Foreign Office	Germany
Amanda Moodie	Policy Fellow, Center for the Study of Weapons of Mass Destruction, National Defense University	United States
Pamela Moraga	Coordinator, Disarmament, Non-Proliferation and Arms Control Unit, Permanent Mission of Chile to the United Nations in Geneva	Chile
Kazuhiro Nakai	Deputy Permanent Representative, Delegation of Japan to the Conference on Disarmament	Japan
Dr. Mary Onsarigo	Senior Analyst, National Commission for Science, Technology, and Innovation	Kenya
Dr. Alexandra Phelan	Assistant Professor, Center for Global Health Science and Security, Georgetown University	United States
Dr. Brian Rappert	Professor, College of Social Sciences and International Studies, University of Exeter	United Kingdom
Dr. James Revill	Head, WMD Programme, UN Institute for Disarmament Research	United Kingdom
Konstantin Vorontsov	Acting Deputy Director, Department for Nonproliferation and Arms Control, Ministry for Foreign Affairs & Head of BWC Delegation	Russian Federation
Dr. John R. Walker OBE	Senior Research Fellow, Royal United Services Institute, the European Leadership Network, and Department of Science and Technology Studies, University College London	United Kingdom
Dr. Zalini Yunus	Deputy Director General, Science and Technology Research Institute for Defence, Ministry of Defence	Malaysia
Dr. Jean Pascal Zanders	Founder, *The Trench*	France

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 7 April 2022 doi:10.20944/preprints202204.0051.v1

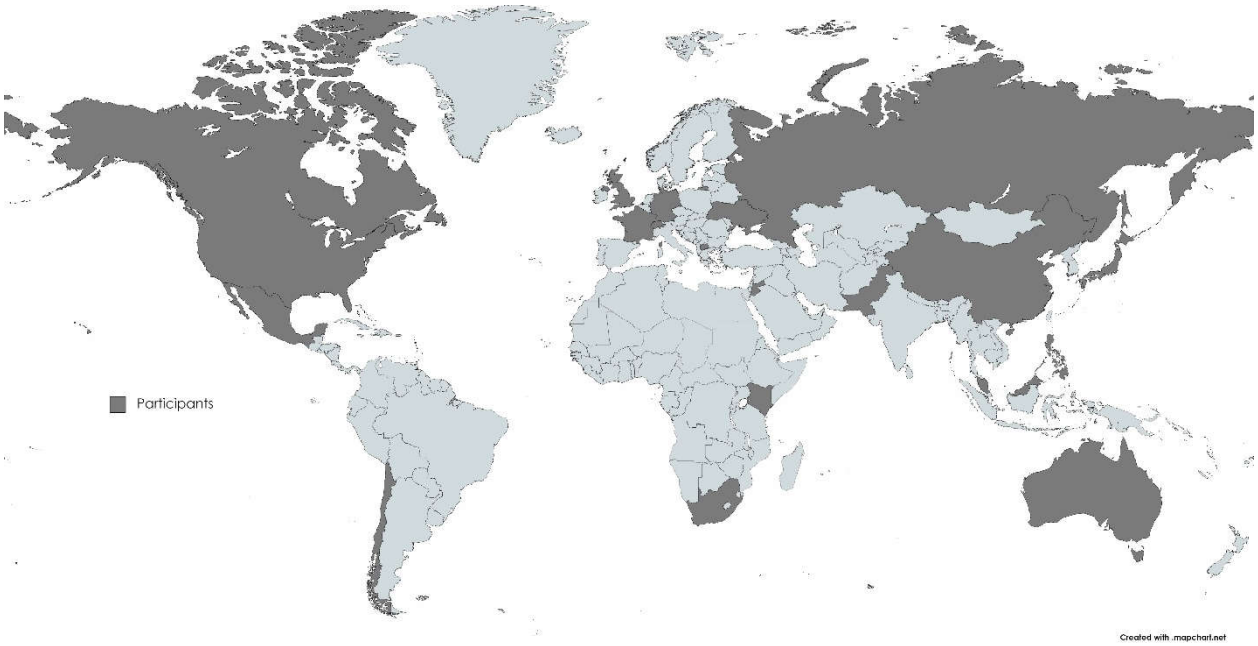

Figure 1. Geographic representation of study participants.

While quantitative approaches were used to identify priority topics for further analysis, this study was not designed to yield quantitative results. The findings attempt to reflect the relative frequency that interviewees discussed certain topics or expressed certain viewpoints (e.g., "some" or "multiple" interviewees); however, these statements reflect only the content of the interviews and are not necessarily representative of BWC SPs or the broader BWC community.

4.2. Terminology

The first portion of the interviews focused on understanding how stakeholders define and approach core concepts under the umbrella of assurance. Interviewees expressed a broad range of views on these terms, without consensus emerging around particular definitions. Notably, there was considerable overlap in how interviewees discussed and defined the terms below, which illustrates the importance of establishing common language around these important and complex topics.

4.2.1. Verification

"Verification" exhibited the most diverse perspectives, some in direct conflict with one another, without any clear definition or understanding of this term. Interestingly, one SP indicated that "verification" is already an established term, with the definition set during the BWC protocol negotiations, whereas others noted that there is no consensus or that the definition has evolved over time. One SP explicitly discussed how some SPs use the ambiguity around verification as a smokescreen to stoke confusion or provoke a response, and s/he argued that a common understanding would be beneficial in BWC discussions. Both SPs and SMEs described a myriad of approaches to the concept of verification, including its purpose, scope, feasibility, and associated activities.

For some interviewees, verification would need to provide concrete evidence that no nefarious activities are taking place, similar to other nonproliferation treaties. These individuals argued, however, that it is not technically feasible to achieve this standard for biology. Others viewed the value of verification in terms of increasing transparency and confidence, which permits a higher degree of uncertainty but enables formal implementation of mechanisms that are not currently part of the BWC. The decentralized nature and democratized access to biological equipment, technology, supplies, and pathogens, coupled with biological organisms' ability to replicate, make it impractical to

 doi:10.20944/preprints202204.0051.v1

apply "material accountancy" approaches used for other nonproliferation treaties to BWC verification [10]. Further, the "dual-use nature" of biology makes it difficult to distinguish appropriate and nefarious activities. In fact, one interviewee commented that verification would be a straightforward process if there were a clear delineation between offensive and defensive biological activities. Without practicable options to concretely assess biological activities, there will always be a relatively high degree of uncertainty, and the acceptable degree of uncertainty for BWC verification remains a point of contention, and the purpose of verification drives the acceptable degree of uncertainty in these assessments.

Interviewees also disagreed regarding the scope of verification, including what exactly would be verified. One of the more straightforward approaches is verifying the accuracy of SPs' declarations, including on facilities, equipment, activities, or pathogens present or in use, like some other nonproliferation treaties. Alternatively, verification could apply to assessing SPs' compliance with their BWC obligations—one of the more common perspectives in our interviews. In fact, one SP commented that compliance assessment is impossible without a means of verification. But even within the scope of compliance assessment, interviewees differed in terms of how they applied various treaty obligations to compliance. Some focused on BWC prohibitions—or negative obligations—such as those in Articles I-III, while others included positive obligations as well, such as national implementation under Article IV, international support under Articles VII and X, and required reporting or declarations. Some interviewees also discussed "internal verification" in the context of SPs assessing their own compliance, as way to ensure the effectiveness of national implementation efforts. These interviewees generally took a broader view of verification, in terms of all treaty provisions and not just the nonproliferation obligations. Beyond compliance assessment, some interviewees discussed additional benefits of verification, such as deterrence value, as verification activities would increase the difficulty of concealing prohibited activities. Certain verification activities could also potentially support investigations of suspected violations of the BWC, including microbial forensics or attribution for suspected deliberate biological events. The scope of a verification regime dictates the activities required to implement it.

Several interviewees discussed verification as a process, as opposed to an endpoint. From that perspective, verification refers to a series of ongoing, long-term measures to maintain and assess compliance, rather than a goal SPs can achieve. These interviewees emphasized the need for a continual cycle of information sharing and follow-up to provide updated assessment regarding ongoing activities and emerging capabilities. Such a process would require a systematic approach, including defined structures and standards for data collection, analyses, and interpreting results or determining compliance. Notably, interviewees indicated that each step of this process introduces additional layers of subjectivity and opportunity for politicization, which further complicates compliance assessment efforts.

While questions remain regarding verification, the concept remains important for many stakeholders, including many SPs. Numerous SPs indicated that implementing a verification regime as part of a legally binding treaty protocol is one of their highest priorities. For them, verification is a core component of the BWC, and arms control treaties more broadly, and one SP argued that verification is necessary to address compliance in a legal sense.

4.2.2. Compliance

The most common description of compliance was in the context of adhering to treaty obligations, but as with verification, there was considerable variation in the scope of how interviewees viewed those obligations. Obligations ranged from those explicitly outlined in the treaty text to consensus and politically binding agreements among SPs (e.g., at Review Conferences) to the more nebulous "spirit of the treaty," which broadly encompassed the norm against biological weapons. Some interviewees also indicated

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 7 April 2022 doi:10.20944/preprints202204.0051.v1

that there is a subtle difference between a SP *operating* in compliance with the treaty and being *assessed* as in compliance, which reflects a distinction between actions or self-assessment and external assessments. Like verification, the scope plays a major factor in the mechanisms needed to ensure or assess compliance.

The most substantial discussion in the context of compliance addressed which specific aspects of the treaty are applicable, or alternatively, the distinction between noncompliance and treaty violations. Some interviewees viewed BWC prohibitions (e.g., under Articles I-III) as the core of the treaty, and noncompliance with these obligations would constitute a violation or breach of the treaty. In contrast, failure to comply with *any* provision, including positive obligations (e.g., under Articles IV, VII, and X), would be considered noncompliance. From this perspective, treaty violations or breaches are a more egregious subset of noncompliance. Some of these interviewees also discussed a third class—technical noncompliance—that covers inadvertent noncompliance or minor aspects of the treaty (e.g., late or incomplete reporting). Notably, while these interviewees emphasized nonproliferation as the core of the treaty and prioritized prohibitions for verification, they acknowledged that all obligations are important. Conversely, other interviewees applied compliance to the treaty as a whole, placing similar importance on all BWC provisions without distinguishing between noncompliance and violation. SPs inevitably weight treaty obligations differently, based on their national priorities, which can be a barrier to consensus on compliance assessment.

4.2.3. Confidence

Interviewees discussed confidence in less specific terms than verification and compliance. For many, confidence was closer to a feeling or perception than a clearly defined standard or process. Interviewees most often discussed it in the context of SPs' compliance with their BWC obligations, but in the context of the BWC's ability to fulfill its intended purpose and reinforce the norm against biological weapons. Many factors contribute to the sense of confidence, including conditions both within and without the BWC. Confidence generally includes a degree of trust, but for some interviewees, trust must be accompanied by supporting data or a concrete demonstration in order to yield confidence. It derives not only from a SP's desire to meet its treaty obligations, but also its capacity to do so. One SP emphasized that trust needs to be demonstratable and grounded in evidence.

Interviewees often discussed confidence in the context of CBMs, and the close association of this concept with a specific BWC tool illustrates part of the motivation for this study. Not surprisingly, CBMs aim to build confidence regarding SPs' biological programs and activities, but numerous interviewees noted that they have major limitations. CBMs were designed to increase transparency and facilitate information sharing regarding relevant biological activities, but interviewees highlighted low participation and challenges with CBM report completeness and accuracy as barriers to improving confidence. Some interviewees, including SPs, disagreed regarding whether CBMs are voluntary or mandatory, and several indicated that voluntary CBMs have less value, both in terms of encouraging participation and the quality of report content. Generally, CBM participation is low, although SPs set a record in 2021 with 92 submissions—surpassing one-half for the first time [11]. The number of submissions is increasing slowly, but many CBMs remain hidden from public view. Several SMEs emphasized that this impedes civil society efforts to monitor SPs' activities. All CBM submissions are available to SPs, but SPs must elect to make theirs available to the public. Interviewees also identified the absence of a systematic effort to analyze CBM report content as a limiting factor in the ability to make use of the data. Many SPs do not have the resources to analyze annual submissions, nor does the ISU, and interviewees indicated that the information itself has limited value in terms of building confidence without associated analysis, such as to identify changes from previous reports or longer-term trends.

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 7 April 2022 doi:10.20944/preprints202204.0051.v1

Whereas trust and evidence support confidence, uncertainty and ambiguity drive mistrust and decreased confidence. Multiple interviewees emphasized that information sharing and transparency can provide both evidence and increased trust that contribute to enhanced confidence; however, when SPs withdraw from cooperative activities, it has the opposite effect. Ambiguity and decreased transparency breed mistrust and concern, which not only affects confidence, but can bleed into other aspects of BWC engagement or other international fora. Several interviewees commented that this is currently a major concern in the BWC, and it could be hindering efforts to make concrete progress on priority topics.

4.2.4. Monitoring

While there was no consensus on the format or scope, interviewees largely described monitoring as a process for gathering information, typically in the context of SPs' biological activities. Generally, interviewees discussed monitoring as a continual or sustained process, as opposed to one-time events. The indicated that monitoring can take a variety of forms, including formal, structured processes, such as those discussed by VEREX or the Ad Hoc Group or analogous mechanisms under other nonproliferation treaties. Several interviewees lamented, however, that the BWC does not have the authority or capacity to conduct monitoring activities. Monitoring can also be implemented on an informal basis, including by SPs or civil society organizations. It can also be active or passive in nature, depending on the degree of effort required to obtain information. Active measures include inspections, site visits, or interviews, whereas passive monitoring could occur via review of reports (e.g., CBMs), declarations, or other available data. Civil society monitoring activities are often limited to open-source data. SMEs emphasized civil society's role in monitoring and accountability, while SPs focused more on civil society's ability to support the BWC (e.g., technical expertise, education and outreach). Publicly available data on exports, imports, purchases, and shipping could support civil society monitoring, but it is difficult to definitively determine activities or intent based on these data alone. One interviewee noted that proprietary processes can make it difficult to interpret these data. Multiple interviewees discussed monitoring in the context of advancements in science and technology and their potential impact on the BWC, again noting that the BWC does not currently have the internal capacity to conduct these activities. Disease surveillance could also fall under monitoring, particularly as a mechanism to identify emerging outbreaks or other events.

4.2.5. Strengthen

"Strengthen" was the most challenging term for many interviewees to define. They noted that it is used pervasively in BWC statements and discussions, but it can apply to a variety of contexts. It generally refers to some form of improvement, but it can address many topics, including the BWC treaty text or implementation, the ISU and institutional capacity, national implementation, or the broader norm against biological weapons. Notably, several interviewees associated "strengthen" with the Ad Hoc Group's mandate and noted that it can serve as coded language to refer to verification [12]. Multiple interviewees emphasized the importance of ensuring that the BWC remains nimble, resilient, and relevant in the face of emerging capabilities and threats. Some commented that the COVID-19 pandemic highlights the potential severity of biological threats and called on SPs to leverage the current attention on large-scale biological threats to stimulate necessary updates to the BWC and its implementation at the national and global levels. One SME emphasized that SPs have a short window of opportunity, perhaps 6-18 months, to make lasting change before attention wanes.

4.3. Assurance Mechanisms

The majority of interviewees, both SPs and SMEs, expressed support for the concept of assurance and identified various ways in which it could provide value to the BWC,

 doi:10.20944/preprints202204.0051.v1

including to increase transparency and mitigate uncertainty or ambiguity regarding SPs' biological activities. Assurance can build trust and confidence that SPs are abiding by their treaty obligations, which allows all SPs to realize the full benefits of biology for peaceful purposes. Even one SP that opposed assurance, in part, because it cannot substitute for verification—although that is not its intended purpose—acknowledged that it would contribute to increased predictability and decreased tensions between SPs. Assurance could also enable the BWC to adapt to evolving threats and capabilities as well as SPs' changing needs and priorities. Assurance is envisioned as a means to facilitate dialogue on concepts core to the functioning of the BWC, including verification, and alternative activities to increase certainty in SPs' biological activities in the absence of a comprehensive verification regime.

Interviewees discussed a broad scope of mechanisms they felt could increase assurance in BWC-related activities. Unsurprisingly, there was no consensus on any particular mechanism, in part, due to the diverse array of options presented over the past several decades. Multiple interviewees emphasized that there are no new ideas in the context of BWC verification, compliance assessment, and related concepts. Rather, new strategies to address BWC compliance are essentially exhausted, and current proposals are iterations of previous strategies. One interviewee emphasized that, if SPs could somehow combine all past proposals, the BWC would be perfect, but the issue remains—and often the point at which consensus fails—that the details of the implementation, purpose, and relative capabilities and limitations can differ and conflict between various proposals.

Interest in specific mechanisms and proposals varied, although some implementation details and goals did cultivate broader support across interviewees. Numerous interviewees indicated that a package or combination of mechanisms is superior to any single mechanism in terms of increasing trust, transparency, and assurance. One interviewee even argued that hundreds of mechanisms were potentially needed to address various aspects of the treaty. Interviewees generally preferred a combination of measures; however, several did note that an incremental approach to implementing assurance mechanisms is better than a stalemate in negotiations on a comprehensive package. Notably, this opinion was shared even among interviewees who ultimately desired a comprehensive, legally binding protocol, which potentially signals opportunity for negotiation on a stepwise path toward a more comprehensive system.

Multiple interviewees argued that multilateral approaches are preferable over unilateral or bilateral efforts. The value of multilateral activities increases with greater participation due to the need for standardization and reciprocal obligations among participating SPs. Consensus agreement and universal participation are ideal, but they are not necessary for assurance activities to have merit. Mechanisms with limited participation can still provide benefit in terms of increasing transparency and mitigating uncertainty. One SME noted that other nonproliferation efforts involving smaller groups of countries can stimulate change in a difficult global geopolitical climate. Humanitarian disarmament efforts (e.g., Anti-Personnel Mine Ban Convention [13], Convention on Cluster Munitions [14], regional nuclear-free zones [15]) illustrate how countries can tackle disarmament independent of an existing treaty, UN support, or the positions or actions of other counties. The collective, organized activities of a few countries can create pressure on others to follow suit and create opportunities for implementing new ideas that would not achieve consensus in larger fora. Similar principles could apply for assurance mechanisms.

Several mechanisms discussed by interviewees are already formal components of the BWC, which allows SPs to focus on improving implementation rather than negotiating new mechanisms. Numerous interviewees prioritized international scientific exchange and expertise engagement to improve assurance, and Article X obligates SPs to support capacity building and information sharing efforts internationally. Several interviewees emphasized the importance of establishing and maintaining biosafety and biosecurity capacities to mitigate the risk of accidental or deliberate biological incidents,

 doi:10.20944/preprints202204.0051.v1

including programs supported by SPs with well-developed biology and biotechnology sectors to share best practices through training and engagement. Additionally, capacity-building efforts to improve preparedness and response systems, including for deliberate events, disincentivize the use of biological weapons by making it clear that they would not achieve their objective—termed "deterrence by denial." SPs discussed Article X support for national implementation more frequently than SMEs, often focusing on support for developing and improving legislation and establishing effective oversight and regulatory systems. One SP argued support for improving national implementation was more valuable than inspecting or monitoring the current state of national programs and policies.

In terms of expertise engagement and scientific exchange, interviewees supported the MXs as a forum for substantive discussions on relevant technical issues. In the absence of a formal body of experts under the BWC, the MXs are one of the principal opportunities to introduce technical expertise. The MXs often focus on technical experts, but several interviewees also emphasized that social sciences should not be excluded, as they can address complex issues around human factors, including barriers to assessing intent. Interviewees indicated that the COVID-19 pandemic forced the BWC to incorporate mechanisms to support remote participation in meetings. Remote participation expands opportunities to engage experts that are unable to attend in person by eliminating logistical and financial burdens, such as travel and lodging, which could allow additional technical representation from many SPs, including low- and middle-income countries. Several interviewees also expressed interest in increasing participation by industry representatives, including identifying "BWC champions" that support BWC principles across relevant sectors. SMEs discussed industry representation more frequently than SPs, likely due to industry falling under the umbrella of civil society. In contrast, SPs tended to focus more on protecting private sector industry, including intellectual property, than on facilitating engagement.

CBMs are an integral mechanism for increasing transparency within the BWC, and while useful, many interviewees discussed opportunities for improvement. The record CBM participation in 2021 is notable, but participation is not the full picture. There was limited discussion of expanding CBM content, including on non-governmental activities (e.g., private sector, academic institutions) and government-sponsored work conducted in other countries. Rather, most interviewees focused on the quality of CBM submissions. CBMs leverage transparency to increase confidence in SPs' activities and programs, and incomplete or inaccurate information limits those benefits. Additionally, several interviewees expressed concern that some CBMs could be deliberately misleading, which introduces uncertainty and concern and breeds mistrust. Numerous interviewees called for CBM reports to be published publicly to encourage accuracy and increase transparency. This was discussed more frequently among SMEs, as civil society largely draws upon open-source information for monitoring and analysis. Numerous interviewees supported a capacity to analyze CBM content, to both assess accuracy and make use of the data. Not all SPs have the resources to authenticate CBM data (e.g., through intelligence services or international partnerships), track changes from previous reports, and monitor longer-term trends. Interviewees expressed interest in establishing a formal capacity to analyze CBMs and report to SPs on their content. One option is through a formal BWC body, potentially the ISU, although this is outside its current mandate. SPs could provide this capacity themselves, but ensuring independence and objectivity of the analysis could be challenging. It could also be conducted by an independent organization (e.g., civil society), but this would require full access to CBM reports, many of which are not publicly available.

Interviewees also prioritized strengthening the BWC's organizational capacity and discussed a myriad of options for doing so. Much of this discussion focused on expanding the ISU, including personnel, resources, and responsibilities, and numerous interviewees, including multiple SPs, desired a BWC analogue to the OPCW or the International Atomic Energy Agency (IAEA). Expanded ISU activities could include CBM anal-

 doi:10.20944/preprints202204.0051.v1

ysis, monitoring advances in science and technology, national implementation support, and coordinating assurance-related activities. Any additional responsibilities, however, would require funding and a mandate from the SPs. Interviewees emphasized the importance of establishing a BWC-specific capacity to monitor advancements in biology and biotechnology, and some discussed proposals for a scientific advisory mechanism or board, although there remains considerable debate regarding the scope and format for such an entity. Some of these functions could be instituted outside the ISU as well, including through independent bodies.

Multiple interviewees, including three SPs, discussed expanded use of Article V consultations to address questions regarding SPs' activities and programs. Crucially, Article V provides a mechanism, explicitly included in the BWC text, to mitigate ambiguity and concern. As a formal component of the BWC, expanded use would not face the same consensus-related challenges as implementing new assurance mechanisms. Interviewees discussed how Article V consultations could increase transparency and trust and avert larger confrontations by allowing SPs to proactively address specific questions. Interviewees also noted that Article V enables SPs to address concerns within the BWC, serving as a firewall between the BWC and United Nations. One interviewee emphasized that once Article VI is invoked, SPs essentially transfer authority to the UN Security Council, and few options exist for regaining control. The Security Council has its own political environment and power dynamics, including veto authority for permanent members, which could limit its effect in investigating suspected breaches. Several interviewees emphasized that historical use of Article V is extremely limited, and it would benefit from formalized procedures. Interviewees also indicated that infrequent use has stigmatized the consultations, and there is hesitancy among SPs to invoke Article V because it can seem accusatory. They suggested that more routine use could reduce this stigma and increase transparency to mitigate concerns and foster cooperation among SPs.

Interviewees also expressed interest in assurance mechanisms outside the formal scope of the BWC. Peer review and voluntary site visits have gained momentum, particularly since the 8th Review Conference, and several interviewees discussed their capacity to increase transparency regarding SPs' activities and foster engagement with technical experts. One interviewee commented that peer review approaches assurance from a holistic perspective by observing how SPs apply national implementation, rather than trying to detect noncompliance. Insight into national implementation can also disseminate best practices and help other SPs adopt more effective policies or practices. Peer review may increase transparency to some degree, but its voluntary nature limits that value. Host countries fully control access to facilities, personnel, activities, and information, and one SP indicated that this degree of control only provides a false sense of assurance, emphasizing that peer review cannot substitute for compliance assessment or verification.

Scientific codes of conduct have also made substantial progress since the 8th Review Conference, and interviewees suggested they can provide indirect assurance by supporting the responsible use of science. They noted that codes of conduct complement educational programs and awareness-raising regarding risks, professional and ethical standards, and nonproliferation norms, and they can establish practices for identifying and reporting concerning activities. They can be instituted at the national, organization, and facility levels and establish both top-down and bottom-up frameworks for monitoring biological activities. These ethical principles apply broadly to the scientific community, including government researchers, private-sector industry, academic institutions, and even public laboratories (e.g., do-it-yourself [DIY] biology), and model codes of conduct can be adapted for a variety of environments [16]. Interviewees also indicated the principles of responsible research can be incorporated into educational programs to build a sustainable ethical foundation among future generations of scientists and policymakers. Establishing widely accepted ethical principles could increase assurance that biology is

 doi:10.20944/preprints202204.0051.v1

being used responsibly and provide frontline monitoring for questionable activities and emerging capabilities.

Beyond existing mechanisms, interviewees also discussed a variety of activities that could be implemented in the future to enhance treaty implementation and increase assurance, most notably including on-site inspections. Inspections are a core component of many other nonproliferation treaties, and they largely aim to support compliance assessments; however, proposals vary widely in how they could be implemented for the BWC. Interviewees discussed options ranging from routine inspections, based on random or quota-based sampling, to challenge inspections for investigating suspected treaty violations, and inspections could assess anything from declaration accuracy to compliance of specific activities. Unlike the OPCW or IAEA, the BWC does not possess the capacity to conduct inspections, so SPs would need to establish that capacity, take on that role themselves, or defer to an independent body. Inspections would also require consensus on standardized procedures and analyses, potentially including the involvement of internationally accredited reference laboratories. Notably, multiple SPs emphasized that advancements in microbial forensics could facilitate efforts to trace pathogens to their source, potentially providing attribution capacity for investigators. Objective and independent analysis would be especially important for these types of inspections.

Numerous interviewees expressed support for a comprehensive, legally binding protocol that includes verification, and this remains a high priority for many SPs and SMEs. Beyond a formal verification regime, interviewees identified a broad range of activities that could be codified under such a protocol, including procedures for invoking Articles V-VII; on-site inspections, including attribution investigations; and incorporating the UN Secretary-General's Mechanism for Investigation of Alleged Use of Chemical and Biological Weapons, which is currently not a component of the BWC. Multiple interviewees also expressed interest in revisiting protocol negotiations in the modern context, accounting for geopolitical shifts and technological developments since 2001 that could alleviate previous roadblocks. Some expressed a preference for restarting discussions from existing protocol texts, such as the Composite Text or Rolling Text from 2001, but others argued that too many technical and political barriers remained and that previous drafts are no longer viable. Regardless of the starting point, there is support for revisiting negotiations on a legally binding protocol.

4.4. Barriers & Facilitators

Individual assurance mechanisms have unique capabilities, limitations, and implementation barriers, particularly in the context of achieving universal participation; however, there are numerous broader, high-level barriers to establishing and implementing assurance-related programs for the BWC. Multiple interviewees noted that the most substantial barriers are political in nature, but technical barriers also exist.

The very definition and understanding of core BWC concepts, including verification and compliance, remain a major barrier, as there is no consensus on how they apply to the BWC. Verification, as applied under other nonproliferation treaties, is largely limited to the context of a comprehensive, legally binding protocol, and many uncertainties remain regarding its scope and purpose under the BWC as well as its relationship to compliance. Without a legally binding agreement in place, the BWC must rely on alternative mechanisms to reinforce the norm against biological weapons, build trust and certainty regarding SPs' activities, and assess compliance with treaty obligations. Interviewees expressed a variety of perspectives regarding the aspects of the treaty to which compliance and verification apply. While some view them as applying equally to all treaty obligations, others prioritized the treaty prohibitions for verification or described varying degrees of noncompliance, depending on the provision. Without consensus understanding on these fundamental concepts, SPs cannot hope to make concrete progress toward implementing formal compliance assessments or a verification regime.

 doi:10.20944/preprints202204.0051.v1

Multiple interviewees indicated that the principal barriers to BWC verification are more political in nature than technical. One of the biggest challenges is the inherent tension between national sovereignty and access. On one end of the spectrum, voluntary activities are less intrusive, and SPs can control access to facilities, data, and personnel; however, this control limits these activities' ability to provide transparency. On the other end, mandatory activities promise a clearer picture of ongoing activities and capabilities, but SPs must be willing to relinquish control to other SPs or external auditors. Similar challenges exist when expanding assurance mechanisms from government programs to the private sector, including academic institutions. Several interviewees indicated a credible verification system is necessarily intrusive, to some degree, while another SP who supported verification commented that intrusive activities would be unacceptable because they encroach on national sovereignty. Technical innovation, including to facilitate remote monitoring, could potentially provide less-intrusive access to specific types of information while mitigating the risk to intellectual property, trade secrets, classified intelligence, or other sensitive materials. Ultimately, what each SP finds acceptable is a political decision, and they must determine the extent to which they are willing to cede sovereignty to implement mandatory activities.

Interviewees indicated that diplomatic conflict and growing mistrust among governments can spill over into BWC-related issues. For example, one interviewee noted that mistrust is already impacting CBMs' ability to increase confidence, as SPs do not necessarily trust in CBM report accuracy. Each step of any assessment, from collecting data to conducting analysis to interpretating findings, becomes progressively more subjective and political, and even given the same objective evidence, SPs could reach very different conclusions. Several interviewees cited speculation regarding the origins of the SARS-CoV-2 virus as an example, emphasizing that the political influence would undoubtedly be even more prominent were an outbreak truly suspected to be deliberate in origin. Several interviewees also described how suspected or documented violations of chemical and nuclear weapons treaties can negatively impact the BWC, both in terms of diplomatic tensions and eroding WMD nonproliferation norms. Additionally, biotechnology is growing economic driver, and competition between SPs can hinder information sharing, technology transfer, and transparency, as governments attempt to protect their investments and relative advantages over other countries.

The dual-use and material balance challenges for BWC verification are well documented [17], and other technical barriers remain to implementing assurance mechanisms. Depending on the scope of these activities, it could be difficult or impossible to gain insight into all ongoing biological activities in a given country, including government-sponsored activities and in private sector industry, academic, and individual or community laboratories. Multiple interviewees described challenges their countries face in terms of engaging the DIY biology community and understanding the breadth of ongoing public biological activities. Interviewees also discussed barriers involving protecting intellectual property and trade secrets for private-sector industry, particularly in the context of the growing bioeconomy. Additionally, several interviewees emphasized that biological activities' legitimacy under the BWC hinges on intent (i.e., peaceful or nefarious), which could be very difficult to arbitrate during a compliance assessment. One SME commented that the contentious geopolitical landscape further complicates assessments of intent due to high degrees of mistrust between governments.

Interviewees also noted that some treaty obligations are less concrete than others, which can make compliance more difficult to evaluate. For example, Article IV obligates SPs to implement the BWC at the national level; however, there are no associated standards for the legislation or regulatory capacity necessary to do so. Similar challenges exist with Articles III, VII, and X as well as other components of the treaty, including CBMs. Interviewees also highlighted that activities undertaken for certain treaty obligations could be viewed as conflicting with others, such as export controls in the context of Articles III and X. There is also uncertainty regarding which party, the assessor or the assessed, would bear the burden of proof for compliance assessments—i.e., would SPs

 doi:10.20944/preprints202204.0051.v1

need to demonstrate compliance or assessors demonstrate noncompliance? These technical barriers may have technical solutions, but they might also require political negotiations to establish boundaries on assurance-related activities that could mitigate their impact.

Nevertheless, there are factors supporting efforts to implement BWC assurance mechanisms, and interviewees expressed broad interest in making progress in this area, whether the end goal is a comprehensive verification regime or increased transparency and trust. SPs and other stakeholders continue to submit and debate proposals, and multiple interviewees expressed support for resuming formal negotiations on a BWC protocol and verification. Scientific advancements and emerging capabilities in biotechnology offer potential solutions to historical technical barriers. For example, one SME identified genetic tags or signatures as a tool to track the origin of biological agents. Interviewees explicitly discussed remote monitoring systems and microbial forensics and attribution as potential benefactors. They broadly expressed support for a BWC mechanism to monitor advancements in science in technology, including to identify technologies that could benefit the treaty and its implementation, and they emphasized that engagement with the scientific community can inform delegations on emerging technical capabilities that could increase benefit or mitigate shortcomings for various assurance mechanisms. Finally, multiple interviewees emphasized that the COVID-19 pandemic could provide the impetus and political attention needed to take positive steps on a variety of BWC issues. While SPs may only have a short window of opportunity before attention wanes or the next crisis emerges, the 9th Review Conference and early years of the next ISP provide fora to act on these important challenges.

5. Discussion

These interviews highlighted the absence of common definitions or understanding for core BWC concepts, including verification and compliance, calling attention to the need for explicit debate and negotiations at the international level to generate consensus around the scope and purpose for these important and complex ideas. The stalemate on BWC verification and a legally binding protocol may be more political than technical, and while there are certainly technical challenges to overcome, perhaps the first step should be agreement on the definitions of key terms. The BWC can draw lessons from other nonproliferation treaties; however, those applications of verification, compliance, and related concepts do not translate directly for biological weapons. There is interest among some SPs to resume negotiations on a legally binding BWC protocol and verification regime, but the need for common definitions and understandings extends across a broader swath of BWC issues.

The absence of common understanding on core concepts makes negotiations difficult, as SPs and other stakeholders may be negotiating entirely different issues. Ambiguity in what is being negotiated—never mind the best way to achieve it—provides little opportunity to maneuver toward concrete improvements to the treaty or its implementation. In the context of a legally binding protocol, there remain questions regarding the scope of activities to which SPs would be bound, and with respect to verification, there exists a myriad of uncertainties and disagreements regarding what would be verified. Additionally, SPs would need to agree on the burden of proof and standards for assessing compliance or verifying other aspects of the treaty. If SPs aim to restart discussions or negotiations on a legally binding protocol and/or verification, solidifying the scope and context for these concepts should be a priority.

Without a formal verification or compliance assessment regime, a broader approach, such as assurance, could help increase transparency, build and maintain trust and confidence, bolster certainty, and mitigate ambiguity and concern across a broad scope of BWC-related obligations and activities. Conflict remains regarding SPs' focus on implementing a legally binding protocol versus improving treaty implementation and impact [18]. Many SPs continue to prioritize a comprehensive, legally binding pro-

 doi:10.20944/preprints202204.0051.v1

tocol and formal verification regime, but there is also support for implementing assurance-related activities incrementally, either as a formal component of the BWC or in an informal or voluntary capacity. By expanding the scope of dialogue beyond explicit concepts like verification and compliance—and their narrow and varying definitions—SPs and stakeholders can identify priority goals under the BWC and appropriate mechanisms to support them. Any assurance mechanism will have its own particular capabilities and limitations, and SPs can participate in those activities that serve their individual needs without requiring consensus across *all* SPs. There are limitations to implementing voluntary mechanisms, but SPs can take incremental steps toward increased transparency and confidence in their activities, which fosters increased trust and mitigates the risk that ambiguity will lead to concern. Universal participation is not necessary to increase assurance in the same way it would be for a formal verification regime. There is support for a broad range of activities and mechanisms, including some that already exist under the BWC and others that could be implemented in formal or informal capacities. Thus, SPs might consider an incremental approach to increasing their degree of assurance regarding other SPs' biological activities, implementing specific mechanisms to support specific goals.

While there is no way to universally determine the benefit of *all* assurance mechanisms, many proposals could provide value by increasing the degree of certainty that SPs are meeting their BWC obligations. Interviewees did not identify any novel assurance mechanisms, but a broad range of options are on the table. The most substantial barrier lies in agreeing on the details of their implementation. Variations in how each mechanism is implemented will affect the degree to which it contributes to assurance. Some options are better suited to facilitating transparency, while others are more appropriate for mitigating ambiguity, and some are better suited to assessing specific activities, facilities, or capabilities. Whatever the purpose, however, no single activity is sufficient to provide a comprehensive assessment of SPs' biological activities. SPs must identify appropriate packages of mechanisms to achieve specific aims, leveraging their relative advantages and selecting combinations of activities to mitigate their respective limitations. These details will directly affect SPs' willingness to participate, and achieving consensus could be extremely difficult. Some SPs may find assurance mechanisms unacceptable in the absence of a consensus agreement, but bilateral and multilateral efforts could still have a positive effect in increasing assurance regarding biological activities, facilities, or events.

Fortunately, some assurance mechanisms already exist formally within the BWC, either as components of the treaty itself or derived from politically binding obligations or other consensus agreements by SPs. Options such as CBMs and Article V consultations offer opportunities to increase transparency, mitigate ambiguity, and build trust among SPs, but existing implementation barriers limit their capacity to increase assurance in their current form. There are many calls to increase CBM participation and improve the quality of reports as well as for SPs to make reports publicly available. Article V consultations have been used previously, but stigma around their use and the absence of clear operational procedures hinder their value. There is interest among some SPs to utilize these consultations more routinely to mitigate concern regarding biological activities. International cooperation and assistance under Article X can facilitate sharing valuable information and best practices and support SPs' national implementation, including oversight and regulatory programs and national legislation, as well as capacity building to mitigate the effects of a deliberate biological event. National implementation demonstrates commitment to the BWC and associated norms as well as the capacity to ensure that domestic biological activities comply with treaty obligations, which increase confidence and mitigate uncertainty. Considering that these options already exist as formal components of the BWC, the 9th Review Conference and subsequent ISP provide an opportunity for SPs to refine these mechanisms, establish operational frameworks, and expand participation.

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 7 April 2022 doi:10.20944/preprints202204.0051.v1

One of the most pressing challenges facing the BWC is responding to emerging science and technology, including capabilities that pose new threats or offer new solutions. SPs and SMEs understand the importance of ensuring that the BWC remains relevant in the face of radical changes in biotechnology since its inception. Efforts are ongoing to promote awareness among BWC delegations regarding emerging capabilities and threats, including the MXs and countless educational events on the margins of BWC meetings. There are calls for the BWC to develop its own internal capacity to monitor these advances, such as a scientific advisory mechanism or board. Despite broad agreement on the importance of this capacity, there remain questions regarding how best to implement it. Regardless of the approach, the BWC should expand the inclusion of technical expertise from the scientific community to update diplomats on cutting-edge progress and emerging capabilities that could pose new threats or offer support for BWC implementation.

The absence of sufficient organizational capacity for the BWC poses major barriers to implementing many of these assurance mechanisms. In contrast to analogues in other nonproliferation treaties (e.g., OPCW, IAEA), the three-person BWC ISU is woefully under-resourced. There is broad support for expanding the personnel, funding, and mandate for the ISU, and the 9th Review Conference is the principal setting for doing so. Prospective activities such as science and technology review or analysis of CBM reports would likely not be possible under the ISU's current form, nor would coordinating assurance-related activities, including on-site inspections or more frequent Article V consultations, or supporting SPs' national implementation efforts. SPs could agree to address the long list of issues described here during the next ISP, but if they are unable to reach consensus on expanding the ISU at the 9th Review Conference, it would likely eliminate any opportunity to do so before the 10th Review Conference.

Many of these issues have been addressed previously in other publications and for a [19–24], but the use of a robust dataset and systematic methodology in this study enabled the identification of key themes related to verification based on current perceptions among SPs and other experts. This data-driven, systematic effort documents both the diversity in how SPs understand core concepts under the umbrella of BWC assurance and general support for a myriad of assurance-related mechanisms, including in the absence of a comprehensive, legally binding protocol. This research identifies priority topics for future debate, including in the next ISP, that offer the opportunity for concrete progress toward strengthening the BWC and its implementation, based on direct input from SPs and other key stakeholders.

Limitations

While this study utilized a systematic methodology, it was not without limitations. Purposive sampling was used to identify key contributors to the BWC—including broad geographic and political diversity—but it was not possible to invite or interview all SPs. Key BWC delegation members for priority SPs were identified through official participant lists for past BWC and other nonproliferation meetings, but it was not always possible to locate contact information for key representatives. While all interviews were conducted on a not-for-attribution basis and appropriate measures were implemented to ensure confidentiality and safeguard interview data, some invitees may have been unwilling to speak to a US-based civil society organization on these issues. Multiple SPs did not respond to invitations, and one declined to participate. Additionally, interviewees' statements may not necessarily reflect the official position of their organization or country. But while interveiwees' comments may not be generalizable across relevant organizations, including BWC delegations, they do provide insight into the breadth of perspectives on these important issues and help identify topics that have support as well as associated barriers and challenges.

The analysis relied on extensive interview notes, rather than transcripts. Internal capacity for transcription was not available. Considering the politically sensitive nature

 doi:10.20944/preprints202204.0051.v1

of these topics, a conservative approach was taken to promote open and transparent conversation, and the researchers elected not to transmit interview audio to an external service. Due to the focus on terminology, the researchers attempted to accurately capture key language in the interview notes, but even with supplementary audio recordings, it is possible that some interview content may have been accidentally omitted, misinterpreted, or not fully contextualized, which could affect the nuanced understanding of these complex concepts. All interviews were conducted in English, which was not the primary language for every interviewee, and differences in translation of key terms could affect the interpretation of their comments. The quantitative analysis placed more emphasis on themes addressed frequently than on remarks made by only one or a few interviewees. In an effort to capture minority perspectives, all coded interview notes were reviewed for priority themes identified *a priori*, independent of quantitative metrics, although it was not possible to reflect all perspectives in the findings.

6. Conclusion

The upcoming 9th BWC Review Conference provides SPs with an opportunity to shape future dialogue on verification and other critical issues. The previous ISP, particularly the MXs, illustrated that SPs can have constructive and substantive debate on issues central to the functioning of the treaty, and these discussions can lead to concrete progress on specific issues. SPs should build on this momentum in the next ISP by ensuring adequate time for MXs and including a diverse selection of topics for discussion, particularly in the context of institutional strengthening. Crucially, SPs should consider and engage in more deliberate and specific conversations about key terms and concepts, including "verification" and "compliance," with an eye toward achieving common understanding. Even if consensus agreement cannot be reached, substantive debate on these issues could provide insight into how other SPs approach these fundamental ideas and help identify potential areas for collaboration. Additionally, there is support for a wide range of mechanisms to achieve specific assurance aims, and technological advancements may offer solutions to existing barriers. These mechanisms can provide value, even in the absence of a comprehensive verification regime or universal participation, and some SPs are interested in pursuing those avenues. Finally, the broader concept of assurance could serve as an option to increase transparency and certainty regarding SPs' compliance with treaty obligations, including in the absence of a comprehensive, legally binding protocol or verification regime.

Acknowledgments: We would like to thank all the participants in our study for taking the time to share their expertise with us, particularly in the midst of a pandemic. We would also like to thank Open Philanthropy for its financial support of this study as well as its continued interest the in BWC and biological weapons nonproliferation issues and commitment to promoting the broadest use of science for peaceful purposes.

References

1. "History of the Biological Weapons Convention," UN Office of Disarmament Affairs, accessed February 17, 2022, <https://www.un.org/disarmament/biological-weapons/about/history/>.
2. Chemical Weapons Convention, April 29, 1997, Annex on Implementation and Verification.
3. Treaty on the Non-Proliferation of Nuclear Weapons, March 5, 1970, Article III, para. 1.
4. "IAEA and the Non-Proliferation Treaty," IAEA, accessed February 17, 2022, <https://www.iaea.org/topics/non-proliferation-treaty>.
5. "Biological Weapons Convention – Meetings of Experts [2018]: Side events," UN Office of Disarmament Affairs, accessed February 17, 2022. <https://meetings.unoda.org/section/bwc-mx-2018-side-events/>.
6. Richard Lennane, "Verification for the BTWC: if not the protocol, then what?," in Disarmament Forum (Geneva, Switzerland: UN Institute for Disarmament Research, 2011).
7. Nicholas S. Sims, Jez Littlewood, "Ambitious Incrementalism," The Nonproliferation Review, Vol. 18, No. 3 (November 2011), pp. 499-511.
8. Statement by Bonnie Jenkins, Under Secretary of State, to the 2021 BWC MSP, November 22, 2021.
9. Statement by the Representative of the Russian Delegation to the 2021 BWC MSP, November 22, 2021.

 doi:10.20944/preprints202204.0051.v1

10. Filippa Lentzos, "Compliance and Enforcement in the Biological Weapons Regime," WMD Compliance & Enforcement Series Paper Four, Geneva: UN Institute for Disarmament Research, 2019.
11. "BWC electronic Confidence Building Measures portal," UN Office at Geneva, accessed February 17, 2022, <https://bwc-ecbm.unog.ch/>.
12. Final Report, Special Conference of the BWC, BWC/SPCONF/1, September 19-30, 1994, Part II, para. 36.
13. Anti-Personnel Mine Ban Convention, March 1, 1999.
14. Convention on Cluster Munitions, August 1, 2010.
15. "Nuclear-Weapon-Free Zones," UN Office for Disarmament Affairs, accessed March 16, 2022, <https://www.un.org/disarmament/wmd/nuclear/nwfz/>.
16. Tianjin University Center for Biosafety Research and Strategy, Johns Hopkins Center for Health Security, The Interacademy Partnership, "The Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists," July 2021.
17. Lentzos, "Compliance and Enforcement in the Biological Weapons Regime."
18. Jez Littlewood, "The Protocol: Useful or Useless?" in The Biological Weapons Convention: A Failed Revolution (Hampshire, UK: Ashgate Publishing, 2005).
19. Lentzos, "Compliance and Enforcement in the Biological Weapons Regime."
20. Sims, Littlewood, "Ambitious Incrementalism."
21. Marie Isabelle Chevrier, "Compliance mechanisms and their implementation: the contrast between the Biological and Chemical Weapons Conventions," The Nonproliferation Review, Vol. 27, Nos. 4-6, pp. 475-486.
22. James Revill, "Compliance Revisited: An Incremental Approach to Compliance in the Biological and Toxin Weapons Convention," CNS Occasional Paper #31, Monterey, California: Middlebury Institute of International Studies at Monterey, August 2017.
23. Trevor Findlay, "Verification and the BWC: Last Gasp or Signs of Life?," Arms Control Today, Vol. 36, No. 7 (2006), pp. 17-21.
24. Iris Hunger, Anna Zmorzynska, "Verifying and Demonstrating Compliance with the BTWC," Non-Proliferation Papers No. 5, EU Non-Proliferation Consortium, December 2011.