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**BTWC SECURITY IMPLICATIONS OF
HUMAN, ANIMAL AND PLANT EPIDEMIOLOGY**

by Graham S. Pearson

**REPORT* OF THE NATO ADVANCED RESEARCH WORKSHOP
CANTACUZINO INSTITUTE : BUCHAREST 3 - 5 JUNE 1999**

Introduction

1. The NATO Advanced Research Workshop entitled "BTWC Security Implications of Human, Animal and Plant Epidemiology" was held in the Cantacuzino Institute in Bucharest, Romania on Thursday 3 through Saturday 5 June 1999 under the co-directorship of Professor Marian Negut, Director, Cantacuzino Institute, and Professor Graham Pearson, Visiting Professor of International Security in the Department of Peace Studies in the University of Bradford, UK. It was attended by 36 individuals, of which 20 came from 6 NATO countries (France, Italy, Netherlands, Norway, United Kingdom and United States), 14 from 5 Partner countries (Czech Republic, Poland, Romania, Slovakia and Ukraine) and one Key Speaker from Brazil and one from South Africa.

2. The workshop was designed to focus on the key issues relating to human, animal and plant epidemiology relating to the Protocol being negotiated by the Ad Hoc Group (AHG) in Geneva to strengthen the Biological and Toxin Weapons Convention (BTWC). As an outbreak of disease may result from non-compliance with the Convention, provision within the Protocol for investigation of a suspicious outbreak is a central element of the Protocol. It is also a contentious point as some States Parties are concerned that an unusual outbreak of disease resulting from a natural cause might be used as a reason for an investigation under the Protocol. Eleven of the experts, from 9 countries, attending the Bucharest workshop are members of the delegations attending the Ad Hoc Group in Geneva. This workshop built on the progress achieved in the Advanced Research Workshop entitled "Scientific and Technical Means of Distinguishing between Natural and Other Outbreaks of Disease" held at the Centre for Epidemiology and Microbiology in Prague, Czech Republic on 18 to 20 October 1998.

3. The Bucharest ARW was designed to address key issues relating to epidemiology that will need to be resolved in the Protocol to strengthen the BTWC. Consequently the ARW was structured to enable discussion of the issues relating to outbreaks of disease in such a way as to maximize the benefits to the negotiators of the Protocol in devising an effective and efficient regime. The workshop had six main sessions:

Session I. Epidemiological Data. The first session set the scene for the workshop by focussing on the realities, problems and prospects for reporting with presentations covering a European, South American and a USA perspective.

* This report is based on material that I presented in the final session of the Workshop giving my appreciation of the outcome of the Workshop. It represents my personal assessment of a highly effective and enjoyable Workshop.

Session II. Epidemiological Analysis and Reporting examined how reported epidemiological data for human, animal and plant diseases was analysed and how these analyses were reported.

Session III. Unusual Outbreaks. This began with an overview of scenarios in which unusual outbreaks may arise and how these might be discriminated. This was followed by two case studies of unusual outbreaks in which attention was given to how their unusual characteristics were analyzed.

Session IV. Molecular Biological Techniques for Sub-species Identification. It is evident that rapid identification of the sub-species strain of an outbreak may provide an early indication as to whether the outbreak is unusual or has suspicious characteristics such as, for example, if the sub-species strain causing the outbreak is not endemic to the area. An overview was followed by examinations of the capabilities of various molecular biological techniques to identify the sub-species involved in an outbreak.

Session V. Epidemiological Advances. These presentations considered what prospects there were for changes in the reporting and analysis of human, animal and plant epidemiology over the next few years.

Session VI. Security Implications. The final session focussed on the issues relating to outbreaks of disease of particular relevance to the negotiation and completion of the legally binding Protocol to strengthen the BTWC.

4. Outbreaks of disease are recognised world-wide as presenting a threat to human, animal and plant health as well as to global trade and prosperity. The World Health Organization (WHO) has recognised that emerging and re-emerging diseases are a priority issue that demands international cooperation and action. This Workshop was unique in that, for the first time, representatives of the three international organizations dealing with human, animal and plant health -- the WHO, the Office International des Epizooties (OIE) and the Plant Protection Service located within the Food and Agriculture Organization (FAO) -- came together for interactive technical discussions with experts who are participating in the negotiations by the AHG in Geneva of a Protocol to strengthen the BTWC. This was immensely valuable and together with presentations on European and South American epidemiological reporting enabled a real advance in the understanding of the participants as to what epidemiological reporting is currently taking place regionally and globally and the extent to which this is increasingly publicly available on the internet -- and hence to reach a view as to what is necessary for an effective Protocol.

5. The Workshop gave particular attention to three key issues:

- a. Reporting of outbreaks of disease
- b. Are lists of agents/diseases needed for reporting/notification?
- c. Investigation of outbreaks of disease

The outcome of each of these issues is considered in turn.

Reporting of Outbreaks of Disease

6. It is evident that there is a great deal of epidemiological data and analysis of disease outbreaks in humans, animals and plants that is publicly available on official websites on the internet. This available data and analysis is increasing with time as more official websites are opened and extended.
7. There is also additional data and analysis that is available to States from restricted access sites on the internet.
8. For the future BTWC Protocol regime, epidemiological data will be required **by States Parties** who wish to request the future BTWC Organization to carry out a field investigation.
9. Background epidemiological data will be required **by the BTWC Organization** in order to carry out that field investigation. Although background epidemiological information **may** be provided by the State Party requesting the investigation as part of its request, such data may have been **selected** to support the request for an investigation. Consequently, the BTWC Organization **should independently** also obtain such background data directly from available public sources.
10. For the BTWC Organization to be credible in carrying out field investigations, it will have to have full-time epidemiological expertise. It will also need to be able to call upon specific experts to provide part-time assistance to the Organization in carrying out a particular field investigation. Its full-time experts will need to have the experience and professional standing to utilize the part-time experts effectively in the field investigation team.
11. The full-time epidemiological expertise in the BTWC Organization would contribute significantly to the effectiveness and professional standing of the Organization by:
 - a. Preparing and updating periodically regional surveys of the sources of epidemiological data and analysis within the region thereby gaining an understanding of the way in which such data is collected and used within the region.
 - b. Preparing and updating periodically regional surveys, using publicly available data and analyses, of particular diseases of relevance to the BTWC.
 - c. Preparing ongoing analyses of global patterns of diseases of relevance to the BTWC.

The full-time epidemiological experts within the BTWC Organization will need to keep up to date with the latest technologies both for the credibility of the BTWC Organization and because of the consequential enhanced deterrent effect resulting from the greater probability that any non-compliance would be detected during an investigation.

12. Such regional surveys would enable deficiencies in infrastructure and capabilities within the regions to be identified. In addition such surveys could also identify where there are shortcomings in the quality of the data being reported to human, animal and plant health organizations nationally, regionally and internationally. Assistance to States Parties to the

Protocol in building capabilities and capacity to remedy such deficiencies would be appropriate for action under Article VII of the Protocol.

13. Reporting of disease outbreaks by States to human, animal and plant health organizations nationally, regionally and internationally is important as:

- a. it enhances the national standing of the State,
- b. it builds trust in the State, and
- c. it enhances human, animal and plant health as it facilitates the effective use of resources in countering outbreaks.

14. If outbreaks of disease are **not** reported by a State to human, animal and plant health organizations nationally, regionally and internationally, this results in reduced human, animal and plant health, in trade restrictions and potential security concerns.

15. Regular reporting of outbreaks of disease removes the "novelty" of outbreaks and will help States Parties to rebut spurious requests for field investigations.

16. Reporting of epidemiological data and of information on outbreaks should be encouraged to human, animal and plant health organizations nationally, regionally and internationally. There should be no mandatory requirement for such data to be declared or notified to the future BTWC Organization as information provided through dual channels is likely to contain discrepancies which do not build transparency but can give rise to suspicions.

17. However, there would be advantages in encouraging States Parties to inform the future BTWC Organization of significant outbreaks of disease that have been reported to human, animal and plant health organizations nationally, regionally and internationally. This would contribute to increased transparency as well as helping States Parties rebut spurious requests for field investigations and might be achieved by a voluntary CBM within the Protocol. In addition, States Parties should be encouraged to respond positively and quickly to requests from the BTWC Organization for assistance including the provision of background information on epidemiology and outbreaks of disease.

Lists of Agents/Diseases

18. The lists of agents/diseases within the draft Protocol are there for the specific purpose of removing ambiguity in the implementation of the Protocol as, for example, in the declarations of facilities working with listed agents.

19. As the consideration of the reporting of outbreaks of disease showed that it was inappropriate to require mandatory disease reporting/notification to the BTWC Organization, there is no need for a list of agents/diseases for reporting/notification.

20. Should a voluntary CBM be included within the Protocol under which States Parties inform the future BTWC Organization of significant outbreaks of disease that have been reported to human, animal and plant health organizations nationally, regionally and

internationally, it would be better **not** to associate this CBM with any list of agents but rather to leave it to the States Party to judge which outbreaks would be the subject of information to the BTWC Organization.

[21. In considering lists of agents/diseases, it was noted that the OIE is the only international health agency with comprehensive lists and that the Protocol animal agent list and the OIE list are largely identical.]

Investigation of Outbreaks of Disease

22. In requesting a field investigation, epidemiological evidence about an outbreak of human, animal or plant disease will be only **one** element of a portfolio of persuasive evidence submitted to the BTWC Organization.

23. In carrying out a field investigation,

Absence of evidence is **not** evidence of absence

Epidemiological curves are an important tool

Natural outbreaks can look unnatural

Natural outbreaks **can** occur in situations where there is evidence of prior presence of the disease **but** absence of prior presence of disease is **not** evidence of unnatural outbreak

Geographical distribution and time of outbreak **can** indicate unnatural event (eg plume distribution)

24. Sampling and analysis is a crucial element in a field investigation:

Cannot have too many samples -- especially if there is a single opportunity to visit site

Samples must be collected, handled, transferred, stored and analysed blind under strict controls (forensic chain of custody)

Analyses must be made by at least **two** accredited laboratories

Internationally standardised and validated analytical methods are essential

Newest methods of analysis increases probability of detecting deliberate outbreak if the outbreak was deliberate

Use of newest methods of analysis enhances **deterrent** role of field investigations

Consequently, new methods, as they mature, **must** be available to the BTWC Organization to use.

25. The time needed to carry out such analyses using validated techniques to provide robust results is such that completion within 60 days, whilst not impossible if the future BTWC Organization was lucky, could not be guaranteed. It has to be emphasised that the quality standards needed for such analyses are extremely high -- and to obtain robust results with a high degree of confidence will take time. Skimping on the quality of analyses will bring the future regime into disrepute. The importance of quality and careful work is particularly true when it is recalled that there will be a single opportunity to visit the site of the field investigation and consequently there will be a strong incentive to collect larger numbers of samples.

26. It further needs to be recognized that the high quality accredited laboratories capable of doing such analyses will normally be engaged in other work and there can be no certainty that ongoing analyses would be shelved to enable the BTWC Organization samples to be given over-riding priority for analysis. It will also be important that analyses are carried out **blind** in accredited laboratories in more than one country selected by the BTWC Organization -- and with the possibility of a repeat analysis in a third country should that be necessary. Time limits for completion of analyses would be unwise.

27. There are several methods of analysis:

- a. Epidemiological data and analysis
- b. Classical agent isolation and culture where possible
- c. Immunological techniques
- d. Genetic techniques

These are **all** required and are complementary. Their use together enhances confidence in the result.

28. Immunological techniques can:

- Identify the agent causing the disease
- Identify, in some specialized instances, additives used to aid weaponization
- Determine if local or foreign strains
- Determine previous population exposure (including reservoirs and vectors)

29. Genetic techniques:

- These are capabilities that are rapidly advancing
- Genetic understanding is also evolving rapidly
 - important to note that the genome is **not** a bag of genes
- Can generally identify the disease gene
- Can sometimes determine if pathogenicity is "normal" -- or "modified" or "imported"
- Can identify species and the specific strain thereby facilitating phylogeny reconstruction
- Can often identify the agent origin -- in some cases geographically or evolutionarily
- Can occasionally determine if the agent has been manipulated or grown in a different environment

30. Both genetic and immunological techniques:

- Can detect both lived and killed agents
- Can, in specialized instances, identify additives used to aid weaponization
- Have high sensitivity, although this is highest for molecular diagnostics
- Can be used in the field although **some** molecular diagnostic techniques require specialist laboratories

Quality control (control samples, **blind** analyses and standards) is **essential** throughout.

31. Analytical techniques for investigating outbreaks of disease are advancing **very** rapidly.

32. In almost all circumstances, an epidemiological investigation can, if provided with adequate access, support capabilities and analytical laboratories, come to a sound understanding of the causes of an outbreak of disease.

33. No measure in the BTWC Protocol can give a **100% guarantee** that non-compliance will be detected. However, advancing analytical techniques increase the prospect that in field investigations non-compliance will be detected thereby increasing the deterrence of proliferation.

34. The BTWC Organization has a quite different role from those of the international human, animal and plant health organizations -- which are primarily to provide aid and assistance to their Member States. The BTWC Organization role is to **investigate** and seek **evidence** to evaluate compliance/non-compliance. The future BTWC Protocol needs to ensure that the necessary provisions for **adequate** and **reliable** epidemiological investigation are incorporated in the text for field investigations.

Overall Conclusions

35. The following overall conclusions emerged from the Bucharest NATO workshop on "BTWC Security Implications of Human, Animal and Plant Epidemiology" held on 3 - 5 June 1999:

a. There is **already** an immense amount of epidemiological information about outbreaks of human, animal and plant disease **publicly** available on national, regional and international websites -- and the numbers of these sites and the data available on them are increasing with time. The future BTWC Organization will be able to access this information and it would be unnecessary duplication if the future BTWC Protocol were to require the mandatory regular reporting or notification of data on outbreaks of disease. However, a voluntary CBM in which a State Party informs the future BTWC Organization of significant outbreaks of disease, which have been reported nationally, regionally and internationally to the human, animal and plant health organization, could increase transparency.

b. The role of the future BTWC Organization will be different from that of the international human, animal and plant health organizations as the future BTWC Organization will be seeking information to determine whether or not an event had resulted from non-compliance with the BTWC. For the future BTWC Organization to be credible in carrying out field investigations, the Organization will require a few full time epidemiological experts, covering the human, animal and plant fields, who will need to be augmented for field investigations by part-time experts selected for the particular investigation.

c. The capabilities of the analytical techniques used to analyse samples collected during a field investigation are rapidly advancing. Epidemiological analysis coupled with genetic **and** immunological analyses are capable of providing increasing amounts of information about the origin of the agent causing a particular outbreak. These expanding capabilities will, over time, increase the deterrent effect of field investigations as perpetrators of non-compliance would have less confidence that their involvement would not be detected. The time needed to carry out such analyses blind

using validated techniques in at least two accredited laboratories to provide robust results was such that completion within 60 days, whilst not impossible if the future BTWC Organization was lucky, could not be guaranteed. This was particularly true when it is recalled that there will be a single opportunity to visit the site of the field investigation and consequently there will be a strong incentive to collect large numbers of samples.

d. In almost all circumstances, an epidemiological investigation can, if provided with adequate access, support capabilities and analytical laboratories, come to a sound understanding of the causes of an outbreak of disease. The future BTWC Protocol needs to ensure that the necessary provisions for adequate and reliable epidemiological investigation are incorporated in the text for field investigations.

e. Technical cooperation and assistance provided to States Parties under the Protocol to improve and sustain national infrastructure for the collection and reporting of human, animal and plant epidemiological data to national, regional and international human, animal and plant health organizations would be an attractive BTWC Article X/Protocol Article VII measure which would benefit **all** States Parties and strengthen the Convention through increased transparency. It would **also** bring significant benefits for the human, animal and plant health of States Parties to the Protocol. Similar cooperation and assistance for analytical laboratory capabilities, particularly in developing countries, through a BTWC Article X/Protocol Article VII measure would be similarly beneficial to all States Parties to the Protocol.