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Conclusions of the International Conference on Ethical Implications of Research into the Prevention of Bioterrorism

A. ETHICAL ARGUMENTS AGAINST BIOWARFARE

1. As any bioweapons, also bioweapons of new generation are incapable of distinguishing between civilian and military targets. They however target mainly civilians also because the threshold at which the civil medical system can be overwhelmed by a biological attack appear to be lower than expected (C.Penn, *Human disease and biodefence research: potential benefits but risks of misuse*, Brussels 3-4 Feb, 2004):
 - in case of biowarfare it is likely that military forces are vaccinated against dangerous biological agents while it is unlikely that the civil population can all be vaccinated against any possible bioweapons: as a consequence victims will be chiefly among civil populations;
 - stealth, or conditionally inducible, viruses can be introduced over years and then used to blackmail entire civil populations;
 - civilians who will most suffer from a biological attack will be the most deprived groups and populations, that is to say those who are less likely to be reached by vaccination campaigns and other public health measures;
 - disabled people, people suffering from chronic medical conditions and other people in poor health are expected to pay the higher price to a biological attack;
 - in case of biowarfare it is likely that hospitals and health services will be overwhelmed by people who panic about infections and consequently many other patients will not be treated and will be harmed;
 - collateral damage among civilians also include people suffering from side effects of vaccines, antibiotics, and other drugs used to contrast bioweapons, esp. vulnerable populations such as infants, pregnant women, elderly people, immune compromised people (AIDS and cancer patients, patients who undergo to any immunosuppressive therapy, etc.).
2. New generation bioweapons produce destruction that largely outweigh military objectives and may provoke disproportionate collateral damage (J.E.Stig Hansen, *Bioweapons, Brussels 3-4 Feb, 2004*):
 - the potential for person-to-person transmission of contagious illnesses can disrupt social life and disorganise human communities;
 - the transnational dimension of contagious illnesses can disrupt economic, commercial and cultural relationships between countries and raise serious problems of international collaboration (e.g., should a nation with limited availability of a vaccine stockpile offer its scarce resources to a neighbouring country under attack while there is the concrete risk that the infection spreads also in its own territories?);
 - BWs anti crops and anti livestock may produce famines, serious economic losses and destabilisation that will harm the weakest and most disadvantaged groups and populations;
 - BWs, such as anti crop fungi, may persist long-term in the soil altering the ecosystem and causing disease in other plants and economic destabilisation in vast geographical areas.
3. New generation bioweapons may produce inhumane harm; they can be even used for genocide (C.Penn, *Human disease and biodefence research: potential benefits but risks of misuse*, Brussels 3-4 Feb, 2004):
 - smallpox-like agents may cause disfigurement and deformity;
 - future BWs can remove immunities and wound healing capabilities;
 - they could induce sterility;
 - they could induce dementia-like diseases;

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- they could produce long term tailored diseases similar to AIDS that could combine serious initial lethality with crippling long-term effect lasting decades;
 - by exploiting knowledge on the genetic makeup of different populations and consequently by targeting weapons at specific ethnic groups, new generation BWs could be used to carry out ethnic cleansing and genocide.
4. New generation bioweapons may target future generation (J.E. Stig Hansen, *Bioweapons*, Brussels 3-4 Feb, 2004):
- dormant biological agents such as genetically modified anthrax spores can persist undetected for decades in the environment and produce long term effects on future generation;
 - BWs, which use transforming viruses or similar DNA vectors carrying Trojan horse genes (retrovirus, adenovirus, poxvirus, HSV-1), can produce inheritable (germline) effects;
 - Non microbiological agents used for altering fundamental biological processes of cognition, development, reproduction can produce inheritable modification.

B. ETHICAL ARGUMENTS TO SUPPORT INTERNATIONAL COLLABORATION IN THE WAR ON TERRORISM

5. A biological attack because of its extreme gravity, vastness and urgency, must be considered too difficult for the rulers of individual States to solve with any degree of success. To face the challenge we need more rather than less globalisation, more rather than less Europe (J.Solana, *A Secure Europe in a Better World: European Security Strategy*, document adopted by the European Council on 12 December 2003);
6. War on terrorism should be based on principles of mutual responsibility and solidarity that are not in contradiction with basic individual rights. Individuals have rights—to life, health, security and liberty, as well as freedom of movement, of scientific research and information. The best strategy to contract terrorism is to promote human rights and license intervention when necessary to enforce such rights. Transnational consultation, reinforced links between different agencies, and resource sharing among states perhaps deserve to be monitored from the human rights perspective, but they must not be seen suspiciously as though they

- were a threat to individual rights (C.Patermann, *Introduction to the meeting*, Brussels 3-4 Feb, 2004) ;
7. National and supranational bodies that run the war on terrorism must have as its special aim the recognition, respect, safeguarding and promotion of human rights. Public national and transnational authorities must have the essential purpose to create world conditions in which global civil society, its networks and organisations can carry out their tasks, fulfil their duties and claim their rights with greater security (E.McNelly, *Bioterrorism*, 3-4 Feb, 2004);
8. The European Civil Society – made up by a complex tissue of civic, scientific, cultural, religious networks coming from 25 different nation states - is an invaluable good because is one of the key components of the global civil society. Promoting in the development of the global civil society is the best policy to promote also global health and security (J.Solana, *A Secure Europe in a Better World: European Security Strategy*, document adopted by the European Council on 12 December 2003).

C. ETHICAL IMPLICATION OF PREPAREDNESS AND RESPONSE

9. If a biological attack is going to happen, it will be a media event. Low media impact attacks are improbable. Media analysts and communication experts should be involved in foresight exercises and their opinions should be highly evaluated in considering actual risks of biological attacks. Information and journalism ethics is vital to face this aspects of the war on terrorism.
10. In democratic societies, citizens have the right to contribute to set the risk agenda and to be involved in establishing priorities between different risks that society has to tackle (E.McNelly, *Bioterrorism*, 3-4 Feb, 2004). "Risk statements are neither purely factual claims nor exclusively value claims. Instead, they are either both at the same time or something in between, a 'mathematicized morality' as it were" (U.Beck, 2000, *Risk Society Revisited: Theory, Politics, and Research Programmes*, in B.Adam, U.Beck, J.Van Loon, eds: *The Risk Society and Beyond*. Sage:London, p.215). The essence of risk is not that it is happening, but that it might happen. Risk assessment is only in part based on empirical knowledge, and any account of risk involves a hidden politics and

ethics. This is particularly true when one has to evaluate the actual risk of bioterrorism threat. Setting the risk agenda is no longer something that can be decided only by experts. The lack of public involvement in debating the implications of biowarfare does not stem from ignorance, but from framing the debate only in terms of scientific expertise of risk perception. Assessing bioterrorism risks is not so much a question of military intelligence but of democracy;

11. Trustfulness, accountability, responsibility are the values on which an effective risk communication can be built. The level of trust by the public, esp. in national governments, is low. There are no communication strategies or other technical approaches that can alone solve the problem but honesty in public communication. Democratic responsible communication requires to balance the necessity for security (and thus for secrecy) with the need for disclosure of information that can allow the public to make informed decisions (E.McNelly, Bioterrorism, 3-4 Feb, 2004);
12. The assumption that people will panic or become irrational following an attack has negative consequences (M.Green, Learning to live with risks, Brussels 3-4 Feb, 2004). Authorities may provide inaccurate information or unfounded reassurances motivated by a wish to calm the public. The panic myth may also lead to the neglect of the public's role in planning and response and missed opportunities to capitalize on the resourcefulness of non professionals and civic organizations.
13. Justice in macro allocation of economic resources (E.Noji, Public Health in Emergencies, Brussels 3-4 Feb, 2004): The difficulty to ethically justify the huge amount of resources internationally allocated on prevention of biowarfare requires that scientific research oriented toward development of drugs to tackle biological agents may also have positive impact on the so called "10/90 gap" (less than 10% of worldwide health research is devoted to diseases that account for 90% of the global burden of disease);
14. Equity in micro allocation of medical resources (E.Noji, Public Health in Emergencies, Brussels 3-4 Feb, 2004): A biological attack could initially foster social cohesion. Through a common enemy and shared sacrifices, most citizens may develop sense of fellowship. Yet medical resources could be unevenly and inequitably distributed. This would immediately reduce risk acceptance and would push citizen groups against one another in an effort to assign blame or to protect access to limited resources;
15. Ethical Awareness and Community's involvement (S.Bird Conclusions, Brussels 3-4 Feb, 2004): Clinicians could face complex ethical issues about how resources should be directed toward treatment and how workforce should be handled. They should be trained in advance to face such dilemmas and priorities should be set accordingly. Community's ethical judgment should be also taken into account in setting priorities for use of scarce medical resources, such as antibiotics and vaccines;
16. Respect for patients who are not directly concerned with the attack (E.Noji, Public Health in Emergencies, Brussels 3-4 Feb, 2004): During a biological attack, hospitals could quickly face unprecedented challenges. They might need to care for overwhelming numbers of patients; manage shortages of personnel, medicines, and equipment; and provide the security needed for crowd control, for the provision of safety for health care workers and patients, and even, perhaps, for the enforcement of mandatory isolation of contagious patients. Attention should be particularly paid to the rights of patients who need urgent medical care for reasons different from the biological attack;
17. International cooperation in resource allocation: As a result of the growing web of interconnections, germs have an easier ride than ever. A local attack can easily become global. In the case of widespread biological attack, who would be responsible for the triage of priority populations for prevention or treatment? Who would be responsible for international resource allocation, e.g. vaccines, antibiotics ? How should international cooperation work in this case (J.E.Stig Hansen, Bioweapons, Brussels 3-4 Feb, 2004)?
18. Respect for the person (including respect for autonomy, integrity, and privacy) remains an ethical cornerstone even in

health emergencies (S. Bird, *Conclusions*, Brussels 3-4 Feb, 2004):

- Health policies have generally avoided collective and compulsory measures in favour of individual autonomy and personal choice. With the spread – either intentional or unintentional – of new lethal infections this policy can pose an increasing problem but the principle should be reaffirmed;
 - Compulsory physical examination, testing, and vaccination, quarantine and isolation each may help contain the spread of infectious diseases. The tendency to use these draconian means increases as fear and anxiety increase. The demand for these actions as well as the failure to use them may contribute to community conflict and erode the public's confidence in the government;
 - Informed consent and respect for individual autonomy are some of the ethical practices that health care workers should struggle to maintain during a public health crisis. Most people will comply with public health programs during emergencies if they are correctly informed and involved in decision making;
 - Other ethical principles that can be challenged are those related to privacy and confidentiality. How can the duty to protect the patient's confidentiality be balanced with the duty to protect the public good?
19. Some fundamental human rights and freedoms can never be suspended or derogated (E. McNelly, *Bioterrorism*, 3-4 Feb, 2004), such as the right to life; the right to freedom from torture and all forms of cruel, inhuman, or degrading treatment; and the right to freedom of thought, conscience, and religion. Any restrictions on other rights must be exceptional and temporary in nature; limited to the extent strictly required by the exigencies of the situation; non-discriminatory solely on the ground of race, color, sex, language, religion or social origin;

D. THE SCIENCE AND SECURITY DILEMMA

20. Science and Security Dialogue (P. Campbell, *Dual-use biomedical research: the roles of journals*, Brussels 3-4 Feb, 2004): The science and securi-

ty communities have till now suffered from a lack of dialogue. This lack of dialogue is mirrored in a lack shared values. If science and security communities must work together, it becomes important to find and identify places and moments in which the two communities can meet and discuss;

21. Scientists' Responsibility (P.S. Wrightson, *The Science and Security Dilemma*, Brussels 3-4 Feb, 2004):
- Scientists involved in research programs with dual use nature are the subjects upon who to rely on for bioweapons control programs. Bioweapons are the only warfare for which the same agent is important for offensive and for defensive purposes. This implies that science is very unlikely to be easily recognized for its own very final use. Composition and behavior of biological agents for offense are being studied for BW defense program as well putting the scientists in a crucial position;
 - There is a need to increase the awareness in the scientific community of the BW-relevant issues and their ethical implications. While there has been a significant increase in the number of regulations governing the activities in the fields of biology and biotechnology, these regulations still do not amount to an ethical prescription. Regulations may only constitute the moral minimum. Today there is a moral consensus about the status of the biological weapon, but not about the status of the technologies that may contribute to BW development and production;
 - Professional and scientific organizations must adopt international prohibitions to misuse of biotechnology in their codes of conduct and ethical norms;
22. Liberty from political control on scientific community (P.S. Wrightson, *The Science and Security Dilemma*, Brussels 3-4 Feb, 2004):
- Scientific Community is by its nature part of the global civil society. Either we rely on self regulation of the scientific community, or we set some international regulations to control the dual use nature of biotechnology, it is vital to establish some liberty rules, which cannot be trespassed by national governments, to protect the scientific community from possible intrusions;
 - Dissemination of scientific information cannot be stopped; scientific journals may

- help to mitigate the damage created by mean of other forms of information dissemination (P.Campbell, *Dual-use biomedical research: the roles of journals*, Brussels 3-4 Feb, 2004)
23. Avoiding the stigma (D.Groncin, *BIG Expert Meeting*, Rome, Jan 24-26, 2003): A very delicate issue concern the possibility of differential treatment of scientists dependent on their country of origin or on the basis of the countries through which they have passed and the time they have spent there. Many of the human-rights documents emanating from international organisations decry the process of discriminating between people of different ethnic, sexual, religious, cultural or racial types. The differential treatment of an individual on the basis of her ethnic, religious, cultural, geographical origins may be ethically problematic.
 24. Regulatory and legal frameworks are the true counterweight to asymmetric war (J.P.Zanders *The coexistence between research policy on certain weapons and disarmament*, Brussels 3-4 Feb, 2004): National implementation remains an undervalued tool in the efforts to counter the use of disease for hostile purposes. The norms in the BTWC also apply to legal and natural persons. Since states parties must ensure that no prohibited activities take place on their territory, they are required to promulgate national legislation. In particular, criminal and penal law based on the conventions can be important tools to prevent and punish biological terrorism and the involvement of companies and individuals in the BW programmes of other states. Internal and external transfer controls will restrict access to relevant technologies to legitimate people, research institutes and companies only.
 25. Human security is a class of human rights (Commission on Human Security, 2003, *Human Security Now*, UN, New York): Human security seeks to complement state security. States have the fundamental responsibility of providing security, but the notion of state security concentrates primarily on safeguarding the integrity of the state and thus has only an indirect connection with the security of the human beings who live in these states. On the contrary, human security should be considered, as in the “The Charter of the Fundamental Rights of the European Union”, intimately connected with liberty (art.6): “Everyone has the right to liberty and security of person”.
 26. Ethical standards must be adopted even in sensitive or classified research (R.Lie *Are international ethical codes applicable to classified biomedical research?* Brussels 3-4 Feb, 2004): Even in the case of classified biodefence research, the ethical standards that govern human medical trials should still apply. According to the Council of Europe’s convention on human rights and biomedicine, even if a country is facing war or conflict, the defence of its economic well being, or a threat to national security, no exceptions are granted to these standards.
 27. Ethical review of a protocol that contains classified or sensitive information: (R.Lie *Are international ethical codes applicable to classified biomedical research?* Brussels 3-4 Feb, 2004): It is not a requirement that a research ethics committee reviews everything there is to know about a study; it is only a requirement that the committee reviews that information that is material to its decision, namely whether the proposed research involves an acceptable risk-benefit ratio, and whether the information provided to the participants will enable the participants to make a valid choice to enter the trial:
 - If the chair of the committee determines that the protocol can be reviewed acceptably without the classified information, then the protocol can be reviewed by a committee whose members to not have security clearance;
 - If, however, this cannot be done, then the only option would be for the protocol to be reviewed by a research ethics committee whose members all have the needed security clearance. If that second option is chosen, one does need to pay attention to the independence of the ethics committee from the research enterprise, but in principle it should be possible to ensure such independence;
 - If neither of these options is possible, there cannot be an appropriate review of the research and the research cannot be carried out.
 28. Informed Consent in a research project that contains classified or sensitive information (R.Lie *Are international ethical codes applicable to classified biomedical research?* Brussels 3-4 Feb, 2004): There is no requirement that potential participants receive all the information that is available about a research project. It is only a requirement that they receive information that is material to their decision to participate, which means that all information that would

make a difference in terms of their decision to participate should be provided. The research ethics committee that reviews the research will have to decide whether the requirement of informed consent can be fulfilled without including any classified information.

- If classified information can be left out, and one can still fulfil the ethical require-

ment of informed consent, then the research project can go ahead.

- If, on the other hand, the research ethics committee determines that a potential participant will have to obtain classified information in order to make a valid decision, the planned research cannot be carried out in an ethically acceptable manner.