



HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

GUIDELINES FOR GOOD PRACTICE IN THE HEALTHCARE PROFESSIONS

RESEARCH, DEVELOPMENT AND USE OF CHEMICAL AND BIOLOGICAL WEAPONS

BOOKLET 15

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THE SPIRIT OF PROFESSIONAL GUIDELINES

Practising as a healthcare professional is based upon a relationship of mutual trust between patients and healthcare practitioners. The term "profession" means "a dedication, promise or commitment publicly made".¹ To be a good healthcare practitioner, requires a life-long commitment to sound professional and ethical practices and an overriding dedication to the interests of one's fellow human beings and society. In essence, practicing as a healthcare professional is a moral enterprise. In this spirit, the HPCSA presents the following ethical guidelines to guide and direct the practice of healthcare practitioners. These guidelines form an integral part of the standards of professional conduct against which a complaint of professional misconduct will be evaluated.

[Note: The term "healthcare " in these guidelines refers to persons registered with the HPCSA].

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¹ Pellegrino, ED. Medical professionalism: Can it, should it survive? *J Am Board Fam Pract* 2000; **13**(2):147-149 (quotation on p. 148).

RESEARCH, DEVELOPMENT AND USE OF CHEMICAL AND BIOLOGICAL WEAPONS: POLICY ON INVOLVEMENT OF HEALTHCARE PRACTITIONERS

1 PREAMBLE

- 1.1 The development of chemical and biological weapons (CBWs) is a major threat to global security and to the safety and health of the world's peoples. A number of countries around the world have continued to pursue scientific programmes to develop such capabilities despite international efforts to control the proliferation of these weapons of mass destruction.
- 1.2 As confirmed by the Truth and Reconciliation Commission (TRC), the South African military authorities under the apartheid government sustained a covert programme for the development of chemical and biological weapons, and recruited healthcare practitioners and scientists to staff the programme. The evidence that emerged in the TRC's investigations into this clandestine project has pointed to the importance of developing clear guidelines for the health professions in regard to participation in such programmes. It was particularly evident that the secrecy surrounding the apartheid government's CBW programme enabled health professional scientists to conduct research outside of any ethical oversight.
- 1.3 Healthcare practitioners are committed to the preservation of life and the alleviation of human suffering. It is completely contrary to the fundamental principles of the ethics of the health professions for a healthcare practitioner to participate in research activities directed at generating materials intended to cause harm to human health and well-being. As stated in the *Declaration of Geneva* healthcare practitioners are expected to adhere to the following principle:

‘I will maintain the utmost respect for human life from its beginning even under threat and I will not use my medical knowledge contrary to the laws of humanity;’

2 GLOBAL CONCERNS

- 2.1 Fears of the consequences of the use of chemical and biological weapons (CBWs) have been exacerbated by the perception of an upsurge in global terrorism. Regrettably this concern has resulted in increased secrecy and restrictions of civil liberties in several countries around the world. This, in turn, creates a climate in which covert work on CBWs may take place under the pretext of developing defences. Secrecy and restrictions on civil liberties are both factors that help to fuel an environment of covert activities
- 2..2 The danger of clandestine work on CBWs and the risk they pose to human rights makes it imperative that the health professions strongly condemn the development of CBWs and the participation of healthcare practitioners in their development and use.
- 2.3 The World Medical Association (WMA) in its *Declaration on Chemical and Biological Warfare* in 1990 declared that it would be “unethical for a healthcare practitioner whose missions are the preservation of life, and the provision and promotion of healthcare - to participate in the research, development and use of the chemical, biological and nuclear capabilities aimed at destroying life” (see below Annexure 1) In the *WMA Declaration of Washington on Biological Weapons* in 2002, the WMA reconfirmed its position that “research specifically for the purposes of creating biological weapons is to be condemned” (see below Annexure 2).

- 2.4 Article 1 of the *Biological and Toxins Weapons Convention* precludes healthcare professionals and scientists from ever undertaking to develop, produce, acquire or retain: (a) microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; (b) weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict - the *Convention* renders all such actions illegal.

3 TYPES OF CBW RESEARCH AND ETHICAL OBLIGATIONS OF HEALTHCARE PRACTITIONERS
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- 3.1 All research to develop CBWs designed to inflict harm on humans is unethical and healthcare practitioners find themselves in dual loyalty situations where they are coerced or experience pressure or threats to comply from the military or other authorities, they should appeal to the HPCSA or any other appropriate professional body for support in resisting such pressures.
- 3.2 No distinction should be made between what has been called “defensive” and “offensive” CBWs. Weapons that have the capacity to inflict harm should be treated as offensive weapons, notwithstanding any claims or intentions that they will be used for non-offensive purposes. Where technologies are being developed to protect military or civilian personnel against CBWs, such research should be subject to open peer review and ethical oversight by a suitably appointed independent body, as indicated below.
- 3.3 A healthcare practitioner who is or becomes involved in research related to combating the effects of CBWs, shall obtain prior permission from the relevant professional board of the HPCSA to conduct such research and, for that purpose the healthcare practitioner shall:
- 3.3.1 Provide full particulars of the nature and scope of the envisaged research, development and use;
 - 3.3.2 Specify whether the protocols pertaining to such research have been passed by a professionally recognised research ethics committee;
 - 3.3.3 Specify how such research, development and use shall be permissible within the provisions of the World Medical Association’s *Declaration on Chemical and Biological Weapons* (1990); and
 - 3.3.4 Specify how such research, development or use is permitted in terms of the provisions of applicable international treaties or conventions to which South Africa is a signatory.
- 3.4 It is recommended that where military secrecy restricts civilian access to the research for reasons of military security, an ethics committee be established by the military authorities which includes suitably qualified civilian participants with expertise in human rights and ethics, to provide ethical oversight over any CBW-related research, consistent with the provisions of these guidelines and the relevant WMA Declarations.
- 3.5 Notwithstanding the condemnation of direct participation in CBW research, and the restrictions on research involving protection against CBW agents, there is a third category of research attracting ethical concerns. This relates to the misuse of *bona fide* biotechnology research for purposes of producing weapons from biological agents, particularly biological agents created through genetic manipulation of micro-organisms to increase virulence and pathogenicity. This type of research may be conducted by researchers who have no connection to CBW programmes or who intend to allow their

research to be used for such purposes, but who are not aware of or able to control the uses to which their research findings are put. Such research has been labelled “dual-use” research because it has peaceful intentions but may be used for non-peaceful purposes. Dual-use research requires careful evaluation for its ethical implications and demands added ethical oversight prior to approval of the research. Healthcare practitioners involved in such research must therefore ensure that no such research is conducted without ethical consideration of the possible misuse of the study findings to develop CBW agents.

- 3.6 Health care Healthcare Practitioners are required to ensure that they are familiar with the provisions of the Non-Proliferation of Weapons of Mass Destruction Act, which are consistent with these guidelines.

4	ADOPTION OF THE WMA DECLARATIONS ON CHEMICAL AND BIOLOGICAL WEAPONS BY THE HPCSA
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- 4.1 The HPCSA has adopted the WMA’s *Declaration on Chemical and Biological Weapons* (1990) and the WMA *Declaration of Washington on Biological Weapons* (2002) which have been reproduced below as Annexures 1 and 2 respectively.
- 4.2 The term “physician” as used in the Declarations refers to health care Healthcare Practitioners and, for the purposes of the HPCSA, should be understood to include all health care Healthcare Practitioners who fall under the jurisdiction of the HPCSA.
- 4.3 Health care Healthcare Practitioners who breach the above guidelines or the provisions of the WMA Declarations of 1990 or 2002 as reproduced in Annexures 1 and 2 below may face disciplinary action by the HPCSA.

ANNEXURE 1

WORLD MEDICAL ASSOCIATION DECLARATION ON CHEMICAL AND BIOLOGICAL WEAPONS (1990)

[Adopted by the 42nd World Medical Assembly, Rancho Mirage, CA, USA, October 1990]

1. The World Medical Association draws the attention of the medical profession throughout the world to the dangers presented by chemical and biological weapons. Among other, more obvious dangers, it should be noted as follows:
 - a. The use of such weapons would have a devastating effect on civilian populations in addition to military personnel, and not only in the target area, but also in distant places, perhaps beyond the national boundaries of the combatants.
 - b. The effects of exposure to chemical and biological weapons present a continuing threat to the health of human beings on a long term basis, possibly causing illness, injury, disease and defects in the population over a long period of time.
 - c. The effects of exposure to chemical and biological weapons may also result in permanent, complex and unpredictable changes in the natural environment, including animals, plant life and water supply, thus destroying the food source of human beings and resulting in extensive morbidity.
 - d. Existing health care services, technology and manpower may be helpless to relieve the suffering caused by exposure to chemical and biological weapons.
2. The World Medical Association Declaration of Geneva asks physicians to consecrate their lives to the service of humanity, to pledge that the health of the patient will be the physician's first consideration, and that the physician will not use medical knowledge contrary to the laws of humanity.
3. The World Medical Association Declaration of Helsinki states that it is the mission of the physician to safeguard the health of the people. The physician's knowledge and conscience are dedicated to the fulfillment of this mission.
4. The World Medical Association Declaration of Tokyo begins with the following statement:

"It is the privilege of the medical health care Healthcare Practitioner to practice medicine in the service of humanity, to preserve and restore bodily and mental health without distinction as to persons, to comfort and ease the suffering of his or her patients. The utmost respect for human life is to be maintained even under threat, and no use made of any medical knowledge contrary to the laws of humanity".
5. Therefore, the World Medical Association considers that it would be unethical for the physician, whose mission is to provide health care, to participate in the research and development of chemical and biological weapons, and to use his or her personal and scientific knowledge in the conception and manufacture of such weapons.
6. Furthermore, the World Medical Association -

- a. Condemns the development and use of chemical and biological weapons;
- b. Asks all Governments to refrain from the development and use of chemical and biological weapons;
- c. Asks all National Medical Associations to join the World Medical Association in actively supporting this Declaration.

ANNEXURE 2

THE WMA DECLARATION OF WASHINGTON ON BIOLOGICAL WEAPONS

[Adopted by the WMA General Assembly, Washington 2002]

A. INTRODUCTION

1. The World Medical Association recognizes the growing threat that biological weapons might be used to cause devastating epidemics that could spread internationally. All countries are potentially at risk. The release of organisms causing smallpox, plague, anthrax or other diseases could prove catastrophic in terms of the resulting illnesses and deaths compounded by the panic such outbreaks would generate. At the same time, there is a growing potential for production of new microbial agents, as expertise in biotechnology grows and methods for genetic manipulation of organisms become simpler. These developments are of special concern to medical and public health professionals because it is they who best know the potential human suffering caused by epidemic disease and it is they who will bear primary responsibility for dealing with the victims of biological weapons. Thus, the World Medical Association believes that medical associations and all who are concerned with health care bear a special responsibility to lead in educating the public and policy makers about the implications of biological weapons and to mobilize universal support for condemning research, development, or use of such weapons as morally and ethically unacceptable.
2. Unlike the use of nuclear, chemical, and conventional weapons, the consequences of a biological attack are likely to be insidious. Their impact might continue with secondary and tertiary transmission of the agent, weeks or months after the initial epidemic. The consequences of a successful biological attack, especially if the infection were readily communicable, could far exceed those of a chemical or even a nuclear event. Given the ease of travel and increasing globalization, an outbreak anywhere in the world could be a threat to all nations.
3. A great many severe, acute illnesses occurring over a short span of time would almost certainly overwhelm the capacities of most health systems in both the developing and industrialized world. Health services throughout the world are struggling to meet the demands created by HIV/AIDS and antimicrobial-resistant organisms, the problems created by civil strife, refugees and crowded, unsanitary urban environments as well as the increased health needs of aging populations. Coping over a short period of time with large numbers of desperately ill persons could overwhelm entire health systems.
4. Actions can be taken to diminish the risk of biological weapons as well as the potentially harmful consequences of serious epidemics whatever their origin. International collaboration is needed to build a universal consensus that

condemns the development, production, or use of biological weapons. Programs of surveillance are needed in all countries for the early detection, identification, and response to serious epidemic disease; health education and training is needed for professionals, civic leaders, and the public alike; and collaborative programs of research are needed to improve disease diagnosis, prevention, and treatment.

5. The proliferation of technology and scientific progress in biochemistry, biotechnology, and the life sciences provides the opportunity to create novel pathogens and diseases and simplified production methods for bio-weapons. The technology is relatively inexpensive and, because production is similar to that used in biological facilities such as vaccine manufacturing, it is easy to obtain. Capacity to produce and effectively disperse biological weapons exists globally, allowing extremists (acting collectively or individually) to threaten governments and endanger peoples around the world. Non proliferation and arms control measures can diminish but cannot completely eliminate the threat of biological weapons. Thus, there is a need for the creation of and adherence to a globally accepted ethos that rejects the development and use of biological weapons.

B. STRENGTHENING PUBLIC HEALTH AND DISEASE SURVEILLANCE SYSTEMS

6. A critical component in dealing with epidemic disease is a strong public health infrastructure. Investment in public health systems will enhance capacity to detect and to contain expeditiously, rare or unusual disease outbreaks, whether deliberately induced or naturally occurring. Core public health functions (disease surveillance and supporting laboratory services) are needed as a foundation for detection, investigation, and response to all epidemic threats. A more effective global surveillance program will improve response to naturally occurring infectious diseases and will permit earlier detection and characterization of new or emerging diseases.
7. It is especially important that physicians be alert to the occurrence of cases or clusters of unusual infectious diseases, to seek help from infectious disease specialists in diagnosis, and to report cases promptly to public health authorities. Because any physician may see only one or a few cases and may not recognize that an outbreak is occurring, cooperation between primary care physicians and public health authorities is especially important.
8. Public health officials, dealing with an epidemic, will require the cooperation of emergency management agencies, law enforcement officials, healthcare facilities, and a variety of community service organizations. For these different groups to work together effectively, advance planning will be important. In addition to developing surveillance activities for early detection and reporting, public health efforts should be directed toward educating primary caregivers and public health staff about potential agents that might be used, building laboratory capacity for rapid identification of biological agents, providing medical and hospital services as well as vaccines and drugs to control the epidemic.

C. ENHANCEMENT OF MEDICAL PREPAREDNESS AND RESPONSE CAPACITY

9. The first indication that a biological weapon may have been disseminated is likely to be the appearance of patients in the offices of practicing physicians, especially those in acute care settings. Physicians thus play a critical role in early detection of an outbreak and must be prepared to recognize and deal with diseases resulting from the use of biological weapons as well as other infectious disease agents and to promptly report suspicious illnesses and diseases to public health officials.
10. In the course of an epidemic, physicians will be directly involved with mass patient care, with mass immunization and antibiotic prophylaxis, with providing information to the public, and in a variety of hospital and community efforts to control the epidemic. Thus, physicians should participate with local and national health authorities to develop and implement disaster preparedness and response plans for intentional and natural infectious disease outbreaks.

D. BIOWEAPONS RESEARCH AND MEDICAL ETHICS

11. Rapid advances in microbiology, molecular biology, and genetic engineering have created extraordinary opportunities for biomedical research and hold great promise for improving human health and the quality of life. Better and more rapid diagnostic tools, novel vaccines, and therapeutic drugs can be foreseen. At the same time, there is concern about the possible misuse of research for the development of more potent biological weapons and the spread of new infectious diseases. It may be difficult to distinguish legitimate biomedical research from research by unscrupulous scientists with the malign purpose of producing more effective biological weapons.
12. All who participate in biomedical research have a moral and ethical obligation to consider the implications of possible malicious use of their findings. Through deliberate or inadvertent means, genetic modification of microorganisms could create organisms that are more virulent, are antibiotic-resistant, or have greater stability in the environment. Genetic modification of microorganisms could alter their immunogenicity, allowing them to evade natural- and vaccine-induced immunity. Advances in genetic engineering and gene therapy may allow modification of the immune response system of the target population to increase or decrease susceptibility to a pathogen or disrupt the functioning of normal host genes.
13. Research specifically for the purposes of creating biological weapons is to be condemned. As scientists and humanitarians, physicians have a societal responsibility to decry scientific research for the development and use of biological weapons and to express abhorrence for the use of biotechnology and information technologies for potentially harmful purposes.
14. Physicians and medical organizations have important societal roles in demanding a global prohibition on biological weapons and stigmatizing their use, guarding against unethical and illicit research, and mitigating civilian harm from use of biological weapons.

E. RECOMMENDATIONS

15. That the World Medical Association and National Medical Associations worldwide take an active role in promoting an international ethos condemning the development, production, or use of toxins and biological agents that have no justification for prophylactic, protective, or other peaceful purposes.
16. That the World Medical Association, National Medical Associations and healthcare workers worldwide promote, with the World Health Organization, the United Nations, and other appropriate entities, the establishment of an international consortium of medical and public health leaders to monitor the threat of biological weapons, to identify actions likely to prevent bioweapons proliferation, and to develop a coordinated plan for monitoring the worldwide emergence of infectious diseases. This plan should address: (a) international monitoring and reporting systems so as to enhance the surveillance and control of infectious disease outbreaks throughout the world; (b) the development of an effective verification protocol under the UN Biological and Toxin Weapons Convention; (c) education of physicians and public health workers about emerging infectious diseases and potential biological weapons; (d) laboratory capacity to identify biological pathogens; (e) availability of appropriate vaccines and pharmaceuticals; and (f) financial, technical, and research needs to reduce the risk of use of biological weapons and other major infectious disease threats.
17. That the World Medical Association urge physicians to be alert to the occurrence of unexplained illnesses and deaths in the community and knowledgeable of disease surveillance and control capabilities for responding to unusual clusters of diseases, symptoms, or presentations.
18. That the World Medical Association encourage physicians, National Medical Associations and other medical societies to participate with local, national, and international health authorities in developing and implementing disaster preparedness and response protocols for acts of bioterrorism and natural infectious disease outbreaks. These protocols should be used as the basis for physician and public education.
19. That the World Medical Association urge all who participate in biomedical research to consider the implications and possible applications of their work and to weigh carefully in the balance the pursuit of scientific knowledge with their ethical responsibilities to society.

Ethical guidelines for good practice in the health care professions

The following Booklets are separately available:

- Booklet 1: General ethical guidelines for health care professions***
- Booklet 2: Ethical and professional rules of the health professions council of South Africa as promulgated in government gazette R717/2006***
- Booklet 3: National Patients' Rights Charter***
- Booklet 4: Seeking patients' informed consent: The ethical considerations***
- Booklet 5: Confidentiality: Protecting and providing information***
- Booklet 6: Guidelines for the management of patients with HIV infection or AIDS***
- Booklet 7: Guidelines withholding and withdrawing treatment***
- Booklet 8: Guidelines on Reproductive Health management***
- Booklet 9: Guidelines on Patient Records***
- Booklet 10: Guidelines for the practice of Telemedicine***
- Booklet 11: Guidelines on over servicing, perverse incentives and related matters***
- Booklet 12: Guidelines for the management of health care waste***
- Booklet 13: General ethical guidelines for health researchers***
- Booklet 14: Ethical Guidelines for Biotechnology Research in South Africa***
- Booklet 15: Research, development and the use of the chemical, biological and nuclear weapons***
- Booklet 16: Professional self-development***