# ETHICAL PRACTICE IN LABORATORY MEDICINE AND FORENSIC PATHOLOGY





WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR THE EASTERN MEDITERRANEAN

# Ethical practice in laboratory medicine and forensic pathology

### Mohamed M. El-Nageh

Quality of Care and
Health Care Technology Unit
World Health Organization
Regional Office for the Eastern Mediterranean
Alexandria
Egypt

### **Brian Linehan**

Medlab House Hamilton New Zealand

### Stephen Cordner

Victorian Institute of Forensic Medicine Monash University Melbourne, Victoria Australia

### **David Wells**

Victorian Institute of Forensic Medicine Monash University Melbourne, Victoria Australia

### Helen McKelvie

Victorian Institute of Forensic Medicine Monash University Melbourne, Victoria Australia



### **WORLD HEALTH ORGANIZATION**

Regional Office for the Eastern Mediterranean Alexandria, Egypt 1999 WHO Library Cataloguing in Publication Data

Ethical practice in laboratory medicine and forensic pathology / Mohamed M. El-Nageh ....[et al.]

p. (WHO Regional Publications, Eastern Mediterranean series; 20)

ISBN 92-9021-246-2 ISSN 1020-041X

[NLM Classification: W 625]

The World Health Organization welcomes requests for permission to reproduce or translate its publications, in part or in full. Applications and enquiries should be addressed to the Manager, Health and Biomedical Information Programme, World Health Organization, Regional Office for the Eastern Mediterranean, P.O. Box 1517, Alexandria 21563, Egypt, who will be glad to provide the latest information on any changes made to the text, plans for new editions, and reprints and translations already available.

### © World Health Organization 1999

Publications of the World Health Organization enjoy copyright protection in accordance with the provisions of Protocol 2 of the Universal Copyright Convention. All rights reserved.

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the Socretariat of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

The authors alone are responsible for the views expressed in this publication.

Cover design by John Shimwell, EMRO

Cover illustration reproduced from a painting by Husam El-Nageh with his kind permission

Printed in Alexandria, Egypt by Bafra Graphics 3000 copies

### **Contents**

Preface		5
Princip	les of ethics	5
Definiti	ions	ç
_		
Part 1	1 : Laboratory medicine	11
1.1	General application of ethical principles	13
1.2	Collection of information	13
1.3	Collection of specimens	14
1.4	Performance of tests	14
1.5	Reporting of results	14
1.6	Storage and retention of medical records	15
1.7	Access to medical records	15
1.8	Financial arrangements and organizational matters	16
1.9	Some special applications	17
Part 2	2 : Forensic medicine	27
2.1	General application of ethical principles to forensic medicine	29
2.2	Special applications: forensic pathology	36
	Special applications: clinical forensic medicine	41
Anne	xes	45
1.	Declaration of Geneva	47
2.	International Code of Medical Ethics of the World Medical Association—1949	48
3.	World Medical Association Declaration of Helsinki	50
4.	International ethical guidelines for biomedical research involving human subjects	54
5.	Code of conduct for forensic mortuary personnel	60
6.	International Society of Blood Transfusion Code of Ethics for Blood Donation	
	and Transfusion	63
7.	Statement on the Ethics of Voluntary Non-Remunerated Blood Donation of the	
	Third International Collegeium on Bermitment of Voluntum Bland Domini	4-

### **Preface**

This publication is intended to enhance practice in laboratory dicine and forensic pathology by raising awareness of ethical issues. While it is directed primarily at those controlling or working in medical laboratories and forensic medical institutions, it may also be of value to health services administrators, funding authorities, health and justice policy-makers, authorities responsible for laboratory quality and accreditation, clinicians, the judiciary system and patients themselves.

It is intended to identify the common ethical issues encountered in a routine clinical laboratory and in forensic medical practice, and to give some guidance on how these issues might be addressed. It does not deal in depth with all the ethical issues in medicine that have a laboratory or forensic dimension; for example, in laboratory medicine, issues related to reproductive medicine, and genetic manipulation and testing, or in forensic medicine, the particularly specialized area of forensic psychiatry. This publication focuses on the issues routinely encountered on a day-to-day basis in public and private laboratory medicine and forensic medicine.

The authors are grateful for the valuable support received from Dr Hussein A. Gezairy, WHO Regional Director for the Eastern Mediterranean, and Dr M.H. Khayat, Deputy Regional Director for the Eastern Mediterranean.



### **Principles of ethics**

The principles of doing "good" and not doing "harm" are the essence of every code of medical ethics. It is the duty of the medical doctors to their patients to exercise their professional skills in an ethical manner and to observe the laws of the community. The essential purpose is to ensure that patients' trust in the medical profession is deserved. This is achieved by protecting patients and ensuring that they are able to obtain the maximum benefits available from medicine. At the same time, medical ethics aim to protect patients from the abuse that can occur when one person is in a position of power (in this case, based on superior medical knowledge and, often, status) vis-à-vis another.

Medical ethics are generally considered to be derived from the teachings of the Greek physician Hippocrates (460–377 BC), commonly known as the Father of Medicine. The ethical principles he taught survive today in the form of an oath (the Hippocratic Oath) traditionally (if not actually) taken by those entering medical practice. While the exact wording has changed to reflect more modern thinking and practice, the essential principle remains the same: the patient's interests are paramount. Codes of ethics have been enriched by the influence of religion and culture. Arabic and Islamic oaths have been developed and are used in medical schools in most of the Eastern Mediterranean Region.

The best known modern version is the Declaration of Geneva, adopted by the World Medical Association (WMA) in 1948 and subsequently amended in 1968, 1983 and 1994 (see Annex 1). The International Code of Medical Ethics of the World Medical Association—1949 was adopted by the WMA at London in October 1949 and has been used as the basis for various codes of ethical practice adopted by different national medical associations (see Annex 2).

In recent times, as an aid to decision-making in medicine and as a starting point for discussions on medical ethics, four principles have been generally agreed as fundamental. These are:

- Autonomy
   The right of patients to make decisions on their own behalf.
- Beneficence
   The duty or obligation to act in the best interests of the patient.

Non-maleficence
 The duty or obligation to avoid harm to the patient.

### Justice

This embodies concepts of fairness and giving what is rightfully due. It applies not only to the individual but also in the wider medical context and it incorporates notions of equity and fair distribution. This is important when medical services are distributed, as they usually are, in an environment of limited resources. In forensic medicine, justice is the goal that is being pursued.

While concern for safeguarding patients' privacy, as manifest by the duty to maintain confidentiality, can be derived from the first two principles above, some have regarded the concern as so important as to list "privacy" as a fifth principle.

The ethical standards of those working in medical laboratories and forensic medical institutions are derived from medical ethics and other codes and incorporate the same principles. Therefore public expectations of them will reflect, with regard to ethical standards, those expected of the medical profession generally. It is the responsibility of the professionals, whether medically qualified or not, working in those institutions, to ensure that these expectations are realized and that they are worthy of the same level of trust that the medical profession has come to enjoy.

After introducing some concepts common to both areas, we have divided this publication into two parts. This reflects the fact that, while the practice of forensic medicine has many health-related aspects and consequences, there is a duality of purpose: the interests of the patients (in clinical forensic medicine) on the one hand, and the proper administration of justice on the other. Working in this different environment carries with it a different, although allied, set of values and ethics to the patient-oriented service of laboratory medicine.

### **Definitions**

### • Doctor

"Doctor" is used in the general sense of "registered medical practitioner". In some parts of the world the term "physician" would normally be used in this way, whereas in other places the term "physician" is restricted to a specialist in internal medicine.

### • Ethical practice

Ethical practice can be regarded as good technical practice accompanied by proper attitudes and behaviour. In deciding what is proper, reference is often made to moral values voluntarily adhered to within the community and to standards espoused in various codes of professional practice.

### Forensic medicine

Forensic medicine is the application of the principles and practice of medicine to the proper administration of justice. For the purposes of this document, it includes the discipline of forensic pathology and clinical forensic medicine. In many parts of the world, these two disciplines are practised jointly, in others separately.

## Part 1 Laboratory medicine

### 1.1 General application of ethical principles

Medical laboratories have responsibilities to others. There are three main groups to whom responsibility is owed:

### Patients

Medical laboratory professionals are accountable for the quality and integrity of the services they provide. This obligation includes maintaining individual competence and endeavouring to protect the patient from incompetent or illegal practices by others.

### Colleagues and the profession

Medical laboratory professionals should strive to uphold the dignity and respect of their professions and maintain a reputation for honesty, integrity and reliability. They should aim to contribute to the advancement of the profession by improving the body of scientific knowledge, promoting high standards of education and practice and collaborating with colleagues and other health professionals where practicable.

### Society

Professionals working in a medical laboratory also have a responsibility to contribute to the general well being of society. This may be within their sphere of professional competence or simply as members of the community.

Medical professionals should comply with relevant laws and regulations pertaining to their professional activities. The medical profession is committed to a high standard of care and practice, and professionals should endeavour to influence those that do not meet this standard.

### 1.2 Collection of information

Laboratories must collect sufficient information to identify adequately patients and specimens. They also should collect sufficient information for other legitimate purposes, but unnecessary information should not be collected. If possible, there should be sufficient clinical information to enable the test to be correctly performed and interpreted. Other legitimate purposes may involve information relevant to the safety of other patients and staff as well as information required for billing purposes and resource management, including utilization reviews. The patient should be aware of the information collected and the purpose for which it is collected.

### 1.3 Collection of specimens

All procedures carried out on competent patients require their informed consent. Where the patient is incompetent by reason, for example, of age or mental state, consent may be given by a parent or other properly authorized person. In exceptional circumstances when this is not possible, necessity may justify the procedure when it is clearly in the best interests of the patient that the procedure be performed. For most routine laboratory procedures, consent can be inferred when a patient presents at a laboratory and willingly submits to the usual collecting procedures, such as venepuncture. However, certain procedures, especially the more invasive procedures (such as bone marrow aspiration), will require a more detailed explanation of their risks prior to consent being given. Some tests, such as certain genetic testing, will require special pre-test counselling to ensure that the patient fully understands the implications of the test result.

Adequate privacy for the patient must be made available. It should be appropriate for the type of specimen (or information) being collected, and the cultural expectations of the patient and the resources available should be borne in mind.

### 1.4 Performance of tests

All tests must be carried out to an appropriate standard which should be determined in detail by professional organizations or regulatory authorities. Accreditation programmes designed to promote standards and ensure compliance are to be encouraged. Where no such guidance is available the patient's interests will prevail. In some situations, this may mean that a laboratory should refuse to attempt a test rather than produce an unreliable result which could result in harm being done to the patient. All laboratory work must be carried out with the high level of skill and competence expected of the medical, scientific and allied health professions.

### 1.5 Reporting of results

Test results are confidential unless disclosure is authorized. They will normally be reported to the clinician who requested the tests and may be reported to other parties with the patient's consent or as required by law. Decisions concerning implied consent for the reporting of results to other practitioners involved (such as consultant practitioners to whom the patient has been referred) should be made

carefully taking into account local customs. The laboratory should have written procedures detailing how various requests are to be handled, and this information should be made available to patients on request. The laboratory is also responsible for taking all reasonable precautions to ensure that the method of transmitting results to requesting clinicians, or other authorized persons, is secure and reliable. This applies whether transmission is by courier, public post or electronic means. The laboratory is also responsible for ensuring that the turnaround time for results is reasonable, taking into account the type of test and the patient's condition. There should be the facility to report urgent results as soon as they are available.

In addition to the accurate and timely reporting of test results, the laboratory is also responsible for ensuring that, as far as possible, the results are correctly interpreted and applied in the patient's best interests. Care must be given to the construction and format of the test report so as to facilitate correct interpretation and diagnosis. When appropriate a pathologist or some other competent professional should be available to discuss results. Consultation with regard to the selection and interpretation of tests is part of a medical laboratory service.

### 1.6 Storage and retention of medical records

The laboratory must ensure that information is stored so that there are reasonable safeguards against loss, unauthorized access, tampering or other misuse. Test results must never be altered or corrected, except by properly authorized persons in accordance with established procedures. The retention of medical records may be defined by various statutory requirements, and these need to be considered together with any guidelines issued by relevant professional bodies. Laboratories should develop their own protocols indicating how long different results, specimens and slides will be kept for. Test results should be physically available for ready authorized access. When the time comes for medical records to be destroyed this should be carried out in a way which minimizes the risk of unintentional disclosure.

### 1.7 Access to medical records

Access to medical laboratory records should normally be available only to the following:

- the clinician requesting the test
- the patient

- laboratory and hospital staff if required for the management of the patient
- other authorized individuals.

Incompetent patients such as children and intellectually impaired individuals have the same right of access as competent adults, although this right may be expressed through a parent or authorized agent. Parents, on the other hand, do not always have *automatic* right of access to their children's medical information, and different countries have different laws and customs in this respect. The laboratory should develop protocols on how to handle different requests taking into account local laws and customs. In exceptional circumstances the withholding of health information from individuals normally authorized to receive it may be justified (the top management of the laboratory would make such a decision). An example of such a circumstance is when disclosure may be contrary to a patient's best interests.

Where a request is made for access to test results by an authorized person the laboratory must first satisfy itself as to the identity of the person making the request. The way in which this is done, and the degree of certainty associated with the process, will vary with different situations.

Different methods may exist in the same laboratory for different tests. For example a degree of certainty associated with the identity of an authorized person seeking an HIV test result may be much greater than that required of one asking for the results of a routine haemoglobin test. Laboratories need to establish appropriate procedures for each situation.

### 1.8 Financial arrangements and organizational matters

Medical laboratories must be able to function with professional independence. They should not be subject to non-medical control where this has the potential to interfere with their ability to act freely in the best interests of the patient. They may not enter into financial arrangements with referring practitioners or funding agencies where that arrangement acts as an inducement or an impediment for the referral of tests or patients, or interferes with the doctor's independent assessment of what is best for the patient. This assessment, however, will usually be made in an environment of limited resources and so excessive application of these resources to any one individual may not be acceptable, particularly if it results in a failure to deliver a fair share of required services to another individual.

It is desirable that private laboratory collecting rooms be completely separate and independent from the referring practitioner's rooms but where this is not practicable, any financial arrangements must not include any element of inducement.

Laboratories should also be aware of situations which could give rise to conflicts of interest and take particular care. Such situations may arise where pathologists in private practice can self-refer work. Any such self-referred work must be justifiable.

The medical laboratory has a difficult ethical responsibility when operating in an environment of limited resources provided by a third party such as the state. On the one hand there is an obligation to ensure that patients receive all the necessary services to which they are entitled but, on the other hand, there is an obligation to see that resources are not wasted so that other patients are consequentially deprived of their fair share, and the tax payer (or other funding agent) is not unreasonably burdened. The practical implications of this will vary in different situations and particularly from country to country. There will also be different pressures on a laboratory depending upon whether funding is on a "budget" or a "fee-for-service" basis, and the extent to which those resources are under the control of the requesting clinician rather than the laboratory. Nevertheless, there is a responsibility on the laboratory to be involved, to the extent that is reasonable and practicable in the equitable allocation of resources.

### 1.9 Some special applications

### 1.9.1 Clinical pathology (clinical chemistry, haematology, microbiology, immunology)

Most of the issues are covered under general principles. As with histopathology and cytology, the results of tests in these areas can have a life-altering impact upon patients. Information provided about the results, and the manner of its provision, must assist the treating doctor to properly advise the patient about the diagnosis and its consequences.

### 1.9.2 Anatomical pathology

Autopsies<sup>1</sup>

Generally speaking, there are two types of autopsy: the "hospital" autopsy, which requires the voluntary consent of a properly authorized person (often the senior next of kin) and the "forensic", which is autopsy performed at the request or

<sup>&</sup>lt;sup>1</sup> This section is complementary to Part 2, on forensic pathology, and should be read in conjunction with it.

direction of a coroner or other authority to meet statutory death investigation requirements. This section deals with the former.

An autopsy is the post-mortem examination of a body to provide information of medical or scientific use, including the cause of death, or for other relevant purposes such as the resolution of legal issues. The autopsy is an investigation which can have significant public and private consequences. The latter may be lost if the autopsy is limited to merely establishing the cause of death. The community, including the next of kin, has a right to expect that systems are developed to ensure that all the potential benefits are realized (these benefits are set out in the section on forensic pathology).

It can be difficult for families to cope with issues related to autopsies at the time of bereavement. Hospitals and forensic pathology institutions should have adequate facilities to advise, counsel and support bereaved relatives. Sudden or traumatic circumstances leading to death are particularly recognized as leading to much psychological stress, and the pathologist and other staff should not add to this by insensitivity. The body of the deceased person must at all times be handled with respect, and the relatives must be able to rely on this occurring.

### Consent for autopsies

Many religions and cultures do not accept the need for or the desirability of autopsies, and this must be accepted. Procedures relating to consent for autopsies will usually be governed by law and these must be followed meticulously. In most countries, the non-forensic or hospital autopsy requires prior consent from the next of kin. This means that the nature and outcomes of the autopsy must be properly and sensitively explained. This will include an explanation of any need to retain tissues for the purpose of the autopsy or the possibility that tissues may be used for research or teaching purposes. In some cultures the removal of the brain and the heart, particularly if they are retained after the rest of the body is released for burial, is particularly sensitive. The interaction with the next of kin should be conducted in a manner that promotes discussion and encourages them to ask questions. The laboratory should have a clear understanding of the procedures for authorization of an autopsy in the absence of any next of kin or if they cannot be contacted.

### 1.9.3 Histopathology and cytology

In the course of a histopathological or cytological examination certain observations may be made (such as the presence of spermatozoa) which are not related to the purpose of the examination. Careful thought should be given as to whether or not such observations should be reported as there could be significant social implications. As in clinical pathology, tissue diagnosis must provide information to assist the treating doctor to properly advise the patient about the diagnosis and its consequences.

### 1.9.4 Reproductive technology

Issues raised by discussions of reproductive technology may touch on deeply held convictions and religious beliefs, as well as on perceptions about what constitutes a human being or a person, about identity, about the family and about the sense of one's own characteristics living on in some form after death. Just as these convictions and perceptions vary, so does the way different societies and religions treat these issues. Consequently it is not possible to arrive at a universally accepted ethical view on this subject. The different and strongly held views on abortion, artificial insemination by donor, *in vitro* fertilization, gamete intrafallopian transfer, and other procedures and techniques are examples of this concern. Detailed discussion of these important areas is beyond the scope of this document.

### 1.9.5 Transfusion medicine

The code of ethics for blood donation and transfusion, which was unanimously approved by the general assembly of the International Society of Blood Transfusion during the Society's 16th Congress (Montreal, 16–22 August 1980) is given in Annex 6. The statement on the ethics of voluntary, non-remunerated blood donation of the Third International Colloquium on Recruitment of Voluntary Blood Donors, which was endorsed by the International Group of Red Cross Blood Transfusion Experts, is given in Annex 7.

### Voluntary donation

Blood donors should give their blood voluntarily and without expectation of payment. No pressure to donate should be exerted on a potential donor. Volunteer blood donors give blood of their own free will and without coercion. This is in line with the right to self-determination and rights to protection of physical integrity and privacy. In this connection family donor or replacement donor systems have been shown not to meet the criteria of a volunteer system and are therefore undesirable and to be discouraged.

### Non-remunerated donation

Blood is regarded in the same light as any other body tissue, so blood donation should be on a non-remunerated basis. There should be no rewarding of the donor with money, merchandise or services.

### Protection of the donor

No coercion or pressure should be exerted on potential donors, who should be provided with adequate information about the process to properly consent to donation. Blood should be collected under the overall supervision of a physician. Confidentiality concerning all personal donor details, including laboratory results, should be ensured.

### Protection of the recipient

The patient in need of a blood transfusion should, where clinically possible, be provided with reliable information of the risks, benefits and any available alternatives to blood transfusion.

A proper application of the principle of autonomy means that patients needing blood (provided they retain the capacity to understand and assess the information provided) are free to accept or refuse blood transfusion.

Quality assurance is paramount throughout all the stages of blood transfusion starting with the detailed criteria for donor selection or deferral. This also includes the complete range of management and operational systems needed to ensure the safety of blood, blood components or blood products, to prevent adverse reactions and transfusion-transmitted infections.

### Self-sufficiency

Blood transfusion does not exist in isolation. It is an integral and indispensable part of a health care system. The public authorities have a responsibility to protect the health of the population and to ensure the availability of services, equity of access to those services and their quality and safety. Inherent in these values is the promotion of national self-sufficiency in blood. Self-sufficiency means that a country provides all the blood it needs from its own resources. If it is not attainable on a national level, then self-sufficiency of a slightly different kind can be achieved through collaboration with other countries in a similar position. Self-sufficiency applies to the source of blood, but not necessarily to the source of essential supplies, equipment, technology and plasma fractionation.

### Optimal use of blood and blood products

Taking into account the scarcity of blood and the dangers inherent in its use, transfusion medicine should be properly practised. The risks of blood transfusion mean that blood should not be given to patients who do not need it. Patients who need blood, blood components, or blood products must receive what they need. There are three general types of misuse in transfusion therapy: use of blood products when not clinically justified, use of too little or too much in patients who require transfusion, and use of the wrong component or product in patients requiring transfusion. All these should be avoided.

### 1.9.6 Molecular biology/genetics

Issues raised by discussions of molecular biology and genetic testing touch upon deeply held convictions about what constitutes a human being or a person, about identity and about the family. Just as these convictions and perceptions vary, so does the way different societies and religions treat these issues. Detailed discussion of these complex areas are beyond the scope of this document.

### 1.9.7 Research

Biomedical research aimed at understanding and preventing disease or at improving the diagnosis or treatment of disease is highly desirable and is often conducted solely with altruistic motives. Many medical laboratories initiate research themselves and, knowingly or unknowingly, are involved in clinical trials. Unfortunately, there are too many examples where biomedical research has been conducted inappropriately and patients or research subjects have suffered. It is for this reason that medical laboratories should understand the implications of research projects with which they are involved to avoid complicity in unethical research. In many countries a system of institutional ethics committees has added a level of formal oversight to medical research. Even this is not a guarantee that the research is ethical in every respect, and a laboratory should be satisfied that the proposed research meets its own standards. Recommendations and guidelines on biomedical research involving humans are given in Annexes 3 and 4.

The involvement of medical laboratories in biomedical research will usually centre on analysis of tissue or fluids. Some of the issues associated with this are dealt in Section 1.9.9 on human tissues, the major one being that proper consent has been obtained, or proper authority has been given, for the analysis. The following

principles may act as a guide to laboratories initiating their own research or participating in other biomedical research:

- Potential benefits of the research should outweigh the risks.
- The risks of the research should be predictable.
- The patient or research subject should be well informed about proposed treatments, procedures, risks, costs, inconvenience, discomforts and relevant alternatives.
- Consent to participate should preferably not be sought by a doctor in a treating relationship with the patient.
- Due regard should be given to issues of privacy and confidentiality.
- The progress of the research should be regularly reviewed, especially in trials of therapeutic agents.
- In randomized clinical trials, control subjects must receive the best currently available means of prevention, diagnosis or treatment.

Volunteers may be used for non-clinical, non-therapeutic biomedical research, but participation must be free of any coercion or inducement. The pharmaceutical industry has contributed enormously to biomedical research in partnership with the medical profession, research institutions and hospitals. This partnership, however, provides opportunities for questionable practices and flagrant abuses of the ethical principles of biomedical research. Codes of conduct regarding the relationship between doctors and the pharmaceutical industry have been developed. National medical associations should be aware of those most relevant to a particular laboratory. In the absence of this awareness, the following may be of assistance:

- Ethical guidelines in the relationship between physicians and the pharmaceutical industry. Sydney, Royal Australian College of Physicians, 1994.
- Physicians and the pharmaceutical industry. Position paper of the American College of Physicians. *Annals of internal medicine*, 1990, 112: 624–6.

### **1.9.8 HIV/AIDS**

Testing for HIV requires special consideration. Tests should normally be performed only on patients who are fully informed of the implications of a positive result. This may require special counselling. Confidentiality is especially important, and it is generally accepted that greater public health gains can be made in preventing the spread of AIDS by ensuring that individuals can be tested and treated with the assurance of confidentiality and sensitivity than by more punitive systems, which often have the effect of driving the whole problem "underground".

In some countries, compulsory testing of certain groups, such as intravenous drug users or prisoners, is required by law. While the wisdom of some programmes may be debated, it is reasonable for a laboratory to participate in the testing even though informed consent may not have been given. In these cases the burden of responsibility for the patient usually rests with the authority organizing the programme, but in some situations, such as testing for visa requirements, where the authorities may have little interest other then the requirement for a negative result, a laboratory could find itself with an obligation to provide counselling and support in the case of an unexpected positive result. The laboratory should ensure that facilities exist for these services to be provided. Screening programmes for epidemiological purposes are acceptable, but if patients with positive results can be identified (and notified) then prior informed consent is required.

Doctors with a dual responsibility both for an affected patient (including specimens from such patients) and for the health and safety of others, such as laboratory staff who may receive needle stick injuries, have a special responsibility. In those situations a doctor may consider that obligations to the new patient (that is, the staff member) supersedes obligations of confidentiality to the first patient. For example, in case of a needle stick injury to a staff member, a doctor may arrange for, say, HIV testing on the "donor" blood (that is, the blood of the first patient) in order that appropriate treatment of the new patient can be determined. Where possible any testing to be carried out on the "donor" blood should be done with the consent of the patient, but there will be situations when this is not possible. Under such circumstances the identity of the patient with the positive test result should be protected as far as possible.

### 1.9.9 Human tissues and fluids

At any one time, a medical laboratory is the repository of quantities of human tissues and fluids. Such tissues and fluids have many potential uses, including therapeutic purposes, teaching, research or even commercial development. Such tissues and fluids include:

- blood
- urine
- faeces
- biopsy specimens
- surgical or autopsy specimens
- histopathology blocks and slides.

The property status of these tissues and fluids has changed in recent times in some parts of the world. The predominant view is that, the tissue or fluid having been provided, the patient had no continuing right to determine how that tissue or fluid would be used subsequently. The analysis or test having been performed, the tissues or fluid had little more status than abandoned goods and could therefore be dealt with at the discretion of the person in effective control of them (the person in charge of the laboratory). Thus, blood specimens were readily available for research purposes, surgical specimens were "potted" for educational purposes (or even public display), and cell lines even appropriated for commercial purposes1. Among the earlier manifestations of changing attitudes was a developing concern with how laboratories dealt with the remains of fetuses, the stillborn, and extremely premature neonates dying within minutes of birth. If the birth was not one that needed to be registered (and sometimes even if it was) the remains were often sent to the hospital incinerator with other laboratory waste or buried, along with other unnamed neonatal deaths, in mass unmarked graves. Mothers (and fathers) began to take exception to this, and were supported by psychologists who pointed out the importance of more formal procedures for dealing with the remains and of helping the parents and other members of the family deal with the bereavement. Such procedures now exist in many laboratories.

The practice of storing and testing blood samples for epidemiological purposes also focused attention on important ethical issues for laboratories. For example, testing batches or large numbers of such samples for HIV antibodies raised issues about contacting patients found to be positive. These patients had not contemplated such a test at the time of providing the blood sample let alone consented to its performance. These and other similar examples have led to formal statements such as that of the Council of Europe:

When in the course of an intervention any part of the human body is removed, it may be stored and used for a purpose other than that for which it was removed only if this is done in conformity with appropriate information and consent procedures<sup>2</sup>.

This means that a surgical specimen, for example, should be "potted" for educational purposes only if the patient has agreed to this use. Properly approached,

<sup>&</sup>lt;sup>1</sup> See Moore v. Regents of the University of California, 793 P.2d 479 (Cal. 1990), rev'g 249 Cal. Rptr. 494 (Ct. App. 1988).

<sup>&</sup>lt;sup>2</sup> Council of Europe. Convention on human rights and biomedicine. Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine. Article 22. Adopted by the Committee of Ministers on 19 November 1996.

few patients are likely to have any difficulty with this and most are likely to be pleased that some general benefit can be derived from preserving their specimen.

It also means that femoral heads and other skeletal tissue, for example, which can be processed, banked and later used as allograft material may only be so used if the donor patient has properly given prior consent. This will have the added practical advantage, without which the use of the tissue as allograft is potentially dangerous, of allowing a proper history to be taken and the appropriate extra tests to be performed to minimize the risk of transmitting an infectious disease to the recipient.

:			

### Part 2 Forensic medicine

While there are important health benefits flowing from the practice of forensic medicine, its primary purpose is to serve the needs of the justice system. The intention of this part is to focus on ethical principles, which, if observed, will promote and lead to good practice in the disciplines of forensic pathology and clinical forensic medicine. In the absence of good practice, injustice will flourish.

### 2.1 General application of ethical principles to forensic medicine

### 2.1.1 Independence of the forensic service

In many countries, forensic practitioners are involved in the investigation of deaths and injuries that are either actually, or perceived to be, related to the security of the state. Serious conflicts of interest can arise where the state is involved in both perpetrating and investigating them. Imperatives associated with these investigations may easily overwhelm the ability or the desire of the practitioners to think and act independently and to discharge their medically derived obligations. It is in these circumstances, however, that an understanding of, and adherence to, fundamental principles of medical ethics helps to ensure the proper administration of justice.

The International Code of Medical Ethics of the World Medical Association<sup>1</sup> states that:

A physician shall, in all types of medical practice, be dedicated to providing competent medical service in full technical and moral independence, with compassion and respect for human dignity.

It is self-evident that the forensic practitioner should be able to come to conclusions without intimidation and in the absence of threat. In practice, unless forensic practitioners enjoy some form of special protection, it will be relatively easy for authorities to promote a particular desired outcome. Investigators, consciously or unconsciously, may coerce or bring considerable pressure to bear on practitioners to provide an interpretation that would wrongly resolve an issue in favour of the state, police or investigators. This is particularly so in cases where national security is threatened (for example, terrorist activities), serious serial offences (for example, multiple murders), or when public interest or anxiety is at a high level. These coercive forces may be particularly strong when the practitioner has a formal relationship with, or accountability to, the investigating authority, or when a close

<sup>&</sup>lt;sup>1</sup> See Annex 2.

personal relationship has developed between investigator and forensic practitioner. The situation is further complicated because the practitioner has the dual, and often conflicting roles of investigator and doctor.

While organizational structure is no safeguard against the potential abuse of power, there is a strong case for forensic pathologists and clinical forensic physicians to be employed in a structure that provides whatever protection can be afforded against such potential abuse. Such a structure, if effective, will promote confidence in the findings of the practitioner in courts of law and the community, and in turn promote confidence in the justice system. Examples of structural arrangements that have the potential to provide an appropriate level of independence for a forensic medical service include establishment of an independent statutory agency, or inclusion of the service as part of a university medical faculty. In the case of a statutory agency, innovative structures could include some form of administrative accountability to the judiciary.

In the administration of the forensic service, account should be taken of the following issues:

- ability to provide independent advice in instances where a patient claims to have been injured by police action, or by the action of other servants of the government;
- availability of an appropriate structure and mechanism for all users to make comments or complaints and for those comments and complaints to be dealt with;
   and
- accountability for the quality, quantity, timeliness and costs of its services.

### 2.1.2 Forensic practitioners as expert witnesses

General requirements for forensic practitioners in meeting the needs of the justice system are to:

- be readily available;
- be familiar with the basic principles and practice of the legal system and with the obligations of those within the system, especially the police;
- reliably collect appropriate samples from victims of crime, scenes of crime and suspects, the proper analysis of which can provide results which can be used as evidence in an investigation and prosecution; and
- make reliable clinical and/or post-mortem observations, which form the basis of reasonable assessments and measured expert opinion.

In terms of attendance in court, there are many pitfalls awaiting practitioners as they give evidence of their observations and conclusions. The pitfalls, or the mistakes that can be made, occur in the following areas:

31

- providing opinions which are at the edge of, or beyond, the expertise of the witness;
- providing opinions that are based on false assumptions or incomplete facts;
- providing opinions based on incomplete or inadequate scientific or medical analysis; and
- providing opinions which are biased, consciously or unconsciously, in favour of one side or the other in the proceedings.

In addition, failures of communication occur between expert witnesses, police and lawyers.

The giving of evidence is the culmination of the forensic practitioner's work in a particular case and there is an obligation to bring to this task the same reasonable care and skill as to other aspects of the practitioner's craft. After all, it is on the basis of the evidence that important decisions will be made affecting the life and liberty of accused persons (in criminal matters) or affecting liability and compensation (in civil matters). The words of the eminent forensic pathologist Keith Simpson are apposite<sup>1</sup>:

Every time a doctor steps into the witness box to give evidence, whether as a young casualty officer or an experienced specialist, s/he needs to make a conscious effort to perform well. The four absolute essentials of success are:

- preparation—familiarity with the facts of the case and possession of the relevant documents before stepping into the box;
- clear exposition—the ability to express things lucidly and briefly in simple words;
- confining oneself to one's field of competence; and
- tolerance and courtesy.

While the above may appear to be the beginnings of a quality manual on the giving of evidence, it is also apparent that an important value is at stake: the truth of what the forensic practitioner saw and concluded must be conveyed to the court impartially, ensuring that a balanced interpretation of the findings is given. Simpson's criteria still apply, but the increasing complexity of medicine and science

<sup>&</sup>lt;sup>1</sup> Simpson K. A doctor's guide to court: a handbook on medical evidence, 2nd edition. London, Butterworths, 1967:51.

and the more rigorous challenging of expert evidence by lawyers means they no longer cover the field. Furthermore, legal procedures may not be adequate in themselves to safeguard a citizen against an unsatisfactory verdict that is based on unsound expert evidence. These factors place an onus on expert witnesses to be more active on behalf of their profession or field of expertise to ensure that the best assistance is given to the courts. Expert witnesses, rather than being a passive agent of the party who is instructing them, are required to become more active so that the court can be the beneficiary of the best possible answers to the medical and scientific issues in front of it.

As there is considerable variation between jurisdictions in the laws of evidence, it is difficult to generalize. However, a particular practical application of the obligation to be more actively involved as a witness, is not to accept a direction from a lawyer to simply answer "yes" or "no" to a question if such an answer is misleading. In most jurisdictions, it is possible to bring a judge's attention to such misleading consequences and to seek his or her guidance on the matter. In bringing the matter to the judge's attention, reference can be made to the usual undertaking given to the court by the witness to tell the truth. In the unlikely event that the judge nevertheless directs the witness to answer "yes" or "no", then the responsibility for the misleading answer passes to the judge.

Apart from the content of the witness's evidence, generally speaking, the value of the expert witness's contribution is proportional to the understanding the lawyer has of the subject matter. Insufficient understanding often leads to confusion and wasted time. A pre-trial conference with the instructing advocate or lawyer may be important. A pre-trial conference provides the witness with an opportunity to educate the advocate or lawyer, to interpret medical and scientific terminology and to apprise him or her more carefully of exactly what it is the witness will say.

In adversarial systems, it is the cross-examination that many doctors find to be the most disagreeable aspect of a court appearance. The feeling is hard to avoid if the trial is regarded as an argumentative battle rather than as a reasonable testing of views. Answers should only be given after due consideration, and if published works are quoted by counsel, the witness should have the opportunity to view them to enable him or her to judge the context, relevance and merits of the material. Any attempt at evasion on the part of an expert witness will usually be recognized and pursued vigorously. Evasion is unnecessary since the limits of an opinion must be admitted freely, as must the limits of one's knowledge. No one is expected to know everything.

Forensic medicine 33

Expert witnesses will serve the legal process well if they are prepared soundly and aim to help the court as much as possible. It is by addressing their professional expertise to the process, rather than being participants in an adversarial battle, that the responsibilities of forensic practitioners are best discharged.

### 2.1.3 Relationships between forensic practitioners and with other medical colleagues

Probably more than any other branch of medicine, forensic practitioners have to deal, often openly and in public, with scrutiny from other forensic practitioners and medical colleagues. As many of the conclusions in the discipline are matters of opinion, to greater or lesser degrees, there is room for proper disagreement in some cases. This can, and does, lead to personal friction which, if not dealt with responsibly and professionally, can lead to future injustices, as personal dynamics overwhelm the obligation to use reasonable care and skill to produce reliable and valid conclusions. This potential problem is sometimes allied to an unhealthy association or identification by the practitioner(s) with the interests of one or other party in litigation. When the results of one's work are directed towards the court or justice, and not necessarily to a particular outcome or towards one side or another in litigation, disagreement may be accommodated in a more dispassionate way.

This problem is exacerbated by legal systems which act to bind a practitioner to one party or another in litigation. While there are probably exceptions, systems which prevent free and open discussion of the forensic issues between forensic practitioners advising different parties are likely, albeit inadvertently, to increase the risk of injustice. This is because, without such interchange, the likelihood of confusion is greater. Such interchange will generally, and often quickly, result in agreement on most issues allowing attention to focus on any real disagreements.

The nature of their work means that forensic practitioners (especially pathologists) from time to time discover problems or mistakes that have occurred in the medical (including surgical) management prior to the death or injury of a patient. Such problems or mistakes should be alluded to in their reports, although care should be taken in the comments made. Forensic practitioners usually do not have close familiarity with all aspects of the increasingly specialized practice of medicine. This limitation of knowledge should be recognized. It may be advisable to suggest that clinical advice of the appropriate kind be sought to evaluate the possible problems or mistakes.

### 2.1.4 Forensic practitioners and human rights abuses

The ethical principles underpinning medical practice, discussed earlier in this document, clearly run counter to any medical practitioners' collusion in any form of human rights abuse. This is especially relevant for forensic practitioners, as their role and responsibilities may entail examining those who have been killed or injured in circumstances of torture or illegal imprisonment, or other circumstances that amount to an abuse of human rights. This can place practitioners in extremely compromising situations, which may, in varying degrees, amount to participation in violations. For example, forensic practitioners may participate:

- actively, by being directly involved in abuses;
- consciously, by failing to record and effectively document signs of abuse, or by failing to ensure that abuse is reported to the appropriate authorities;
- reluctantly, where their own or professional values are outweighed by pressure from government or other agencies; or
- unconsciously, where insufficient training or skills result in failure to recognize and record abuses adequately.

Any form of participation in human rights violations amounts to a breach of a forensic practitioner's professional ethical obligations. However, it is not the function of this document to strictly prescribe behaviour for practitioners in all circumstances, only to set out ideals of ethical conduct for use as a reference. Decisions to adhere, or not to adhere, to ethical standards are made consciously or unconsciously by individuals, taking into account other matters such as their own and others' safety and security.

One context in which forensic practitioners may be faced with ethical dilemmas involving human rights violations is in examining current or former prisoners or detainees. They may see injuries that have resulted from the illegal actions of prison staff and illnesses resulting from malnutrition, poor hygiene or other inadequacies attributable to the prison administration. Practitioners may be subject to pressure to cover up these abuses.

In 1982 the United Nations General Assembly adopted a general code of ethics drafted by the Council for International Organizations of Medical Sciences, entitled Principles of medical ethics relevant to the role of health personnel particularly physicians in the protection of prisoners and detainees against torture and other cruel, inhuman or degrading treatment or punishment. This Code contains six basic principles with which forensic practitioners should be familiar.

Forensic medicine 35

The first is that prisoners should be afforded medical care of the same quality and standard as is available to the general public. The second makes it clear that it is a gross contravention of ethics for medical staff to condone or participate in torture, cruel, inhuman or degrading treatment or punishment. The third principle deals with the role of doctors in prison management. It is a contravention of medical ethics for health personnel to be involved in any professional relationship with prisoners or detainees, the purpose of which is not solely to evaluate, protect or improve their physical or mental health. The fourth principle deals with doctors' involvement in making judgements about a person's fitness to be punished. It states that health personnel may not participate in the interrogation of prisoners or certify their fitness for punishment where that punishment could adversely affect their health. The fifth principle states that for health personnel, and in particular physicians, the assistance in any procedure for restraining prisoners or detainees contradicts medical ethics unless it is based on purely medical criteria presenting no hazard to the health of prisoners or detainees and necessary for the physical or mental health and the safety of the prisoner himself and/or other prisoners, detainees and guardians. The last of the six principles underlines the fact that all the principles should be adhered to at all times and under all circumstances.

Forensic practitioners should be alert to the possibility of torture when examining patients who are in or have been in custody or other relevant circumstances. This will require some knowledge of the diagnostic techniques required to accurately detect signs of torture and be able to give evidence about them. Without the required knowledge, a forensic practitioner may present an incorrect (false) report, which benefits the torturer and, as mentioned above, implicates the practitioner as an unconscious participant in the torture.

The following are some factors forensic practitioners should bear in mind when examining someone who may have been tortured.

- Torture is practised for many reasons including obtaining confession or information, as a sort of punishment, or even for sadistic purposes. The aim of torture, usually, is not to kill, but to inflict physical and mental harm trying not to leave detectable signs. The torturer may apply treatment to remove signs of torture.
- A tortured person may be detained for long enough for the physical symptoms of torture to have disappeared. In living subjects, psychiatric examination is therefore an important element of making a forensic diagnosis.
- In many cases advanced diagnostic investigations must be undertaken, if possible. For example, to diagnose beating and bastinado (severe beating on the soles of

the feet) bone scintigraphy can be used; for testicle twisting or squeezing, dynamic scintigraphy; for electrical torture, biopsy can be used; for suspension torture, electromyography, ultrasonography or magnetic resonance imaging can be effective; and for ear lesions audiometry is helpful.

For a more detailed examination of human rights issues as they relate to health professionals, Amnesty International has a useful publication, *Prescription for change—health professionals and the exposure of human rights violations* (AI Index ACT 75/01/96. London, Amnesty International, 1996).

#### 2.2 Special applications: forensic pathology

#### 2.2.1 The importance of autopsies

Forensic pathology is increasingly relied on by judicial systems, even in countries with strong religious and cultural opposition to the performance of autopsies. There are very few, if any, countries in the world where no autopsies for forensic purposes are performed. The numbers and types of death investigated by autopsy vary considerably from country to country. While the disinclination on cultural or religious grounds to perform any more autopsies than are absolutely necessary must be respected, this must be accompanied by caution.

In many countries, major reliance is placed on the external examination of a body by a local medical officer when investigating the cause of death. While this is clearly a reasonable screening process, it is only that. Without autopsies, there will be many cases where it will not be possible to say why death occurred; it will not be possible to disentangle and distinguish, say, between natural and accidental deaths or suicides and homicides. Even with autopsies, some cases remain enigmatic. There must be acknowledgement that coming to correct conclusions about the cause and manner of death based simply on history and external examination is a process which is inherently and substantially flawed. Judicial decisions based on conclusions about the cause and manner of death reached without the benefit of an autopsy will have a high rate of error.

#### 2.2.2 Death investigation systems, education and training

As can be inferred from the above, there are several potential sources of error in forensic pathology systems which must be recognized if injustice is to be avoided. These sources of error are both structural and personal to the medical officer and should be minimized as follows.

Forensic medicine 37

• In those countries where reliance is placed on medical officers to examine bodies externally to make conclusions about the cause and manner of death, undergraduate medical education should reflect the seriousness of this responsibility. This undergraduate education should impart the uncertainties inherent in providing conclusions about the cause and manner of death based on the history and external examination only.

• In many countries, where the allocation of scarce resources is at issue, it should be realized that it is unreasonable to expect reliable and valid results from autopsies conducted by medical practitioners without the benefit of further substantial supervised postgraduate training and experience in pathology in general, and forensic pathology in particular.

As for all branches of medicine, there is a responsibility on practitioners in the field of forensic pathology to understand and freely acknowledge the limits of their knowledge and experience. This can be difficult for practitioners operating in unsupportive or otherwise difficult circumstances.

The net effect of this is that judicial systems where autopsies are discouraged or which cannot provide properly trained personnel should be aware that injustices will occur at a greater rate than when reliance is placed on systems where autopsies occur more frequently and properly trained personnel are available.

#### 2.2.3 To whom does the forensic pathologist owe a duty?

The answer to this question can sometimes be confused because the subject of the pathologist's examination is dead. The issues for most other doctors are clearer because there is a living patient. However, there is at least the argument to be made (and it is the instinctive feeling of many forensic pathologists) that a duty is owed to the deceased, or at least the memory or reputation of the deceased, that the true cause and circumstances of the death be revealed. If such a duty is doubted, a stronger case can be made that the forensic pathologist has a duty to the community at large, because of the trust that the community (including the deceased's relatives) has in the integrity of the medical profession generally. On that basis the forensic pathologist has a duty not to collude in wrongly hiding or obscuring the cause and circumstances of the death.

#### 2.2.4 What is the content of the forensic pathologist's duty?

The forensic pathologist's broad duty is to make sure that the cause and circumstances of the death are revealed, and not to collude in wrongly hiding or

obscuring these. As with other health professionals, the more specific content of the forensic pathologist's duty is to exercise at least a reasonable degree of care and skill in his or her work, that is, in the production of valid and useful observations and conclusions. In assessing what is a reasonable degree of care and skill, reference can be made to the practice of colleagues of similar training and expertise. However, such practice is sub-standard if it does not produce reliable and valid results. What this means in practical terms requires an understanding of the basic aims of the forensic autopsy. These are as follows.

- To discover, describe and record all the pathological processes present in the deceased, and where necessary, the identifying characteristics of the deceased.
- With knowledge of the medical history and circumstances of the death, to come
  to conclusions about the cause and time of death and factors contributing to death
  and, where necessary, the identity of the deceased.
- In situations where the circumstances of death are unknown or in question, to apply the autopsy findings and conclusions to the reconstruction of those circumstances. This will, on occasion, involve attendance at the scene of death, preferably with the body *in situ*.
- To record the positive and relevant negative observations and findings in such a way as to enable another forensic pathologist at another time to independently come to his or her own conclusions about the case. As forensic pathology is essentially a visual exercise, this involves a dependence on good quality and preferably colour photography.

#### 2.2.5 Managing the mortuary

An autopsy is a unique procedure in medicine. Virtually all other procedures in almost every other aspect of medicine are performed for the benefit and with the consent of the individual. In a forensic pathology context, the deceased person has been taken out of the control of the relatives and the autopsy is often performed without the express consent of the deceased person (while alive) or the next of kin. These two factors alone place a heavy responsibility on forensic pathology systems to ensure that the autopsy is carried out in a dignified way with appropriate respect for the deceased person and interests of the next of kin. This obligation is often expressed in relevant legislation dealing with autopsies. In discharging this obligation regard should be had for the following.

- facilities and equipment available for the receiving and proper storage of bodies and the subsequent performance of autopsies;
- facilities for the viewing of bodies by relatives;

Forensic medicine 39

• the performance of the autopsy competently within a reasonable time of receipt of the body;

- the ability of the next of kin, or other properly interested parties, to be represented by an appropriate qualified person at the autopsy;
- the reconstruction of the body after the autopsy;
- the availability of the body for funeral purposes within a reasonable time of the autopsy;
- the provision of the results of the autopsy within a reasonable time and their availability to next of kin and other properly interested parties; and
- the provision of the formal report within a reasonable time and its availability to next of kin and properly interested parties.

In managing the mortuary, considerable responsibility is usually given to scientific and technical staff. Historically, problems have arisen when financial relationships have developed between funeral directors (or undertakers) and mortuary staff. Such relationships are intended to ensure that the mortuary delivers funeral business to a particular undertaker, which is normally to the detriment of next of kin. Other problems include the handling of personal property arriving with the deceased at the mortuary. This includes clothing, jewellery, and not infrequently, considerable quantities of money. Unless the mortuary has well documented and reliable procedures to record such property, false accusations against the mortuary can easily be made and will be difficult to refute. Such allegations if not properly refuted will adversely affect the reputation and credibility of the mortuary, its staff and its work. Annex 5 is a sample code of conduct for forensic mortuary personnel developed by mortuary managers in Australia.

#### 2.2.6 Other proper uses to be made of the autopsy

In a forensic context, the autopsy is performed not only without the consent of the next of kin, but on occasion also over their objection. It is generally agreed that an autopsy is a procedure of considerable ethical significance as it interferes with the body. This significance is such that the community has a right to expect that systems are developed, within legal and resource constraints, and with community input and understanding, to ensure that the substantial potential benefits of performing an autopsy are realized and that autopsy is not meeting only narrowly defined needs.

These potential benefits relate to the use of knowledge or information gathered at the autopsy and the use of tissues available as a consequence of the autopsy.

In addition to the autopsy's role in judicial and security systems, knowledge gained from an autopsy can:

- contribute to clinical audits (processes to ensure that illness is being correctly diagnosed and treated);
- contribute to the evaluation of poorly understood diseases;
- contribute to the evaluation of new medical therapies, surgical techniques and procedures;
- assist families with reproductive decisions if diseases with genetic components are identified;
- assist families by providing a factual basis for counselling of relatives in relation to any anxiety that action or inaction on their part contributed to the death;
- contribute to the maintenance of accurate mortality statistics which can inform government health policy;
- act as an early warning system for issues affecting public health or safety thereby contributing to the prevention of disease and accidents; and
- contribute to medical and paramedical education and research.

Subject to observance of relevant law and in accordance with local customs (which may include ensuring that the permission of the next of kin is obtained), tissue available as a consequence of the autopsy may:

- be retained for further dissection, analysis or testing in relation to establishing the pathological processes present in the deceased;
- be retained for evidentiary purposes or for later examination by representatives of other properly interested parties involved in legal proceedings related to the death:
- be used for therapeutic purposes (corneas, aortic valves, bone, skin); or
- be retained for medical or paramedical education and research.

#### 2.2.7 Preventing the preventable

In 1915, William Brend wrote<sup>1</sup>: "If prevention of deaths is not now regarded as the main purpose to be served by inquests, the inquiry becomes of relatively little value". Thus far, this part has focused on the primary, judicial role of forensic pathology. In carrying out this role, the forensic pathology service accumulates

<sup>&</sup>lt;sup>1</sup>. Brend WA. Inquiry into the statistics of death from violence and unnatural causes in the United Kingdom. London, Charles Griffin, 1915:66.

information and experience, which has importance in issues of public health and safety. Death investigation can be the early warning system for dangerous hazards in the community. Patterns of preventable death may be identified in the workplace, on the road, associated with recreation or associated with disease. Identifying these patterns, because they may be occurring over large geographical areas and over time (so-called "diffuse disasters"), requires that information handling systems be developed. There is arguably a responsibility for forensic pathology systems to advance the cause of death and injury prevention by contributing, as far as possible, to identifying such patterns. As can be seen from the quotation above, some have argued that this responsibility is of greater importance than that of the judicial role of forensic pathology.

### 2.3 Special applications: clinical forensic medicine

#### 2.3.1 The scope of clinical forensic medicine

While forensic pathology deals with examination of the dead, clinical forensic medicine deals with the living. It is principally concerned with the provision of medical advice in the investigation of crimes and other offences where medical knowledge and experience is essential to assist the legal process. Without accurate documentation and expert interpretation of injuries by forensic clinicians who can also properly evaluate medical history and circumstances, conclusions about how the injuries occurred might be flawed. Such conclusions will affect investigations and both criminal and civil trials.

Forensic clinicians are uniquely placed to provide constructive commentary on some of the more pressing criminal and social problems endemic in many modern societies. These include cases of child abuse, sexual assault, domestic violence, assault by law enforcement agencies, torture and substance abuse. Clinical forensic services may also be utilized to assist with aspects of community welfare such as the protection of children, health care within the custodial system, assessment of mentally ill or behaviourally disturbed people, traffic medicine, and other miscellaneous medico-legal services that may be requested by government departments or agencies. Some forensic physicians may also become involved in the diagnosis of occupational disease and injury, or insurance medicine.

## **Declaration of Geneva**

Adopted by the Third General Assembly of the World Medical Association, Geneva, Switzerland, 1949 and amended by the 22nd World Medical Assembly, Sydney, Australia, 1968, the 35th World Medical Assembly, Venice, Italy, 1983, and the 46th WMA General Assembly, Stockholm, Sweden, in 1994, the Declaration of Geneva was one of the first and most important actions of the Association. It is a declaration of physicians' dedication to the humanitarian goals of medicine, a declaration that was especially important in view of the medical crimes which had just been committed in Nazi Germany. The Declaration of Geneva was intended to update the Oath of Hippocrates, which was no longer suited to modern conditions.

# At the time of being admitted as a member of the medical profession:

I SOLEMNLY PLEDGE myself to consecrate my life to the service of humanity;

I WILL GIVE to my teachers the respect and gratitude which is their due;

I WILL PRACTISE my profession with conscience and dignity;

THE HEALTH OF MY PATIENT will be my first consideration:

I WILL RESPECT the secrets which are confided in me, even after the patient has died;

I WILL MAINTAIN by all the means in my power, the honour and the noble traditions of the medical profession;

MY COLLEAGUES will be my sisters and brothers;

I WILL NOT PERMIT considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, or social standing to intervene between my duty and my patient;

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;

I MAKE THESE PROMISES solemnly, freely and upon my honour.

# International Code of Medical Ethics of the World Medical Association—1949

Adopted by the Third General Assembly of the World Medical Association, London, England, October 1949 and amended by the 22nd World Medical Assembly, Sydney, Australia, August 1968, and the 35th World Medical Assembly, Venice, Italy, October 1983.

#### **Duties of physicians in general**

- A PHYSICIAN SHALL always maintain the highest standards of professional conduct.
- A PHYSICIAN SHALL not permit motives of profit to influence the free and independent exercise of professional judgement on behalf of patients.
- A PHYSICIAN SHALL in all types of medical practice, be dedicated to providing competent medical service in full technical and moral independence, with compassion and respect for human dignity.
- A PHYSICIAN SHALL deal honestly with patients and colleagues, and strive to expose those physicians deficient in character or competence, or who engage in fraud or deception.

The following practices are deemed to be unethical conduct:

- a) Self-advertising by physicians, unless permitted by the laws of the country and the Code of Ethics of the National Medical Association.
- b) Paying or receiving any fee or any other consideration solely to procure the referral of a patient or for prescribing or referring a patient to any source.
- A PHYSICIAN SHALL respect the rights of patients, of colleagues, and of other health professionals and shall safeguard patient confidences.

A PHYSICIAN SHALL act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient.

A PHYSICIAN SHALL use great caution in divulging discoveries or new techniques or treatment through non-professional channels.

A PHYSICIAN SHALL certify only that which he has personally verified.

#### Duties of physicians to the sick

A PHYSICIAN SHALL always bear in mind the obligation of preserving human life.

A PHYSICIAN SHALL owe his patients complete loyalty and all the resources of his science. Whenever an examination or treatment is beyond the physician's capacity he should summon another physician who has the necessary ability.

A PHYSICIAN SHALL preserve absolute confidentiality on all he knows about his patient even after the patient has died.

A PHYSICIAN SHALL give emergency care as a humanitarian duty unless he is assured that others are willing and able to give such care.

### Duties of physicians to each other

A PHYSICIAN SHALL behave towards his colleagues as he would have them behave towards him.

A PHYSICIAN SHALL NOT entice patients from his colleagues.

A PHYSICIAN SHALL observe the principles of the "Declaration of Geneva" approved by the World Medical Association.

### World Medical Association Declaration of Helsinki

Recommendations guiding physicians in biomedical research involving human subjects. Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and amended by the 29th World Medical Assembly Tokyo, Japan, October 1975, the 35th World Medical Assembly, Venice, Italy, October 1983, and the 41st World Medical Assembly, Hong Kong, September 1989.

#### Introduction

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfilment of this mission.

The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the etiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research a fundamental distinction must be recognized between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

#### I. Basic principles

- Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.
- 2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.
- 3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.
- 4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
- 5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.
- 6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
- 7. Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be

- predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.
- 8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.
- 9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely given informed consent, preferably in writing.
- 10. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.
- 11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.
  - Whenever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.
- 12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

# II. Medical research combined with professional care (clinical research)

- 1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, reestablishing health or alleviating suffering.
- The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.

- 3. In any medical study, every patient—including those of a control group, if any—should be assured of the best proven diagnostic and therapeutic method. This does not exclude the use of inert placebo in studies where no proven diagnostic or therapeutic method exists.
- 4. The refusal of the patient to participate in a study must never interfere with the physician–patient relationship.
- 5. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (I, 2).
- 6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

# III. Non-therapeutic biomedical research involving human subjects (non-clinical biomedical research)

- 1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.
- 2. The subjects should be volunteers—either healthy persons or patients for whom the experimental design is not related to the patient's illness.
- 3. The investigator or the investigating team should discontinue the research if in his/her or their judgement it may, if continued, be harmful to the individual.
- 4. In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.

# International ethical guidelines for biomedical research involving human subjects

Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), Geneva, 1993

#### The guidelines

#### Informed consent of subjects

Guideline 1. Individual informed consent

For all biomedical research involving human subjects, the investigator must obtain the informed consent of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the proxy consent of a properly authorized representative.

Guideline 2. Essential information for prospective research subjects

Before requesting an individual's consent to participate in research, the investigator must provide the individual with the following information, in language that he or she is capable of understanding:

- that each individual is invited to participate as a subject in research, and the aims and methods of the research;
- the expected duration of the subject's participation;
- the benefits that might reasonably be expected to result to the subject or to others as an outcome of the research;
- any foreseeable risks or discomfort to the subject associated with participation in the research;
- any alternative procedures or courses of treatment that might be as advantageous to the subject as the procedure or treatment being tested;
- the extent to which confidentiality of records in which the subject is identified will be maintained;

• the extent of the investigator's responsibility, if any, to provide medical services to the subject;

- that therapy will be provided free of charge for specified types of research-related injury;
- whether the subject or the subject's family or dependents will be compensated for disability or death resulting from such injury; and
- that the individual is free to refuse to participate and will be free to withdraw from
  the research at any time without penalty or loss of benefits to which he or she
  would otherwise be entitled.

#### Guideline 3. Obligations of investigators regarding informed consent

The investigator has a duty to:

- communicate to the prospective subject all the information necessary for adequately informed consent;
- give the prospective subject full opportunity and encouragement to ask questions;
- exclude the possibility of unjustified deception, undue influence and intimidation;
- seek consent only after the prospective subject has adequate knowledge of the relevant facts and of the consequences of participation, and has had sufficient opportunity to consider whether to participate;
- as a general rule, obtain from each prospective subject a signed form as evidence of informed consent; and
- renew the informed consent of each subject if there are material changes in the conditions or procedures of the research.

#### Guideline 4. Inducement to participate

Subjects may be paid for inconvenience and time spent, and should be reimbursed for expenses incurred, in connection with their participation in research; they may also receive free medical services. However, the payments should not be so large or the medical services so extensive as to induce prospective subjects to consent to participate in the research against their better judgement ("undue inducement"). All payments, reimbursements and medical services to be provided to research subjects should be approved by an ethical review committee.

#### Guideline 5. Research involving children

Before undertaking research involving children, the investigator must ensure that:

- children will not be involved in research that might equally well be carried out with adults;
- the purpose of the research is to obtain knowledge relevant to the health needs of children;
- a parent or legal guardian of each child has given proxy consent;
- the consent of each child has been obtained to the extent of the child's capabilities;
- the child's refusal to participate in research must always be respected unless according to the research protocol the child would receive therapy for which there is no medically acceptable alternative;
- the risk presented by interventions not intended to benefit the individual childsubject is low and commensurate with the importance of the knowledge to be gained; and
- interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child-subject as any available alternative.

#### Guideline 6. Research involving persons with mental or behavioural disorders

Before undertaking research involving individuals who by reason of mental or behavioural disorders are not capable of giving adequately informed consent, the investigator must ensure that:

- such persons will not be subjects of research that might equally well be carried out on persons in full possession of their mental faculties;
- the purpose of the research is to obtain knowledge relevant to the particular health needs of persons with mental or behavioural disorders;
- the consent of each subject has been obtained to the extent of that subject's capabilities, and a prospective subject's refusal to participate in non-clinical research is always respected;
- in the case of incompetent subjects, informed consent is obtained from the legal guardian or other duly authorized person;
- the degree of risk attached to interventions that are not intended to benefit the individual subject is low and commensurate with the importance of the knowledge to be gained; and

• interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual subject as any alternative.

#### Guideline 7. Research involving prisoners

Prisoners with serious illness or at risk of serious illness should not arbitrarily be denied access to investigational drugs, vaccines or other agents that show promise of therapeutic or preventive benefit.

#### Guideline 8. Research involving subjects in underdeveloped communities

Before undertaking research involving subjects in underdeveloped communities, whether in developed or developing countries, the investigator must ensure that:

- persons in underdeveloped communities will not ordinarily be involved in research that could be carried out reasonably well in developed communities;
- the research is responsive to the health needs and the priorities of the community in which it is to be carried out;
- every effort will he made to secure the ethical imperative that the consent of individual subjects be informed; and
- the proposals for the research have been reviewed and approved by an ethical review committee that has among its members or consultants persons who are thoroughly familiar with the customs and traditions of the community.

#### Guideline 9. Informed consent in epidemiological studies

For several types of epidemiological research, individual informed consent is either impracticable or inadvisable. In such cases the ethical review committee should determine whether it is ethically acceptable to proceed without individual informed consent and whether the investigator's plans to protect the safety and respect the privacy of research subjects and to maintain the confidentiality of the data are adequate.

#### Selection of research subjects

#### Guideline 10. Equitable distribution of burdens and benefits

Individuals or communities to be invited to be subjects of research should be selected in such a way that the burdens and benefits of the research will be equitably distributed. Special justification is required for inviting vulnerable individuals and,

if they are selected, the means of protecting their rights and welfare must he particularly strictly applied.

Guideline 11. Selection of pregnant or nursing (breastfeeding) women as research subjects

Pregnant or nursing women should in no circumstances be the subjects of nonclinical research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the research is to obtain new knowledge about pregnancy or lactation. As a general rule, pregnant or nursing women should not be subjects of any clinical trials except such trials as are designed to protect or advance the health of pregnant or nursing women or fetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable subjects.

#### Confidentiality of data

Guideline 12. Safeguarding confidentiality

The investigator must establish secure safeguards of the confidentiality of research data. Subjects should be told of the limits to the investigators' ability to safeguard confidentiality and of the anticipated consequences of breaches of confidentiality

#### Compensation of research subjects for accidental injury

Guideline 13. Right of subjects to compensation

Research subjects who suffer physical injury as a result of their participation are entitled to such financial or other assistance as would compensate them equitably for any temporary or permanent impairment or disability. In the case of death, their dependents are entitled to material compensation. The right to compensation may not be waived.

#### Review procedures

Guideline 14. Constitution and responsibilities of ethical review committees

All proposals to conduct research involving human subjects must be submitted for review and approval to one or more independent ethical and scientific review committees. The investigator must obtain such approval of the proposal to conduct research before the research is begun.

#### Externally sponsored research

Guideline 15. Obligations of sponsoring and host countries

Externally sponsored research entails two ethical obligations:

- An external sponsoring agency should submit the research protocol to ethical and scientific review according to the standards of the country of the sponsoring agency, and the ethical standards applied should be no less exacting than they would be in the case of research carried out in that country.
- After scientific and ethical approval in the country of the sponsoring agency, the
  appropriate authorities of the host country, including a national or local ethical
  review committee or its equivalent, should satisfy themselves that the proposed
  research meets their own ethical requirements.

# Code of conduct for forensic mortuary personnel

#### **Preamble**

This document is not intended to replace local or existing codes of conduct/state legislation; rather it should be read in conjunction with them.

#### I. Introduction

- This Code is intended as a guide for the ethical conduct of forensic mortuary personnel.
- It is acknowledged that certain standards of conduct are essential not only for good mortuary practice but also for the reputation of forensic mortuary personnel. This Code is a statement of what is acceptable conduct.
- Forensic mortuary personnel should always uphold their own professional and ethical standards, despite any personal or peer pressure which may sometimes make it difficult to do so.
- The application of these standards will allow forensic mortuary personnel to apply their skills, labour and knowledge (i.e. with integrity within the justice system).
- Forensic mortuary personnel who operate in accordance with this Code can be assured of the support of their colleagues.
- Breaches of this Code are not acceptable and could be regarded as incompatible with employment as a forensic mortuary worker.

### II. Work practices

- 1. Forensic mortuary personnel acknowledge the dignity of the deceased person and will recognize this in all their work practices.
- 2. Cultural and religious beliefs where identified will be recognized and accommodated wherever practicable.

- 3. Forensic mortuary personnel should maintain a standard of dress which reflects favourably on their organization and profession.
- 4. Forensic mortuary personnel must be objective and unbiased. They should not be influenced by outside sources or self-interest.
- 5. Forensic mortuary personnel should carry out their work to the highest standard practically available to them.
- 6. Forensic mortuary workers should use generally recognized and accepted methods and procedures wherever possible. They should do whatever is practicable to keep abreast of new developments in their field and be prepared to test and introduce new or superior methods and procedures.
- 7. Forensic mortuary personnel should always seek to extend their knowledge through study and further training programmes, and to apply this knowledge to their work. They acknowledge that ongoing assessment of performance is an important aspect of good mortuary operation.
- 8. Forensic mortuary personnel should ensure that they are aware of the importance of the chain of legal process in matters potentially involved in criminal investigations and maintain their training in relevant legal and scientific aspects such as contamination prevention, security and integrity of specimens, labelling and recording.
- Forensic mortuary personnel will comply with all occupational health and safety requirements, including manual handling procedures and infection control procedures.
- 10. Forensic mortuary personnel recognize the importance and significance of security to all aspects of mortuary operation and will comply with all security and access control procedures.

#### III. Ethical behaviour

- 1. General behaviour. Forensic mortuary personnel should, by their professional and personal behaviour, try to advance the reputation and standards of mortuary operation. They should treat their colleagues with due respect, and avoid making unwarranted critical or disparaging remarks about either their colleagues or other organizations.
- 2. Confidentiality. Information of a confidential nature shall be treated with due respect. Information concerning cases should not be discussed socially or promoted in any other than a professional capacity.

- 3. *Mistakes*. If forensic mortuary personnel become aware at any stage that a mistake has been made, the onus is on them to disclose or admit it. Forensic mortuary personnel should promote an environment of open discussion and corrective action to ensure that the mistake is not repeated.
- 4. Conflict of interest. Any conflict of interest or potential conflict of interest must be declared clearly to management at the earliest possible time. Forensic mortuary personnel will not use any work-related procedure or situation for personal benefit or gain.
- 5. Corrupt conduct. Forensic mortuary personnel declare that there is no place in forensic mortuary operation for corrupt conduct. Stealing, pilfering and dishonesty are not acceptable.
- 6. Harassment. Harassment of any kind will not be condoned.
- 7. Working with others. Effort should be made to understand the working procedures and constraints of other relevant groups such as police officers, forensic scientists, funeral directors, health professionals and members of the legal profession.
- 8. *Media*. Forensic mortuary personnel should not encourage the media association of their names with specific cases as a means of gaining undue personal publicity or prestige.

# International Society of Blood Transfusion Code of Ethics for Blood Donation and Transfusion

The preamble to the above Code, which was unanimously approved by the General Assembly of the International Society of Blood Transfusion, held during the Society's 16th Congress (Montreal, 16–22 August 1980), states that its purpose is "to define the principles and rules to be observed in the field of blood transfusion; these should form the basis of national legislation or regulations". The text of this Code (accompanied by an editorial describing its development) was originally published in the ISBT newsletter, 1980, No. 9, and in Transfusion international, 1981, No. 26. It is reproduced here with the kind permission of the International Society of Blood Transfusion. The text of the Code (which has been approved by the International Federation of Red Cross and Red Crescent Societies) reads as follows:

#### The donor

- 1. Blood donation shall, in all circumstances, be voluntary; no pressure of any kind must be brought to bear upon the donor.
- 2. The donor should be advised of the risks connected with the procedure; the donor's health and safety must be a constant concern.
- 3. Financial profit must never be a motive either for the donor or for those responsible for collecting the donation. Voluntary non-remunerated donors should always be encouraged.
- 4. Anonymity between donor and recipient must be respected except in special cases.
- 5. Blood donation must not entail discrimination of any kind, either of race, nationality or religion.
- 6. Blood must be collected under the responsibility of a physician.
- 7. The frequency of donations and the total volume of the blood collected according to the sex and weight of the individual, as well as the upper and lower age limits for blood donation, should be defined by regulations.
- 8. Suitable testing of each donor and blood donation must be performed in an attempt to detect any abnormalities:

- a) that would make the donation dangerous for the donor,
- b) that would be likely to be harmful to the recipient.
- 9. Donation by plasmapheresis should be the subject of special regulations that would specify:
  - a) the nature of additional tests to be carried out on the donor,
  - b) the maximum volume of plasma to be taken during one session,
  - c) the minimum time interval between two consecutive sessions,
  - d) the maximum volume of plasma to be taken in one year.
- 10. Donations of leukocytes or platelets by cytapheresis should be the subject of special regulations that specify:
  - a) the information to be given to the donor about any drugs injected and about the risks connected with the procedure,
  - b) the nature of any additional tests to be carried out on the donor,
  - c) the number of sessions within a given time frame.
- 11. Deliberate immunization of donors by any foreign antigen with the aim of obtaining products with a specific diagnostic or therapeutic activity should be the subject of special regulations that would specify:
  - a) the information to be given to the donor about the substance injected and the risks involved,
  - b) the nature of any additional tests which have to be carried out on the donor.
- N.B. The purpose of the special regulations in items 9, 10 and 11 above is to safeguard the donor. After being told about the nature of the operation and the risks involved, a statement of informed consent must be signed by the donor. For donors immunized against red cell antigens, a special card should indicate the antibodies and specific details as to the appropriate blood to be used in case the donors need to be transfused.
- 12. The donor must be protected by adequate insurance against the risks inherent in the donation of blood, plasma or cells, as well as the risks of immunization.

### II. The recipient

- 13. The object of transfusion is to ensure for the recipient the most efficient therapy compatible with maximum safety.
- 14. Before any transfusion of blood or blood products, a written request, signed by a physician or issued under his responsibility must be made, which specifies the

- identity of the recipient and the nature and quantity of the substances to be administered.
- 15. Except for the emergency use of type O blood or red blood cells, every red cell transfusion necessitates preliminary blood grouping tests on the recipient, and compatibility tests between the donor and the recipient.
- 16. Before administration, one must verify that blood and blood products are correctly identified and that the expiry date has not been passed. The recipient's identify must be verified.
- 17. The actual transfusion must be given under the responsibility of a physician.
- 18. In case of a reaction during or after the injection of blood or blood products, appropriate investigations may be required to ascertain the origin of the reaction and to prevent its recurrence. A reaction may require the interruption of the transfusion.
- 19. Blood and blood products must not be given unless there is a genuine therapeutic need. There must be no financial motivation on the part of either the prescriber or of the establishment where the patient is treated.
- 20. Whatever their financial resources, all patients must be able to benefit from the administration of human blood or blood products, subject only to their availability.
- 21. As far as possible the patient should receive only that particular component (cells, plasma, or plasma derivatives) that is needed. To transfuse whole blood into a patient who requires only part of it may deprive other patients of necessary components, and may carry some additional risks to the recipient.
- 22. Owing to the human origin of blood and to the limited quantities available, it is important to safeguard the interests of both recipient and donor by avoiding abuse or waste.
- 23. The optimal use of blood and blood products requires regular contact between the physicians who prescribe and those who work in blood transfusion centres.

#### III. Controls

- 24. Appropriate controls should be required by the Health Authorities to verify that blood transfusion practices meet internationally accepted standards and that the guidelines or regulations issued in accordance with this code are effectively respected.
- 25. The following should be regularly checked:
  - a) the proficiency of the staff,

- b) the adequacy of the equipment and premises,
- c) the quality of methods and reagents, source material and finished products.

## Statement on the Ethics of Voluntary Non-Remunerated Blood Donation of the Third International Colloquium on Recruitment of Voluntary Blood Donors

The following statement was adopted at the Third International Colloquium on Recruitment of Voluntary Blood Donors, held in Hanover, Germany, on 22–24 August 1990; it was thereafter endorsed by the International Group of Red Cross Blood Transfusion Experts at its 19th Meeting, held in Los Angeles on 9 November 1990.

The League of Red Cross and Red Crescent Societies, in keeping with its humanitarian principles, has always maintained uncompromising support for the concept of voluntary non-remunerated blood donation.

The 24th International Conference of the Red Cross in Manila in 1981 reaffirmed the Movement's commitment to voluntary non-remunerated blood donation, and in this context approved the Code of Ethics developed by the International Society of Blood Transfusion as consistent with the principles of the Movement. The rapid changes of the last decade have thrown new light on the ethical aspects of blood donation.

Voluntary non-remunerated blood donation is considered among the safest kind of blood donation in terms of security to the recipient as the blood donor does not benefit from the transaction. The donor is expected to communicate without hesitation any contraindication which could have potential harmful effects on a recipient. In recent years, this responsibility has become more onerous, and the questions asked by the transfusion services have become of necessity more personal and more detailed than before.

For these reasons, there are increased ethical responsibilities, some old, some new, placed on transfusion services which collect blood from voluntary non-remunerated donors. They include the following:

- 1. No coercion or pressure should be brought to bear on a potential donor to donate;
- Every transfusion service should have current detailed criteria for donor selection and deferral, and these should be explained to the donor when an occasion for deferral arises;

- 3. Staff and volunteers who have donor contact should be carefully selected and trained so as to ensure that donors are handled sensitively and thoughtfully;
- 4. Donors should be made aware of the ethical responsibilities that they have towards the recipient(s) of their donation;
- 5. Donors should be assured by every available means that his or her donation is being utilized for patients in need without financial gain for any intermediate party;
- 6. Donors should be assured that blood and blood products made available through voluntary non-remunerated donation are being used optimally within hospitals for patients in need;
- 7. Donors should be assured that the transfusion service will treat in a confidential manner all personal donor details, including the results of all laboratory tests.

The Red Cross and Red Crescent Movement continues to support, as consistent with its principles, the ethical implications of voluntary non-remunerated blood donation.

This publication is intended to identify the common ethical issues encountered in a routine clinical laboratory and in forensic medical practice, and to give some guidance on how these issues might be addressed. It is also intended to enhance practice in laboratory medicine and forensic pathology by raising awareness of ethical issues.

While the publication is directed primarily at those controlling or working in medical laboratories and forensic medical institutions, it may also be of value to health services administrators, funding authorities, health and justice policy-makers, authorities responsible for laboratory quality and accreditation, clinicians, the judiciary system and patients themselves.

ISBN 92-9021-246-2 Price: US\$ 4.00