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IFCC Position Paper: Report of the IFCC Taskforce on Ethics: Introduction and framework[1),2)]

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Abstract

Laboratory Medicine organizations and their professional members have a goal and responsibility to benefit the health and wellbeing of the patients and communities they serve. Newer genetics and biochemical techniques raise significant issues of community concern, impacting on privacy, informed consent, access to and retention of samples and information. Balance may be required to ensure protection of individual rights against potential benefits to the broader community. While many national organizations may already have appropriate policies addressing various ethics issues, there is a need for an international framework to assist those nations that have not yet developed such policies, as well as to enable alignment of existing national policies. We have proposed a generic ethics framework, incorporating a hierarchy of four fundamental guiding principles: autonomy, justice, non-maleficence and beneficence. Proposals or issues requiring policy development can be considered and tested against this hierarchy, resulting in the development of policy and positions consistent with the above framework, acceptable to all participating stakeholders.
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[2)] IFCC Sections printed in J. Clin. Chem. Clin. Biochem. are listed in the Cumulative Index, which appeared in connection with the contents of this journal in Volume 27, 1989 and since 1991 have been printed in (Eur.) J. Clin. Chem. Clin. Biochem.
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1. Background

During its 1997–1999 term the IFCC Executive Board accepted the principle of establishing an Ethics Committee. It was identified that the greatest need was not for a Committee that would look inwardly at personal and professional ethics or codes of behavior, since these can best be dealt with at the level of the individual society or country. Rather, the Committee would assist in the development of a policy framework by which the IFCC as a supra-national professional body can advance contributions to Laboratory Medicine as a whole. The Taskforce on Ethics was formed in 2001 to perform the functions of this proposed Ethics Committee, and commenced its work in 2002.

For more than a decade there has been an increasing range of pre-symptomatic tests that can be offered to the community. Some of the challenges have been in laboratory organization and testing, but these are minor compared to broader issues affecting those targeted for screening and the general community.

DNA testing combined with newer genetic and biochemical techniques raises significant issues of community awareness, education, informed consent and pre- and post-test counseling. The genetic information stored and used must also have safeguards that ensure there are no stigmatization and discrimination issues. In various parts of the world individual professional organizations have raised awareness of these issues among their members and have produced documents addressing some of the key issues.

In general, the Laboratory Medicine community has not provided organized discussion in which the members can actively participate. There has been even less effort at the international level to create a collective voice for Laboratory Medicine.

Laboratory Medicine organizations have a goal and responsibility to advance the interests of their members, but the IFCC strategic vision also clearly states that the ultimate goal is to benefit the health and well-being of the patients and communities we serve. This test of our professional responsibility demands that we do not simply perform tests and use technology uncritically. We cannot be isolated from the impact of our work on society.

1.1 Committee process

An Ethics Committee consisting of up to six members was established by seeking nominations from National Societies and Corporate Members. This Committee will initially report to the Executive Board, and its function and activities will be reviewed on an annual basis. At the commencement of the Committee's work, five members were appointed, assisted by four associate members.

The Committee will work on producing and completing two papers in the following way: At any time, half the committee should produce a draft of one paper and the other half prepare a draft of the second paper. These drafts are each reviewed by the other half of the Committee, leading to finalization of the draft by the full Committee. The drafts will then be circulated to the National Societies and Corporate Members for their response and, based on the responses, the Committee will produce the final versions of both documents and submit them for consideration for publication. This cycle will be completed over a 1-year period.

2. Aims

- To increase awareness among Laboratory Medicine professionals of ethical issues.
- To encourage the practice of Laboratory Medicine to the highest ethical standards.
- To develop position papers on appropriate ethics policy issues.
- To provide a voice for Laboratory Medicine on ethics policies.
- To link Laboratory Medicine, ethics and the public interest.

3. Objectives

- Recognizing that the IFCC consists of representatives from Clinical Chemistry and Laboratory Medicine in more than 70 countries plus more than 30 corporate members, it is unlikely that position papers will have the complete agreement of all of our members. They are position papers and should not be put to a vote. The objective is to produce a statement with widespread support from the members of the Federation.
- Many IFCC members may already have appropriate policies addressing various ethics issues in place. These may have been developed by regulatory bodies or by various national professional bodies and associations. These existing national policies may be able to support the IFCC policies as bibliographic references to inform and improve international frameworks. In turn, these IFCC policies may assist members that do not yet have such formal national policies, or that are planning to review existing national policies.
- A secondary objective is to ensure that each paper is published in professional journal(s) and that it is also made available to the general public.

The Committee will focus on broad policy development to assist IFCC members, rather than the evaluation of individual projects arising from within the jurisdiction of any individual IFCC member. Such national projects are intended to be left to the individual IFCC members to address, seeking to draw on the IFCC Ethics Committee's policy frameworks and identification of resources.

4. Ethics

Ethics and ethical principles extend to all spheres of human activity. They apply to our dealings with each other, with animals and with the environment. They should govern our interactions not only in conducting research and undertaking laboratory practice, but also in our general life and society. Ethics serve to identify good, desirable or acceptable conduct and provide reasons for those conclusions (1). It includes the whole field of moral science, and encompasses the consideration of moral principles and of the rules of conduct.

The word ''ethics'' is derived (via Old French and Middle English) from the Greek *ethikos*, meaning ''characteristic spirit and beliefs of community, people, system, literary work, or person''.

There are two broad schools or bodies of ethics:

i) Community Consensus; and
ii) Human Absolutes.

The Community Consensus view of ethics holds that society defines the boundaries to ethical behavior, through formation of a majority view or through conformance with societal norms. Within the Community Consensus framework, ethics can change or evolve over time. Most secular Western societies subscribe to this view of Community Consensus towards an ethical framework, although within this framework some absolutes may be superimposed.

The other major school of ethics holds that there are certain values or behaviors that are absolute. The prohibition of the taking of human life by another person or a prohibition of incest are examples of human absolute ethical values. These absolute values cannot be changed by society consensus or majority view. The source of human absolutes is often of divine origin, and various jurisprudential mechanisms exist to interpret and apply these ethical absolutes to contemporary society. Many major religions subscribe to this view of human absolutes governing the ethical framework, although within this framework there is opportunity for community consensus to be applied, provided it is consistent with the over-arching absolute values.

4.1 The application of ethics

The application of ethical values and frameworks to problems and issues in contemporary society requires a consideration of the issue within and in relation to these values and frameworks.

Such an ethical framework will be dependent on societal value systems and ethno-cultural belief systems. For those societies in which the community consensus framework operates, there will be further consideration of the impact of the issue on, or from, the political environment and the economic climate.

4.2 Historical context

The development of modern codes of ethical principles (1) related to all research involving humans is a comparatively recent phenomenon, although codes related to health and health-related research commenced in the early part of the last century. The awareness of the importance of respect for ethical codes in research involving human participants was accelerated in response to revelations of unethical practices, particularly during the Second World War. The judgement of the Nuremberg military tribunal on war crimes contained a set of principles and standards relating to permissible medical experiments. These have significantly influenced the subsequent development of codes of ethics.

Despite the emergence of these codes, incidents of unethical treatment of people in health research occurred. Most nations have published codes of ethical conduct in health research, often observing the *Declaration of Helsinki* published by the World Medical Association and a succession of international documents prepared during the last five decades (see Bibliography). These documents demonstrate a trend towards making more explicit the ethical standards that must be met if research on human beings is to be ethically acceptable. Continuing revision of standards for and systems of review of research involving humans is necessary.

5. Ethics in Clinical Chemistry and Laboratory Medicine

Laboratory Medicine organizations and their professional members have a goal and responsibility to benefit the health and wellbeing of the patients and communities they serve. This test of their professional responsibility demands that they do not simply perform tests and use technology uncritically. They cannot be isolated from the impact of their work on society.

Ethics has the potential to affect Clinical Chemists and Laboratory Physicians at different levels:

i) Personal ethics;
ii) Professional ethics;
iii) Ethics of our profession.

Personal ethic relates to how each of us lives our lives. Professional ethics relate to the standards we pursue in our working environment and organizations. Some of our professional ethics are governed by scientific protocols and standards and relate to the way in which we operate our laboratories, while others relate to the way in which we conduct ourselves to promote the good standing and advancement of our profession.

But it is at the level of the ethics of our profession that we must consider what we must do to meet our societal obligations in Clinical Chemistry and Laboratory Medicine.

5.1 Why the need for an ethics policy?

We live in an exciting time when there have been rapid and major advances in genetics and biochemical technologies. These raise broader issues of ensuring

community education and knowledge, and of dissipating any anxiety arising from the unknown.

We have professional obligations relating to the potential impact of our work on our societies. It is important that we be proactive in our approach to fill this policy and information void. By being proactive, we seek pre-emptive avoidance of societal backlash due to fear, anxiety or ignorance.

There is a need to balance issues of privacy and civil liberties with the great benefits that can arise from the use of information generated by analysis of individual patient samples for scholarship and research, and in some cases for the use of this information for national or international security.

The importance of ethics in Laboratory Medicine has been recognized by its inclusion in ISO 15189 (Quality Management in the Medical Laboratory) of standard ISO/TC 212/WG 1 of the Clinical Laboratory Standards Institute (formerly the National Committee for Clinical Laboratory Standards).

We envisage that the development of appropriate policies may help member national societies by providing a resource on which they can draw to assist policy formation within their own jurisdictions.

5.2 What are the unique ethical aspects of Clinical Chemistry and Laboratory Medicine?

There are some situations in Clinical Chemistry and Laboratory Medicine that will require particular attention, and the development of ethical guidelines.

5.2.1 The ethics of indirect patient contact The clinical laboratory in most instances does not have direct contact with patients, but rather has the clinician, healthcare worker or research academic as intermediary. This poses a problem for the clinical laboratory, since the principles of autonomy especially, but also justice, beneficence and non-maleficence to some degree, may require input from the patient as to what his or her interests and opinions are. The patient, or the patient's clinical caregivers, may need to convey to the laboratory the wishes of the patient, and the laboratory may need to initiate dialogue, seek clarification or respond to patient concerns. We need to consider how the laboratory should handle this bidirectional flow of information that is necessary for high standards of ethics in our practice. There may also be a need to ensure that the intermediary clinician or healthcare worker, acting as the agent for the patient, is aware of and subscribes to the same or a similar ethical framework as that to which we subscribe. In some settings, this may well be best addressed by clinicians acting on behalf of the clinical laboratory.

5.2.2 Inappropriate laboratory practice includes both physical risk and information risk In the laboratory environment, laboratory risk focuses primarily on ensuring the provision of a safe physical working environment, guidance as to appropriate work practices, and staff education on safety issues. Risk management increasingly extends to providing an environment for laboratory staff that is free from harassment and intimidation. Similarly, traditional medical risk analysis, whether in clinical work or research, is largely focused on physical risk to the patient. For example, physical handling of specimens carries a physical risk of misidentification or faulty analysis, and this can result in a risk of an incorrect result being issued, leading to inappropriate treatment of the patient.

Added to this physical risk, we also have the risk of inappropriate use of the information derived from physical analysis of the specimen. The clinical laboratory generates much of the most sensitive information in medicine, including the fields of infectious disease, genetics, and drug abuse. We need to develop an ethical strategy for the secure storage and appropriate distribution of this type of information. On the one hand, this strategy must balance the needs of clinicians and healthcare workers to access this information for optimal healthcare of the individual patient and the public health needs of broader society, and on the other hand the potential use of many clinical laboratory results for stigmatization and discrimination against the individual patient.

5.2.3 Storage of physical specimens and derived or potential information There are many reasons why a clinical laboratory may retain and store a portion of the patient's original sample, and similarly why the laboratory may retain records of the results of analysis. These reasons may include quality control, method development, teaching and research. This sample represents a source of additional information about the patient, which can potentially be accessed at a later time and under circumstances to which the patient may, or may not, have originally consented. In the case of genetics and forensics, the sample may also represent a source of information regarding the patient's relatives, who almost certainly were not involved in the consent obtained for the original specimen.

The clinical laboratory needs appropriate policies regarding the creation, storage and subsequent access to and utilization of material stored in these ''biobanks''.

6. A proposed framework of guiding principles

The international nature of the IFCC means that we have to address supra-national issues of universal human ethics. We will need to be mindful of the cultural differences between nations, and from that to derive frameworks that will meet these diverse needs.

We have developed a framework within which the Ethics Taskforce can consider various proposals. This framework is intended to be both transparent and robust.

By transparency, we refer to the need for the framework to reveal the reasoning that the Taskforce applies to the consideration of a particular issue. This will enable member societies to ensure that the ethical framework and reasoning used to develop a particular policy is sympathetic to and compatible with the

value system appropriate for their particular national culture.

By robustness, we refer to the need for the framework to be consistent in its application. This means that the framework should result in the same or similar outcome, regardless of the particular composition of the Ethics Taskforce members.

6.1 Description of the ethics framework

It is proposed that a hierarchy of guiding principles be adopted. These principles should be chosen from a set of universal principles that are likely to achieve acceptance by all stakeholders, regardless of their belief system.

Proposals or issues requiring policy development can be considered and tested against this hierarchy of guiding principles. This comparison is intended to identify and highlight issues of difference or potential concern, which can then be discussed, refined or modified. The output of the process will be the development of policy and positions consistent with the above framework, and acceptable to all participating stakeholders.

7. Fundamental guiding ethics principles

We propose an ethical framework that incorporates the following four fundamental guiding principles (2):

1. Autonomy;
2. Justice;
3. Non-maleficence;
4. Beneficence.

7.1 Autonomy

Autonomy refers to the principle of self-determination. This confers personal freedom and free will in decision-making. It is important to note that self-determination carries an implicit assumption that the individual has sufficient information and capacity to be able to exercise that self-determination. Autonomy is a fundamental principle in secular democracies. As an individual right it may have to be balanced against the rights of others and is therefore not an absolute.

Following from the principle of autonomy, one can derive further principles (3):

- Information provided to the individual must be complete and accurate.
- Information provided to an individual may need to recognize the shared nature of genetic information, and that a decision by the individual may potentially impact on other family members.
- Recognition that an individual has the right to decline to receive information.
- Recognition that there is a balance between the individual's right to privacy, and a duty of care to other family members. This balance may be particularly important when access to such information may allow medical treatment for another family member.
- The need for awareness that the nature of genetic testing may involve clashes of cultural or religious beliefs, particularly in respect of prenatal diagnosis and termination of pregnancy.

Consent must be informed, and coercion must not occur. The wish of the individual is paramount, except in rare selected circumstances when it may impinge on others, or on society.

It should be noted that in all societies, autonomy can be subsumed to other criteria, either at times of emergency or as part of prevailing cultural values.

There is a duty of confidentiality to the individual, with an implicit assurance that a health professional will not reveal personal information without the consent of the individual. However, this duty of confidentiality may be overridden in special circumstances that relate to the public good.

7.2 Justice

Justice refers to the principles of fairness, equality and non-discrimination. It implies that we must not impose our own views on those of others.

Justice requires that citizens respect the laws and regulations of their country. Note that there is an implicit assumption that laws and regulations are themselves lawful and ethical. For example, it is possible that the laws of a country may not be compatible with international convention, or actions that are lawful in one country may be considered unlawful in another. Clinical chemists and laboratory physicians need to be aware of international guidelines and how they interrelate with their own societal norms and values. At times they may be called upon to advise lawmakers who may not always fully appreciate the complex functions and ethical obligations of the clinical laboratory.

Implicit within the concept of justice are the following principles (3):

- Justice implies respect for all members of society, regardless of any physical or mental disability.
- Justice also implies equity of access to and allocation of scarce or limited resources, regardless of place of residence, ethnicity, gender, religion, age or disability.

7.3 Beneficence and non-maleficence

7.3.1 Beneficence Beneficence refers to the extent to which one works towards the greater public good of the patient and the community.

7.3.2 Non-maleficence Non-maleficence refers to the minimization or avoidance of doing harm to the primary client. Within medicine, there is the guiding principle of *primum non nocere* (above all, do no harm), and this principle is consistent with the positions of many major religions.

Laboratory Medicine will face situations that will require the laboratory community to consider the balance between non-maleficence and broader benefi-

cence. In modern genetics, there are issues relating to the shared nature of genetic information between family members. What is for the good of the patient may result in harm or disadvantage to others. For example, there may be tension between the issues of individual good and family harm when an individual may seek to withhold consent for a procedure that may benefit others in their family.

Practically all interventions by healthcare professionals have a capacity to cause harm. Judgement must be exercised as to whether any particular intervention is justified by the balance of potential benefit and potential harm.

8. Template hierarchy

Each project considered by the Ethics Committee will be assessed against these guiding ethical principles. The project will be systematically scored as to the extent to which each ethical principle is met, and areas of potential controversy or gap will be identified. These issues and gaps will then be examined in greater detail, with the intention of either modifying the project or policy to address these gaps, or of highlighting them to enable member societies to form an opinion as to the relevance of the gap to their ethical and cultural norms.

It is proposed that the template hierarchy against which projects will be assessed will meet the following criteria:

Ethical principle	Characteristic and detailed test
Autonomy	1. Self-determination and informed consent
	2. Recognition of and respect for potential tensions between individual self-determination and cultural or religious belief
Justice	1. Consistent with national *and international* law[a]
	2. Consistent with major ethical belief systems
	3. Respect for intrinsic values of individuals
	4. Equal, non-discriminatory and equitable access to relevant healthcare resources
Non-maleficence	1. Minimize or avoid doing harm to the individual by the policy
	2. Ensuring that the autonomy and privacy of the individual is protected
	3. Minimize the effect of the decisions of individuals on others who may be impacted by those decisions
	4. Minimizing the impact on an individual's ethnic, cultural, moral, religious or other relevant personal background and views
Beneficence	1. Contribute to the collective good of indivi duals in society through the policy
	2. Balance societal needs against individual good/benefit
	3. Encourage individuals to accept their responsibilities with regard to the needs and rights of others

[a]As outlined in the objectives section of this document, the IFCC Ethics position papers are intended to provide a supranational framework with widespread support from members of the Federation. IFCC members may have local national policies that differ from the consensus.

In reviewing a proposal, all elements of the template hierarchy must be considered and addressed. However, some elements of the hierarchy may not apply to particular proposals.

8.1 Outcome of evaluation against the template hierarchy

Potential Policies and Projects should be forwarded to the Chairman of the Ethics Taskforce, along with supporting background and documentation explaining the issue, assessing its importance and priority, and outlining work already done within particular national jurisdictions.

The Chairman will assign Projects and Policies to a Committee member, who will develop the proposal, and examine it against the Template Hierarchy. A recommended outcome and a summary of the reasoning leading to this outcome will form part of the proposal.

The proposal will normally be further developed by half of the Ethics Committee, and reviewed by the other half of the Ethics Committee. After review, the proposal will be finalized by the full Committee and then released for consultation, discussion and ratification as outlined earlier in this document.

9. Bibliography

The following bibliography has been taken from the National Statement on Ethical Conduct in Research Involving Humans of the National Health and Medical Research Council of Australia (1).

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