

# Codes of ethics for laboratory medicine: definition, structure and procedures – a narrative review based on existing national codes

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*On behalf of the IFCC Task Force on Ethics (TF-E)*

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## ARTICLE INFO

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## ABSTRACT

### **Background**

It behoves every national society of clinical laboratory medicine to have a well formulated and publicly accessible policy concerning the morally acceptable way in which its members should practise their profession; such a policy is published as a Code of Ethics.

This Code assists its members in the performance of their duties in relation to the patients they share with other clinicians, within their own particular professional environment and, at large, to the rest of their national society.

### **Methods and result**

The International Federation of Clinical Chemistry and Laboratory Medicine's (IFCC) Task Force on Ethics here examines a curated selection of extant Codes and provides guidance at the level of definition, structure and procedures to assist national societies

and their clinical chemistry and laboratory medicine professionals in the task of crafting their own Ethics Code.



The leading aims of the Task Force on Ethics of the IFCC (TF – E), the International Federation of Clinical Chemistry and Laboratory Medicine, are:

- To increase awareness among Laboratory Medicine Professionals of ethical issues, *whence*
- To encourage the practice of Laboratory Medicine to the highest ethical standards *and to assist in the process,*
- To develop guidance documents for member societies on ethics related issues.

Whilst the TF – E accepts that it cannot produce documents for individual member societies at the national level, such guidance documents may be seen as a part of a “tool kit” with which such member societies can construct a Code of Ethics that is fit for purpose within their individual jurisdiction whilst at the same time preserving the essentials accepted world-wide as vital to such codes.

This work was envisaged by the foundation TF – E group nearly 20 years ago, and is now offered for use. The prior input from the initial TF members led by the then chairman, Professor Leslie Burnett, and subsequent chairholders and members is acknowledged here and in pertinent references.

## HISTORICALLY

TF – E members have previously noted [1] that the evolution of biologically focussed ethics over the years is well documented and includes

- the Nuremberg Code from 1947 [2],
- the Declaration of Geneva from 1948 [3],

- the Declaration of Helsinki from 1964 [4], and
- the Belmont report from 1978 [5].

The need for these documents was driven by developments in medical research, initially during and then after the twentieth century’s “World War 2”, but concepts in the Declaration of Geneva and the Belmont report are also applicable to the practice of clinical medicine.

The Belmont Report [5] is one key work concerning ethics and healthcare research. Created in 1978, by the U.S.A. National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, it outlines a number of ethical principles and guidelines for the protection of human subjects. It identifies the following three core principles:

1. Respect for persons: The acknowledgement of human autonomy but, complementarily, the need for protection of those with diminished autonomy.
2. Beneficence: The duty to act in the best interests of patients or research subjects, the goal being to maximise benefits and minimise harm, the latter sometimes Latinised as *non-maleficence*.
3. Justice: The obligation to treat all patients equally and to distribute, by allocating fairly, what is rightly due in terms of benefits, risks and cost.

These principles can be applied to both research and clinical settings. They must be applied equally to clarify the ethical issues in clinical chemistry and laboratory medicine.

## THE SCENARIO ENVISAGED

The scenario to be addressed has altered little since Burnett wrote in 2007 [6], though further specific demands may have appeared. Burnett is paraphrased and extended.

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 make demands of all laboratorians, whichever discipline they work within, and at no less than the three different levels described below.

Firstly, personal ethics describes the pertinent, personal set of moral beliefs which governs how each of us lives our life. One's personal moral code will probably stand on and spring from a universally acknowledged minimal framework, and it thus may readily resemble other humans' efforts thereat, but it is also vital to acknowledge that each human is a unique individual and must be respected as such. The extent to which the individual's personal code is driven by community consensus, religion, personal study and reflexion, or some combination thereof, is the individual's choice. Apart from the interplay at the level of respecting autonomy and ensuring beneficent outcomes from the individual's personal professional activity, this aspect of one's conformance with ethics is not *sui generis* within the scope of this review. It is the responsibility of the individual.

Secondly, one's professional ethics describe the set of standards we each personally seek to apply 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. Here we are aiming to most beneficially serve the needs of both our patients and our peers.

Thirdly, the ethics of our profession is not the same thing as one's own professional ethics. It goes further: to our work as a body of professional practitioners, working together as a profession where we must consider what together we should do to meet our societal obligations in Clinical Chemistry and Laboratory Medicine at large, in short, the needs of the people. In practice, however, professional ethics and the ethics of the profession cannot be dealt with separately since we are the practitioners. The profession is us. What we do as individual craftsmen is what is done by the profession; it is thus seen by society.

In constructing an Ethics Policy that is fit for purpose within their individual jurisdiction national societies will thus formulate their own unique document, integrating as they do, the demands cited above.

### **Terminology, a footnote in text**

It seems necessary to address explicitly a potentially confounding conundrum, thereby to avoid confusion. Thus, although the practice of Clinical Chemistry and Laboratory Medicine is driven by science and should vary little across the world, related terminology does vary at national level.

Clinical Chemistry and Laboratory Medicine may be described as Biochemistry, Clinical Biochemistry, Chemical Pathology and by still other titles. Similarly, the term "Laboratory Medicine Professionals" both encompasses an array of terms that describe the practitioners and also incorporates all levels of expertise within the profession. Practice concerning who may do what within a laboratory hierarchy differs between different jurisdictions.

In some countries both technologists (meaning by this term people without university degrees) and scientists (people with such degrees) may work as laboratory practitioners, but in others

only pertinent degree holding scientists qualify for employment. In some countries only people who initially trained as medical practitioners and who have gone on then to gain post-graduate qualifications as Laboratory Physicians or Pathologists may lead or direct laboratories, but in others such a level within the laboratory's hierarchy may also be open to scientists or, further, to other initially scientifically trained people such as pharmacists.

The term “practitioner” may be a convenient general description for the practicing laboratory professional that can be deployed across the board. It necessarily also permits levels of expertise and responsibility to be categorised within the body of practitioners by a suitable set of titles.

The underlying need in drafting Ethics Codes is to be consistent with the given jurisdiction's legal requirements for the qualifications and experience required by, and the description of, the given practitioner at the given level of expertise. The requirement to practice Laboratory Medicine to the highest achievable ethical standards equally challenges practitioners at all levels of expertise.

## THE CURRENT SCENE

Only a minority of pertinent national societies have a published Ethics Code as of 2019. It is the hope of the TF-E that this instrument may help many more to craft, and to publish, theirs.

### ISO

Why ISO? ISO, the International Organization for Standardization, based in Geneva, Switzerland, is an independent, non-governmental international organization with a membership of 164 national standards bodies [7]. In its words, it “develops voluntary, consensus-based, International Standards, documents that provide requirements, specifications, guidelines or char-

acteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.”

In particular, the ISO standard 15189:2012, *Medical laboratories – Requirements for quality and competence*, specifies requirements for quality and competence in medical laboratories [8]. It “can be used by medical laboratories in developing their quality management systems and assessing their own competence. It can also be used for confirming or recognizing the competence of medical laboratories by laboratory customers, regulating authorities and accreditation bodies”, and routinely is so used. Its comments on ethics are therefore potentially essential input into the process of crafting a national Laboratory Ethics Code. In prior editions cited as an appendix to the Standard, the inclusion in 2012 of the ethics material in to the text of the Standard itself raises its level of “importance”.

ISO 15189's section 4, Management requirements, at 4.1.1.3 thus specifically requires that “Laboratory management shall have arrangements in place to ensure the following:

- a. there is no involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgement or operational integrity;
- b. management and personnel are free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work;
- c. where potential conflicts in competing interests may exist, they shall be openly and appropriately declared;
- d. there are appropriate procedures to ensure that staff treat human samples, tissues or remains according to relevant legal requirements;
- e. confidentiality of information is maintained.”

Given that this listing is framed as advice to management for the purpose of ordering a laboratory's activity, its sequence is understandable and it goes to many of the questions that need a directive, however as a model for framing a Society's own Ethics Code, its prioritising the avoidance of evil ahead of actively doing good may not be the better order (of those two) to choose.

### Extant society policies

In general, there are two different approaches that have been adopted in writing such policies by National Societies. Both focus on the duties involved in acting ethically well.

One approach categorises the task by the focussed target of duty, thus almost invariably:

- patient,
- professional peer, and
- pertinent population or wider society,

usually, though not necessarily, in that order.

The other categorises the task by form of activity, and here the products are rather more variable, defying tabulated comparison. In each case many of the extant national society policies seen have been examined. Three illustrative

policies were selected as exemplars for comparison of each of the two methods.

### Policies codified by focus of duty as the segregator

Here three typical codes have been selected, one from each of the U.S.A. [9], Poland [10], and Australia [11], and cross tabulated; the Polish code was originally published in Polish. Each code is at least a decade old in 2019. There is a range of linguistic prolixity and depth of detail addressed, although the textual cross dependence is obvious. Whether the subsequent users have improved the prior published text is a decision for the reader.

These examples might be considered to contain the essentials accepted world-wide as vital to such policies, the elements *sine que non*, but of course individual Societies must be free to add elements that their own circumstances, or their jurisdiction's law, or both, demand, and equally, are free to choose the style of drafting that suits them. Similarly, they should not be afraid to utilise pre-existing text if it appears to be as close to an acceptable statement of the matter addressed as can be achieved. (Table 1)

**Table 1** Three extant clinical laboratory ethics codes, textually compared, using the focus of duty as the task segregator

	USA, (American) Society for Clinical Laboratory Science [9]	Poland National Chamber of Medical Laboratory Specialists [10]	Australasian Association of Clinical Biochemists [11]
<b>Year</b>	< 2009	13 January 2006	< 2010
<b>PREAMBLE</b>	The Code of Ethics of the American Society for Clinical Laboratory Science sets forth the principles and standards by which Medical Laboratory	The Code of Ethics of the Laboratory Diagnostician is a set of basic ethical norms which should guide each representative of this profession and is the	The Code of Ethics of the Australasian Association of Clinical Biochemists (AACB) sets forth the principles and standards by which clinical laboratory

	Professionals and students admitted to professional education programs practice their profession.	basis for the personal and professional formation of a laboratory diagnostician.	practitioners practice their profession.
<b>1. Duty to the Patient</b> <i>Focus</i>	<p>Medical Laboratory Professionals' primary duty is to the patient, placing the welfare of the patient above their own needs and desires and ensuring that each patient receives the highest quality of care according to current standards of practice.</p> <p>High quality laboratory services are safe, effective, efficient, timely, equitable, and patient-centered.</p> <p>Medical Laboratory Professionals work with all patients and all patient samples without regard to disease state, ethnicity, race (<i>sic</i>), religion, or sexual orientation.</p> <p>Medical Laboratory Professionals prevent and avoid conflicts of interest that undermine the best interests of patients.</p>	<p>The laboratory diagnostician, ... following the principles of reliability, honesty, impartiality ... should perform his professional activities with respect for the human person.</p> <p>... performs his professional activities with the utmost care and the awareness that the results of his work are used to protect human health and life.</p>	<p>Clinical laboratory practitioners are accountable for the quality and integrity of the laboratory services they provide.</p> <p>This obligation includes maintaining individual competence in judgement and performance and striving to safeguard the patient from incompetent or illegal practice by others.</p>
<i>Method</i>	<p>Medical Laboratory Professionals are accountable for the quality and integrity of the laboratory services they provide. This obligation includes maintaining the highest level of individual competence as patient needs change the limits of their level of practice.</p>	<p>A laboratory diagnostician, applying all his knowledge, skills and experience, strives to obtain reliable results of research and interprets them for the needs of practical medicine and science.</p> <p>A laboratory diagnostician in relations with other laboratory diagnosticians,</p>	<p>Clinical laboratory practitioners maintain high standards of practice. They exercise sound judgment in establishing, performing and evaluating laboratory testing.</p>



	<p>Medical Laboratory Professionals exercise sound judgment in all aspects of laboratory services they provide. Furthermore, Medical Laboratory Professionals safeguard patients from others' incompetent or illegal practice through identification and appropriate reporting of instances where the integrity and high quality of laboratory services have been breached.</p>	<p>in the case of noticing mistakes in their conduct, should pay due care first to the person concerned, or consult his supervisor. [But ...] A laboratory diagnostician in the presence of a patient does not assess the work of other diagnosticians, doctors and specialists involved in the treatment process.</p>	
<b>Practice</b>	<p>Medical Laboratory Professionals maintain strict confidentiality of patient information and test results. They safeguard the dignity and privacy of patients and provide accurate information to patients and other health care professionals. Medical Laboratory Professionals respect patients' rights to make decisions regarding their own medical care.</p>	<p>The laboratory diagnostician ... is obliged to keep secret everything he learned about the patient in connection with the conducted tests. ... The test results belong to the person they concern and can be made available only to that person or with his consent to other persons or institutions. He is also thus obliged to provide information from medical records to [nominated] third parties.</p>	<p>Clinical laboratory practitioners maintain strict confidentiality of patient information and test results and thereby safeguard the dignity and privacy of patients and any samples removed from them. They provide accurate reports about patients' results to other health care practitioners.</p>
<p><b>2. Duty to Colleagues and the Profession</b>  <i>Focus</i></p>	<p>Medical Laboratory Professionals uphold the dignity and respect of the profession and maintain a reputation of honesty, integrity, competence, and reliability.</p>	<p>The laboratory diagnostician is obliged to build the ethos of his profession, to its promotion and development. Bearing in mind the importance of the</p>	<p>Clinical laboratory practitioners uphold and maintain the dignity and respect of our profession and strive to maintain a reputation of honesty, integrity and reliability.</p>

		<p>profession, the laboratory diagnostician performs his professional duties with a sense of responsibility for shaping impeccable attitudes in the professional environment of which he is an integral part.</p>	
<b>Method</b>	<p>Medical Laboratory Professionals ... contribute to the advancement of the profession by improving and disseminating the body of knowledge, adopting scientific advances that benefit the patient, maintaining high standards of practice and education, and seeking fair socioeconomic working conditions for members of the profession.</p> <p>... accept the responsibility to establish the qualifications for entry to the profession, to implement those qualifications through participation in licensing and certification programs, [and] to uphold those qualifications in hiring practices ...</p>	<p>Taking into account the dynamic development of laboratory medical diagnostics, the laboratory diagnostician should constantly expand his professional knowledge and improve his professional qualifications.</p>	<p>Clinical laboratory practitioners ... contribute to the advancement of the profession by improving the body of knowledge, adopting scientific advances that benefit the patient, maintaining high standards of practice and education, and seeking fair socio-economic working conditions for members of the profession.</p>
<b>Practice</b>	<p>Medical Laboratory Professionals establish cooperative, honest, and respectful working relationships within the clinical laboratory and</p>	<p>The laboratory diagnostician should share his knowledge with co-workers. [and] ... is obliged to motivate them to develop and facilitate</p>	<p>Clinical laboratory practitioners ... actively strive to establish cooperative and respectful working relationships with other health care</p>



	with all members of the healthcare team with the primary objective of ensuring a high standard of care for the patients they serve.	the improvement of qualifications. The Laboratory Diagnostician, as a teacher of the profession, should act as an example worth imitating and make every effort to ensure that the knowledge conveyed by him is up-to-date and corresponds to the principles of the profession.	practitioners with the primary objective of ensuring a high standard of care for the patients they serve. ... demonstrate honesty and integrity in business dealings with manufacturers, suppliers, competitors and customers.
<b>3. Duty to Society</b> <i>Focus</i>	As practitioners of an autonomous profession, Medical Laboratory Professionals have the responsibility to contribute from their sphere of professional competence to the general wellbeing of society.	<i>The laboratory diagnostician for society ...</i> should follow general standards of social coexistence, ...	As members of an autonomous profession, clinical laboratory practitioners have the responsibility to contribute from their sphere of professional competence to the general wellbeing of the community.
<i>Method</i>	Medical Laboratory Professionals comply with relevant laws and regulations pertaining to the practice of Clinical Laboratory Science and actively seek, to change those laws and regulations that do not meet the high standards of care and practice.	In relation to the patient, his family and the surroundings, the laboratory diagnostician pays due respect to, and observes the principles of, personal culture.	Clinical laboratory practitioners comply with relevant laws and regulations pertaining to the practice of clinical laboratory science and actively seek, within the dictates of their consciences, to change those which do not meet the high standards of care and practice to which the profession is committed.
<i>Practice</i>	Medical Laboratory Professionals serve as patient advocates. They apply their expertise to	The diagnostician performs laboratory tests with a view to obtaining a reliable result and cannot make	Clinical laboratory practitioners ensure scientifically appropriate, accurate and cost-effective

	improve patient healthcare outcomes by eliminating barriers to access to laboratory services and promoting equitable distribution of healthcare resources.	the service provided by him dependent on other circumstances including additional gratuities ... from people and institutions in any way interested in them.	application of health-care pathology service funding, guarding against waste, particularly clinical futility, inefficiency and needless investigative duplication.
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### **Policies categorising the task by form of activity**

Here, the three selected codes were all originally published in English, those of the English Royal College of Pathologists [12], (which is a Code of Practice, incorporating ethical advice), the Canadian Society for Medical Laboratory Science [13], and from Australia, its Royal College of Pathologists of Australasia [14]. Tabulation was attempted, on the model above, but is patently impracticable. Each code lists many elements in common with the other two, and all also in common with matters dealt with in the first examined format, but each also cites many elements that are not readily discernible elsewhere; moreover, there is no obviously discernible pattern.

One important detail the Pathologists' Colleges specifically mention does also deserve specific consideration. The array of testing that has become available in recent years is vast by comparison with the menu laboratories offered 70 years ago, and inevitably as new, more precise and accurate, tests are offered there is a duty of care on the part of the laboratorian *vis à vis* the laboratory's clinician clientele to educate them about newly offered tests, thus to ensure that patients are best served by both.

The Australasian College has had a specific policy document addressing this need since 2004 [15], thus:

"Policy 3/2004: Ethical responsibility of pathologists in relation to test utility.

Specific Scenarios ...

*The test requested is inappropriate, not indicated or unnecessary:*

The pathologist may elect not to proceed with the test, in which case they may choose to contact the referrer personally or to include a qualifying note on the report ... [and] ... The medical practitioner may benefit from education on what would be a more appropriate test considering the clinical context."

In general, the Canadian Code, which is also supported by a Guidance Document [16], notes explicitly that the "...ethical principles contained herein are not listed in order of importance, but rather, should be considered in relation to each other during their application within situations involving ethical dilemmas." Specifically, however it does also mimic in text the exact tripartite focus seen above, thus (with numbering inserted).

"MLPs [medical laboratory professionals] shall practise ... for:

1. the protection and integrity of patients ...,
2. colleagues, health care providers, [and]
3. society, the environment and one's self."

### **CONCLUSIONS**

On balance, it seems that using the target of care as the primary sorting category when constructing an Ethics Code probably works best at a practical level. It also resonates with the

Belmont categorisations and may well have arisen therefrom; thus:

1. Respect for persons,  
*thus, the laboratorian's primary duty is to the patient*
2. Beneficence,  
*thus, the laboratorian will uphold the dignity and respect of the profession and maintain a reputation of honesty, integrity, competence, and reliability ..., and*
3. Justice  
*thus, practitioners have the responsibility to contribute from their sphere of professional competence to the general wellbeing of the community.*

To reiterate, whilst the Task Force cannot write documents for individual National Member Societies at the national level, it hopes that this guidance document, published also online on the IFCC website, will become a useful instrument in their “tool kit”. With it such member societies can construct an Ethics Code that is fit for purpose within their individual jurisdiction whilst at the same time preserving the essentials accepted worldwide as vital to such policies.



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