## *A survey of extant Ethics Policies*

The leading aims of the IFCC Ethics Task Force [TF-E] 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 it is accepted that the Task Force cannot write documents for individual member societies, at national level, such guidance documents may be seen as a part of a "tool kit" with which such member societies can construct an Ethics Policy that is fit for purpose within their individual jurisdiction whilst at the same time preserving the essentials accepted world-wide as vital to such policies, the elements *sine que non*.[1]

**Historically**

TF-E members have previously noted[2] that the evolution of biologically focussed ethics over the years is well documented and includes

- the Nuremberg Code from 1947,
- the Declaration of Geneva from 1948,
- the Declaration of Helsinki from 1964, and
- the Belmont report from 1978.

The need for these documents was driven by developments in medical research, initially after World War 2, which ended in 1945, but concepts in the Declaration of Geneva and the Belmont report are also applicable to the practice of clinical medicine.

The Belmont Report[3] is one of the key works concerning ethics and healthcare research. Created in 1978 by the U.S.A. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, it outlines ethical principles and guidelines for the protection of human subjects and identifies 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 Latinate as *non-maleficence*.
3. Justice: The obligation to treat 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 laboratory medicine.

**The scenario envisaged.**

The scenario to be addressed has altered little since Burnett wrote in 2007,[4] 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.

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

[2] http://www.ifcc.org/media/477698/07ifcc_tf_ethics_in_lab_medicine.pdf

[3] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Ethical Principles and Guidelines for the Protection of Human Subjects of Research. http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

[4] Burnett L, McQueen MJ, Jonsson JJ, Torricelli F. IFCC Position Paper: Report of the IFCC Taskforce on Ethics: Introduction and framework. Clinical Chemistry and Laboratory Medicine 2007; 45: 1098-104

Ethics has the potential to make demands of Clinical Chemists and Laboratory Physicians in at least three different levels:

1. Personal ethics – the pertinent, personal set of moral beliefs which governs how each of us lives our entire life.
   Whilst one's personal moral code will probably stand on and spring from a universally acknowledged minimal framework, itself containing some rules so basic as to be seen by all rational humans as absolutely binding, undeniable, absolutes, and it thus may readily resemble other humans' efforts thereat, it is also vital to acknowledge that each human is unique in her or his self and must be honoured as such, and as she or he chooses to embody in her or his personal moral code. And, moreover, the extent to which it 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 her and his personal professional activity, this aspect of one's conformance with ethics is not *sui generis* within the scope of this brief. It is the responsibility of the individual.

2. Professional ethics – the set of standards we 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.

3. The ethics of our profession – this is not the same thing as one's own professional ethics. It goes 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, in short, the needs of the people.

In practice 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.

**Terminology.**

Although the practice of Clinical Chemistry and Laboratory Medicine is driven by science and thus should vary little across the world, internal terminology does vary. It is useful to explicitly record that individual member societies should deploy the terminology used in their jurisdiction. Thus …

1. Clinical Chemistry and Laboratory Medicine may be described as Biochemistry, Clinical Biochemistry, Chemical Pathology and by other titles still.
2. Similarly, "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.
   a. In some countries both technologists (without university degrees) and scientists (with such degrees) may work as laboratory practitioners, but in others only pertinent degree holding scientists qualify for employment.
   b. 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 also to other initially scientifically trained people such as pharmacists.

c. 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 Policies 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: 1, hither and thither.**

Only a minority of national societies in 2019 currently have a published Ethics Policy.
It is the hope of the TF-E that this tool will help many more to craft, and to publish, theirs.

**The current scene: 2, 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.[5] In its words, it “develops voluntary, consensus-based, International Standards, documents that provide requirements, specifications, guidelines or characteristics 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.[6] 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 Policy.

ISO 15189’s section 4, Management requirements, at 4.1.1.3 specifically addresses “Ethical conduct”.
It 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.”[7]

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.

[5] https://www.iso.org/standards.html
[6] https://www.iso.org/standard/56115.html
[7] Previously, in prior editions, an appendix to the Standard, the inclusion of the material in to the text of the Standard itself raises its level of “importance”.

**The current scene: 3, 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,

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 Policies seen have been examined and several selected for comparison.

***Focus of duty as the segregator***
Here three typical codes have been selected, (the Polish code originally published in Polish), and cross tabulated. Each is at least a decade old (in 2019). There is a range of prolixity, both linguistically and in the depth of detail addressed, and although the textual cross dependence is obvious, we are not yet certain which is original and which is derivative. Whether the subsequent users have improved the prior published text is a decision for the reader.[8]

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 a perfect statement of the matter addressed as can be achieved.

| | USA, (American), Society for Clinical Laboratory Science[9] | Poland National Chamber of Medical Laboratory Specialists[10] | Australasian Association of Clinical Biochemists[11] |
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| Year | < 2009 | 13 January, 2006 | < 2010 |
| **PREAMBLE** | The Code of Ethics of the American Society for Clinical Laboratory Science sets forth the principles and standards by which Medical Laboratory Professionals and students admitted to professional education programs practice their profession. | 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 basis for the personal and professional formation of a laboratory diagnostician. | The Code of Ethics of the Australasian Association of Clinical Biochemists (AACB) sets forth the principles and standards by which clinical laboratory practitioners practice their profession. |
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| **1. Duty to the Patient Focus** | 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 | The laboratory diagnostician, …<br><br>following the principles of reliability, honesty, impartiality … should perform his professional | Clinical laboratory practitioners are accountable for the quality and integrity of the laboratory services they provide.<br><br>This obligation includes |

[8] **EDITING NOTE** Attempts to accurately date first publication have SO FAR! failed. I'm working on it.
[9] American Society for Clinical Laboratory Science. Code of Ethics. https://www.ascls.org/about-us/code-of-ethics
[10] Poland National Chamber of Medical Laboratory Specialists. Code of Ethics. Krajowa Izba Diagnostów Laboratoryjnych, Kodeks Etyki Diagnosty Laboratoryjnego. http://kidl.org.pl
[11] Australasian Association of Clinical Biochemists. Code of Ethics. https://www.aacb.asn.au/documents/item/49

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| | quality of care according to current standards of practice.<br><br>High quality laboratory services are safe, effective, efficient, timely, equitable, and patient-centered.<br><br>Medical Laboratory Professionals work with all patients and all patient samples without regard to disease state, ethnicity, race (*sic*), religion, or sexual orientation.<br><br>Medical Laboratory Professionals prevent and avoid conflicts of interest that undermine the best interests of patients. | activities with respect for the human person.<br><br>… 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. | maintaining individual competence in judgement and performance and striving to safeguard the patient from incompetent or illegal practice by others. |
| Method | 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 yet practicing within the limits of their level of practice. Medical Laboratory Professionals exercise sound judgment in all aspects of laboratory services they provide.<br><br>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. | 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.<br><br>A laboratory diagnostician in relations with other laboratory diagnosticians, 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. | Clinical laboratory practitioners maintain high standards of practice. They exercise sound judgment in establishing, performing and evaluating laboratory testing. |
| **Practice** | 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 | 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 | 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 |

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| | Laboratory Professionals respect patients' rights to make decisions regarding their own medical care. | consent to other persons or institutions.<br>He is also thus obliged to provide information from medical records to [nominated] third parties. | reports about patients' results to other health care practitioners. |
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| **2. Duty to Colleagues and the Profession Focus** | Medical Laboratory Professionals uphold the dignity and respect of the profession and maintain a reputation of honesty, integrity, competence, and reliability. | The laboratory diagnostician is obliged to build the ethos of his profession, to its promotion and development. Bearing in mind the importance of the 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. | Clinical laboratory practitioners uphold and maintain the dignity and respect of our profession and strive to maintain a reputation of honesty, integrity and reliability. |
| **Method** | Medical Laboratory Professionals<br><br>… 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.<br><br>… 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 … | Taking into account the dynamic development of laboratory medical diagnostics, the laboratory diagnostician should constantly expand his professional knowledge and improve his professional qualifications. | Clinical laboratory practitioners …<br>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. |
| **Practice** | Medical Laboratory Professionals establish cooperative, honest, and respectful working relationships within the clinical laboratory and with all members of the healthcare team with the primary objective of ensuring a high standard of care for the | The laboratory diagnostician should share his knowledge with co-workers. [and] … is obliged to motivate them to develop and facilitate the improvement of qualifications.<br><br>The Laboratory Diagnostician, as a teacher | Clinical laboratory practitioners … actively strive to establish cooperative and respectful working relationships with other health care practitioners with the primary objective of ensuring a high standard of care for the patients they serve. |

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| | patients they serve. | 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. | … demonstrate honesty and integrity in business dealings with manufacturers, suppliers, competitors and customers. |
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| **3. Duty to Society Focus** | 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. | ***The laboratory diagnostician for society*** **…**<br><br>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. |
| **Method** | 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. |
| **Practice** | Medical Laboratory Professionals serve as patient advocates. They apply their expertise to improve patient healthcare outcomes by eliminating barriers to access to laboratory services and promoting equitable distribution of healthcare resources. | The diagnostician performs laboratory tests with a view to obtaining a reliable result and cannot make the service provided by him dependent on other circumstances including additional gratuities … from people and institutions in any way interested in them. | Clinical laboratory practitioners ensure scientifically appropriate, accurate and cost-effective application of health-care pathology service funding, guarding against waste, particularly clinical futility, inefficiency and needless investigative duplication. |
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***Categorising the task by form of activity***

Here also three illustrative codes were selected, 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] the "Australasia" indicating that it also services New Zealand and several countries in south-east Asia such as Singapore that are in the British Commonwealth, or were formerly so.

12 The Royal College of Pathologists. Code of practice for clinical biochemists/chemical pathologists and clinical biochemistry services. www.rcpath.org

13 The Canadian Society for Medical Laboratory Science. Code of Ethics. https://www.csmls.org/About-Us/Our-Members/Code-of-Ethics.aspx

14 The Royal College of Pathologists of Australasia. Code of Ethics. https://www.rcpa.edu.au/getattachment/6ed66de4-222a-44e4-9545-95a0f014ba0b/Code-of-Ethics.aspx

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 there is no obvious pattern discernible.

One important detail the Pathologists' Colleges specifically mention also deserves 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, 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 …
> 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,[15] 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 "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."[16]

***Recommendations***

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.*

[15] The Canadian Society for Medical Laboratory Science. Code of Ethics. Guidance Document.
https://www.csmls.org/csmls/media/documents/Governance/Code_of_Ethics_Guidance_Document.pdf
[16] Numbering inserted.