

Ethics and Laboratory Medicine

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Ethical issues have been given limited attention by professionals in laboratory medicine. Professional ethics is the moral bond that links a profession, the people it serves, and society. Understanding the complexities of individual and common good is essential for full professional participation in major issues in health care. Specific issues that challenge laboratory professionals in clinical research are allocation of health-care resources, testing conducted nearer the patient, confidentiality, screening tests, and molecular biology. A voice in ethical issues is an essential element of professional independence. The ethical attitudes we display influence the kind of people who choose to work in our profession. More open discussion about ethics is necessary in our professional literature.

Have laboratory professionals given much thought to the subject of ethics? Do we consider it important? A brief review of some historical landmarks indicates that in 1975 the American Association for Clinical Chemistry (AACC) issued its Guide To Ethics Governing the Conduct of Clinical Chemistry. In 1978 and 1981 at the Xth and XIth IFCC Congresses of Clinical Chemistry in Mexico City and Vienna, E. Ben Gershom addressed ethical aspects of clinical chemistry, on both occasions stating that clinical chemists were not participating as fully as they should in the decision-making process. In November 1984, an editorial in the *British Medical Journal*, Ethics in Clinical Chemistry (1), commented on a series of four articles that appeared in the April-July 1984 issues of the *News Sheet of the Association of Clinical Biochemistry* in the United Kingdom. The questions, but not the answers, were published in issue 39 of *IFCC News*, from the International Federation of Clinical Chemistry. Because of the large number of questions and the relative brevity of the answers, many issues, including those of confidentiality, inadequate analytical standards, and professional responsibility, were given limited attention.

In a more provocative presentation (2) in 1986 in Seville, Spain, Giovanni Ceriotti dealt with the classical professional duties relating to the quality of service and the role of the laboratory professional in education and applied research. He discussed the need for strong professional interaction and communication with patients, laboratory colleagues, and clinicians, but was critical of what he saw as an almost exclusive concern with technical problems

rather than addressing the issues to which technology could be applied. He argued that to be less than full involved is to have a diminished role as a professional. This reflects international guidelines, which propose that "concern for the interest of the subject must always prevail over the interest of science and society" (3).

Recently, the National Committee for Clinical Laboratory Standards (NCCLS) in the United States has addressed some of the needs that arise from issues relating to the ethics of laboratory testing.

In a personal view column in the *British Medical Journal* (4), Gunnar Biörck, Emeritus Professor of Medicine, Karolinska Institute, and a member of the Swedish Parliament maintained that the real problem we face is not how to provide the most expensive treatment but how to secure decent and knowledgeable treatment for those who really need it. Discussing ethics and the needs of patients may have a greater practical value than attempting imprecise definition of qualities such as health, disease, and illness.

Why Do We Need to Have a Well-Developed Sense of Ethics?

This need develops from our understanding and image of ourselves as professionals. The medical, moral, and legal responsibility of the physician for the patient is not in dispute. There is an obvious ethics, a public obligation, in the practice of medicine. Laboratory medicine, as a branch of that practice, has to be clear as to its own place and obligation, whether the laboratory professional is a physician, a scientist, or both. Our public responsibility is inherent, and I believe we are obliged to define it and to attempt to develop it. This is what we have not been doing well enough, which is why many laboratory professionals have been following the more passive and technical role criticized by Professor Ceriotti. We do not diminish the importance of that technical role if we ask the question: How do we see ourselves?

This is the age of the professional (5). More specialized knowledge and more complex technology give new power to those who master them. However, there is an enormous danger in this unless with that growth and power comes a strengthening sense of ethical responsibility. Professional ethics should give voice to that moral bond that links a profession, the individuals it serves, and the society as a whole. We have an impact on the interests and well-being of individuals, and we should play an important role in the pursuit of the public interest and the common good. Ethical standards are the key elements of public trust in the profession. "They give professionalism its moral dimension; they transform the career of selling services into the calling of providing service" (5).

The idea and understanding of public duty are surprisingly uncertain and ill-defined. It is essential that as a profession we think, talk, and write about this; otherwise

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we cannot understand what is at stake in conflicts between the interests and service to the individual user of laboratory resources and broader societal obligations. How we will achieve a proper balance between duties to the individual and duties to the public is by no means clear, but we should be involved in the efforts to do so. We must ask ourselves how we might avoid taking roads that are simply socially harmful struggles for privilege, power, and position. Most health-care professionals have an individualistic focus; i.e., they direct their efforts towards the individual patient or client, but they also have a focus on the common good. The patient-centered ethic probably dominates, but the concept of the common good as expressed in European and North American society has its roots in ancient Greek political thought, revitalized during the Renaissance. We need to add to these traditions the understanding of individual and common good developed over thousands of years by many individuals and peoples in Africa and Asia. We need this intermingling of insight if we are to arrive at a more profound understanding, if we are to face the problems of choosing between the conflicting interests or needs of two or more choices, and when we must ration scarce resources. If we consider our profession to be a calling, then the line between professional identity and citizenship is not as easily or clearly drawn.

The following are some specific issues that challenge laboratory professionals and our professional ethics.

Clinical Research

Many service laboratories in developed and developing nations are involved in clinical trials; some choose to do so for professional and academic reasons, others because they may have particular expertise. Still others may have very little choice, because they are the only laboratory resource available in a city, region, or country. The first phase of such trials involves exploring the toxicity and method of delivery of a drug or treatment by using human volunteers. Clinical chemistry and hematology laboratories provide the tests that often play an important part in Phase I assessment of toxicity. This is also the case in Phase II, when a drug is administered to a specific group of patients who have the disorder being investigated, and in Phase III, when a randomized, control study is undertaken. We have an ethical obligation to know the details of the study. Poor science is poor ethics. We need to know that those entering the study have not been coerced and have given fully informed consent. Unless we have that information before we provide the laboratory services, then we are unable to give our informed consent to participate. In its absence we are not meeting our own ethical standards.

Even when our laboratory is being used as a means to obtain blood samples from patients, regardless of whether the tests will be performed there, we should be aware of the use to be made of the samples. We should also know that the patient understands what is being done and has given informed consent; otherwise, we are participating in an assault on that patient. We should uphold the autonomy of the patient we serve; we should not be a party to unethical procedures. We are not there simply to obey orders; rather, we are called upon to be a responsible profession exercising professional responsibility. For instance, as a profession, we need to know where we stand on the following question: Are patients entitled to know what treatment they are being given and why? There is little evidence that this issue has been discussed by laboratory professionals. Not to

discuss this means that we have taken the passive road, that we are saying that it is someone else's business and not ours.

Allocation of Health-Care Resources

This is clearly a moral dilemma, with a potential conflict between the interests of society and the interests of individual patients (6). There are also various degrees of scarcity of resources. Have we as a profession analyzed fully the role of the clinical laboratory in the allocation of health-care resources? Have we eliminated waste, do we do all we can to curb unnecessary testing, do we use our resources well? Do we act as though all laboratory investigations are useful and allow them to be done, even when we do not believe them to be useful? Do we see increased testing as good because it means that more resources will come our way, producing a bigger personal empire with more prestige? Can we argue ethically that we should do nothing and that we have no part to play in the better allocation of scarce resources? We may ask these questions, but it is not clear that as a profession we have debated them sufficiently clearly so that ethically we know what we should be doing.

If our laboratory has significant involvement in the private sector, in an environment predominantly served by a public health system, how do we handle questions of distributive justice, access to care, and the extent of acceptable inequality in health-care delivery? Do we have concerns about inequality of the quality of laboratory work being done as well as inequality of access to laboratory services?

Tests Conducted Away from the Laboratory (Nearer the Patient)

Professional laboratory organizations, including those of clinical chemists, have identified many of the issues. For the diagnostic systems used for such testing, we should try to see if common ground can be found among all the approaches taken by the various societies of laboratory professionals. Is there some consensus as to the responsibility of the manufacturer and the responsibility of the profession? Is it ethical to sell instrumentation without including education and training as part of the deal? Professionally we have made significant contributions in this area through the various reports that have been produced. However, the impact would be even greater if we could find among all of these reports some consensus and identify the underlying ethical positions justifying the recommendations.

Confidentiality

What procedures do we have in place to safeguard our patients when someone telephones a laboratory asking for the test results for an individual? Do we give out laboratory information requested by insurance companies about patients? Even if the information goes back only through the attending physician, do we have evidence that the patient has agreed that all, rather than some, of that information should be given (7)?

Clinical laboratories frequently do tests on employees. To whom do we send the results—to the employer? Do we ask for any assurances as to the use to which they are put? Do we know whether the workers have freely agreed to have this information released to their employer? Do we insist that the results go only to the worker or, with the individ-

ual's permission, to his or her personal physician? Do threats of loss of employment coerce people to have blood tests done in the workplace? Is appropriate action being taken on the results? If we are computerized, how secure are our laboratory information systems? Do our staff receive adequate instruction as to their important role in maintaining confidentiality? Do we regularly make them aware of this responsibility? Do we have clear professional policies to cover these situations?

Screening Tests

As a profession we probably have, in company with clinical epidemiologists, the best understanding of the predictive value model for assessing test performance by means of the two standards, sensitivity and specificity. We know that as sensitivity increases, specificity decreases, and vice versa. We need to apply this critical understanding to many screening and testing programs, to let people know that we have particular insights into the clinical relevance of tests. How good is the evidence, what is the outcome, what are the results and benefits of the utilization of any procedure? The AACC has become active in drug-screening issues in the workplace in the United States, pointing out that very sensitive tests can lead to many false positives, and, therefore, that all such patients who give a positive test result require a confirmatory test by a definitive method. These studies have focused on the technical aspects. Laudable though this may be, would it have been better, at a much earlier stage in the debate, for the AACC to have developed a professional view as to the desirability of the whole program (8)? This would have been an important role in educating the public, other health professionals, and legislators. Even if this view were not accepted, an ethically developed approach to the whole question would have enhanced the professional image of clinical chemists. Does mass screening in such a situation begin to lead to assumptions of guilt until the individual is proven innocent, rather than the other way around? It is the punitive aspect arising from the presence of a positive test result that makes it different from screening for phenylketonuria or screening for cervical cancer. Yes, we have a professional role in quality assurance that includes technical and interpretational components, but we should also see our involvement in the discussion of the ethics from the point of view of the patient, society, medicine, and our profession, as being integral with our involvement with quality assurance.

When physicians who are critical enthusiasts for the cholesterol-health risk hypothesis meet a patient and propose various laboratory tests, they are also letting the patient know that they are prepared to do something based on the results. The physician has to be quite clear as to what action is proposed. I believe it is important to tell the patient what is likely to be the outcome of the intervention, what are the risks and benefits. In applying this hypothesis to the individual patient with hyperlipidemia, despite all the clinical studies, there is a lack of clear information on risks and benefits for anyone other than middle-aged men whose serum cholesterol exceeds 6.8 mmol/L. A physician with good laboratory knowledge knows that the test result is valuable only if the assay is done with a precision and accuracy greater than 96% and that it is probably clinically invalid when the analytical accuracy and precision is around 92-94%. Have we really thought through all the ethical issues in the doctor/patient relationship in this

hyperlipidemia scenario? Have we completely satisfied ourselves that there are no ethical problems as to the quality of the laboratory results, particularly when there are an important and problematic component in widespread cholesterol screening?

Molecular Biology

Some of the developments in this area have produced detection tools more developed than the ability to manage the disorders diagnosed. The profession of laboratory medicine has not yet accepted the challenges raised by these developments. Many of the techniques are very straightforward and, with appropriate technician training, could be used in routine laboratories. They might be used in service laboratories, not because the laboratory is particularly interested in the area but because there are pressing economic reasons not to set up yet another series of laboratories, or because the limited laboratory facilities available leave no other choice. In laboratory medicine we need to develop a position relating to molecular biology—not only from a technical standpoint but also for the issues surrounding the development and application of such techniques. Gene probes may reveal determinative genes for conditions such as Huntington's chorea and adult onset polycystic kidney disease. The issues raised by the identification of such genes are significant. However, they are less complicated than trying to evaluate the seriousness of a contingent condition revealed by gene probes of less determinant genes, such as those that confer "susceptibility" to such conditions as Alzheimer's disease, abnormal lipid concentrations and heart disease, or bi-polar (manic depressive) illness. These latter genes may cause disease 5 or 60 years later but only if there is an interaction of unknown genetic or environmental factors (9). Do we measure the accuracy of a molecular test against the presence of identifying DNA sequences or against the eventual development of the predicted condition? What comparative standards are to be used for measuring the costs and benefits? Furthermore, the most stubborn and difficult of previous dilemmas will emerge once more in a new analysis, for example: definitions of normalcy and disease, controversy surrounding the elimination or treatment of genetic disease, mandatory testing and the proper role of the state, arguments about non-directive counseling and the limits of beneficence, genetic discrimination, and laws and safeguards for the control and protection of genetic information.

Although DNA fingerprints have been acquiring great influence in legal cases in the United States, the limitations of such procedures are also being discussed (10, 11). At this time we should be using some of the critical appraisal skills we have acquired. Our laboratory experience tells us that in research laboratories the specimens may be relatively pure and uncontaminated; in a criminal situation, they may be very contaminated. This contamination could be from the victim's own cells, or from multiple sperm when several assailants are involved in a rape. Clothing dye, yeast, bacteria, environmental proteins, and the way the sample has been handled may also lead to contamination. The restriction enzymes may slice the DNA in the wrong places, or the radioactive probes may lock on to the contaminants, rather than the target sequences. If additional ions are present, these will affect the electrophoretic mobility. The profession of laboratory medicine has a major understanding to contribute to the widespread a

reciation of the limitations of laboratory techniques and technology. We are unusual in having a long and tested tradition of trying to quantify our limitations. Our knowledge of the theory and practice of reference values helps us to be more readily appreciative of the fact that the frequency of the bands in DNA fingerprints of 200 people of one ethnic group in Detroit may not be genetically representative of the same ethnic community in Los Angeles, and even less so if that same group is in another part of the world. All of this is part of the enhanced concept of quality assurance that must be an essential part of ethical laboratory medicine.

Conclusion

Ethical issues have been around for centuries. A careful exploration shows they have surfaced in almost all societies. Our current interest is a case of old wine in new bottles. We need input from developed and developing countries. We need insights that have not yet had the opportunity to be publicized. When we talk about individual rights, we have to consider the balancing concepts of duties, obligations, and responsibilities. We do not seem to have been very good at having open discussions about this in our professional literature. We have technical and medical expertise, but we need to educate ourselves and our students who follow us, as well as the people we serve, so that they can understand and make informed ethical decisions. Ethics should permeate and influence the whole range of our profession. Without a voice in ethical issues we lack an essential element of our professional independence. The attitudes we display may well help to determine what

kind of people choose to work in our hospitals and in our profession. Do we work as a profession within a tradition of human rights, and do we seek to promote this in areas of the world where these have been denied or where this tradition does not exist? These are a few of the questions I believe we must consider when we look at ethics and laboratory medicine.

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