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Ethics for Laboratory Medicine

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Guests: Dr. Sheldon Campbell is Professor in the Department of Laboratory Medicine at Yale School of Medicine. Dr. Ann Gronowski is Professor in the Department of Pathology and Immunology at the Washington University School of Medicine. And Dr. Melissa Budelier is a Fellow, also at the Washington University School of Medicine.

Bob Barrett: This is a podcast from *Clinical Chemistry,* sponsored by the Department of Laboratory Medicine at Boston Children's Hospital. I am Bob Barrett.

Maintaining high ethical standards is a characteristic we expect in many professionals, but perhaps most in the field of medicine. Although biomedical ethics is a relatively new field, there have been discussions of moral issues in medicine since ancient times. The Hippocratic Oath, for instance, was written by Hippocrates at approximately 400 B.C. It requires that a new physician swear to uphold specific ethical standards. Over 2000 years later new physicians still swear by the Hippocratic or a similar oath.

The December 2019 issue of *Clinical Chemistry* published a Review paper that provides a broad overview of ethics as it pertains to laboratory medicine. The authors, Dr. Ann Gronowski, a Professor in the Department of Pathology and Immunology at the Washington University School of Medicine, Dr. Melissa Budelier, a Fellow also in the Department of Pathology and Immunology at the Washington University School of Medicine, and Dr. Sheldon Campbell, a Professor in the Department of Laboratory Medicine at Yale School of Medicine, are all here with us today to discuss this Review.

Dr. Gronowski, let's start with you. Why did you feel it was important to write this Review, and what did you hope to accomplish?

Ann Gronowski: Yeah. So, laboratorians, like all medical professionals, must adhere to high ethical standards. However, because many laboratorians don't directly see or treat patients, I think we often forget that laboratorians have a fiduciary duty to act in the patient's best interest. For us, that means making sure that the testing that patients are having performed is in their best interest and does not harm them. Unfortunately, studies have shown that many clinical laboratory training programs don't teach medical ethics. This is a real oversight in my opinion, and one that we need to work to correct. This Review that we wrote is meant to serve as a

broad foundation for the study of ethics within laboratory medicine. It doesn't go in-depth into any single topic, but rather it provides a framework of biomedical ethics for laboratorians. Each one of the topics we cover could constitute its own Review. But our manuscript gives examples of real-world cases, it provides published references that are specific to laboratory medicine, and it suggests resources that laboratorians can access when faced with difficult ethical issues.

Bob Barrett: Okay. Well, Dr. Budelier, can you explain for us the core principles of biomedical ethics?

Melissa Budelier: Yes. Most experts identify three, sometimes four, core principles of biomedical ethics. One of these principles is respect for person. This means maintaining the autonomy of the person and treating people with respect and dignity. In addition, the idea that people with diminished autonomy are entitled to protection.

The second core principle is beneficence, which refers to the concept of doing good. In other words, the duty to act in the best interest of patients or research subjects. The opposite of this term is maleficence and describes a practice which opposes the welfare of a person. Non-maleficence means to do no harm. Some experts break non-maleficence out as a fourth principle of bioethics because doing good and doing no harm are two different concepts. For the purposes of our Review, we grouped them together.

And finally, the third principle is justice, the duty or obligation to treat people equally and to distribute what is rightly due in terms of benefits, risks, and cost. In practice, the application of these principles includes the use of informed consent, the assessment of risks and benefits, and a fair and equitable treatment and allocation of resources. These principles can be applied to both medical research and medical practice.

Bob Barrett: And Dr. Gronowski, what are some of the ethical issues that laboratorians face, and what in your opinion is the most challenging?

Ann Gronowski: Well, some examples of ethical issues that are of particular interest to laboratorians include, for instance, the use of leftover specimens, incidental findings, genetic testing, and biobanking, just to name a few. In my opinion, one of the most challenging ethical dilemmas occurs when patients refuse treatment or testing that health providers believe are necessary. This causes a conflict between the healthcare provider's obligation to beneficence, but it opposes the patient's right to autonomy. This happens, for instance, when patients refuse in-patient drug testing for fear of the

negative implications that might occur to their job or to health insurance. Or, when patients decline blood products due to, for instance, religious beliefs.

Healthcare providers can override patient autonomy, but justifying the actions that violate ethical principles requires really careful consideration of whether the proposed action, one, is likely to achieve the underlying goal; two, that it presents the lowest degree of infringement; three, that it minimizes any negative consequences; four, it has no morally preferable options; and five, finally, that it was arrived at through the proper process. This usually is a group effort including a healthcare team, risk management, or an ethics committee. These kinds of decisions are taken very seriously and can be extremely difficult.

Bob Barrett: I'm sure they are. Now Dr. Budelier, your Review included a section on lab utilization. Can you explain how this is an ethical issue?

Melissa Budelier: I'm glad you asked about this. Although most laboratorians rarely interact with their patients, they're still ethically bound to provide healthcare that is in the best interest of the patient. This is consistent with the core ethical principle of beneficence. Therefore, laboratorians should advocate for proper test utilization and communicate with physicians when they feel testing has been ordered inappropriately, in order to do good and do no harm. As this audience knows, inappropriate laboratory testing can lead to additional discomfort for the patient, or false positive results which can lead to unnecessary testing and intervention, or even misdiagnosis, as well as increased costs for the patient and society as a whole.

As stewards of healthcare resources, laboratory professionals should be particularly aware of the medical practices that pose conflict between the interests of patient and society, and medical practices that have no or undetermined value. In proving lab utilization should be considered a fundamental part of a laboratorian's professional and ethical duties.

Bob Barrett: So, Dr. Campbell, let's go to you now. Your focus has been on outbreaks of dangerous and highly contagious diseases such as Ebola, and the ethical issues that arrive when we have to balance the risk to laboratorians versus the benefits to patients. Can you talk a little about this balance?

Sheldon Campbell: Yes, of course. This is a place where we have to balance complicated and frequently poorly-defined risks against one another. On one hand, laboratory testing is essential to the care of each individual patient. During the Ebola outbreak, many laboratories wouldn't accept samples from patients

until they were ruled out for Ebola, which took hours to days. Ebola symptoms overlap with many other infectious diseases and some non-infectious diseases, some of which can be emergencies.

In the best documented cases, appropriate diagnosis and treatment of malaria was delayed. At least one patient died, though it's impossible to establish that the delay was responsible. Additionally, the risk of any particular patient having Ebola was small. There were nearly 30,000 suspected cases in the entire outbreak, and that's probably an underestimate. But there are over a million cases of malaria in Liberia alone each year. On the other hand, laboratory workers deserve to be protected from excessive risk. How great is the risk of handling a sample from an infected patient in a modern laboratory? We don't really know.

If a laboratory were to become contaminated and unusable, what impact would that have on the care of hundreds and maybe thousands of patients? Unfortunately, during that outbreak many laboratories, under the banner of such phrases as "an abundance of caution," simply failed to address the need to address the challenging questions.

Bob Barrett: Well finally, Dr, Campbell, what would help laboratories prepare for and manage the next pandemic?

Sheldon Campbell: We do know that there will be a next pandemic. The combination of microbial diversity and adaptability, climate change, and globalization makes it nearly inevitable. The laboratory profession needs to discuss these issues more proactively, in advance of the next event, and create tools for addressing moral risk, as we have for assessing quality and safety risks. The resources to build robust safety programs wouldn't hurt either, but when the next outbreak occurs, we're going to have to adjust in real time. We'll desperately need consistent messaging from public health and professional organizations, and as much information on the disease itself, route to transmission, virulence, persistence, and all the other parameters that impact risk, as possible. Finally, laboratories need to create policies on how they will balance patient, worker, and systemic public health type-risks.

Bob Barrett: Dr. Sheldon Campbell is a Professor in the Department of Laboratory Medicine at Yale School of Medicine. Dr. Ann Gronowski is a Professor in the Department of Pathology and Immunology at the Washington University School of Medicine. And Dr. Melissa Budelier is a Fellow, also in the Department of Pathology and Immunology at the Washington University School of Medicine. They have been our guests in this podcast about ethical questions for

laboratory medicine. A Review paper on that subject appears in the December 2019 issue of *Clinical Chemistry*. I'm Bob Barrett. Thanks for listening.