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PEARLS OF LABORATORY MEDICINE

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TITLE: Ethics in Laboratory Medicine

PRESENTER: Ann M. Gronowski

Slide 1:

Hello, my name is Ann Gronowski. I am a Professor of Pathology & Immunology and Obstetrics & Gynecology at Washington University School of Medicine in St Louis. Welcome to this Pearl of Laboratory Medicine on “Ethics in Laboratory Medicine” which was put together on behalf of the IFCC Task Force on Ethics.

Slide 2: Terminology

In order to discuss ethics in laboratory medicine, let’s start first with some basics on ethics in the medical and research community. According to the Merriam-Webster Dictionary, the term "ethics" refers to "rules of behavior based on ideas about what is morally good and bad," while the Encyclopedia Britannica defines "bioethics" as a "branch of applied ethics that studies the philosophical, social, and legal issues arising in medicine and the life sciences." Bioethicists are concerned with the ethical questions that arise in the relationships among life sciences, biotechnology, medicine, politics, law, and philosophy. The term "medical ethics" refers to the "study of moral values and judgments as they apply to medicine." The terms bioethics and medical ethics are often interchanged. Although bio/medical ethics is a relatively new field, there have been discussions of moral issues in medicine since ancient times.

Slide 3: Medical Ethics

An early example of medical ethics is the Hippocratic Oath. The Hippocratic Oath is believed to be written by Hippocrates or one of his students in approximately 400 BC. It requires that a new physician swear, by a number of healing gods, to uphold specific ethical standards.

Slide 4: Nuremburg Code

Prior to 1947, there was no generally accepted code of conduct governing the ethical aspects of human research. The atrocities of World War II, and the Nuremburg trials that followed, brought about new awareness of ethics in medicine and research as well as sensitivity to doing research on vulnerable populations.

In 1947, as a part of the Nuremburg Trials, a set of ethical principles for human experimentation was developed and is referred to as “The Nuremburg Code.” There are 10 points to the Nuremburg Code which are summarized here. The code outlines specific requirements for consent of subjects, experiments that will benefit society, avoiding physical & mental suffering, qualified staff, and conditions under which the experiment must stop. This code represents the beginning of what we now know as modern bio or medical ethics.

Slide 5: Declaration of Geneva

While the Nuremburg code is a set of ethical principles for **human research**, the Declaration of Geneva, which was drafted shortly after the Nuremburg Code, is a **physician’s oath** intended as a revision of the Hippocratic Oath. It is a declaration of a physician’s dedication to the humanitarian goals of medicine. This declaration was especially important after the heinous medical crimes which had been committed during WWII. This declaration was adopted by the General Assembly of the World Medical Association in 1948 and has been amended several times since then. The declaration is shown on this slide. Upon graduation, most medical schools administer some type of an oath; most frequently a version of the Hippocratic Oath or the Declaration of Geneva.

Slide 6: Declaration of Helsinki

In 1964, the World Medical Association went on to tie the 10 principles of the Nuremburg Code and the Declaration of Geneva into a document known as the “Declaration of Helsinki.” This document is a set of ethical principles for human research, developed for the medical community. It has undergone numerous revisions since its first draft in 1964. Important concepts of this document include:

- The well-being of the subject prevails over the interests of science and society
- Consent should be in writing
- Introduced the concept of oversight by an independent committee
- Use caution if participant is in dependent relationship with researcher
- Limited use of placebo
- Greater access to the benefits of the research

While it is not a legal binding document, the Declaration of Helsinki is considered the foundation of human research ethics in countries around the world.

Slide 7: Belmont Report

In 1978, in the United States, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research created the “Belmont Report” which outlines ethical principles and guidelines for the protection of human subjects. The Belmont Report is one of the leading works concerning ethics and healthcare research. It identifies three core principles:

1. *Respect for persons* means that the autonomy of the person is maintained and that persons are treated with respect and dignity and not deceived in any way.

2. *Beneficence* is a concept in research ethics in which researchers should have the welfare of the research participant as a goal. The opposite of this term, maleficence, describes a practice which opposes the welfare of any research participant. Non-maleficence means do no harm.
3. *Justice* means that the person will be treated fairly and equally and will not be exploited.

Application of these principles includes use of informed consent, assessment of risks and benefits, and selection of subjects.

Slide 8: The Common Rule

In the United States, all government-funded research is regulated by a set of Federal-enforced regulations under the Department of Health and Human Services. These regulations are referred to as the "Common Rule." The Common Rule is written into the US Code of Federal Regulations, Title 45 (Public Welfare), Volume 46. The principles of the Belmont Report, the Nuremberg Code, and the Declaration of Helsinki are encompassed in the Common Rule. While the Common Rule is intended to guide all Federally Funded research in the US, most universities in the US apply its principles to ALL research within the University with requirements for an institutional review board approval of all research that involves human subjects.

Slide 9: ISO 15189:2012

Let's discuss ethics as it relates to laboratory medicine in particular. Laboratory medicine is obliged to adhere to high ethical standards just as other areas of medicine. Many organizations have developed policies and guidance materials on ethical issues related to laboratory medicine. For instance, the International Organization for Standardization (ISO) has created ISO 15189:2012 "Medical laboratories-Requirements for quality and competence" (5). Within this document, section 4.1.1.3 summarizes the ethical conduct expected in laboratories. The document states that laboratories should have means in place to ensure the following:

a) "there is no involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgment or operational integrity;
b) management and personnel are free from any undue commercial, financial, or other pressure and influences that may adversely affect the quality of work;
c) where potential conflicts in competing interests 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."

Slide 10: AACC Guidelines for Professionals

Many professional organizations have also outlined codes of ethics for clinical laboratory professionals. For instance, the American Association for Clinical Chemistry (AACC) has published a set of Ethics guidelines. It states that the AACC endorses the following principles of ethical conduct in their profession:

- upholding standards of professionalism
- avoiding scientific and professional misconduct

- reporting healthcare professionals who engage in fraud
- maintaining a high level of quality in all professional endeavors
- respecting privacy and confidentiality
- continuously striving to augment one's professional qualifications
- promoting safety
- avoiding and/or disclosing any conflicts of interest
- encouraging disclosure of medically relevant medical errors
- complying with relevant laws

Ethical guidelines differ by associations but generally cover similar relevant areas.

Slide 11: Ethics Education in Laboratory Medicine

Despite the importance of ethics in laboratory medicine, there is variability in education that is focused on ethics in the laboratory. A recent report by the IFCC Task Force on Ethics indicates that formal teaching of ethics is absent from many clinical chemistry and laboratory medicine training programs.

This slide shows what percentage, of the 80 training programs that were surveyed, offered these various topics in ethics and what percentage of programs require this training.

- 35% offer training in Research ethics
- 29% offer Medical ethics
- 20% offer Professional ethics
- 6% offer Business ethics

Only 3 of the 80 programs, or 3.8%, offer all four categories. Very few programs actually require ethics training. 32% of the programs required at least one of these categories of ethics training. For more on ethics training, I refer the reader to another Pearl by Jón Jónsson on behalf of the IFCC Task Force on Ethics which specifically deals with Ethics Education.

Slide 12: Ethics in Laboratory Medicine

There are a number of ethical issues to be considered within the field of laboratory medicine. These include topics such as: consent, confidentiality, codes of conduct, conflict of interest, publishing, biobanking, medically actionable results, proficiency, equity or allocation of resources, genetic testing, and direct access testing. We do not have time in this Pearl to cover each of these topics.

Slide 13: Ethics in the Pre-Analytical Phase

For the purposes of this presentation, we will focus on ethical issues encountered during the daily routine work of laboratory medicine specialists. As a framework, we have broken down the ethical issues into the pre-analytical, analytical, and post-analytical phases, and we will look at the three main ethical principles from the Belmont report: Respect for persons, Beneficence, and Justice.

In the pre-analytical phase, in order to maintain “Respect for Persons”, all patients should give consent, either implied or expressed, to have samples collected. Informed consent may pose an ethical problem if the patient is incompetent to make a decision due to age, mental status, or critical illness. Patients have a right to refuse to have samples collected and this right should be respected. However, there are certain situations in which patient autonomy is not absolute. For instance, a patient may be deemed incompetent to make a decision about their health, as when the patient is unconscious, mentally ill, or under the influence of drugs. Children are generally deemed not competent to make decisions for themselves unless they are legally emancipated from their parents. There are cases of compulsory testing in certain groups such as intravenous drug users and prisoners. In these exceptional cases, healthcare professionals have an obligation to consult the guidelines provided by each institution in which they practice, and they must weigh the risks of loss of autonomy versus the benefits of the testing. In addition, all information obtained at the time of sample collection should remain confidential.

In order to maintain “beneficence,” the testing that has been ordered should have clinical utility with the intent of benefiting the patient. The sample collection process should do no harm. Additional samples collected for the purpose of research should only be collected if expressed consent is obtained.

In order to maintain “justice,” there should be no preference given to individuals to facilitate or expedite the collection process at the expense of other patients.

Slide 14: Ethics in the Analytical Phase

In the analytical phase, in order to maintain “Respect for Persons,” the patient's right to refuse testing even after the sample has been collected needs to be respected. Special care should be taken to maintain confidentiality as much as possible, including in a point-of-care setting in which testing is often in a more open, less private, setting.

In order to maintain “beneficence,” the laboratory needs to provide the best possible analytical result. This is achieved through good laboratory practice and maintenance of professional standards. Good laboratory practice should involve the establishment of a rigorous quality assurance program encompassing quality control testing, proficiency testing, and laboratory accreditation. The maxim “a wrong result is worse than no result” is a guiding principle in this regard. Good laboratory practice includes refusal to analyze or report a result when there is evidence of poor sample integrity, incorrect or poor labeling, or other situations that may compromise the test result. Facilities should develop an appropriate policy on analysis of specimens when specimen integrity or identification is compromised. Only qualified, properly trained personnel should perform point-of-care testing.

In order to maintain “justice,” there should be no discrimination in the analysis of patient samples based on gender, age, or racial origin. All patient samples are to be treated equally. It is recognized, however, that specimens designated as “STAT” or priority must be analyzed promptly to meet the medical need as well as possible. Laboratories should develop appropriate operating procedures for this type of testing, and state which tests are included and the expected turnaround times. It is expected that all specimens are analyzed accurately and in a timely manner.

Slide 15: Ethics in the Post-Analytical Phase

The post-analytical phase includes reporting and interpretation of results, residual specimen storage, and data access. Laboratories should have a policy for specimen storage that is analyte-dependent. In order to maintain “Respect for Persons,” patient results need to be kept confidential. Exceptions are made if the patient is a juvenile or is incapable of receiving or understanding laboratory results. Respect for local customs as to legitimate recipients of laboratory data should be taken into account. Again, the right to refuse sharing data needs to be respected.

Patients have a reasonable expectation that their samples will be used solely for the laboratory testing requested by the clinician. Individuals have the right to decide when and if their records or specimens shall be used outside normal medical care for which they have consented. Policies should be established regarding further testing on residual samples.

Because misinterpretation of results can lead to patient harm, in order to maintain “beneficence,” only qualified personnel should interpret reports. The reporting of results should be performed in a manner such that the patient’s clinician receives the right result within an appropriate time with information that allows for correct interpretation.

Delays in reporting, for whatever reason, should be avoided. Incorrect results can lead to mismanagement. Ordering clinicians should be notified of errors as soon as they are identified and test results should be corrected as soon as possible. The change should be marked on the report, and the incorrect result or results should be clearly identified as erroneous.

In order to maintain “justice”, the reporting of results should be consistent for all patients. Rapid reporting may be required for some results, such as for "critical" and "significant-risk" results, but the rules for rapid reporting must apply regardless of the source of the sample and the patient’s ability to pay. Withholding laboratory results because the patient has not paid should be avoided. A policy on the use of residual samples should be developed. Residual samples are often used without the patient’s knowledge. There is much discussion in the literature about who owns patient specimens and whether patients should share in profits if financial gains are derived from leftover samples. Rules and practices vary by region and institution.

Slide 16: Summary

In summary, the modern history of bio/medical ethics is well-documented and grew significantly after WWII and the Nuremburg trials. The Belmont report identifies three core ethical principles: Respect for persons, Beneficence, and Justice. These principles can be used as a guide to addressing ethics. Laboratory professionals must maintain ethical standards just as any other medical professional. Many professional laboratory societies have established codes of ethics. The core ethical principles should be maintained during the pre-analytical, analytical, and post-analytical phases of laboratory testing.

Slide 17: References

Slide 18: Disclosures

Slide 19: Related Pearls

Slide 20: Thank You from www.TraineeCouncil.org
Thank you for joining me on this Pearl of Laboratory Medicine on “Ethics in Laboratory Medicine.”