

Ethics and Quality Assurance in Biomedical Laboratory Science

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The biomedical laboratory science profession and the professionals who work in this field are dedicated to deliver the best possible services to patients because it is essential in the promotion of quality health care. The information generated with the completion of human genome project has and continues to transform human clinical medicine by pinpointing at the molecular level the causes of diseases that heretofore were unknown. In addition, the impact of the human genome project has created the emerging science of “biological” therapy, meaning future medicines will be tailored made for every patient, each with their own specific diagnosis based upon their own individual genetic blueprint. Thus, as discoveries are made at the bench then tested at the bedside to eventually enter delivery to communities, the revolution of “translational” medicine is upon us. How will the biomedical laboratory respond to these changes both in terms of the profession as a whole but importantly how each and every laboratory professional addresses these changes that are revolutionizing the practice of the laboratory profession and laboratories in general? To best address these changes will require all laboratory professionals to have a quality sense of ethics, especially as it relates to making good, sound decisions. This quality will be paramount to determining how these changes will be implemented such that the delivery of quality health care to our patients will not be compromised. This paper addresses many of the concerns involved in making sound ethical decisions.

Key words: biomedical laboratory science, ethics, good decision making

Introduction

The International Federation of Biomedical Laboratory Science (IFBLS) is a global organization established to best address issues directly related to the promotion and function of the profession of biomedical laboratory science globally. Through efforts targeting both education and practice focusing through working partnerships, IFBLS seeks to increase opportunities for all biomedical laboratory science professionals. To em-

phasize this commitment, IFBLS is a non-governmental partner with the World Health Organization (WHO) working collaboratively to attain mutual goals pertinent to deliver basic laboratory policies in both developed and developing countries.

As the result of the focus to promote the profession of biomedical laboratory science, IFBLS promotes Good Laboratory Practice (GLP) (www.ifbls.org) [1]. It accomplishes this task by concentrating on establishing an environment of GLP in diverse environments. It is within this objective that IFBLS stresses the importance of a Code of Ethics (www.ifbls.org) [2]. Such a code was

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established in order to promote the relationship between the patient and the laboratory within the scope of GLP. It is through this effort that a Code of Ethics was established that addresses the following elements of good clinical practice for the profession: (a) be dedicated to the use of the biochemical laboratory to benefit mankind; (b) provide expertise to advise and counsel other health professionals; (c) maintain strict confidentiality of patient information and test results; (d) safe guard the dignity and privacy of patients; (e) be dedicated to the use of the biochemical laboratory science to benefit mankind; (f) provide expertise to advise and counsel other health professionals, maintain strict confidentiality of patient information and test results; (g) be responsible for the logical process from the acquisition of the specimen to the production of data and the final report of the test results; (h) be responsible for the quality and integrity of biochemical laboratory services; and (i) exercise professional judgment, skill and care while meeting established standards. Although a code of ethics has essentially focused on the performance and conduct of the clinical laboratory practitioner, within the past several years there has been a paradigm shift that will raise new questions and concerns about how biomedical laboratory science as both a profession and those who practice within it will respond.

A New Paradigm Shift - A Cause for Concern or Promising Opportunity?

Currently in the United States based upon data generated in 2010, more than \$30 billion is spent on medication [3]. In a population of 330 million people, 48% of the population takes one medication daily, two drugs are taken daily by 31% of the population, while for the percentage of those above the age of 60 taking at least two medications per day jumps to 76%, and at the same time 37% of the population takes FIVE medications per day [4]. However, in the final analysis, within all groups only a small percentage, <10% are actually helped taking this medication. Is this a concern? Should it be a concern?

Why Must it be Considered a Concern?

Each and everyone is born with our own specific genetic blueprint - our DNA, therefore an individual's response to any medication is really based upon our genomic profile [5,6]. Thus, our genetic predisposition

influences, if not determines, our ability to respond to any medication as it relates not just to its efficacy, but also to whether there will be any toxic side effects. Over time the method used to test drug efficacy is through what is described as the "block buster" model of testing - needing to conduct large randomized drug trials (>10,000) in order to demonstrate an even small effect. This is both inefficient and ineffective and a challenge in an environment of ever limiting financial resources [7].

What will be implemented to assist in the efficacy of drug medication design and effectiveness? It will be through genomics. In the future genomics testing will be performed on every patient to determine whether a medication is worthwhile to administer. As an example, in cases of Hepatitis C the prescribed medication is PEG-interferon. The required dosing is for 48 weeks at a cost of \$50,000 [8]. There are many side effects including flu-like symptoms, but the medication is only effective in 50% of patients. In order for the medication to be effective a patient must test positive for IL-28B. Thus, in the future patients will need to be tested for IL-28B. Thus, the ability to digitize the human population through genomic testing thus moving in the direction of providing guaranteed success to patients, which by all standards patients are consumers. Moving from the current status of testing large numbers of patients in order to demonstrate at best modest effects will be changed as the result of genomic testing in order to pinpoint who will respond to new drugs as defined as biological therapies. Performing a genomic and molecular biological analysis of an individual with a suspected disease will provide insight as to what is precisely accounting for how that patient responds to any medical treatment. Once this "data base" has been produced, it will no longer be necessary to conduct the very expensive and very large and multi-center clinical trials currently in practiced by the pharmaceutical industry.

But it is not just about drugs or medications, it will also be about devices and vaccines. In the United States annually the use of 250,000 defibrillators are implanted in patients costing \$6 billion yet less than 10% implanted last the life of the patient [9]. Thus, in the future biomarkers will guide the use of these devices especially for those patients who are not currently candidates for receiving defibrillators a fact that results in the death of an additional 300,000 - 400,000 individuals annually. With respect to vaccines the example was developed in 2010 for prostate cancer, the cost per patient is \$93,000, but the extended quality of life - four months. The question then becomes - does the extended quality of life at

only four months justify the cost?

Thus, with these challenges is it time to create a new ethics in the performance of clinical trials? Also, in the United States 60,000 new cases of malignant melanoma are diagnosed annually [10]. The average median length of survival is eight months. Through genomic testing it has been shown that the presence of the BRAF mutation is expressed in 60% of patients. Thus, the focus has been to develop a biological therapy as an inhibitor targeting the BRAF mutation. A biological therapeutic agent has been developed and when tested initially it showed a marked suppression of the tumor in 81% of patients. Compared with the “standard of care,” the drug dacarbazine, only shows a 15% response rate with considerable toxicity [11]. Known as the “Lazarus Effect” is it ethical to perform additional clinical trials where patients would be randomized to receive new “biologics” therapies vs. standardization when the preliminary results are so positive in favor of the biologic? The question then becomes can you ethically assign a group of patients to receive standard medication when the results for the new biologic are far superior?

Making Ethical Decisions

As the search continues based upon genomic analyses to identify new therapies for many human illnesses that are targeted with respect to their precision and site of action while at the same time minimizing toxicity will be the targeted focus for the future of clinical laboratory medicine. It will be the biomedical laboratory that will be responsible for the testing to determine individual patient genomic profile as well as the quantitation and monitoring of the biologic generated therapy and its target site of action.

Thus, the challenges that await the biomedical laboratory science profession and its professional work force during this time of transition will be daunting. Adding to this responsibility will be the demands of forces that are in play directing the future of clinical laboratory medicine both from the legislative perspective but also the demand to provide accurate and precise diagnoses of medical ailments while at the same time demanding cost-effectiveness in delivering these services. Will the biomedical laboratory science profession and its professional workforce be ready for these changes?

Making ethical decisions requires the professional to have at his or her disposal the necessary skill sets to best respond to any of these ever more demanding and complex set of circumstances. In order to “best” equip

the profession and its professional work force to be able to meet these issues when confronted in order to address any potential situation or scenario the following approach has been developed. It was created by professionals who deal with ethical issues and dilemmas regarding of the discipline on a regular basis.

The “Tool Box” Approach

The rationale behind the tool box approach and decision framework is to ensure that each and every individual needing access to the tool box will find useful a set of “instruments” that will best equip any professional to best deal with the ethical issue at hand. The decision framework is based upon the following:

- Identify the Issues & Stakeholders Involved
- Use of the Toolbox to Address the Situation
- Justify a Course of Action
- Decide & Act

The tool box approach allows the professional to use three “ethical lenses” (Figure 1) (a) weigh the options, checking the consequences; (b) check the impact of one’s decision in terms of its fairness, rules and truth; and (c) is the decision one that makes a positive difference. If followed, the toolbox of lenses used with the decision framework should provide the best possible in terms of its moral judgment. With this approach in place it should create an atmosphere where a Code of Ethics can be used when conditions call for its implementation.

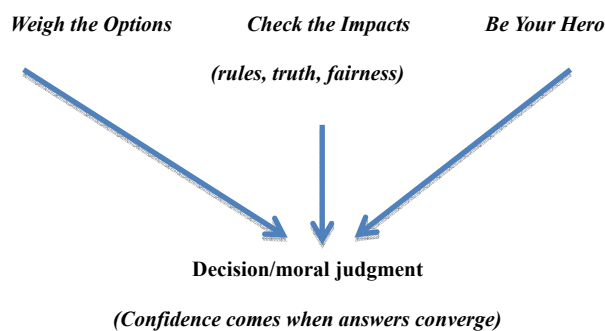


Fig.1 The ethical tool-box approach encompassing all of its components

- Uphold and maintain the dignity and respect of the profession and strive to maintain a reputation of honest, integrity and reliability
- Strive to improve professional skills and knowledge and adopt scientific advances that benefit the patient and improve the delivery of test results

How does the tool box work to provide for ethical

decision-making? What is the incentive to make ethical decisions? What are the issues? What is at stake? Who are the stakeholders? These are some of the important questions needed to ask when one encounters an ethical decision making situation. One important consideration when addressing ethical decision-making: is or have the rules been applied fairly & consistently?

When these questions are to be addressed they should be stated in an analytical fashion such that using each “lense” of the tool box should generate an answer - what answer do you obtain? Are the answers consistent across the lenses? If so then the confidence in your actions will be raised because of this consistency. Thus, your confidence should be well established because the process has allowed you to make decisions effectively and with confidence.

Finally, the premise by which all ethical decisions need and must be made is based upon integrity. Why? Because

- **Integrity** is the project of a lifetime
- **Integrity** is an investment opportunity
- **Integrity** builds wealth in relationships and organizations

Keeping integrity in focus at all times will definitely assist and help each and every biomedical health professional in their ability to address any ethical dilemma one would face in their everyday practice. Importantly, it will provide and contribute to all of the necessary and needed skill-sets required to perform in the ever-changing practice of biomedical laboratory science.

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