Mini Review
Open Access
CrossMark

Laboratory medicine at the threshold of the new century

Abstract

The purpose of this work is to make a brief review of the impact that new technologies including automation, cybernetics, informatics, robotics, and telecommunications have had in today's society with a particular focus on the Clinical Laboratory where significant evolution has been evolving through the last two decades of the 20th Century and the first two decades of the 21st Century. Laboratory Medicine is a specialty in which multiple disciplines converge, including Clinical Chemistry and Clinical Pathology, so that nowadays the concept of Clinical Laboratory Professionals has been increasingly accepted. Given that the Medical Relevance is currently the fundamental premise, the understanding and application of the Biological Variability and its importance on the establishment of Analytical Goals is better understood and accepted day. The recognition of the suitability of the laboratory should include the human dimension and the technological dimension starting with the fulfillment of bioethics so each laboratory must have a Code of Ethics dated and signed by all personnel in which they commit themselves not to incur in conflicts of interest, always placing the patient's interest above any other.

Keywords: bioethics, medical relevance

Volume 9 Issue 1 - 2022

Arturo M Terres-Speziale
Clinical Pathology, Mexico

Correspondence: Arturo M. Terres-Speziale, MD, Clinical Pathology, Mexico City, Mexico, Tel 555-4340-7626; Email aterres@qualitat.cc

Received: September 12, 2022 | **Published:** October 04, 2022

Abbreviations: GST, general systems theory; MBE, medicine based on evidence; QSM, quality systems Management; IQCP, internal quality control program; EQA, external quality assessment; CQI, continual quality improvement

Introduction

Quality Management Systems are living entities that evolve over time through a process of continuous improvement, increasing availability, reliability, importance, transcendence and dependence on results. In 1979, Alvin Toffler published a highly visionary work which he titled Third Wave, in which he developed the thesis that humanity is evolving through three ages from the moment he stopped being nomadic, so that it tells us about: an agricultural era of more than 3,000 years, an industrial era of more than 300 years and a technological era for just over 30 years.[1] The changes of the technological era have intensified in the first decades of the 21st century when we are in a great transition due to the phenomenon of globalization in which demographic, social, political, economic and technological changes occur on an unprecedented scale (Figure 1). As Toffler mentioned the changes are and will be of such magnitude that the illiterate of the 21st century will not be those who cannot read or write, but those who cannot learn, unlearn and relearn.[2]

Paradigm	Industrial	Technological
Century	20th	21st
Vision	Local	Global
Competence	National	International
Complacence	Autosomal	Accreditation
Fundament	Based on eminence	Based on evidence
Organization	Structural	Process
Intelligence	Human	Cybernetics
Direction	Top control	Democratic
System	Manual	Automated
Innovation	Gradual	Accelerated
Quality	Improvement	Reengineering
Communication	Fax	Internet

Figure 1 Paradigms of the 20th Century have changed through the technological impact.

Evidence based medicine

In this new era in the field of Clinical Laboratories, we have advanced at an accelerated pace by incorporating automation, cybernetics, informatics, robotics, and telemedicine so each day we have more and better tests to meet the needs of the (EBM)Evidence Based Medicine which consequently allows the patient to be granted the maximum benefit at the lowest risk and at the best cost (Figure 2).

Paradigm	Industrial	Technological
Economy	Protectionist	Open
Sufficiency	Centralized	Subrogation
Structure	Independent Units	Consolidated
Value	Inventory	Knowledge
Effort	Physical	Intellectual

Figure 2 Paradigms in the field of medicine since the 20th century through the technological impact towards the 21st century.

Laboratory medicine

The impact of Laboratory Medicine on all Medical Specialties including Preventive Medicine and Public Health is unquestionable thanks to the research and development processes in biomedical sciences. In addition to the development of Quality Management Systems (QMS) where the sum of Internal Quality Control Programs (IQCP) and External Quality Assessment Schemes (EQAS), plus Continuous Quality Improvement Programs and Accreditation of Suitability, has had a highly significant impact on the importance of Laboratory Medicine resulting in an increase in the number of tests and procedures available to detect diseases, confirm the diagnosis, establish the prognosis, indicate and evaluate medical treatment.

Clinical laboratories have progressed gradually in such a way that we can identify four stages, which, in developing countries coexist depending on the level of medical care, which goes from the first level, where outpatients are treated to the third level in that there are high specialty services.[3]

Stage 1. Manual tests: Those responsible buy devices and acquire each or all of the supplies separately, including calibrators and reagents, giving minimal importance to the purchase of controls and the establishment of quality control programs, which if they exist are poorly systematized, since in general, statistical calculations are not applied and the results are not plotted, as long as the data falls within what the inserts establish.

Stage 2. Semi-automated tests: Laboratories buy equipment that includes all the necessary supplies that include calibrators, reagents, analyzers and in some cases the controls provided by the manufacturer. In the best trained laboratories, the results are plotted and some basic statistical calculations such as the mean, standard deviation and the percentage variation coefficient are performed, especially when the analyzers provide this information by themselves.

Stage 3. Automated tests. Those responsible buy equipment that includes automation, computing and robotics. In certain cases, the owners of the laboratories delegate the analytical process and quality control to analysts trained in the management of the systems, assuming that the equipment auto controls by itself. To confirm this assumption and comply with the mandatory standards, they participate in external evaluation programs that are nothing more than "user clubs" regardless of whether the provider has any accreditation.

Stage 4. - System consolidation. Those responsible demand products and services integrated into which there are three elements:

1. QMS: Quality Management System that has training, technical assistance and advice in order to achieve ISO/IEC 15189 accreditation
2. IQCP: Internal Quality Control Program of the pre analytical, analytical and post-analytical phases capable of assessing reliability, timing, traceability, calibration, uncertainty, etc. In which the analytical goals and the clinical decision levels are carried out based on the biological variability so that the results have medical relevance.
3. EQA: External Quality Assessment that is accredited in accordance with the requirements of ISO/IEC 17043 & 13485. Although Internal Programs are essential to achieve accuracy, it is necessary to complement them with Proficiency Testing by External Quality Assessment Schemes, which represents an additional tool to demonstrate reliability, traceability and comparability not only among participating laboratories, but also among the diagnostic systems available including analyzers, calibrators, controls and reagents (Figure 3).

Paradigm	Industrial	Technological
Century	20th	21st
Medicine	Curative	Preventive
Provider	Local	Transnational
Medical attention	Hospitalization	Ambulatory
Criteria	Price	Service
Informatics	Local	Web
Clinical History	Paper	Digital
Laboratory	Central	Net
Selection	Single Tests	Problem oriented
Structure	Specialties	Cor Lab
Diagnostics	Phenotype	Genotype
Reports	Printed	Electronic
Quality control	Internal	Total quality management

Figure 3 Paradigms in the field of Proficiency Testing since the 20th century through the technological impact towards the 21st century.

Human dimension

Bioethics is the systematic study of human behaviour in the field of life sciences and health care, examined in the light of values and moral principles. To achieve suitability and guarantee quality, its application is essential in the Clinical Laboratory. To be ethical is to avoid unfair practices. Being ethical is fighting dichotomy. To be ethical is to carry out internal and external quality management and control programs. To be ethical is to comply with the rules, regulations and good practices. To be ethical is to be responsible for the design, implementation, maintenance and improvements of the quality management system, including policies and procedures to ensure the protection of confidential information. Being ethical is to put the welfare of the patient first and that medical relevance is the fundamental premise. Based on all of the above, it is clear that every Clinical Laboratory must have a Code of Ethics.[4]

The impact of Laboratory Medicine on the prevention, diagnosis and treatment of all types of diseases has increased significantly in all Medical Specialties including Internal Medicine, Paediatrics, Gynaecology and Surgery in addition to Preventive Medicine and Health Public which together has generated an increasing impact on the volume and complexity of the workload in the management and study of acute or chronic conditions including from communicable to degenerative diseases which have been increased as a consequence of the epidemiological transition, social and political due to the increase in longevity and life expectancy of the world population.

The inspection and accreditation of clinical laboratories must verify and demonstrate that the owners, shareholders, managers, managers and that the entire person complies with ethical standards including:

- Confidentiality: Keep patient information secret.
- Comply with technical and professional standards regardless of cost pressures.
- Equity: based to non - discrimination on race, gender, political beliefs, religious, or economic circumstances.
- Avoiding conflicts of interest in any form including commercial, economic and financial conflicts of the organization.

- Patients are becoming more and better informed about matters related to their health care, so they want to participate in decisions that may affect them. We must all recognize that the greatest responsibility of the doctor and the clinical laboratory is the patient. Adherence to bioethics through quality standards including punctuality in the delivery of test results. The accuracy and precision, training and personnel training and error prevention are the responsibility of each and every person involved.

For over 2,000 years, the Hippocratic Oath which was applied to Physicians at the end of their studies. Over the years this Oath has been evolving and has been replaced by the 1948 Geneva Convention although in reality the essence remains the same as the original Hippocratic Oath.

Upon admission among members of the medical profession, I solemnly commit to:

- Consecrate my life to the service of humanity.
- Perform my work with dignity and conscience.
- Respect the secret of those who have trusted me.
- Maintain, in every measure, the honour and noble traditions of the medical profession.
- Give my teachers the respect and recognition they deserve.
- Consider my colleagues as brothers.
- Have absolute respect for human life.
- Use my knowledge in accordance with the laws of humanity.
- Not allow considerations of religion, nationality, race, party or class between me and the patient.

Clinical Laboratory Professionals are members of the medical profession so in principle we should know and apply the oath in addition to knowing and working on the basis of the Code of Ethics of the Pan American Health Organization in which the combat dichotomy, which, as evidenced by attentive experience threatens the quality of health services as it harms patients.

Conclusion

In the field of medicine, quality is synonymous with safety. In the 21st century, in the context of the technological era, medicine has been becoming increasingly scientific. It is currently fully documented that MBE Evidence Based Medicine depends fundamentally on the good quality of the Clinical Laboratory, starting from the indication of the tests and the analytical control to the interpretation of the results, which has conditioned that based on the information obtained in the Clinical Laboratory, more than 70% of medical decisions are taken.

It is likely that the most significant advance of ISO 15189 is precisely that of Medical Relevance, which in our opinion dignifies the work of Clinical Laboratory Professionals leaving behind the idea that laboratories are only factories of results in the only thing that workers must do is to process samples, handle analyzers and press buttons efficiently to obtain economical, reliable and timely results. It is not acceptable to want to see the Clinical Laboratory as a factory or as a lucrative business in which the patient's well-being is overrated and is not placed above all else.

To satisfy the expectations of the Medicine Based on Evidence of the 21st Century, the Professionals of the Clinical Laboratory provide proven support through various activities demonstrating our competence in multiple disciplines within which we have clinical biochemistry, cytology, haematology, immunology, endocrinology, microbiology, etc. Which have been extended and deepened to molecular diagnosis, genetics and nuclear medicine.

To meet the needs of the population, the Clinical Laboratory must operate effectively, efficiently and effectively in a Quality System in which structures, processes, performance indicators and analytical goals must be installed and monitored from time to time. real systematically in the three stages of the analytical process comprehensively encompassing the entire Quality Management System (QMS) according to ISO 15189 not only in the Internal Quality Control Program (IQCP) and an External Quality Assurance Scheme Quality (EQAS) which must be carried out in accordance with ISO 17043 for Providers of Fitness Programs.

In order to achieve suitability and guarantee quality, it is essential that the Professionals of the Clinical Laboratory be integral persons and that in each organization there is a Bioethics code in accordance with the Hippocratic Oath and the Code of the Pan American Health Organization.

Acknowledgements

None.

Conflicts of interest

The author declared that there are no conflicts of interest.

References

1. Alvin Toeffler. THE THIRD WAVE. March 1999.
2. María Luisa Castillo de Sfinchez et al. Continuous Improvement of Quality. *Guide for the Clinical Laboratories of Latin America.* 1st ed;1995.
3. Arturo M. Terres Speziale. *Clinic And Laboratory: Science And Technology*. 2nd ed;2002.
4. Arturo M. Terres-Speziale et al. Bioethics Quality and Relevance in laboratory medicine. *Promecal*. *Latin American Guide for Clinical Laboratories*. 1st ed;2013.