CHAPTER 2

The History of Laboratory

By modern standards, the laboratories of a large medical center represent a place for the synthesis and application of the basic sciences to the treatment of patients by engaging in clinical and basic research, performing thousands of procedures daily, and providing discrete teaching programs. These laboratories depend on the institution while the institution and its students, physicians, and patients depend on them.

2.1 Early Development of Pathology and Laboratory Medicine

Pathology has its origins in ancient medicine but developed only as science advanced. Herophilus, one of the great Greek physicians, along with Erasistratus, provided a beginning for anatomical pathology and autopsy.

They performed the first scientific human cadaveric dissections over a period of 30 to 40 years. Human dissection was then forbidden and not allowed again for over 1800 years.

This humoral theory was disproved during the Enlightenment of the 18th century as hospitals and medical education developed. The study of pathology began to develop rapidly as autopsies were performed more frequently, especially those performed after a patient's illness had been monitored in the hospital. As a result, physicians began to believe that pathology could inform diagnosis. During this period, Auenbrugger (1722–1809) developed a method of auscultation (thumping the chest and noting the resulting sound) by working on cadavers and then on patients.

Advances in scientific knowledge impacted both medical practice and medical education in Europe and America. The acceptance of anatomy as the basis of disease led to the study of anatomy, both theoretical and practical, "as the cornerstone of all medical teaching".

Much-needed reforms in medical education were made in the USA in decades after the Civil War. Harvard University made reforms in 1871, emphasizing "learning by doing."

These reforms were followed by reforms at the University of Pennsylvania and the University of Michigan. The most spectacular innovation in the history of American medical education, however, was the opening of the Johns Hopkins Medical School, which provided 2 years of instruction in the basic sciences and mandatory laboratory work.

2.2 Regulatory and Legal changes

Laboratory services are an integral part of disease diagnosis, treatment, monitoring response to treatment, disease surveillance programs and clinical research. The World Development Report 1993, regarded provision of Essential Health Technology as an important ingredient of Essential Clinical Services. Use of diagnostic techniques aid early diagnosis enabling appropriate and prompt intervention thereby reducing overall disease burden and promoting health. All laboratories are not equipped with facilities for carrying out complex investigations. The structure and function of a clinical laboratory varies according to the level of health care facility. Peripheral laboratories carry out simple tests like urine analysis and hemoglobin estimation whereas higher centers are equipped with sophisticated technology and trained manpower to carry out complex investigations.

Establishing a network between peripheral and higher laboratories allows collection of specimens at periphery and their storage and transport for testing at higher centers and communicating report to the peripheral center efficiently without actually having to transfer the patient. In the event of patient transfer, the higher centers do not need to repeat investigations carried out at the peripheral health center, thereby saving crucial time as well as cost and providing continuity in patient care. Networking between laboratories is also essential in disease surveillance programs and outbreak investigations in order to obtain quick and reliable results.

Realizing the rapid pace, wide spectrum and potential for clinical research in our country, the Indian Council of Medical Research (ICMR) launched the Ethical Guidelines for Biomedical Research on Human Subjects in 2000 (revised in 2006) and Central Drugs Standard Control Organization (CDSCO) released the Indian Good Clinical Practices

(GCP) guidelines in 2002 to guide biomedical research in the country. To harmonize practices and generate mutually acceptable data for non-clinical health and environmental safety studies the Organization for Economic Cooperation and Development (OECD) evolved Good Laboratory Practice (GLP) guidelines. India is a signatory to OECD and National GLP Compliance Monitoring Authority established in the year 2002 by the Department of Science & Technology, Government of India, provides GLP compliance certification to the test facilities involved in conducting safety studies on chemicals (viz. industrial chemicals, pharmaceuticals, veterinary drugs, pesticides, cosmetic products, food products, feed additives, etc.).

2.3 Managed Care

Managed care a method of health care delivery that focuses on collaboration among and coordination of all services to avoid overlap, duplication, and delays and to reduce costs. There is an emphasis on efficacy and timeliness of interventions to prevent unnecessary delays in discharge from the hospital or agency. Managed care plans typically cover a wide range of health services such as preventive care and immunizations for adults and children, general checkups, diagnosis and treatment of illness (including necessary tests, doctors' visits, prescription medications, and hospital care), and complete prenatal (pregnancy) and newborn care. Additionally, most managed care plans offer some services for the diagnosis and treatment of mental health conditions and substance abuse problems.

Faced with this state of affairs we want to explore if it is at all conceivable for developing countries like India to offer a comprehensive high-quality healthcare solution to all her citizens. It is my view that, given the unique nature of healthcare, a pure laissez faire, demand driven approach will not produce first-best outcomes for India and nor do existing "solutions" have the potential to do so. Managed Care with its emphasis on offering a structured set of solutions with strong gate-keeping functions, in my view, represents the ideal model both from a cost control and healthcare point of view, irrespective of whether it is operated by the Government or the private sector. One could have a long debate on the

pros and cons of Managed Care but even assuming for the moment that we all agree that this indeed is the direction that a developing country like India must go, all the practical challenges that have dogged Indian efforts at providing healthcare do not magically vanish merely because a new model of healthcare has been proposed.

2.4 Pathology and Laboratory Medicine in the 21st Century

Pathology and laboratory medicine developed rapidly during the 20th century and are likely to develop even more rapidly in the 21st century. Physicians are poised to provide the best in patient care because of their main focus on patients—rather than on teaching and research, as is the case at academic medical centers.

Standardization will allow ICMR to make sure it has equal quality at all of its sites. The goal is to standardize methodologies, collect feedback across facilities, and aggregate and analyze results. Through these means, pathologists can develop organizational confidence around each standardized procedure.

To provide the highest-quality care, ICMR will need to continue to attract, retain, and support the professional practices of increasing numbers of physicians and medical scientists. New professional skills will need to be available. Physicians and scientists retiring from practice will need to be replaced. Moreover, future chiefs of services will need to be attracted in competition with academic medical centers, medical schools, voluntary hospitals and health systems, health care companies, pharmaceutical companies, research institutes, and other entities.

A final challenge relates to education. In pathology and laboratory medicine, more residencies, fellowships, and PhD programs will need to be offered by various institutions approved by Indian Council of Medical Research. Exceptionally well qualified individuals will need to be attracted as residents and fellows. PhD and postdoctoral opportunities will need to be provided at Indian Council of Medical Research and in cooperation with medical schools and graduate schools of universities.

Categories of Some of the technologies in the future are:

- Resources for clinical decision support.
- Error prevention and quality assurance.
- Telecommunications infrastructure. For example, to be able to send a patient a text message reminder to take meds or measure blood glucose levels. This will lead to better self-care management behaviors.
- Collaborative practice connectivity, achieved through a combination of electronic prescribing (e-prescribing) and the ability to connect to and exchange data with labs and physician offices.
- Delivery service support, using GPS-driven telecommunications systems for routing, tracking, order status, dispatch, locating, and oversight.

Clinical Laboratory that does not step up to this challenge will lose the ability to handle important drugs, and this will mean loss of some of their most valuable prescriptions and patients.

Several companies sell software and hardware that increase the efficiency of laboratory by managing workflow.

2.5 Benefits of Proposed System

The Clinical Laboratory Management System is a basic pack of web-application that helps to enhance the pace of workflow and to organize an effective data management system for a laboratory.

Once the CLMS has been installed at your workplace, you will have a lot of data that can be easily retrieved. There will be no fear of data loss or damage as the CLMS can store all data with 100% reliability.

A CLMS system will provide various levels of security and audit trails to enable you to trace activity and provide accountability.