Public Policy and Health

Clinical, Research, or Clinical Research Laboratory—A Review of Laboratory Types and Regulating Bodies

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Introduction: Oversight of individual clinical and research laboratories is variable and site dependent. There are several regulating bodies, each with their own requirements, leading to confusion in the certification process and returning information to study participants.

Methods: A literary and web-based review of research, clinical research, and clinical laboratories compared regulatory differences among different laboratory types and regulatory bodies. A research laboratory generally performs scientific investigations, whereas a clinical laboratory investigates safety, devices, diagnostics, or potential treatments and specifically uses human biospecimens for diagnosis, treatment, or disease prevention. The Occupational Safety and Health Administration, the US Food and Drug Administration, and individual institutions have published guidelines on good laboratory practices and safety, but there are no regulating bodies that govern research laboratory practice. Clinical laboratories are expected to follow good clinical laboratory practices, and if they perform human testing, certification through Clinical Laboratory Improvements Amendments (CLIA) is required. Historically, genetic testing may be pursued through clinical or research avenues. CLIA prohibits releasing test results obtained from research; however, research results are freely released in many countries. The Health Insurance Portability and Accountability Act privacy rule contains an exception that could allow participants to obtain their results from a non-CLIA research lab.

Conclusions: Determining laboratory regulatory requirements can often be difficult for research and clinical laboratories. It would be beneficial for CLIA and others to consider individual oversight for preanalytic processes. Insurance coverage for genetic testing is still variable and limited, so research testing could offer a cost-effective alternative for those affected by genetic conditions if return of results to participants is appropriately sanctioned. It is still unclear as to who would be responsible for disseminating, explaining, and determining if any follow-up care or monitoring is required from research results. Further guidelines are needed to direct release of research results and secondary findings.

Introduction of Clinical Meetings as an Avenue for Improved Health Care in My Home Country

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Objectives: A clinical meeting refers to a formal meeting at which health care professionals such as medical doctors, laboratory professionals, nurses, pharmacists, and so on meet to discuss the clinical case of their patients, new information is relayed, and patient welfare skills get enhanced. It helps in improving the general well-being of the patient(s) and serves as a platform for the clinical staff to tackle loopholes in their health care delivery. In this way, quality and safety for both the hospital/clinic, staff, and patients are ensured.

Methods: This research was carried out in eastern, Federal Capital Territory, and southern Nigeria. The control group included patients who had patient relatives, health care staff, and heads of departments of the hospitals where this research was carried out. Questionnaires were mostly used whereby patient relatives were questioned on what they felt about the quality of care provided them. Staff were equally probed about their jobs and facility.

Results: It was discovered from this research that health care facilities that engaged in frequent clinical meetings took better care of their challenges and their patients than the health care facilities that did not. Each member of the health care team had a clear idea of how and when to handle each patient under their care, what image to portray of the hospital, and how not to overstep each other’s boundaries. Thus, a clear need for frequent clinical meetings was noted as most of the subjects affirmed they felt more at ease and in control of their daily functions.

Conclusion: This is of particular importance to me because for Nigeria, my home country, to have adopted this Western method of extended health care meant that our health care system is plying a good lane.

Becoming a Healthier U: A Descriptive Study of Sexual Health Risk Factors Among Selected Patients From the Open Arms Health Care Center in Jackson, MS

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Objectives: The Becoming a Healthier U (BHU) Program is a community-based initiative that aims to provide a comprehensive, integrated health care approach for improving community access to health services. The