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LABORATORY DIAGNOSTICIAN IN THE IMPLEMENTATION OF CLINICAL TRIALS - A NEW ROLE OF A LABORATORY EMPLOYEE

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BACKGROUND-AIM

Laboratory tests are an indispensable part of each phase of clinical trials. Apart from the obvious role of the principal investigator, which is performed by a clinician, the complexity of procedures (including laboratory procedures) has forced the participation of laboratory diagnosticians in a new area of activity – commercial and non-commercial clinical trials.The aim of the work is to determine the role of the laboratory and the tasks of the laboratory diagnostician in the implementation of clinical trials.

METHODS

In order to determine the role of the laboratory and the tasks of the laboratory diagnostician, the Integrated Supplement to the Principles of Good Clinical Practice (ICH GCP R2) was analysed, as well as the documentation of clinical trials currently carried out.

RESULTS

The requirements for handling biological material obtained during a clinical trial are described in the Clinical Trial Protocols and the so-called Laboratory Manuals, which are increasingly co-created by heads of laboratories or diagnosticians. To ensure the safety of study participants, laboratory diagnosticians perform and analyse the results of, among others: morphology, biochemistry, serology or coagulation. They are responsible for preparing material for analytical studies, such as pharmacokinetics (PK) and pharmacodynamics (PD), as well as for biobanking and shipping to central project laboratories. Detailed assessment of parameters regarding absorption, metabolism and excretion of the tested product depending on age and gender allows for an objective assessment of the effect of the new product. The researcher and laboratory diagnostician, as partners, are able to notice changes in the state of health at early stages that may be related to the tested product. The role of laboratory diagnosticians is very often also to supervise the preparation of the clinical trial participant for the collection procedure, blood collection, transport of samples, and their processing.

CONCLUSIONS

Laboratory diagnosticians are currently responsible for a number of new tasks, taking care of the quality of samples subjected to analysis, their correct processing guarantees the reliability of the data obtained, and thus the credibility of conducted clinical trials.

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THE ROLE OF A LABORATORY DIAGNOSTICIAN IN THE DIAGNOSIS AND MONITORING OF TREATMENT OF A PATIENT WITH DIABETES

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BACKGROUND-AIM

Diabetes mellitus (DM), classified as a civilization disease, is an excellent example of a disease in which laboratory tests play a leading role. In this disease, laboratory tests are used not only for diagnostics (glucose - GLU, glycated hemoglobin - HbA1c, insulin - INS, c-peptide - C-pep, autoantibodies against pancreatic islet cells - ICAs), but also for monitoring the course of the disease (GLU, HbA1c). Their correct selection, execution and interpretation are the basic competencies of laboratory diagnosticians.

METHODS

The aim of this review is to emphasize the role of laboratory diagnosticians in the diagnosis and monitoring of treatment of patients with DM.

RESULTS

Laboratory diagnosticians perform, among others, determination of random glucose concentration, in the case of symptoms of diabetes and determination of fasting glucose concentration, when there are no symptoms, but there are suspicions of abnormal glycemia tolerance. At the stage of determining the type of diabetes, diagnosticians additionally perform a number of specialist tests, including genetic tests or ICAs. As part of POCT (point of care testing) diagnostics, which both clinicians (at the place of patient care) and patients themselves (outside the hospitalization site) perform using glucometers, laboratory diagnosticians also play a leading role. Work in this area involves the appropriate selection of medical equipment, quality control of tests performed and training of people performing these tests, i.e. patients, doctors, nurses, midwives or paramedics. Another undoubted advantage is the support of clinicians in consulting laboratory test results and expanding diagnostics with further, necessary tests, which will significantly facilitate the doctor's diagnosis and shorten the time for the patient to start the correct treatment or modify it.

CONCLUSIONS

The work performed by laboratory diagnosticians for patients with suspected or diagnosed DM significantly goes beyond performing laboratory tests and should be included in the future as a separate medical service, e.g. in the form of diagnostic advice, and laboratory diagnosticians themselves should join the staff of diabetes teams.

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THE YOUNG SCIENTISTS FROM FRANCOPHONIE HAVE THEIR DEDICATED GROUP WITHIN THE FIFBCML

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BACKGROUND-AIM

The Francophonie represents a vast network of communities united by the French language. Spanning five continents, Francophonie encompasses over 300 million French speakers, including professionals in laboratory medicine. Within this dynamic environment, voices and initiatives of young scientists (YS, < 40 y.o.) often lack visibility or structured support. Establishing a group of YS within the international Francophone federation of laboratory medicine (Fédération Internationale Francophone de Biologie Clinique et de Médecine de Laboratoire, FIFBCML) is a strategic response to this challenge, fostering Francophone YS to connect, collaborate, and amplify their contributions worldwidely.

METHODS

One YS representive was nominated by each full member of the FIFBCML: ALAM (Algeria), RBSLM (Belgium), SCBC (Cameroun), SFBC (France), SBDL (Lebanon), SMCC (Morocco), and STBC (Tunisia). A participatory approach among the nominated YS permitted to jointly design the group's structure, objectives, and action plan.

RESULTS

The group defined several ambitious objectives to strengthen the YS Francophone community:
- Building a Francophone network: establishing an inclusive network that connects YS across regions, supported by digital tools and social media platforms.
- Encouraging experience sharing: exchanging ideas, best practices, and career experiences, thereby enriching YS perspectives and skills.
- Fostering international links: linking with the actions of national and international societies in favor of French-speaking YS.
- Facilitating mobility opportunities: enabling YS to access mobility programs, including laboratory visits, international exchanges and scientific events, to enhance their expertise and professional development.
- Identifying scientific themes: encouraging the development of scientific frameworks through international collaborations.
- Promoting our profession and advocating for its recognition.

CONCLUSIONS

In contrast to English-speaking networks that dominate our profession, this YS initiative highlights the need to preserve the linguistic diversity and the unique potential of the Francophonie as a space of professional improvement. Future efforts will focus on improving YS participation, ensuring long-term activities, and addressing emerging challenges faced by Francophone YS.

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GAMIFICATION AND AI ENABLED QMS EDUCATIONAL PROGRAM: LEVERAGING TECHNOLOGY-ENHANCED LEARNING FOR CLINICAL LABORATORY EXCELLENCE

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BACKGROUND-AIM

The post-COVID era has transformed Healthcare education through utilizing advanced e-learning technologies, and enhancing engagement. Previously seen as low-engagement, these methods are now standardized by globally which can be used for the development of Clinical Laboratory Management workforce.
The program aims to improve understanding and application of QMS coordinators through utilizing technology-enhanced methods like AI tools, gamification, and digital framework

METHODS

The study used a quasi-experimental design with pre- and post-assessments to evaluate a 42-hour blended learning program for clinical laboratory QPS coordinators in a public sector hospital. The program combined in-person lectures with a paperless, technology-enhanced model to teach. Pre- and post-tests measured knowledge improvement, while qualitative feedback assessed the program's impact. Results were analyzed using descriptive statistics and visualized through box plots to highlight score improvements.

RESULTS

The analysis of pre- and post-assessment scores demonstrates a significant improvement in participants' knowledge and understanding with the average post-assessment scores being notably higher mean score (i.e. 100) than pre-assessment scores (i.e. 88.7)
The box plot analysis indicated a shift in the median score towards higher values after the training, with a narrowing of the interquartile range (IQR), suggesting greater consistency in participants' understanding of QMS.
The use of paperless, digital training environment was well-received and demonstrated effectiveness in enhancing knowledge and skills related to QMS, highlighting its potential as a training tool in resource-limited settings.

CONCLUSIONS

The blended learning program enhanced QMS and patient safety knowledge among coordinators in LMIC public sector laboratory using an AI-driven model for active learning. Improved assessment scores demonstrate its effectiveness as a sustainable alternative to traditional training.

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SPECIALIST TRAINING FOR PHYSICIANS IN MEDICAL BIOCHEMISTRY: A GLOBAL SURVEY OF TRAINING AND REGISTRATION REQUIREMENTS.

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BACKGROUND-AIM

The training of physicians who practice as specialists in the area of medical biochemistry (chemical pathology, clinical biochemistry, clinical chemistry) is not consistent between countries. The current medical biochemistry training in Canada is a sub-specialty of internal medicine or paediatrics rather than a “laboratory medicine” specialty. The Canadian Association of Medical Biochemists wanted to get a better understanding of training programs around the world.

METHODS

A survey was developed to capture information on the post-medical school training for medical doctors. The survey included questions on entry to training, training, registration requirements, and opportunity for direct to patient clinical practice. The survey was distributed using Microsoft forms.

RESULTS

Thirty-two responses were received, and data obtained for 28 countries. Routes to becoming a registered medical specialist identified include: a period of general training followed by specialty training in medical biochemistry (n=20), direct entry to medical biochemistry training (n=3), period of training in laboratory medicine followed by additional training in medical biochemistry (n=2), as an optional addition to the general training in laboratory medicine (n=1) and general training followed by laboratory medicine (n=1). Only Canada requires specialty training in a clinical discipline followed by sub-specialty training in medical biochemistry. The shortest period in training is 3 years and the longest 8 years. The curriculum content identified appeared to be substantially similar for all regions. The curricula, examination process and registration process are similar between regions but typically requires the local medical degree and specialist certification. Over half of the regions allow some form of direct to patient clinical work.

CONCLUSIONS

There are two major routes that most countries follow for training of medically qualified doctors in the specialty of medical biochemistry: 1) through a direct primary specialty training or 2) through a general laboratory medicine training followed by some specific sub-specialty training. There is an opportunity to better align training routes and training time in the specialty of medical biochemistry between countries.

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EMPOWERING NURSES THROUGH PEER-LEAD TRAINING: IMPACT ON REDUCING PRE-ANALYTICAL LABORATORY ERRORS

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BACKGROUND-AIM

Pre-analytical errors (PAE) account for more than 60% of all laboratory errors, posing a significant threat to the quality and reliability of laboratory results. Given the magnitude of this issue, it is imperative to proactively identify and mitigate these situations, ensuring accuracy in laboratory processes. Evaluate the level of knowledge hospital nurses have regarding pre-analytical errors and biological sample collection. Analyze the impact of a training workshop on nurses' professional skills. Identify the most critical areas of the pre-analytical phase and propose targeted strategies for its optimization.

METHODS

Medical student and a clinical pathology resident developed a workshop and questionnaires on the most common PAE founded in a Hospital Unit. The initial questionnaire was administered prior to voluntary training, and a follow-up questionnaire was applied one month later to assess knowledge progression.

RESULTS

Among the 80 participants, 82.5% were women, with an average age of 33.8 years. Only 47.5% had a subspecialization, which was more common among those who attended the workshop. Adherence was 36.3% with a positive impact on knowledge and performance, especially regarding PAE such as labeling and collection order. Participants who attended the workshop showed significant post-training questionnaire improvements, answering over half the questions more accurately and achieving a final score improvement exceeding 70%, substantially higher than the 50% improvement seen among non-attendees. There was also increased use of the sample collection manual for resolving doubts. The results emphasize the necessity of regular training, demonstrating that the project significantly enhanced nurses' skills and awareness, consistent with existing literature that associates structured training with a reduction in errors.

CONCLUSIONS

This project reinforces the role of continuous investment in healthcare professionals' training. However, it revealed a notable and somewhat concerning lack of motivation for such initiatives, even among early-career nurses, which raises other issues, mainly of a labor nature. Peer-to-peer training or students as teachers are a simple strategy with the potential to generate substantial improvements in the quality of patient care.

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DEVELOPMENT OF THE CORE COMPETENCY-BASED ENTRUSTABLE PROFESSIONAL ACTIVITIES FOR UNDERGRADUATE INTERN IN CLINICAL LABORATORY IN CHINA

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BACKGROUND-AIM

Background: The development of entrustable professional activities (EPAs) as a framework for work-based training and assessment in medical education has gained significant attention. EPAs are observable and measurable in both their process and outcomes, reflecting one or more competencies within a set time frame. In the context of clinical laboratory workforce education, EPAs offer promising prospects by providing a structured and competency-based approach to developing essential professional skills. Objective: To develop and evaluate a core competency-based EPAs framework for Chinese undergraduate intern in clinical laboratory.

METHODS

A three-stage approach was adopted for the EPAs development, including: forming a research team, drafting an initial EPAs framework, reviewing EPAs framework. This study adopted a literature review and the Delphi method.

RESULTS

By retrospectively analyzing research on EPAs in the internship phase of medical specialties, we initially constructed 15 core EPAs and 48 detailed EPA descriptions. After two rounds of expert letter review and one expert panel review, we screened and optimized the core EPAs for the undergraduate intern in clinical laboratory. The experts exhibited high levels of enthusiasm, authority, coordination, and concentration, successfully developing 10 core EPAs and 37 detailed EPA descriptions specifically tailored for clinical laboratory interns. The scores for importance, familiarity, observability, universality, and accuracy all exceeded 3.5 points, and the coefficient of variation for each indicator was less than 0.25. Furthermore, expected confidence levels for each indicator were established at four key internship milestones: the third, sixth, ninth, and twelfth months of one year internship.

CONCLUSIONS

A reliable EPAs framework was developed to assess the core competencies of Chinese undergraduate intern in clinical laboratory. This framework not only offers clear training objectives and evaluation criteria for supervisors and educational administrators but also effectively measures interns' professional development at various stages of their internship.

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DEVELOPMENT AND IMPLEMENTATION OF DIGITAL INTERACTIVE LEARNING ENVIRONMENT (DILE) FOR TRAINING LABORATORY PERSONNEL

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BACKGROUND-AIM

Clalit Health Services is one of the largest healthcare organizations globally and the largest in Israel. Training laboratory personnel has traditionally been inconsistent at 12 laboratory sites located across the nation. Hence, development of a structured learning roadmap is essential for the 1,400 employees and managers nationwide. Objectives:
1. Definition of essential professional skills.
2. Enhance knowledge sharing and promote excellence.
3. Develop a digital platform enabling daily training and remote learning.
4. Equip managers with tools for monitoring professional progress.
5. Improve satisfaction within the laboratory sector.

METHODS

#Collaboration with Experts: 24 experts from 10 professional domains mapped learning needs and defined career development paths.
#Feedback Mechanisms: Learning preference surveys followed by satisfaction assessments questioners, performed. Following analysis, further optimization obtained by multi-center designated expert group.
#Timeline: The project carried out between 2020–2024, involving laboratory managers and learning technology teams.

RESULTS

Five structured learning frameworks “LabTrain” (Biochemistry, Hematology, Blood bank, Genetics, Endocrinology) developed for new and experienced employees. This state-of-the-art DILE, extend along the professional life span, is essential contributor for improvement and maintenance of professional and organizational knowledge. Each LabTrain include updated content tailored to employee roles and experience, covering the entire professional lifespan. Additional training content delivered through: pre-recorded lectures (36), webinars (20), peer forums (10), team meetings (8) and annual courses (9).E-learning module for Clinical Laboratory Safety Regulations being used annually by all 1,400 employees.

CONCLUSIONS

The development of professional multi-disciplinary roadmaps for laboratory staff appears to be unique. Initial feedback shows high satisfaction levels. Moreover, the follow-up tool we lately added for managers, could aid large organizations (especially multi centered) to centrally manage and compare professional knowledge. Future recommendations include designing dedicated professional mentoring programs (now in progress).

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TEAMS BASED LEARNING AS A METHOD OF FOSTERING COMMUNITIES OF LEARNING AND STANDARDISATION OF EDUCATION IN A CLINICAL SCIENTIST TRAINING PROGRAMME

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BACKGROUND-AIM

The NHS Scientist Training Programme (STP) is a competitive, three-year apprenticeship-style programme combining workplace-based training with a part-time MSc. The MSc for Blood Scientist trainees is delivered nationally by the Manchester Academy for Healthcare Scientist Education (MAHSE). Clinical Biochemistry trainees attend block-release teaching, requiring optimised face-to-face sessions to apply theoretical knowledge to clinical scenarios. To enhance this, we adopted Team-Based Learning (TBL), a method recognised in medical education for fostering peer-to-peer learning in a collaborative environment.

METHODS

We implemented TBL across two cohorts of Clinical Biochemistry trainees (n=101) in three face-to-face sessions. Each session began with an Individual Readiness Assurance Test (iRAT), where students answered multiple-choice questions (MCQs) based on pre-session resources, indicating their confidence for each answer. Trainees were then placed in geographically diverse teams of 6–8 for the Team Readiness Assurance Test (tRAT). In this stage, teams reviewed the same MCQs, viewing their team members' answers and the most popular responses. Discussions led to consensus answers, with the option to flag questions for facilitator input. The session concluded with application exercises, where teams worked through case-based clinical scenarios and submitted answers collaboratively. Facilitators and subject matter experts addressed queries from the tRAT and application tasks, ensuring understanding of key concepts.

RESULTS

Post-session feedback, collected via 5-point Likert scales and qualitative comments, was overwhelmingly positive. Teamwork stood out, with 92% agreeing that team members' ideas were respected, 85% feeling encouraged to contribute, and 77% reporting enhanced learning in a team setting. Comments highlighted the value of assessing individual understanding and learning from peers.

CONCLUSIONS

TBL proved to be an effective method for applying theoretical concepts to real-world scenarios in clinical scientist education. Its emphasis on teamwork promotes professional skill development while enhancing learning outcomes.

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BUILDING FOUNDATIONAL CORE COMPETENCIES FOR MEDICAL TECHNOLOGISTS IN CLINICAL LABORATORIES: A PIONEERING FRAMEWORK FOR LOW MIDDLE INCOME COUNTRIES

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BACKGROUND-AIM

The clinical laboratory workforce in LMICs faces a multitude of challenges including a lack of standardized curricula and assessment, limited opportunities for continuing education, and training. In some countries, there is a lack of governance by a national accreditation body. Consequently, there is inadequate career advancement and professional development, with resultant disparities in working competencies and hence standards of clinical laboratories. The purpose of this study was to seek consensus from field experts to delineate the exit competencies essential for medical laboratory graduates for development of competency-based curriculum for a medical laboratory training program.

METHODS

The study was conducted at Aga Khan University (AKU), Karachi. Using CDC/APHL recommendations as a source document, expert stakeholders' pathologists and related disciplines engaged in flipped-style workshops to establish competencies for local context. Subsequently, a Delphi survey was employed to achieve consensus, inviting 50 experts to evaluate competencies and sub-competencies across two iterative rounds. Responses were gathered via a Likert scale, with consensus defined as ≥80% agreement. Data was analyzed using SPSS, and ethical approval was obtained from the AKU Ethical Review Committee.

RESULTS

A total of 11 workshops were conducted in flipped format to finalize 106 competencies from the source guideline. 95 competencies achieved consensus in round 1, whereas three additional competencies reached consensus in round 2. These competencies encompassed the domains of quality management system, ethics, management and leadership, communication, security, emergency management and response, safety, surveillance, general laboratory practices, informatics, microbiology, chemistry, hematology and blood bank, bioinformatics, and research.

CONCLUSIONS

A total of 98 competencies across 17 domains were finalized for medical laboratory trainees, with most aligning with global trends emphasizing medical laboratory graduates as integral members.

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DEVELOPING AND OPTIMIZING A NOVEL TOOL THAT MAKES CLINICAL CHEMISTRY CLICK

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BACKGROUND-AIM

Obtaining expert knowledge in the field of Laboratory Medicine and Clinical Chemistry can be challenging, in part due to the broad nature of topics and vast amount of information that fall under the auspice of Laboratory Medicine and Clinical Chemistry. Educational resources in these areas can be costly and difficult to access, which can be compounded by the need to stay up to date in an ever-changing field. The CliCK (Clinical Chemistry Knowledge) Study Tool was developed as an accessible resource for education in Laboratory Medicine and Clinical Chemistry. Individuals who may benefit from the CliCK Study Tool include clinical chemistry trainees, clinical chemists, undergraduate, graduate, or medical students, medical residents, and medical laboratory technologists.

METHODS

Using the Canadian Academy of Clinical Biochemistry syllabus as a starting point for topics, flashcard decks were developed using Anki software. Five decks covering three topics (Chromatography Techniques (analytical), Calcium Metabolism & Bone Disorders (clinical and analytical), and Oncology (clinical and analytical)) were launched on the Canadian Society of Clinical Chemists website (cscc.ca) in June 2023. Following this initial launch, and feedback received, improvements were pursued.

RESULTS

Expert review decks now includes citations for easier reference to source materials. Once initial development of the decks is completed, decks undergo peer review by two subject matter experts, and revisions are incorporated as needed into the decks. Artificial intelligence is also being investigated as a tool to assist in building content for decks and later reviewed by subject matter experts. Lastly, a beta-tester reviews the deck to ensure appropriate formatting. Re-launching of the initial set of decks, along with an additional 16 decks, is scheduled for early 2025.

CONCLUSIONS

The CliCK study tool supports learning through easy access to up to date, reliable, information on topics of laboratory medicine and clinical chemistry in an efficient format for learning and strengthening knowledge. Addition of new deck topics, inclusion of resource citations, peer review by subject matter experts, and beta testing of decks will ensure the information included remains a valuable resource.