Project Proposal for "Foundation for Emerging Nations" (FEN) on "E-Learning Course: Continuous Quality Improvement in Laboratory Medicine" (Distance Learning Development) for Clinical Labs in Developing Regions

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Clinical laboratory quality is crucial for patient care. A high percentage of clinical decisions depend on lab results, and patient safety hinges on the accuracy and timeliness of those results (1). Unfortunately, many laboratories in developing countries suffer from poor quality due to resource gaps, weak regulations, and limited training (2).

"Ensuring quality is a journey without a destination," requiring continuous attention and participation from all stakeholders in the testing process (2). In recognition of this, the IFCC **Foundation for Emerging Nations (FEN)** supports programs to improve the quality and delivery of laboratory services in emerging nations (1). FEN-funded projects must yield measurable quality improvements and lay the groundwork for **sustainable local impact** (1).

Below is a project proposal aligned with FEN's mission and example formats. This proposal focus on **Continuous Quality Improvement (CQI)** in clinical laboratories of resource-poor settings, addressing key areas such as **quality indicators** (in the pre-analytic, analytic, and post-analytic phases), **critical/panic value management**, and **practical problem-solving methods** for quality issues.

Format: Development of a comprehensive **distance learning course** (online) on laboratory CQI and quality management, tailored for learners in emerging nations. This could be a self-paced **e-learning module series** or a facilitated online course delivered via a learning platform. It includes multimedia content, assessments, and possibly certification.

Overview: This project will create an **online training program** that can reach a broad audience of laboratory professionals, specialists, and postgraduate students in resource-limited settings. By leveraging internet technology, the course overcomes geographic and cost barriers, delivering vital CQI education to those who cannot attend in-person training. The curriculum will span all aspects of lab quality, aligning with international standards but contextualized to common challenges in low-resource labs (e.g., erratic supply chains, workforce shortages). Users will learn about establishing quality indicators, improving pre-analytic/analytic/post-analytic processes, managing critical values, and solving quality problems in their laboratories. The course will incorporate interactive elements like case studies, quizzes, and discussion forums to reinforce learning. This initiative responds to FEN's recognition that **educational support is required to improve lab quality in emerging nations** (1) and aligns with its aim to **expand educational opportunities through innovative e-learning and distance programs** (as reflected in IFCC's strategic vision) (1).

Objectives:

- **Develop a Comprehensive CQI Curriculum:** Create a structured set of modules covering the theory and practice of continuous quality improvement in labs. Key topics will include: Quality Management System essentials (the 12 quality system essentials per WHO ad CLSI, e.g. documents, assessment, process control, etc.), detailed exploration of **quality indicators** for each phase of testing, **EQA and proficiency testing** participation, **laboratory accreditation** concepts (ISO 15189

requirements), **critical result management**, and **quality improvement tools** (PDCA cycle, Six Sigma basics, root cause analysis techniques). By the end, learners should have a 360-degree understanding of how to build and maintain quality in a laboratory.

- **Reach a Wide Audience with Flexibility:** Enable at least **200–300 laboratory professionals** in the first year (and more in subsequent years) to access this training at their own pace. The online format removes the need for travel and can accommodate learners from multiple countries simultaneously. Particularly, it targets those in remote or underserved areas who often miss out on training opportunities. The course will be designed for **low-bandwidth settings**, e.g., mostly text and compressed video, downloadable PDFs to ensure accessibility even in areas with internet constraints.
- **Enhance Practical Problem-Solving Ability:** The course won't be purely theoretical; it aims to improve learners' ability to *apply* knowledge. Through scenario-based learning, participants will practice analyzing quality problems and formulating solutions. For instance, a module might present a scenario of rising patient complaints about lab turnaround time and ask learners to identify which phase issues might be causing delays and what QI approach could address them. This meets the goal of teaching **practical problem-solving methods related to CQI** in a reproducible format.
- **Certification and Motivation:** Offer a certificate of completion or even a digital badge for those who finish the course and pass a final assessment. This provides motivation and recognition. Where possible, introduce the **IFCC's PROCEED™** accreditation for continuing education credits (e.g., through IFCC's Taskforce on Global eLearning/eAcademy (TF-GEL) (https://ifcc.org/executive-board-and-council/eb-task-forces/taskforce-on-global-elearningeacademy/) and the Accreditation Committee (EB-AccC) (https://ifcc.org/executive-board-and-council/eb-committees/accreditation-committee/), so that learners not only gain knowledge but also a credential that can support their career advancement. The course could be used as part of postgraduate programs or requirements for lab personnel promotions, embedding CQI education into professional development (11).

Course Content and Implementation Plan:

- **Module Outline:** The course will be organized into ~8–10 modules, each focusing on a theme:
    1. *Introduction to Quality in Laboratory Medicine:* Importance of lab quality (with statistics like "70% of clinical decisions depend on lab results" (1), and stories of patient impact), an overview of the total testing process and where errors occur, the concept of continuous improvement (*"quality journey without destination"* ethos (2).
    2. *Pre-Analytical Phase Quality:* Detailed discussion of pre-analytic errors (patient prep, identification, phlebotomy, sample transport), using examples such as mislabeling rates, hemolyzed sample frequencies. Strategies to improve (training phlebotomists, using checklists, automating labeling, etc.). Case study exercise: Learners analyze a spike in sample rejections at a clinic and figure out the causes (maybe reagent issues or collection technique).
    3. *Analytical Phase Quality:* Covers internal quality control (IQC) procedures, setting up QC charts, interpreting QC failures, method validation and calibration, and participation in **proficiency testing/EQA** – how it works and why it's crucial. Include a real example from a pilot EQA in a developing country: e.g., *"In a pilot EQA in Zambia, between-lab result variability dropped significantly when labs began EQA, proving its value* (5). Also, introduce the concept of sigma metrics to assess analytical performance. Interactive element: a quiz where learners diagnose QC chart patterns (random vs systematic error).
    4. *Post-Analytical Phase Quality:* Discuss the result reporting process, avoiding transcription errors, report formatting, and ensuring timely delivery of results to clinicians. Emphasize

critical value management – how to design a critical result policy, concerning guidelines (like CLSI GP47). Use an example: *"A delay in communicating a critical potassium result can be life-threatening; thus, labs should aim to report criticals within 30 minutes"* (6). Provide a template for a critical results log. Perhaps a short video role-play demonstrating a lab technologist calling a physician about a critical result (to model effective communication).

5. *Quality Improvement Tools and Techniques:* Introduce the PDCA cycle in detail (Plan–Do–Check–Act steps, with a downloadable template for learners to apply to a small problem). Provide an example from a lab context (e.g., plan to reduce sample labeling errors by introducing a barcode system, do a pilot, check data, and act on it – showing how errors dropped). Teach root cause analysis: there could be an interactive "5 Whys" exercise where learners click through a problem (e.g., why did we get a wrong blood in tube incident?) to uncover root causes. Also cover the basics of data analysis for QI – how to calculate error rates, and percentages, and make simple charts.
6. *Building a Quality Culture:* Discuss management aspects – leadership, staff engagement in quality, training, competency, and incident reporting systems. Also highlight the role of **national regulations and accreditation**: how ISO 15189 or national standards provide a framework, and the steps to prepare for accreditation. Possibly include testimonies or interviews (recorded) with lab managers from emerging countries who successfully improved quality or achieved accreditation, to inspire learners.
7. *Special Topics:* These could include sections on **biosafety and quality**, **equipment maintenance**, **supply chain, inventory management** (since stock-outs can directly affect quality), and **ethics** (e.g., honesty in QC/EQA reporting). These ensure the course covers a broad swath of the quality system essentials, but always ties back to continuous improvement.
8. *Project Assignment:* At the end, learners might be tasked to create a brief CQI proposal or plan for their lab (identifying a problem, proposing an indicator, and an intervention). This serves as a capstone demonstrating they can apply the content to their environment.

- **Content Development:** A team of subject matter experts (including experienced laboratory quality managers from both developed and developing settings) will develop the curriculum. We will use existing reputable resources – e.g., adapt content from WHO's Laboratory Quality Stepwise Implementation (LQSI) tool and LQMS training modules, IFCC's publications on quality indicators, CLSI guidelines, and case studies from the literature. All content will be reviewed to ensure accuracy and relevance. We will also incorporate short **video lectures** or interviews for engagement, but keep them concise. Each module will have learning objectives and conclude with a quiz to reinforce key points.
- **Platform and Delivery:** The course could be hosted on the **IFCC eAcademy platform** (which already offers free lab medicine e-learning) or a widely accessible MOOC platform (like Moodle, Coursera, if partnership allows, or a custom website). It will be asynchronous, allowing enrollment and completion at any time, but we might also offer scheduled cohorts with an instructor/moderator for those who prefer structure. Where the internet is very limited, the possibility of offline access (like downloadable content or even distribution on USB drives) will be explored to maximize reach.
- **Interactivity and Support:** To prevent this from being a passive experience, we will include interactive elements: e.g. discussion forums where learners can ask questions and share experiences (moderated by volunteer experts or alumni of FEN programs), assignments where they get feedback (in instructor-led cohorts), and perhaps live Q&A webinars occasionally. Engaging learners increases completion rates and helps build a learning community.
- **Pilot and Rollout:** Before full launch, pilot the course with a small group of, say, 20 lab professionals from different regions. Gather feedback on content clarity, technical access, and cultural relevance.

Use this to refine the course. Then roll out widely through IFCC channels, FEN partners, national societies, and even social media. We could also encourage ministries and hospital networks to recommend the course to their lab staff.

Integration of the IFCC PROCEED™ Accreditation for CE Credits:

To enhance the educational value and professional development impact of the proposed e-learning course, this initiative will be formally aligned with the **IFCC's PROCEED™** program (***Providing Continuing Education Excellence and Development***). This pioneering IFCC accreditation system ensures that participants of IFCC-endorsed educational activities, especially those in distance learning formats, can earn internationally recognized **Continuing Education (CE) credits** for their efforts.
The course will be developed and submitted for accreditation in full compliance with the **"Guideline for Providing Continuing Education (CE) Credits for Distance Learning"** published by the IFCC EB-AccC. This includes:

- **Establishing measurable learning objectives** for each module using Bloom's Taxonomy to ensure structured, outcome-based education.
- **Designing assessments** in each module, including quizzes with a minimum of 4 questions, from which at least 3 must be correctly answered for CE credit eligibility, with a passing score of 75%.
- **Tracking participation and engagement**, including course registration, content completion, and quiz outcomes, per IFCC's evaluation and record-keeping standards.
- **Issuing official CE certificates** for those who complete each module or the full course, in collaboration with the IFCC Task Force on Global eLearning (TF-GEL), ensuring recognition under the PROCEED™ trademark.

Accredited CE credits will motivate learners and offer value beyond knowledge acquisition by contributing to:

- Professional license renewals and career advancement,
- Postgraduate program fulfillment,
- CPD portfolio requirements for national societies and accrediting bodies.

Additionally, the course will be hosted on the **IFCC eAcademy platform** or other approved learning platforms eligible for CE accreditation under **PROCEED™**, ensuring global accessibility. Where possible, the Adaptive Learning model may also be piloted or incorporated to enable **personalized learning pathways** and adaptive assessments as described in IFCC's educational vision.
By integrating **PROCEED™**, the course not only delivers essential CQI training but also strengthens the **formal recognition and lifelong learning culture** for laboratory professionals worldwide, especially in resource-limited settings.

Expected Outcomes:

- **Large-Scale Knowledge Dissemination:** Within the first 1–2 years, we anticipate that a few hundred laboratory professionals will complete or partially complete the e-learning course. Because the content is open and reusable, the number can grow each year at a low marginal cost. This creates a **far-reaching educational impact**, raising the baseline knowledge of quality principles in labs across multiple countries. Importantly, even if only, say, 50% of enrollees finish the whole course (typical for free online courses), many more will still access certain modules and benefit (e.g., someone might only study the critical values module to improve their practice).
- **Documented Learning Gains:** Through pre- and post-module quizzes and a final assessment, we expect to see significant improvement in participants' understanding. For example, average quiz scores might improve from 60% on pre-tests to 85% on post-tests, indicating knowledge gained (e.g., knowing the correct steps to take when a QC result is out of range, or how to calculate a quality

indicator). We will gather testimonials or surveys where learners report increased confidence in handling quality issues, such as *"Before the course, I didn't know how to start an audit; now I have a clear checklist and plan to do one next month."*

- **Quality Improvements Initiated:** As a result of the course, many learners will implement changes in their workplace. Since the course encourages and guides a final mini-project, we anticipate concrete outcomes like: a participant establishing weekly internal QC review meetings in their lab where none existed, or creation of a new SOP for critical result reporting using the course template, or initiation of enrolment in an EQA scheme after understanding its importance. Some participants might share success stories on the course forum, for instance, *"We applied the PDCA cycle from Module 5 to reduce our sample rejection rate from 10% to 3% over three months by retraining phlebotomists and improving labeling."* These anecdotes, backed by data where available, illustrate real-world impact.
- **Integration into Training Programs:** A knock-on effect could be the adoption of the course (or its content) into formal curricula. For example, a university medical laboratory science program might include this online course as a supplement or require students to take it, thereby standardizing CQI education. Or a national lab accreditation preparatory program might assign modules from this course to labs going through accreditation. Such integration ensures that the **knowledge becomes embedded** in the training pipeline of lab professionals, sustaining its influence.
- **Global Community of Practice Online:** As participants from various countries interact via discussion boards or social media groups associated with the course, a **virtual community** forms. People can continue to ask questions and share quality improvement tips even after finishing the course. Over time, this can grow into a support network, for instance, a participant in one country might seek advice on how to convince hospital management to invest in QC, and another from elsewhere who faced similar issues can share their approach. This global peer support accelerates problem-solving beyond what any one-off training could achieve.

Sustainability and Long-Term Maintenance:

- **Evergreen Content with Updates:** Once developed, the e-learning course can be **maintained and updated** at a relatively low cost. We will ensure that course materials are updated as needed (for example, if CLSI releases new critical value guidelines or if new best practices emerge, the relevant module can be edited). The modular design makes it easy to update one section without overhauling the entire course. FEN or IFCC's Education and Management Division can take ownership of keeping the content current past the initial project period, incorporating feedback from users.
- **Cost-Effective Scaling:** After the initial development investment, each additional learner incurs minimal expense (mostly platform hosting and minor support). This makes the model highly **cost-effective and scalable**. It can run for years, becoming a self-paced resource that new lab staff continuously use. If demand grows, we could consider multilingual versions (translating content into French, Spanish, etc.), possibly with the help of local societies – this further extends sustainability by making the knowledge accessible to non-English speakers widely found in emerging nations.
- **Local Facilitation for Sustainability:** While the course is online, we can involve local stakeholders to increase uptake and completion. For instance, national lab associations could appoint course **facilitators** or "champions" who encourage their members to enroll and finish. These facilitators can host periodic meet-ups (virtual or even physical if within one institution) to discuss the course content, thus blending e-learning with community learning. This approach has been used effectively to improve completion rates for online courses and ensure learners have support. By building such local ownership, the course's continuation and relevance are secured.

- **Alignment with FEN/IFCC Initiatives:** The course materials can be reused or cross-utilized in other FEN projects (for example, the **Train-the-Trainer** initiative in Project 4 might use these modules as part of the knowledge base for trainers, or the **workshops (Project 2)** can assign some e-learning segments as pre-workshop preparation). This integration means the content stays alive and is regularly evaluated in different contexts, leading to iterative improvement and sustained usage.
- **Certificate Program Evolution:** If successful, this CQI course could evolve into a more formal **certificate program or diploma** in collaboration with an academic institution. That could potentially generate a revenue stream (from those who can pay a small fee for an accredited certificate), which can be used to fund continuous offerings of the course for those who cannot pay. Even if kept free, the prestige of a recognized certificate ensures ongoing interest and support (possibly attracting sponsors or partnerships with global health programs that need laboratory strengthening). In all, the e-learning project is inherently sustainable because it creates a durable educational resource that fills a persistent gap, ensuring that even as technology and times change, the foundational knowledge of quality improvement is accessible to every laboratorian who seeks it.

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