Editorial

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Six years of progress – highlights from the IFCC Emerging Technologies Division

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Emerging and disruptive technologies continue to (re)shape all areas of laboratory medicine. For laboratory medicine, an emerging technology (ET) has been defined as "an analytical method (including biomarkers, software applications, and algorithms) or device that by virtue of its stage of development, translation into broad routine clinical practice, or geographical adoption and implementation has the potential to add value to clinical diagnostics" [1, 2]. The key attributes usually include its novelty, relatively fast growth, coherence, prominent impact, and uncertainty/ambiguity. Implementation of ETs are important continuous improvement activities that aim to enhance the value of laboratory testing practices to optimize clinical decisions that support patient care. However, the process that takes an ET from its inception through to implementation is complex. Therefore, supporting the processes of selection and successful implementation of ETs across all aspects of the total testing process (pre-pre-analytical, pre-analytical, analytical, post-analytical, and post-post-analytical phases) is essential for the success of the smart laboratory.

With the goal of guiding the implementation of ETs for Laboratory Medicine, the IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) formed the Emerging Technologies Division (ETD) in 2018. Over the last six years, the IFCC-ETD has developed committees and working groups within the division to implement specific projects across three streams: 1) clinical need – Committee (C) for Emerging Technologies in Pediatric Laboratory Medicine and the Working Group (WG) Neonatal Bilirubin; 2) Technology Forecasting and Readiness – WG-Metabolomics, WG-Genomic Custom Panels, WG-Single Cell and Spatial Transcriptomics, and C-Mobile Health and Bioengineering in Laboratory Medicine; and 3) Implementation processes – WG-Health Technologies Assessment, WG-Artificial Intelligence, and WG-Method Evaluation Protocols (Figure 1). Celebrating the achievements of establishing and growing the IFCC-ETD, a compilation of perspectives was proposed to highlight the work to date and the significant need to continue and enhance these activities.

In this special issue of *Clinical Chemistry and Laboratory Medicine*, the collation of eight articles showcasing the breadth of work undertaken by the IFCC-ETD in their first six years is presented. These articles build on key questions and predictions for laboratory medicine [3] and highlight the three areas: clinical need, technology forecasting and readiness, and implementation processes [2]. These themes, also featured in the recent toolkit from the division, are emphasized across the eight articles of this special edition [4–11].

The clinical need is exemplified in two articles focusing on neonates [5, 9]. In the first of these two articles, "*Considerations for applying emerging technologies in paediatric laboratory medicine*", an overview is provided highlighting four conditions (hypoglycemia, hyperbilirubinemia, sickle cell disease (SCD) and congenital adrenal hyperplasia (CAH)) where there remains significant unmet clinical need that could be addressed through implementation of new technologies [9]. These conditions highlight the breadth of consideration for ETs, including: 1) their global availability (e.g. newborn screening); 2) advances in technology that highlight improved measurands (e.g., 21 deoxycortisol by mass spectrometry for CAH) [12, 13]; 3) opportunities to repurpose technologies for different population groups (e.g., continuous glucose monitoring devices to improve neonatal hypoglycaemia monitoring); 4) novel omics

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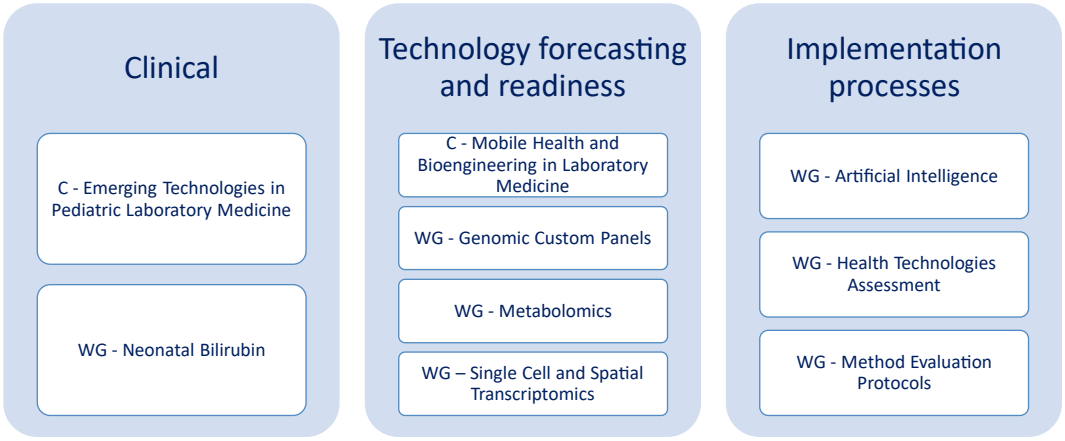

Figure 1: International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Emerging Technologies Division (ETD) structure showing the current committees (C) and work groups (WG) across the three streams of 1) clinical need 2) technology forecasting and readiness, and 3) implementation processes.

applications to improve screening and workflow (e.g., for sickle cell disease [14]); and 5) the development of sensors and other near patient testing devices (e.g., for timely screening of neonatal jaundice [15]). In the second neonatal article our attention is clearly turned back to the laboratory and to an old test with a long-standing problem of variation between platforms [5]. This article clearly details the clinical need for improvement in serum total bilirubin testing for intervention decisions and to support comparison and standardization of ETs in this area [5]. How ETs are deemed fit for their clinical purpose, standardized and compared remains a significant challenge for neonatal laboratory medicine.

Exciting advancements in technologies are forecasted to impact laboratory medicine practice at every stage of the total testing process. These technologies are at various stages of readiness and in this edition, three articles highlight the breadth of these technologies and the potential impact for patient care [4, 6, 10]. In "*Skin is the game*", advances in single-cell RNA sequencing and spatial transcriptomics technologies are providing new research insights into complex diseases (such as psoriasis) and their treatment, showcasing the potential for precision medicine and highlighting skin as a testing matrix for omic applications [4]. In the more advanced technology of metabolomics, the WG-metabolomics has provided a novel global perspective (through a survey of 400 professionals from 79 countries) on clinical metabolomics, which underscores the diverse applications and the need for standardization and readiness to adopt these technologies widely [10]. The third technology themed publication addresses the development and validation of frameworks for biosensors and *in vitro* diagnostic devices, which is crucial for ensuring their reliability and integration into routine clinical practice [6]. In all these technologies a continuing challenge is the differing regulatory requirements between countries and within and outside of laboratory testing.

The implementation processes for ETs requires clear management and guidance. In the three articles of this special issue, aspects of implementation management are discussed [7, 8, 11]. The newest WG of the IFCC-ETD on Health Technology Assessment (HTA) provides a global overview of assessment models to implement new laboratory technologies, that considers organizational, economic, and clinical aspects [8]. This structured approach supports informed decision-making at various levels, from individual laboratories to national health. On implementation, method evaluation is required and the IFCC-ETD through the WG-Method Evaluation Protocols is progressing towards an open access white paper to provide this direction, and one of the supporting publications on linearity assessment is presented as part of this special issue [7]. Finally, in the implementation process of new technologies, authors will look to publishing their work and using the example of mass spectrometry publications, the information provided in publications and the choice of method evaluation protocols is varied and often less than ideal. Hence to support ET overall and provide consistent information, the LEAP checklist for laboratory evaluation and analytical performance characteristics has been developed to offer a standardized approach for reporting and validating new measurement procedures, enhancing the reliability of laboratory results [11].

Moving forward, the responsibilities of the IFCC-ETD will include defining the clinical needs and education criteria for specialists in Laboratory Medicine and

caregivers for each emerging technology. This entails establishing the appropriate infrastructure and laboratory organization, ensuring pre-analytical, analytical, and post-analytical processes are well-defined, and integrating quality programs and certifications such as ISO15189 to maintain high standards. Continuous assessment of the clinical value of each test, along with promoting global collaboration and harmonization, will be crucial to effectively address unmet clinical needs. The structured HTA model and the LEAP checklist will provide comprehensive frameworks to evaluate, certify, and implement new technologies reliably.

Additionally, embracing innovation and adaptability will be essential as technology evolves. The concept of technology readiness levels (TRL) will guide the maturity and readiness assessment of new technologies, ensuring laboratories are prepared to adopt innovations that enhance diagnostic capabilities and improve patient care. The experiences from the COVID-19 pandemic highlight the importance of global collaboration, rapid development, and deployment of new diagnostic technologies. By focusing on these areas, the IFCC-ETD aims to ensure that laboratory medicine continues to leverage emerging technologies to improve patient outcomes and support healthcare worldwide effectively. To conclude, we can say that successful integration of emerging technologies in laboratory medicine hinges on meticulous planning, robust frameworks, and a commitment to continuous improvement, ensuring that we not only meet the current clinical needs but also anticipate future challenges and opportunities.

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