Letter to the Editor

Toward Standardization of Laboratory Terminology

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Abstract

Background: Laboratory medicine is fundamental to evidence-based healthcare, providing critical data on human properties for diagnosing and managing diseases. The increasing complexity and size of laboratory data necessitate robust information technology (IT) systems for efficient management.

Purpose: This manuscript elucidates the roles and infrastructure requirements of laboratory IT systems by stating the purposes of laboratory medicine and examining the challenges and prerequisites associated with their achievement.

Methods: We explore the primary purpose of laboratory medicine in supporting clinical decisions and the opportunities for secondary data use. The challenges of data heterogeneity, insufficient and lack of metadata, and the need for standardized terminologies are addressed. We further emphasize the prerequisites including international collaboration and education.

Results: Technological advancements have enabled automation in laboratories, reducing errors, improving quality, and increasing efficiency and capacity for 24/7 sample processing. IT systems facilitate rapid results, enhance resource allocation, and manage the entire testing process from ordering to result interpretation. The establishment of two coherent and comprehensive laboratory information models - one for communication in the laboratory and another for communication between diverse health care providers - is proposed as essential for accurate data exchange and maximizing data utility.

Conclusion: Achieving successful exchange of laboratory results and optimal use of laboratory data hinge on international collaboration, shared resource commitment, and an approach to standardised terminologies and data structures. This work lays the foundation for ongoing efforts to develop international laboratory information models, critical for advancing patient care and leveraging the full potential of laboratory medicine.

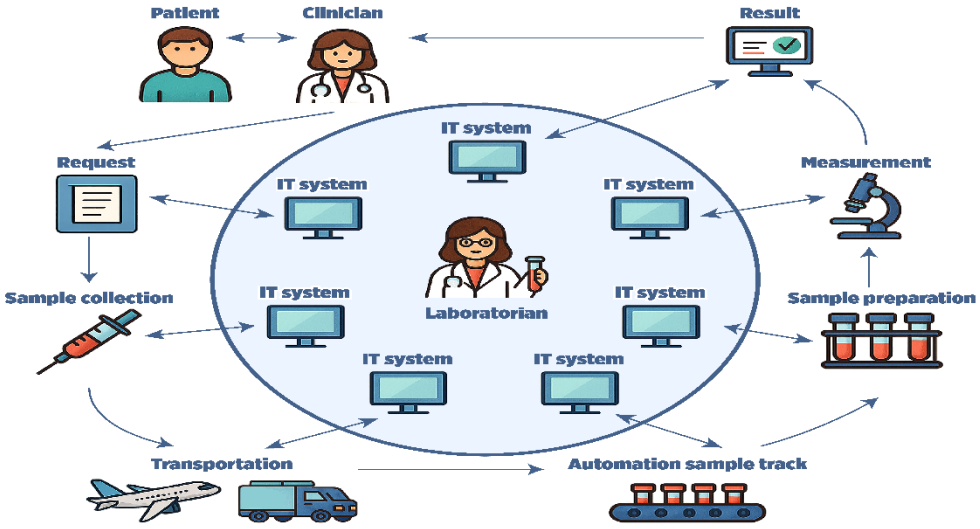
Background

Medicine determines human properties to diagnose, monitor, predict, prevent, and treat diseases or injuries. Identifying an individual's biological and physiological properties is therefore fundamental to effective medical care. By recognizing patterns in these properties, clinicians can classify individuals into specific syndrome or disease categories, enabling targeted and personalized treatment strategies. Precise determination and interpretation of human properties form the cornerstone of evidence-based medicine.

The core function of laboratory medicine is to examine and measure an individual's chemical, biological, immunological, histological, and genetic properties through *in vitro* diagnostic (IVD) analysis of patient-derived materials. The vast number of laboratory tests performed globally each year reflects its central role in healthcare.

To ensure that the results of *in vitro* determinations accurately reflect the patients' true biochemical, physiological, or pathological conditions, not only the analytical steps but also the pre-and post-analytical steps (total testing process) must be upheld [1, 2]. Errors in any of these steps can compromise the result, obscure pathological processes, and potentially lead to improper patient treatment. With the developments of IT systems, laboratories may manage and control each aspect of the total testing process, thereby reducing these errors (Figure 1). It should be noted that structured information is required for machine-interpretability, decision algorithms and for proper training of AI systems.

Figure 1: Laboratory IT systems supporting the brain-to-brain loop.



The integration of total laboratory automation has dramatically increased laboratory efficiency and capacity, enabling rapid processing of a vast number of samples 24/7. This allows clinicians to receive test results shortly after sample collection, facilitating fast clinical decision-making. Furthermore, the lab information systems manage test requests, sample tracking, quality assessment, and transmit test results to Electronic Health Records (EHRs) for easy access by healthcare professionals and patients.

The integration of IT systems within laboratories has also created a foundational network facilitating digital connectivity between healthcare providers. First, this communication may provide real-time access to previous laboratory results from any health care provider involved in individual patient care at any given time and place. This is particularly critical in acute and life-threatening situations where immediate access to historical data can guide crucial treatment decisions, and it can also prevent unnecessary repeated examinations. Secondly, IT enables streamlined communication and eliminates the practice of commuting patients acting as carriers for their own laboratory information, often withcomplex technical terminology and nomenclature, between primary and secondary care and different healthcare organizations. Thirdly, the digital storage of laboratory results in extensive databases creates significant opportunities for data-driven (secondary) purposes.

This paper aims to elucidate the essential roles and infrastructure requirements of laboratory IT systems by stating the purposes of laboratory medicine and by examining the challenges and prerequisites associated with their achievement. Finally, we present a proposal for future directions on how to achieve the prerequisites.

Purposes of laboratory medicine

The primary purpose of laboratory medicine is to support informed clinical decisions for individual healthcare providers and patients. Laboratory requests and results should be appropriately presented to all relevant healthcare providers involved in individual patient care at any given place and time. Beyond this immediate clinical management, laboratory results, generated routinely for individual patient management, often accumulate in extensive databases. The substantial aggregated

data presents a significant opportunity for secondary use [3]. These secondary purposes include:

- Research and development [4].
- Providing evidence to support political healthcare decisions and clinical practice guidelines.
- Optimizing laboratory operations: enhancing laboratory production processes, for example through resource allocation and workflow management.
- Enabling local quality management: using patient data to assess analytical performance [5].
- Epidemiological surveillance: facilitating monitoring of drug utilization, antibiotic resistance, infectious disease trends, etc. [6].
- Administrative procedures: streamlining processes like billing and forecasting future laboratory workload.
- Conducting clinical value assessment: supporting evaluation of medical technologies, implemented procedures and their impact on patient outcomes [7].
- Directly enhancing patient health: identifying high-risk patient groups and supporting clinical value assessments that lead to improved care pathways [8].

In addition to high quality input data, the effective realization of these secondary purposes relies heavily on implementing appropriate IT tools capable of managing and analysing large datasets. The advent of IT tools, including AI, offers unprecedented capabilities for rapidly processing and interpreting this vast data [9, 10].

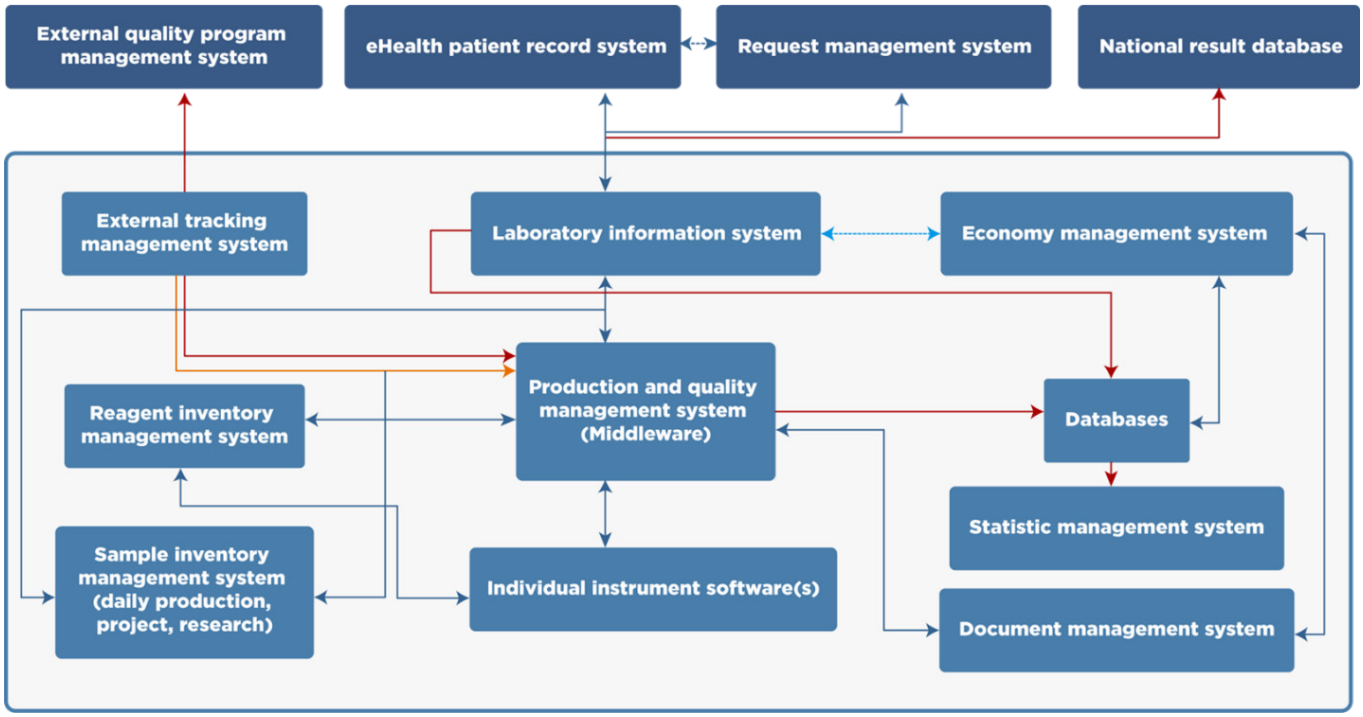
Challenges and Prerequisites for common laboratory data

Whether the goal is successful communication of individual patient results or accurate analysis of large laboratory datasets for secondary purposes, the underlying challenges and prerequisites are fundamentally the same. Accurate and consistent data exchange depends on the use of standardized, well-defined, and structured information that ensures that both the sender and the receiver interpret information in a shared and uniform manner. History has shown that this is not an easy task. Prior to the International System of Units (SI) results were reported with of hundreds of thousands of measurement units varying across countries, regions, towns and even districts [11, 12]. The number of units has decreased, but measurement units are still not standardized. Today, the existence of multiple “languages” for test requests and interpretation of test results arising from different cultures among healthcare providers and vendors of measuring systems, and adjusted to the needs of specialties,scientific fields and organization, continues to pose challenges. This heterogeneity can lead to communication errors, misinterpretation of results, and even patient harm, particularly when individuals transition between different hospitals or laboratory systems. For example, a clinician unfamiliar with the measurement unit used by another institution might misinterpret the unit for mass concentration of a critical quantity such as plasma digoxin instead of the unit for substance concentration [13]. Moreover, it requires cognitive actions to understand which one of the three units “µg/mL”, “mg/L” and “mg/dL” that give numerical values that differ by a factor of 10, or to understand how to compare platelet counts if reported with the alternative units “cells per µL”, “10^3/µL”, “cells per nL”, “10^9/L”. Finally, Monjas et al. recently showed that despite the availability of UCUM, almost 60% of laboratory codes in routine healthcare data still use non-standard units, creating substantial obstacles for data interoperability and secondary use such as AI-based analytics or multicentre research [14].

Another crucial issue is the insufficiency or absence of essential information associated with laboratory test results. For example, lack of information about the method, calibration hierarchy, instrument type (and vendor) complicates the comparison of results from the same patient and property when different instrument types are used [15-17]. These inconsistent and insufficient information also hinder the effective secondary use of large datasets, necessitating time-consuming post-analysis data organisation and harmonization [18]. As calibration and procedures for the same property remain unharmonized or unstandardized, structured information is needed to address these differences to identify whether the results or data are comparable Braga et al. showed that, even after harmonisation efforts using successive generations of WHO reference materials for plasma ferritin, bias persisted among the various end-user measurement systems[19]. Until a robust solution is established, each result may be accompanied by information on the traceability of the quantity (and related metadata).

A practical consequence of these different data structures is the significant difficulty in exchanging data between different IT systems and platforms, a task that may seem technically feasible but is often complex and challenging. Data flow between existing, differently structured IT systems can be nearly impossible, and historical data may be lost during IT system transitions due to incompatible data structures. While a single IT system across all laboratories would be a solution, in practice, a uniform data exchange between interconnected IT systems from different laboratories may be a more feasible and scalable solution (Figure 2).

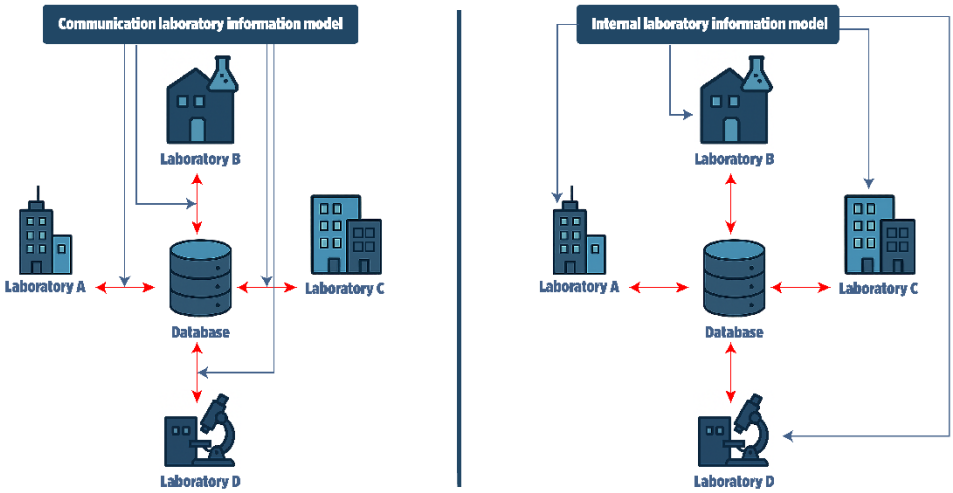
Figure 2: Data flow from different function in a future internal IT network.



The primary desired outcome is the establishment of an IT network and/or system that accurately reflects the entire laboratory process, from patient preparation to result interpretation. The second crucial outcome is the ability to present and communicate laboratory test results through IT networks to support correct clinical decision-making in any healthcare situation, at any place, and at any time. Furthermore, the collected data should provide support for laboratory automation, functions, artificial intelligence, and management.

To achieve these outcomes, two coherent, comprehensive, and information models should be established: one to support and communicate internal laboratory functions and another specifically for the communication and exchange of laboratory requests and results (Figure 3). The latter can be a subset of the first. Establishing these standardized models is essential for realizing the full potential of laboratory medicine in both clinical and analytical domains.

Figure 3: The communication laboratory information model is necessary for communication between different hospitals (left figure). Internal laboratory information model is the communication infrastructure within each laboratory (right figure).



Laboratory information model

A laboratory information model (also known as a laboratory data model/semantic data model/logical information model) serves as a dedicated "data structure" specific to laboratory medicine. It is characterized by "a representation of concepts, relationships, constraints, rules, and operations to specify data semantics for a chosen domain of discourse" [20, 21]. This model necessitates a structured content framework, incorporating internationally approved and standardized nomenclatures and terminologies [22], to ensure a meaningful and near-true representation of reality. The laboratory information model dictates the content and organization of laboratory databases. Consequently, a thorough description and analysis of desired outcomes' prerequisites are essential to identify relevant information types and propose content organization, structuring, and expression. Both the content and data model must possess the necessary granularity to provide sufficient and relevant information for achieving the particular outcome. Crucially, the structure and content of the models must be able to be revised to adapt to future advancements in science and technology.

Organization

Until a coherent laboratory information model has been agreed upon, the exchange of laboratory data across diverse organizational, national, and even temporal borders will remain a significant hurdle, potentially hindering collaborative research, public health initiatives, and the advancement of global healthcare.

The efforts to reach common understanding must be driven by international collaboration and coordination, actively engaging the full spectrum of stakeholders. Key participants should include experts in the laboratory, medical and terminology fields, while also representing international organizations (e.g., WHO, IFCC, EFLM, IUPAC, JCTLM (under BIPM), SNOMED CT, LOINC, ISO, etc.). IFCC could take a leading role in the coordination of this work. Furthermore, active involvement from laboratory IT, electronic health record providers and IVD companies is crucial to leverage technological expertise and ensure the practical implementation of the proposed laboratory information model. National governmental agencies and regulatory bodies must also be integral partners to facilitate the adoption and enforcement of agreed-upon frameworks within their respective jurisdictions.

The path from concept to international applicability includes four escalating phases:

Phase 1 – Definition

Agreement on core laboratory terminology and information model structure under the leadership of international scientific organizations. E.g., IFCC.

Phase 2 – Mapping

National terminologies are mapped to the master standard. Outputs include crosswalk tables usable by EHRs, LISs and IVD instruments.

Phase 3 – Pilot Deployment

Regional pilots (e.g., 3–5 countries or 20–50 laboratories) test live interoperability across systems.

Phase 4 – Progressive Adoption

Standardization

A prerequisite for achieving standardization (or at least harmonization) of laboratory result communication and data-driven initiatives is robust international collaboration. Engaging stakeholders, particularly the international laboratory communities, is paramount in establishing an accepted laboratory information model that ensures both quality and information relevance. Such international collaboration promotes a crucial sense of community and shared ownership, indispensable for reaching the international agreement (e.g., European Health Data Space (EHDS), FHIR (HL7) and openEHR [23-25]). This approach stimulates a common understanding of the challenges and proposed solutions, thereby securing widespread consensus and commitment.

A significant advantage of this collaborative framework is the avoidance of proprietary monopolies of laboratory information models, hindering interoperability. Establishing and continuously administering a shared organization and a comprehensive laboratory information model, while undeniably requiring resources and dedicated effort from all stakeholders, will ultimately impose a far smaller cumulative burden. A shared model inherently reduces the need for individual organizations to develop and maintain their own unique, potentially overlapping, data structures and communication standards, thereby minimizing redundant efforts in design, implementation, updates, and troubleshooting. Furthermore, it simplifies the training of laboratory personnel and IT professionals, as they only need to learn and manage a single model and a certain set of communication standards.

A central component of this shared model is the standardization of terminologies and nomenclatures. A lack of consistency leads to miscommunication - for instance, the ambiguous use of homonyms (same term, different meanings) and synonyms (different terms, same meaning) across publications and practice. These inconsistencies necessitate concerted international standardization efforts.

Achieving comprehensively standardized terminologies and nomenclature worldwide is a complex undertaking. Controversial concepts, e.g., gender/sex and ethnicity (biological inheritance), can pose significant challenges due to differing societal perspectives on the terms and their definitions. However, consistent, and carefully defined categories are essential for accurate clinical decision-making across patient categories. For instance, reference intervals for laboratory measurements may be specific to biological sex or ethnicity, directly impacting the accuracy and appropriateness of patient care. Therefore, reaching a consensus on the definitions of these fundamental concepts is paramount for ensuring consistent and appropriate healthcare delivery. Moreover, a well-designed and collaboratively maintained model, built upon standardized terminologies, can be more easily adapted to incorporate new technologies. Isolated systems, lacking this foundation, may struggle to keep pace with such advancements.

Conclusion

The path towards successful and rational exchange of laboratory results and optimal use of laboratory data hinge on robust international collaboration and coordination, a commitment to shared resources, and a meticulous approach to standardize terminologies and data structures. This initial letter lays the foundation for an ongoing series that will explore in greater detail the motivation, obstacles, and active efforts involved in building a functional proof of concept for international laboratory information models.

Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this work the author(s) used Gemini (Google) and LUMO (PROTON) in order to clarify and improve the readability and language of the manuscript. After using this tool/service, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the published article.

Declaration of Conflict of interests

All authors are affiliated to the Committee on Nomenclature for Properties and Units (C-NPU), IFCC.

Ethical Approval

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Authors' contribution

Young Bae Hansen: Conceptualization, Writing – Original Draft, Visualization
Fatma Meriç Yilmaz: Conceptualization, Writing, Review, Editing, Visualization.
Gunnar Nordin: Conceptualization, Writing, Review, Editing,
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Madeleen Bosma: Conceptualization, Writing, Review, Editing,
Rebecca Ceder: Conceptualization, Writing, Review, Editing,
Sridevi Devaraj: Conceptualization, Writing, Review, Editing,
All authors have read and approved the final manuscript.

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