IFCC SYMPOSIUM 2 - Future laboratory IT systems and standardized laboratory terminology

LACK OF STANDARDIZATION IN LABORATORY TESTS AND UNITS – CASE EXAMPLES DEPICTING GLOBAL IMPACT

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Laboratory testing plays a crucial role in clinical decision-making, yet the lack of standardization in test methodologies, reference ranges, and especially in reporting measurement units presents significant challenges in healthcare. Variability in laboratory test units across different countries can lead to misinterpretation, misdiagnosis, and inappropriate clinical interventions. Here, we explore the impact of non-standardized laboratory units by examining case examples where inconsistencies in test reporting have led to clinical errors and impacted health globally.

The first case is the measurement of HbA1c levels for diabetes, where differences in assay methods and reporting units (% vs mmol) yield varying results, affecting patient management. Assays are well-standardized, but problems lie in measurement scale (no single factor to convert values between % and mmol/mol). Dual values lead to confusion for patients and providers. Another case involves troponin assays, used for myocardial infarction diagnosis, which exhibit significant inter-laboratory variation due to differing detection limits (antibodies recognize different molecular forms) and unit reporting (ng/L vs. µg/L). Similarly, the absence of uniformity in electrolyte reporting, such as potassium and sodium concentrations, can influence treatment decisions, especially in critical care settings. In this case, there are differences in methodologies (direct ISE vs. indirect methods) as well as mass vs substance concentration (mmol/L vs meQ/L), Lastly, there is huge variability in units in reporting of measurands such as prostate specific antigen, reflecting a variation in standardization, and can affect care of the patient.

This lack of harmonization stems from differences in analytical techniques, calibration standards, units of measure and local laboratory policies. To address these discrepancies, initiatives by committees such as the C-NPU in the IFCC and implementation of universal units of measurement is critical. The world has become small and with many people travelling across different countries, further research and policy interventions are necessary to minimize variability in laboratory test reporting and enhance patient safety through standardized laboratory practices.

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ANALYTICAL CONSIDERATIONS IN TEST STANDARDIZATION

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Laboratory results must be comparable e.g. with earlier results for the same patient, with reference intervals, medical action limits and with other results cited in literature references. A key element for comparability is metrological traceability to a common reference material and a reference measurement procedure of higher order.
When laboratory test results are communicated from the laboratory, the result must be provided with necessary information about traceability. This is often assumed or hidden in the test name and the LOINC or NPU code. For measurands that are clearly defined and for which higher order reference materials and reference procedures are available this is sufficient. Further analytical details and information about how the measurement is performed is not needed for the interpretation of the result.
If test results differ significantly due to different measurement principles or measurement methods, the results are not comparable, primarily because the measurands are not the same. The measurands should then be distinguished by giving them different test names and codes.
When results for the same measurand using the same measurement principles are not comparable because of significant variation between different analytical platforms it might be necessary to include information about the specific platform together with the result to allow correct interpretation.
Thus, depending on the type of measurand various amounts of supporting information must be provided together with a laboratory result. In addition, information about pre-analytical factors, such as specimen type, might be needed for the proper interpretation. All supporting information must be conveyed in a structured form together with the test result.
To share laboratory results together with supporting information of this type among EU member states an information model has recently been developed in the X-eHealth project. The model is now further developed in the project extended EHR@EU Data Space for Primary Use (Xt-EHR) to enhance patient care, streamline data exchange, and improve overall efficiency in the EU healthcare ecosystem.

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WARRANTED IT SOLUTIONS IN LABORATORY AND THE DIGITAL ECOSYSTEM

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To support informed clinical decision for individual patients, laboratory request and results must be readily accessible to all relevant healthcare providers involved in individual patient care at the given time and place. Patients may be commuting between health care providers within a health care sector and in between the sectors. To avoid patients being carriers of their own laboratory information, often in complex and technical terminology, communicating laboratory results between different health care providers is current possible with different IT platforms.
To ensure that the sender and receiver understand the laboratory results with the same meaning, a common and agreed "language" is necessary. Moreover, to ensure that results for the same measurand may be compared or not, information about e.g. method procedure must be included. Such a common, comprehensive and coherent laboratory information model that contain all these information does currently not exist.
The laboratory information model for presenting and exchanging laboratory results needs to be standardized and structured using international terminologies and nomenclatures, so different IT systems can exchange laboratory results without loss of meaning across organisations, geography and time.
Beyond patient care, a separate lab information model is needed for real-time quality and production management. The integration of total laboratory automation and automated in vitro diagnostic (IVD) instruments has dramatically and necessarily enhanced laboratory efficiency and capacity. Data from the entire testing process can further optimize resource allocation, prevent bottlenecks, and reduce turnaround time.
Developing and implementing these models requires international collaboration within the lab medicine community and engagement with all stakeholders.

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STANDARDIZATION OF LABORATORY TERMINOLOGY, INCLUDING QUANTITY, MEASUREMENT UNITS, AND MEASUREMENTS

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The standardization of laboratory terminology is a cornerstone of effective and reliable healthcare, particularly as it relates to laboratory test results. In order to improve the accuracy and comparability of laboratory data, it is critical to establish consistent terminology for quantities, measurement units, and measurements across all healthcare systems and institutions. Quantities such as concentration, mass, volume, and activity must be consistently defined to avoid confusion between clinicians and laboratories across different regions. Standardized terminology helps ensure that measurements reflect the intended biological or chemical entity, facilitating accurate results interpretation. The correct and uniform use of measurement units is fundamental to ensuring comparability of test results. Whether it's milligrams per deciliter (mg/dL), millimoles per liter (mmol/L), or any other unit, standardizing units is crucial for consistency. Standardizing measurement procedures across laboratories is important to guarantee that tests are performed with similar sensitivity, specificity, and under similar conditions, irrespective of the institution or country. This includes the calibration of equipment, sample handling, and test methodologies. Uniform procedures improve the reliability and reproducibility of laboratory results. The use of standardized coding systems, such as LOINC (Logical Observation Identifiers Names and Codes) and C-NPU (Nomenclature, Properties, and Units), allow for the consistent identification of laboratory tests, ensuring that results are reported in a way that is universally understood. Achieving global standardization involves aligning measurement practices, definitions, and terminologies across countries and healthcare systems. Laboratory results can be impacted by biological factors (e.g., gender, pregnancy, menstrual cycle) and preanalytical factors (e.g., sample collection, transport, processing), as well as by the methods, calibrators, and properties of instruments used. Standardizing and reporting these influencing factors alongside test results ensures that clinicians have a complete picture, improving the accuracy of clinical decision-making.