

EDITORIAL

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Harmonization in Laboratory Medicine: The Big Picture

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Editorial

Harmonization of laboratory testing refers to ability to achieve the same result, within clinically acceptable limits and the same interpretation irrespective of the measurement procedure used, the unit or reference interval applied, and when and/or where a measurement made is in agreement.¹ The purpose of harmonizing laboratory data is to enhance patient care quality, leading to better patient outcomes and safety. Initiatives for harmonization and standardization have primarily concentrated on analytical processes carried out within the laboratories, particularly clinical chemistry testing.²

Though there have been a number of prominent successes in harmonizing laboratory tests based on reference methods, such as cholesterol, glucose and hemoglobin A1C, the total number of laboratory tests that have been harmonized based on reference methods are less.³

Concepts of standardization and harmonization are used for ensuring optimal laboratory service, so that the results from different measurement procedures for the same measur and are equivalent within stated specifications which in turn shall enable the reliability test results for clinical decisions. Standardization refers to uniformity of test results based on relation to a reference method. Harmonization establishes uniformity of test results when a reference method is not available. All test results should be harmonized based on calibrations that are traceable to a reference method and/or a reference material.⁴

The improvement of clinical chemistry assays was the primary goal of the early standardization and harmonization operations, but it is now critically necessary to take a broader strategy that encompasses the entire domain of laboratory medicine. Apart from harmonization of the assays, instrument harmonization is an important aspect of harmonization of the analytical phase. Instrument harmonization permits the interchange of instrument usage in circumstances of greater demand or when an instrument is experiencing mechanical or operational issues.⁵

In reality, harmonization should be encouraged throughout the testing process, not just the analytical phase, taking into account not only clinical chemistry tests but the entire field of laboratory medicine, including cutting-edge fields of molecular diagnostics. In pre-analytical phase, the standard operational procedures for sample collection and transport may be harmonized. Harmonization of biological reference intervals and quality indicators monitoring post analytical errors like transcription

errors, delayed reports are integral in the post analytical phase. [5]

Benefits of harmonization are realized when improved clinical guidelines for diagnosing and treating are based on the test results, reliable screening and diagnosing and lead to⁶

- better clinical decision-making by clinicians with limited medical errors
- avoiding duplication of tests due to false positives or false negatives
- avoiding additional unnecessary follow-up testing and
- overall reduction in operational costs leading improved healthcare delivery services

In conclusion, clinical laboratories and the field of laboratory medicine have seen significant transformation in recent years. It is imperative that regardless of time, place, and measurement process, laboratory information must be comparable in order for clinical research, patient safety, and quality patient care to occur. Harmonization of the total testing process encompassing the pre-analytical, analytical and post analytical phases is the big picture.

References

- 1) Tate JR, Myers GL. Harmonization of Clinical Laboratory Test Results. *EJIFCC*. 2016;27(1):5–14. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4975212/>.
- 2) Plebani M. Harmonization in laboratory medicine: more than clinical chemistry? *Clinical Chemistry and Laboratory Medicine*. 2018;56(10):1579–1586. Available from: <https://doi.org/10.1515/cclm-2017-0865>.
- 3) Miller WG, Tate JR, Barth JH, Jones GR. Harmonization: the sample, the measurement, and the report. *Annals of Laboratory Medicine*. 2014;34(3):187–187. Available from: <https://doi.org/10.3343/alm.2014.34.3.187>.
- 4) Miller WG, Greenberg N. Harmonization and Standardization: Where Are We Now? *Journal of Applied Laboratory Medicine*. 2021;6(2):510–521. Available from: <https://doi.org/10.1093/jalm/jfaa189>.
- 5) Tate JR, Johnson R, Barth J, Panteghini M. Harmonization of laboratory testing — Current achievements and future strategies. *Clinica Chimica Acta*. 2014;432:4–7. Available from: <https://doi.org/10.1016/j.cca.2013.08.021>.
- 6) American Association for Clinical Chemistry. The need to Harmonize Clinical Laboratory Test Result. A White paper of the American Association for Clinical Chemistry. American Association for Clinical Chemistry. 2015. Available from: https://www.harmonization.net/media/1086/aacc_harmonization_white_paper_2015.pdf.