



International Alliance for  
Biological Standardization

**Maintaining the Quality of Vaccines Through the Use of Standards:  
Current Challenges and Future Opportunities  
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Abstract**

**Development and Implementation of WHO measurement Standards for vaccines**

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Developing international standards for biologicals and promote their implementation are core functions of the WHO. WHO establishes international measurement standards (IS) through the Expert Committee on Biological Standardization (ECBS), assigning unitage such as International Unit. These standards serve as the primary standard and are used by National Control Laboratories (NCLs) and manufacturers for the calibration of national and other secondary standards, including working standards, for quality control and evaluation of vaccines. They play a crucial role in ensuring the quality, safety and efficacy of vaccines worldwide.

Nowadays, many factors posed challenges to developing and implementing IS, including, but are not limited to:

- new and modern technologies: diverse types of vaccines for a single pathogen and broad range of assays in use may impact on the suitability and applicability of a unified IS.
- assignment of unitage to different types of assays: for example, assigning unitage for antibody-binding assays versus neutralization assays may be complicated.
- fast-evolving epidemiological situation in particular in a public health emergency, like the COVID-19 demands for rapid development of IS to respond to the rapidly changing situation.
- evolving development of vaccines: IS is usually needed and developed at early stage to facilitate vaccine development; however, vaccine development is dynamic and issues may arise when an IS is established after a product is licensed or before a new type of vaccine becomes available.
- need for proper understanding of IS and its use.

Timely development and provision of IS facilitate development, assessment and licensure of biological products, and enable comparability of data across different settings. After the establishment of standards, continuous technical support is crucial to ensure their appropriate use. Ongoing efforts are being made to provide technical support to Member States, targeting NCLs, vaccine developers and manufacturers, which include organizing implementation workshops to elaborate on and promote the use of WHO standards. Global collaboration and synergy among academia, kit and vaccine developers/manufacturers, regulators, NGOs and in cooperation with WHO are highly demanded to develop international standards.