Governing uncertainty in pandemic times: connecting national standards to the world

Doyoung Lee (Korea Research Institute of Standards and Science, Republic of Korea)

Abstract

COVID-19 has had significant economic and social implications for every country in the world. Given how preemptive/follow-up response measures are implemented based on diagnostic results, the development of verified reference standards and the enactment of international documentary standards will be important considerations going forward to ensure the reliability of these measures. This paper highlights the significant role of standards governance as a mode of scientific and social coordination for identifying and managing global health risks and uncertainty.

Uncertainty in public health management during the COVID-19 pandemic

Since the World Health Organization (WHO) first reported cases of pneumonia of unknown causes in Wuhan City on December 31, 2019, the novel virus, subsequently named “SARS-CoV-2,” has spread throughout the world at an unprecedented rate. Numerous variants of the virus, some with high transmissibility, have appeared since the start of the pandemic. As of February 6, 2022, WHO has reported 394,381,395 confirmed cases of COVID-19 and 5,735,179 deaths related to the disease.1 In general, statistics regarding COVID-19 cases are based on laboratory-confirmed and clinically diagnosed cases [1, 2]. For laboratory confirmation, viral nucleic acid tests (reverse transcription polymerase chain reaction [RT-PCR] assay or genome sequencing) have remain the gold standard for COVID-19 diagnosis [3-5]. Presently, the PCR test is considered as the most sensitive and accurate diagnostic method. However, this method requires trained personnel, specific chemical supplies, and expensive analytical instruments.

Such sophisticated laboratory requirements for coronavirus diagnosis pose challenges for many developing countries that lack medical resources and public health infrastructure. Furthermore, due to the steep rise in confirmed cases of the Omicron variant, countries that had previously been active in employing these tests are now being overwhelmed by the sudden influx of test samples. Hence, many governments are opting for rapid antigen and antibody self-diagnosis tests over laboratory tests to monitor COVID-19 due to accessibility considerations [6].

Currently, issues regarding uncertainty associated with COVID-19 span across all aspects of infectious disease management, including diagnosis, treatment, and symptoms. However, it is especially vital to first ensure the accuracy and speed of diagnosis methods given that diagnosis results often serve as a basis for public health management policies. According to a 2021 National Institutes of Health (NIH) study [7], 16.8 million SARS-CoV-2 infections went undiagnosed in the United States during the first six months of the pandemic, which was almost five times greater than the number of diagnosed infections over the same period. To help manage public health emergencies, it is imperative that we develop international standards that provide a foundation on which health authorities can identify and manage uncertainties related to infectious diseases.

Accurate and reliable diagnostic results can be achieved by using internationally/nationally verified standards to manage potential uncertainty factors in clinical measurement processes [8]. Since 1875, the International Bureau of Weights and Measures (BIPM) – a global network of national metrology institutes (NMIs) – has strived to establish scientific and internationally agreed upon verification schemes for measurement standards. In terms of achieving comparability, reliability, and equivalence of clinical laboratory measurement results, the Joint Committee for Traceability in Laboratory Medicine (JCTLM) developed a platform of internationally recognized and accepted measurement standards [9]. Under the current global pandemic situation, a greater emphasis is placed on establishing common standards and guidelines that can augment the effectiveness and reliability of diagnostic accuracy assurance [10-16].

Reference standards for building public trust in COVID-19 testing results

The RT-PCR test method for COVID-19 diagnosis amplifies a specific gene only found in the SARS-CoV-2 virus using a diagnostic reagent [17]. The diagnostic kit returns a positive result when the number of cycles of gene amplification exceeds a certain threshold; otherwise, the test returns a negative result. The problem is that diagnostic kits have different thresholds

---

In July 2020, the Korea Research Institute of Standards and Science (KRISS, the NMI of Korea) and the Center for Convergent Research of Emerging Virus Infection (CEVI) conducted joint research to develop a SARS-CoV-2 reference material [18]. This reference material minimizes the uncertainty of diagnostic kits by using the reverse transcription digital PCR (RT-dPCR) technique to determine the presence of viruses on a probe and accurately estimate the copy number of viral genes [19]. The developed SARS-CoV-2 RNA reference material, which has already been supplied over 280 times within Korea as of November 2021, has contributed to the improvement of virus diagnosis efficiency and reliability as it is used for the development and quality assessment of prototype diagnostic kits and proficiency tests performed in hospitals.²

KRISS attained international equivalence for reliable COVID-19 diagnosis by participating in a comparison study of SARS-CoV-2 RNA measurement methods with 21 institutions from 16 countries in December 2020 [20]. To ensure that standards can be shared and utilized domestically and internationally, national standards should be mutually recognized and verified with international standards.

In addition to measurement standards, documentary standards (which regulate procedures, methods, and terminology) are a major part of international standards systems. The Korean government is striving to establish what it is referring to as the ‘3T: Testing-Tracing-Treating’ strategy, and it is also promoting international standardization by sharing its disease prevention experience and response methods with countries that lack the capacity to effectively combat the pandemic [21, 22]. As a result, an international standard regarding diagnostic testing methods for infectious diseases (like COVID-19) that was proposed by Korea was enacted on December 2, 2020.³

Currently, participation in international standards systems is limited to countries with sufficient resources and capabilities in science and technology. For the world to effectively manage the various uncertainties and risks entailed by the pandemic, it will be important to rapidly disseminate reliable standards that have been established using advanced technologies of developed countries to the rest of the world – we cannot solely wait for developing countries to advance their medical and scientific capabilities. For this purpose, it will be vital to expand the global network of international standards systems.

Policy recommendations

1) Expanding and connecting international standards governance to respond to future health risks and uncertainty

The COVID-19 pandemic has shown us the limits of epidemic-scale disease prevention measures and national lockdowns. To effectively monitor and combat novel infectious and chronic diseases that threaten our health and safety, it will be important to develop and distribute reliable reference standards based on empirical studies and innovative technologies. However, this must take place within a global network of standards governance that connects national and international standards, and such a network should not be limited to a select group of countries. Furthermore, instead of viewing standards governance solely as a means of regulation, it should be viewed as a means of creating a common language and method for managing the complexities and uncertainties of public health risks.

This goal will necessitate greater participation and cooperation among member states of international bodies and organizations that link and implement global standards systems, such as the Metre Convention (the international treaty that coordinates international metrology and the development of the metric system), the International Organization for Standardization (ISO, a body that develops and publishes standards), and Organisation Internationale de Metrolgie (OIML, a body that ensures the legal/institutional application of standards).

2) A hybrid forum for developing and circulating a ‘scientific and social standards package for all’

Additionally, it is recommended to hold hybrid forums that involve various parties: scientific and industrial experts related to the development and application of reference standards, public policy experts in charge of the institutionalization of standards, and the general public (whose daily lives will be affected by new standards). Such forums could serve as a scientific and social mode of coordination to establish trust and


consensus for the consistent and continuous use of “standards” as a safety device. Standards cannot be implemented solely with laboratory data or with documents written by a group of experts. The value of standards is only truly realized when public trust is established for the activation of a standards package (consisting of an assemblage of scientific, social, and institutional elements) that is specific to the problem at hand.

Humanity will continue to be exposed to various risks in the future even after the COVID-19 pandemic. The rate at which this will happen and the impacts of such risks mean the world will need scientific and social safety devices that can manage uncertainty at a level far beyond the capabilities of any individual country. To achieve the Sustainable Development Goals (SDGs), more nations will need to participate in the international network of standards governance. This network should aim to develop and share standards that are needed to produce confirmed information and data; only then will the world be able to collectively face issues like pandemics.

References


[9] BIPM (2002) Declaration of cooperation between the NIPM, IFF and ILAC, for the operation of the Joint Committee for Traceability in Laboratory Medicine (JCTLM). Available at: https://www.bipm.org/documents/20126/42177518/BIPM-IFFC- ILAC+Declaration+of+Cooperation.pdf/14d72edf-14c0-41b2-d7b2-57211089794d


https://doi.org/10.1038/s41579-020-00461-z

https://doi.org/10.3390/ijms22116150


https://doi.org/10.4014/jmb.2009.09006

