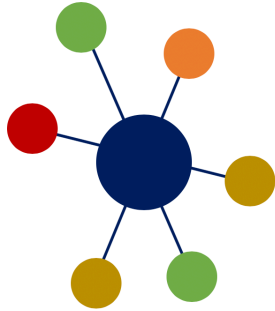




UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION



QUALITY & STANDARDS AND THEIR ROLE IN RESPONDING TO COVID-19



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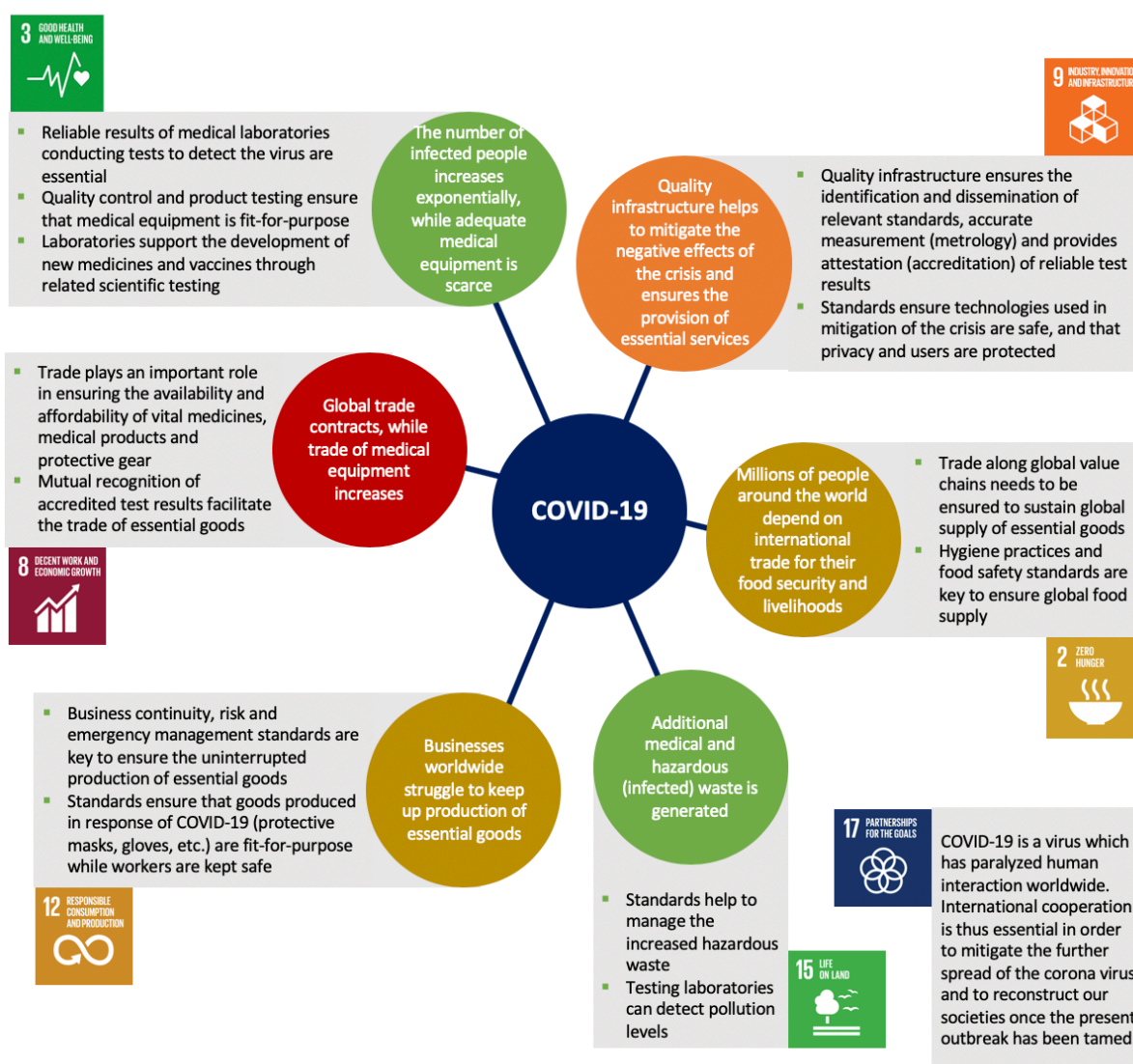
This document has been published without formal United Nations editing. The document focuses on implications, challenges and potential responses related to the application of quality and standards, thereby not claiming to be exhaustive. For more detailed information on the overall UNIDO response to COVID-19, please refer to the UNIDO website: <https://www.unido.org/unidos-comprehensive-response-covid-19>

INTRODUCTION

This document contains a first analysis conducted by the United Nations Industrial Development Organization (UNIDO) in April 2020 as a consequence of the global outbreak of COVID-19, also referred to as the corona virus. This document shall serve to better assess the implications and potential responses related to the application of quality and standards in mitigating the negative effects of the global crisis as a result of the COVID-19 pandemic. The document aims at addressing two elements:

- **PART 1:** Elaborate on the overall implications of COVID-19, specifically focusing on trade and quality infrastructure, thereby outlining the link between the main elements/actors of quality infrastructure and COVID-19.
- **PART 2:** Present an initial analysis of the emerging challenges due to the COVID-19 outbreak in achieving the Sustainable Development Goals and provide a first problem analysis related to quality and standards with regard to achieving the Global Development Agenda 2030.

The graph below summarizes the link between the challenges faced due to the global outbreak of COVID-19, the potential role of quality and standards in mitigating its negative effects in the context of the UN Sustainable Development Goals.



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Figure 1: Quality and Standards in the fight against COVID-19, UNIDO 2020

PART 1: COVID-19 Implications and the Role of Quality and Standards

1. Global Context

The ongoing “coronavirus disease 2019” or “COVID-19” caused by the SARS-CoV-2 virus (Severe Acute Respiratory Syndrome-Corona Virus 2) pandemic is primarily a health crisis, but it also has far-reaching economic consequences. Worldwide, it is disrupting millions of people’s livelihoods, with disproportionate impact on the poor. As a global crisis it is posing challenges to humanity that have never been experienced before: almost all communal activity globally (education, work life, sports, theatre, cinema, music concerts etc.) has ground to a halt. No country has been left untouched by the outbreak, and as such governments worldwide have been scrambling to adapt to and to mitigate the spread of the virus. The facts and figures (thus) far surrounding the ongoing pandemic are heartbreaking and are likely to worsen in the coming weeks and months. In early April around 1,3 million positive cases have been diagnosed globally, while more than 70,000 people have died¹.

Beyond the immediate stress and pain of possible illness or death, COVID-19 has also robbed millions of people of their security and livelihoods. Sectors such as manufacturing, tourism, agriculture and agro-processing, aviation and hospitality have been hit hard by the global lockdown, precipitating lay-offs, pay cuts, uncertainty in trade and investment and many being forced to fall back on welfare payments.

Those who live in poverty will find it more difficult to find work at the moment, due to the present uncertainty and a fallback in global trade, local supply chains and investment flows. The United Nations Conference on Trade and Development recently estimated that global trade investments may decline by 30-40 per cent in 2020 as a result of COVID-19. The World Bank estimates that 24 million people globally live in poverty and this could rise due to the economic pressures afoot.

In this context, women are disproportionately at risk of negative outcomes arising from the pandemic. They are disproportionately employed in low salaried or insecure posts relative to men, and are thus at greater risk of a financial shortfalls and insufficient health coverage. In terms of social maladies, women and girls also suffer an asymmetrical threat; several countries have reported a spike in incidences of domestic violence and abuse since the beginning of the COVID-19 outbreak.

Implementing effective sanitation is one of the most important public policy objectives to combat COVID-19. But the sheer scale of global inequality makes this a giant challenge: more than 3 billion people are estimated to lack even basic handwashing facilities in their homes. This presents a risk not just of contracting Covid-19 but also other deadly conditions such as cholera, typhoid inter alia.

COVID-19 is a virus which has paralysed human interaction worldwide; it does not respect borders and has proliferated in every country despite efforts by many governments to pull up their ramparts. International cooperation is thus essential in order to mitigate the further spread of the corona virus and to reconstruct our societies once the present outbreak has been tamed.

The coronavirus pandemic presents an opportunity for the human family to act in solidarity and turn this crisis into an impetus to achieve the Sustainable Development Goals². The current crisis touches upon many of the UN Sustainable Development Goals, most importantly goal 3: Good Health and Wellbeing.

UNIDO has an important role to play in the human dimension of these efforts. Its mandate of promoting inclusive and sustainable industrial development places a strong emphasis on expanding productive capacity of medical essentials, protecting labor health and safety, creating shared prosperity, mitigating risks of supply chain disruption, maintaining business continuity, accelerating post-crisis rehabilitation, creating greater opportunities for women and girls, training and skills development for young people, inter alia.

¹ Source: <https://www.worldometers.info/coronavirus/> (6 April 2020)

² For a more detailed analysis on the emerging issues from COVID-19 related to the SDGs please refer to annex I

2. COVID-19 and World Trade

The COVID-19 pandemic represents an unprecedented disruption to the global economy and world trade, as production and consumption are scaled back across the globe. The World Trade Organization (WTO) recently noted that the COVID-19 crisis had caused dramatic supply and demand shocks in the world economy, and that these shocks are inevitably causing major disruptions to trade.

Governments need to recognize that it is of mutual interest to ensure that trade lines remain open, including via air and sea freight, to facilitate the flow of goods including essential supplies. It is essential to refrain from the imposition of export controls or tariffs and non-tariff barriers and of removing any existing trade restrictive measures on essential goods, especially medical supplies, at this time.

Food supply chains

In light of the increasing number of nationwide lockdowns and border restrictions today, governments are called upon to ensure production of food continues as before trade takes place across border. A failure to do so will have serious negative consequences for the global economy and viability of food supply chains. Meanwhile, the outbreak has also created opportunities in the food and beverage industry. As reported by the seafood industry, demand for prepared and ready to eat seafood in retail sector has increased. Demand for canned tuna in oil is booming. To address such challenges and opportunities, there is a need for public and private consultation for any decision around the supply of food and for a coordinated response and industry-wide strategy to cope with the impact of COVID-19 and to guarantee supply of healthy food for the world population.

Developing countries already face significant food security challenges and current measures in containing COVID-19 that directly and indirectly impact the agri-food supply chain, which will only place further stress on food value chains. This is especially critical as the food supply chain is a complex web that involves producers, agricultural inputs, transportation, other logistics, availability of workers and so much more. Constraints in any one area will have significant knock-on effects throughout country and regional supply chains.

The key role that governments need to play to ensure a stable food supply is ensuring that the manufacturing of food and beverage products, ingredients and other raw materials, as well as distribution by the retail sector, can continue uninterrupted. They also need to ensure that travel restrictions, including border management controls, do not result in the disruption of food supply chains.

Access to medical supplies

Trade plays an important role in ensuring the availability and affordability of vital medicines, medical products and health care services, particularly among its most vulnerable members. International trade is crucial to ensuring access to medicines and other medical products - no country is entirely self-reliant for the products and equipment it needs for its public health systems.

Trade in medical products which have now been described as critical and in severe shortage during the COVID-19 crisis totaled about US\$ 597 billion in 2019, accounting for 1.7% of total world merchandise trade according to the report. The ten largest supplying economies accounted for almost three-quarters of total world exports of the products while the ten largest buyers accounted for roughly two-thirds of world imports.

As part of a collective response to combat COVID-19, governments should be committed to maintaining open and connected supply chains. They should work closely to identify and address trade disruptions with ramifications on the flow of necessities.

Trade restrictions

That said, each WTO member is free to determine what is necessary to protect its citizens and take the measures it deems appropriate. In general, WTO rules provide broad space for members to adopt trade measures deemed necessary to protect public health and public welfare (including import and export bans, quantitative restrictions on imports and exports, and non-automatic import licensing). These measures should be applied in a manner that does not discriminate between WTO members and should not constitute a disguised restriction on international trade.

In addition, two WTO agreements address measures adopted by members to protect public health or public safety – the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement).

The SPS Agreement establishes that members have the right to restrict trade by taking SPS measures necessary for the protection of human, animal or plant life or health. These measures should only be applied to the extent necessary to achieve their objectives, be based on scientific principles and be supported by scientific evidence. In situations where relevant scientific evidence is insufficient, members may provisionally adopt SPS measures on the basis of available pertinent information.

The TBT Agreement aims to ensure that technical regulations, standards and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade. At the same time, it recognises WTO members' right to implement measures to achieve legitimate policy objectives, such as the protection of human health and safety.

Both the SPS and TBT agreements require WTO members to notify others of any new or changed requirements which affect trade, and to respond to requests for information on new or existing measures.

3. Quality Infrastructure in the Context of COVID-19

QUALITY INFRASTRUCTURE

The system comprising the organizations (public and private) together with the policies, relevant legal and regulatory framework, and practices needed to support and enhance the quality, safety and environmental soundness of goods, services and processes. It relies on metrology, standardization, accreditation, conformity assessment and market surveillance.

Against the backdrop of promoting inclusive and sustainable industrial development, quality infrastructure plays a particularly important role in the fight against the global pandemic. In fact, quality infrastructure preparedness to face highly contagious viral outbreaks, such as that sustained by SARS-CoV-2, become imperative for preventing the health system from being strained and laboratory quality services from collapsing. Quality infrastructures and standards are important in ensuring the availability of key medical devices, diagnostic tests and personal protective equipment. It is now very evident that laboratory services by ensuring the quality and accuracy of laboratory-developed tests will increasingly provide an essential contribution to the diagnostic reasoning, managed care and therapeutic monitoring of the vast majority of human diseases, including the highly infectious COVID-19, which has now been defined as global health emergency by the WHO. Interestingly, Taiwan's containment of COVID-19 outbreak demonstrates importance of rapid response, including fast access to laboratory QI and tests.

UNIDO’s approach to quality infrastructure development is systemic and holistic, from building awareness to helping initiate, develop and strengthen a fit-for-purpose QI that runs efficiently and is cost-effective. UNIDO promotes good practice, capacity building and training, and fosters global cooperation in the development of standards- setting, measurement and compliance along value chains. It works with partners from the public and private sectors, academia, national and international organizations engaged in standards development, and global metrology, standards and conformity assessment practice.

Following the UNIDO approach to quality infrastructure development, the following areas have been identified to have a direct impact on the mitigation of negative effects due to the current health crisis, COVID-19, and to better protect patients and healthcare providers alike. Further, QI services are an essential industry by itself and cannot stop operating even during crisis times.

| Policy | Standards | Accreditation | Metrology | Conformity Assessment | Enterprises |
|-------------------------------------|--|--|---|--|---|
| Quality Policy Laboratory Policy | Medical equipment / protective gear (Medical) laboratory standards Business continuity / emergency management Quality control techniques Health, safety & hygiene Sanitation and waste management | Attestation of technical competence International /mutual recognition | Accurate measurement for reliable testing Quality and accuracy of laboratory tests | Health care facilities and testing laboratories Quality control of medical supplies Medical testing for COVID-19 Development of new medication / vaccines Market surveillance and inspection | Shift to produce medical equipment / protective gear Business continuity Enhanced sanity protocols Avoid disruption of essential inputs to global value chains |

Policy

All countries have taken extensive and unprecedented policy measures in the fight against COVID-19. The following does relate only to the role of quality and laboratory policy within the context of the COVID-19 outbreak, not to overall policy responses to the pandemic.

A **Quality Policy** serves to clearly identify and define roles and responsibilities of all actors of the Quality Infrastructure, including the National Standards Body, the National Metrology Institute and the National Accreditation Body but also the role of private and public conformity assessment service providers. The clear definition of roles and responsibilities is particularly important in times of uncertainty, when emergency management needs to act quickly and synchronize efforts around a particular priority like consumer protection, trade or now COVID. Clearly, Quality Policy contributes to effective emergency management.

Laboratories, particularly (medical) testing laboratories, or laboratories for the conformity assessment of medical protective gears or products (masks, clothing, sanitation products) play a particularly important role in the fight against the COVID-19. Governments make policy decision based on reliable data. The consequences of having false positives and/or false negatives of infected people in a sanitary outbreak can be disastrous. Having a **laboratory policy** which clearly maps and defines roles and responsibilities of testing laboratories, may it relate to testing of medical equipment or medial testing to detect the virus, certainly increases the capability to identify the right actors.

Standards

Standardization distils and makes available international expertise and knowledge regarding usability, quality, safety, performance or any other characteristics required by users, buyers and producers. Standards contain technical specifications for products or product components (e.g. dimensions, sizes, formats, tolerances, performances and interfaces). They are also repositories of knowledge for product testing; for requirements for services, processes and systems; for guidance on how to conduct activities; for descriptions of best practices applied by experienced professionals in a given field, and for other specific information.

Today, more than ever, the use of standards is very important to ensure that products and services meet the requirements. Standards can help in mitigating the negative effects of the global pandemic in multiple ways, as outlined below:

Medical equipment

- Product standards for **medical equipment** (respiratory protective devices) and **protective equipment** (medical gloves, medical face masks, personal eye protection, etc.) are particularly important to ensure that the equipment meets the requirements and is reliable and that safety and medical personnel is sufficiently protected.
- **Acceptance** of equivalence of standards among trade partners important to mobilize medical resources globally and meet the soaring demands for medical equipment within a short time period.
- **Harmonization** of standards for medical equipment at regional or global level could increase accessibility to essential medical products and therefore improve capacity of health authorities to respond rapidly to public health crisis like COVID-19 pandemic.

(Medical) laboratory standards

- **Medical laboratory standards** (e.g. ISO 15189, ISO 22367, ISO 14971, ISO 20395) are important to evaluate the safety and efficacy of diagnostic tests and to ensure that medical tests to detect SARS-COV-2 provide accurate and reliable results.
- **Testing laboratory standards** (e.g. ISO 17025) ensure that product test for medical equipment are performed accordingly and provide reliable results. Providing quality high-

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