



Importance of National Quality Infrastructure in Fighting COVID-19 Pandemic

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Covid-19 Pandemic From a Quality Professional's Lens

Every day we are flooded with Covid-19 related news and numbers such as total no. of cases, fatalities, recoveries, test performed including trend graphs, charts, results by countries, cities etc.

Putting on a quality professional lens, behind these numbers I see enormous contribution of national quality infrastructure (NQI) and quality strategies, tools and techniques to fight this pandemic.

Lets first start with NQI. United Nations Industrial Development Organization (UNIDO), defines¹ NQI as a *“system comprising the organizations together with the policies, relevant legal and regulatory framework, and practices needed to support and enhance the quality, safety, environmental soundness of goods, services and processes”*.

For safety, security, prosperity etc. of people and nations, many countries have established robust NQI and created institutions responsible for Metrology, Standardization, Accreditation, Conformity Assessment etc. These institutions are essential to develop and implement a comprehensive and cohesive NQI system.

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Standards

Standards are integral part of our daily life. Standards help establish specifications and procedures designed to ensure the reliability of the materials, products, methods, services etc. we use every day. Standards help establish a shared and common understanding among people and organizations and are used as tools to facilitate communication, measurement, trade, manufacturing etc.

The International Organization for Standardization (ISO)², based in Geneva, develops product and management systems standards. Industry relies on these standards extensively and uses them to design and manufacture products which are safe, secure, fit for purpose. Adopting international standards by all helps develop high level of assurance and trust among organizations and nations. Pertaining to current Covid 19 pandemic, ISO has published several standards such as ISO: 10651 for *“Manufacturing Lung Ventilators for Medical Use”* or ISO: 374-5 for *“Protective Gloves Against Dangerous Chemicals and Micro-Organisms”* and many more. Globally medical devices and related health care industries are using relevant standards to manufacture safe, reliable and performing ventilators, gloves, masks. Pharmaceutical companies use standards to produce drugs which save lives and treat people. These drugs need to be precise and effective. In absence of standards, industries can develop drugs and medical devices which are not fit for purpose and can result in fatality - a patient suffering from serious Covid 19 condition can die if put on a defective ventilator.

To support global efforts in dealing with the COVID-19 crisis, the International Organization for Standardization has made available many relevant standards freely available.

Or medical face mask not meeting the approved standard requirements may result in infecting the Healthcare worker treating a Covid 19 patient. Having standards are helping humanity in a big way in keeping us safe and secure from Covid 19.

Standards also define how the medical diagnostic tests are to be performed. Health care industry uses test standards to develop strict protocols for testing. These are also used to training Healthcare workers such as Pathologists to conduct the tests such as how to take

nasal or throat swab for Covid 19 test.

In addition to developing product specific standards, ISO also develops management systems standards such ISO: 13485 for “Medical Devices — Quality Management Systems - Requirements for Regulatory Purposes”.

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- *ISO:13688:2013 Protective clothing – General requirement*
- *ISO 10651-4:2002 Lung ventilators for medical use — Part 3: Particular requirements for emergency and transport ventilators*
- *ISO 22395:2018, Security and resilience – Community resilience – Guidelines for supporting vulnerable persons in an emergency*
- *ISO 22301:2019, Security and resilience – Business continuity management systems – Requirements*

Please visit <https://www.iso.org/covid19> to access standards available to fight Covid-19 on complimentary basis. It’s a great kind and thoughtful gesture from ISO organization.

Measurements/ Metrology

Having standards is not enough. We also need accuracy, precision and reliability of physical and chemical measurements. Reliable measurements are essential to our livelihood including for health care. Our health depends critically on the ability of Healthcare workers to make correct diagnosis and reliable measurements are very important in the diagnosis process. E.g. wrong measurement of blood pressure can lead to wrong prescription of medicine. Or administering high dose of hydroxychloroquine (used for treatment of malaria), due to error in quantity measurement, can cause irreversible damage to the retina of eye.

Because of the need for international agreement on matters concerning metrology, an international treaty known as the “Metre Convention³” was signed way back in 1875. This treaty founded the International Bureau of Weights and Measures (BIPM) and remains today the basis of international agreement on units of measurement.

For Covid – 19 testing, it is critical that instruments and equipments used are calibrated and measurements are accurate so that the diagnosis is correct. We have heard in the media that testing kits received from a country were defective and did not provide accurate tests results. Or initial Covid 19 test result was negative whereas subsequent result was positive and vice versa. This can happen due to many reason including errors in measurement. We cannot afford such errors as it can have serious consequences including transmission of virus to others.

Another very interesting form of measurements used in treatment of infections is for Healthcare workers to measure the viral load in a patient i.e. number of viral particles found in each milliliter of blood. Measuring viral load gives an idea to the Healthcare workers of how much of the virus is in patient’s body. This test results help Doctor follow what's happening with infection, how well treatment is working, and guide further course of treatment. Integrity of measurements is very critical.

As we see Metrology plays a very important role in ensuring accuracy, precision and reliability of health diagnosis including fight against Covid-19. It is also important that results are understood in a uniform and standardized manner across different health care providers irrespective of laboratory/ city/ country where the test has been performed.

Conformity Assessment & Accreditation

In addition to establishing Standards and Metrology capabilities, NQI also requires Conformity assessments and Accreditation capabilities. Conformity assessment provides scientific and technical evidence of whether or not products meet the standards and products are fit and safe for humans, animals and environment. Accreditation bodies support the correct functioning of the Conformity assessment system. Accreditation bodies provide a formal attestation of the integrity of conformity assessment bodies and their competence to perform conformity assessments.

What Causes What - Louis Pasteur Contribution

In mid 1800s Louis Pasteur, French Chemist, conducted several experiments establishing that bacteria / germs were the cause of many common diseases which led to the development of first vaccines and antibiotics as well as making dairy products safe for consumption. Pasteur’s Germ theory described the actual causal mechanisms of disease transfer to humans and allowed the development of ways to prevent its spread – personal and social hygiene and thereby saving millions of lives. Social Distancing being widely advocated and practiced these days is another

“social hygiene technique” to fight transmission of Covid-19. Pasteur’s causal theory⁴ made enormous contribution to the science of understanding “What Causes What”.

*Louis Pasteur, French Chemists
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Measurement and analysis are essential to understand What Causes What. Over the last several decades Quality management body of knowledge has developed lot of useful measurement and analysis tools such as Statistical Process Control, Basic 7 QC tools, Design of Experiments etc. These are being used extensively by Scientists, Researchers, Healthcare workers, Practioners, Academicians etc to better understand this current pandemic i.e. how Covid-19 virus is behaving, spreading, effecting human body organs, etc.

Applying Quality Management Thinking & Tools

Quality management thinking, techniques and tools have very wide application across all industries. I am listing below couple of examples of how Quality management tools are being / can be applied related to humanity’s fight against Covid-19

- a) Controlling information: Covid -19 pandemic has evolved so rapidly and wildly across the world that the information and data that was considered reliable only a few weeks back is now either obsolete or updated by newer information. E.g. International or National Guidelines on how to conduct tests, how to isolate people infected with Covid-19 virus, what precautions to take – wearing face masks or not, etc. Creating, updating and controlling of information calls for an effective management system of controlling document, data and information including its dissemination to all relevant stakeholders especially vulnerable segments of the population. Controlling documented information is one of the mandatory requirements in ISO:9001 (Quality Management Systems standards) has a
- b) Fact and Risk based thinking: With rapidly evolving situation in uncertain times, limited availability of resources on multiple fronts (supplies, equipment, staff, knowledge, etc.) it is very important to apply risk-based thinking to prioritize focus areas based on their severity and prevalence (e.g. which city/hospital/unit should receive what items (e.g. Ventilators) Which business should close/open first in order to minimize the impact of Covid – 19 virus on the larger population, etc?
- c) Lean Management & Innovation: Current situation has called for an unprecedented need to increase capacity in healthcare sector in a very short period of time e.g. manufacturing of ventilators, PPEs rapidly and reliably and which are fit for purpose. China built a 1000 bed

hospital in Wuhan 10 days. Lean management & TRIZ (Theory of Inventive Problem Solving) are very useful to apply in these times.

Concluding Thoughts

Covid 19 pandemic has forced / taught us to act quickly, be agile, be bold in decision making, work together across borders, use latest technologies etc. Extensive use of latest technologies like Robots, Drones, Artificial Intelligence, Internet of Things etc. coupled with NQI and Quality management tools and techniques will only further enhance our ability, readiness and capacity combat current pandemic in a more effective manner and better, faster, cheaper. This will also help us prepare better for future.

Thanks to leadership and foresight of many world leaders, national NQI bodies and international organizations such as UNIDO, ISO, BIPM, International Accreditation Forum, International Network of Quality Infrastructure etc. humanity has been able to successfully contain, control and beat earlier diseases like SARS, Ebola, and HIV etc. We should continue to acknowledge, recognize and support the great work being done by these institutions. Learning about the role and contribution of NQI and Quality management body of knowledge in world's fight against Covid-19 makes me feel happy and proud of my quality profession.

Learning about the role and contribution of NQI and Quality management in world's fight against Covid-19 is a matter of pride for quality professionals

This article is inspired by webinar titled "Standards & Testing in the Fight Against Covid-19" organized by UNIDO on 17th April 2020 and my little contribution in Nigeria NQI project for UNIDO. I thank Mr. Kaveh Houshmand Azad, (Kaveh.H.Azad@gmail.com.) Director, Value Improvement Office, Univ. Southern California, USA for his valuable contribution to it."

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3. <https://www.bipm.org/en/worldwide-metrology/>
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