BUSINESS CONTINUITY FOR LABS: **PARTNERING WITH THE INDUSTRY IN TIMES OF COVID-19**

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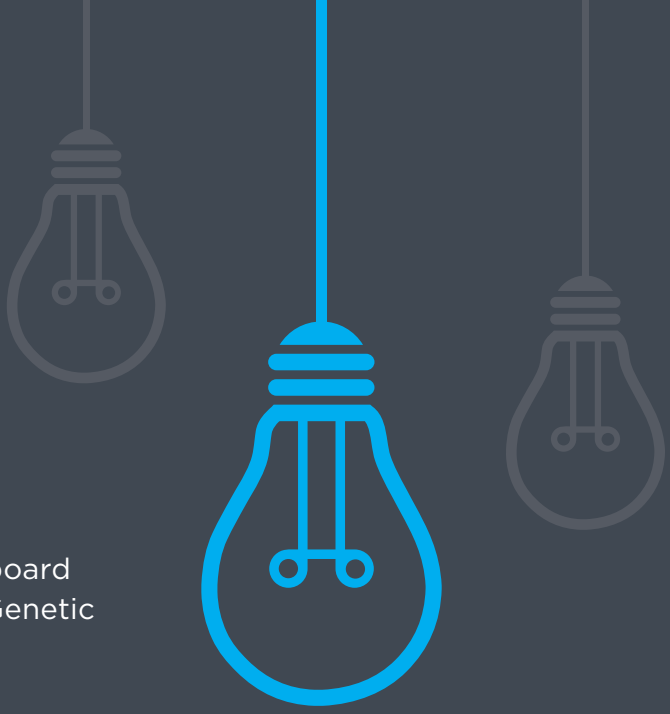

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The SARS-CoV-2 virus and the COVID-19 disease have turned our lives upside down. As of mid-March 2020, the virus has spread to all continents, and over 100 nations are scrambling to respond to this pandemic.

At the time of writing this article, the COVID-19 epidemic has been declared as a global pandemic by the World Health Organization (WHO). In each country, the healthcare sector- and in particular, the clinical laboratory infrastructure was caught off-guard. Global supply chains are now frozen and we are seeing long lines of patients and healthcare workers who want to be tested or need to be tested.

On 13 March 2020, the United States declared a national emergency. The public health authorities have come under intense criticism for delaying the roll-out of extensive scale testing.[1] Laboratories are concerned that the shortage of laboratory supplies will lead to decreased testing, ultimately leading to an underestimation of the prevalence of COVID-19.[2]

In summary, as a society, we are in an unprecedented condition of widespread confusion and loss that has overwhelmed the capacity of societal resources that can be used to cope with it.

For the laboratory, disaster conditions like the COVID-19 epidemic can severely disrupt the functioning of the laboratory and cause unpredictable human, material, technological, and economic impact. While laboratories have experience in planning for natural disasters (e.g., floods), the COVID-19 is a disaster of many levels and challenges us to think out of the box.

IS IMMEDIATE RECOVERY ENOUGH?

I posit that laboratories can use the current COVID-19 crisis to critically analyze their existing disaster management plans. Perhaps, the first lesson from COVID-19 is that we need to look beyond immediate recovery as the sole objective. Maybe, we need to take into account a distinct possibility that a full recovery may not be immediate rather it may be prolonged over several weeks to months.

GOING BEYOND IMMEDIATE RECOVERY

Laboratory testing cannot occur without the availability of instrumentation, reagents, technical support, and a consistent supply chain. Ergo, a laboratory's BCMS cannot be complete without the active participation of its suppliers, especially the in-vitro diagnostic suppliers (IVDS). If so, the laboratory industry should now draft and deploy business continuity management systems (BCMS). A formal BCMS will allow laboratories to:

1. Constantly evaluate the internal conditions
2. Plan for contingency readjustments in staffing and instrumentation
3. Predict if the readjusted services continue to meet clinical needs
4. Identify the external conditions that need to be continually monitored
5. Continually re-evaluate and re-assess the BCMS

THE NEED FOR MUTUAL BCMS

Both laboratories and IVDS should recognize mutual interdependence and seek to support each other through unforeseen incidents and disaster situations. The first step on this journey may be the creation of mutually inclusive BCMS. Herein, I present a few initial thoughts on how laboratories and IVDS can partner and have a step by step approach to synthesizing a coordinated and effective BCMS- before and after a disaster strikes.

BEFORE THE DISASTER:

1 **Start by clearly defining what is essential and what is not necessary.**

The laboratory needs to plan and create a list of tests that it must perform under any circumstances and a separate list of tests that can be either be temporarily outsourced or suspended. This list may be a beneficial guide allocation of resources during a disaster, and it is best created under the advice of the medical leadership of the laboratory as well as the clinics served by it.

2 **Invest extra resources for mission-critical inventories.**

For essential testing services- the laboratory can allocate disproportionately more resources, including purchasing extra instrumentation (i.e., create redundancy), maintain a more extensive buffer stock for all reagents, and draft loaner agreements with IVDS.

3 Understand the geography and vulnerabilities of the lab supply chain.

The laboratory should inventory all consumables and instrumentations and work with its IVDS partner to answer five basic questions:

1. What is the origin of each instrument and reagent- domestic or international?
2. What is the surge capacity for deploying the IVDS, and where is it located?
3. Can the IVDS handle higher than usual orders?
4. What is the timeline for fulfilling higher than usual orders?
5. Are there any acceptable substitutes that may be used in case the original item is not available?

4 Create a detailed decision-making matrix.

During disasters of unprecedented or unexpected magnitude, members of the leadership may not be available for decision making and needed approvals. The laboratory leadership should identify and authorize surrogates for critical decision-makers, especially around who can and who cannot work with IVDS. Such proxies need to be appropriately trained and deemed competent in their knowledge of administrative processes. The entire laboratory should be aware of the primary as well as alternative decision-makers- so that valuable time is not wasted during an actual disaster.

5 Create an internal and external communication plan.

During a disaster, clear communication is the key to keeping the laboratory and IVDS aligned. Excellent communication is characterized by the use of precise terms, up to date information, and clear expectations on what is expected and what is realistic. Poor communication is characterized by the use of ambiguous words, outdated information, and an unclear statement of what is being asked or shared. When connections are vague, both laboratories, as well as IVDS, can lose valuable time and confidence in each other.

The communication plan for both internal and external communications should include specificity on:

1. What will be communicated
2. When will it be communicated
3. With whom to communicate
4. Who else needs to copied on the communication
5. How to communicate
6. Who will communicate
7. What to do if the primary method of communication fails

DURING THE DISASTER:

1 **Ensure the safety of laboratory staff and critical instrumentation**

This entails making sure that no one has been hurt, and no one is under potential harm. If the conditions are not conducive to safe operations or instrumentation has been damaged- the laboratory may need to shut down or scale down operations.

If critical instrumentation needs to be repaired- IVDS would need to be informed as soon as possible.

2 **Check the status of critical communication infrastructure.**

This entails making sure that information technology (IT) networks, including phone lines, middleware, lab information system (LIS), and electronic medical record (EMR), are still functioning. In times of a crisis that impacts more than one site, it is not unusual that critical IT infrastructure starts to fail under stress. For example, if everyone starts to use telephones and teleconferencing, the supporting infrastructure may begin to malfunction.

More importantly, when IT infrastructure malfunctions, IVDS may not be able to access instrumentation and do routine and urgent troubleshooting.

3 **Establish a core crisis management and a separate communication group.**

In times of a disaster, a laboratory needs to take swift decisions and start to transmit and receive information from within and outside it. Often, decision making can be impaired if requests for information and action inundate the decision-makers. The latter may include phone calls, emails, teleconferences, and presentations with other groups. In my opinion, the decision-makers should be insulated from back-forth communication with external groups.

The decision-makers at the laboratory should have a direct line of contact with the decision-makers at the IVDS.

4 **Focus beyond what is happening now, ask if the situation is going to get better or get worse.**

The after-effects of the majority of disasters are often not apparent in the period immediately following it. In essence, a constellation of downstream after-effects starts to occur after a gap of a few days. For example, one of the significant concerns with the COVID-19 epidemic is that healthcare workers are now at a higher risk of acquiring the infection, potentially impacting the entire healthcare system.[3] A significant after-effect of such diseases will be an exponential self-quarantine of healthcare workers, including phlebotomists as well as medical technologists. In an evolving situation, it might be prudent to think through best-case as well as worst-case scenarios and start planning for both. A laboratory may need to start considering alternatives such as conserving capacity by centralizing instrumentation from external sites or go the opposite way by decentralizing made possible through widespread point-of-care testing.

Both approaches require close coordination with IVDS partners.

5 Look beyond the test-kit, keep an eye out for other consumables.

In times of extreme duress, our minds are focussed on taking care of the immediate issue or problem. Often, we miss an opportunity to identify another weakness that is one or two steps downstream. For example, COVID-19 testing depends on the continuous availability of RNA-extraction kits. Thus, as COVID-19 testing ramps up, the expected shortage in these RNA-extraction kits will soon slow down COVID-19 testing across the globe. One of the largest manufacturers of these RNA-extraction kits is a global company with primary manufacturing locations in Europe. This company is now working three shifts and seven days a week.[4]

This example shows that the laboratory BCMS has to inventory all its IVDS and also include their strengths and weaknesses in its planning.

FINAL THOUGHTS

The COVID-19 pandemic teaches us that the only certainty about disasters is that they are unpredictable. The traditional risk assessment and risk remediation frameworks work best for predictable issues that occur with some predictable frequency. Therefore, organizations need to create robust and interconnected BCMS frameworks so that they can continue to support each other through global disasters.

The *ISO 22301:2012, Societal security- Business continuity management systems-Requirements* is an excellent resource. This standard applies a management systems approach. A formal accreditation to this standard demonstrates that the organizations are adhering to good practices and ensures that when incidents occur, responses are escalated in a timely manner and people are empowered to take the necessary actions to be effective.[5] I hope that as the laboratories industry recovers from COVID-19, we will come together with our IVDS partners and chart a new course in business continuity.

1 https://www.washingtonpost.com/business/2020/03/16/cdc-who-coronavirus-tests/
2 https://www.politico.com/news/2020/03/10/coronavirus-testing-lab-materials-shortage-125212
3 https://www.washingtonpost.com/health/covid-19-hits-doctors-nurses-emts-threatening-health-system/2020/03/17/f21147e8-67aa-11ea-b313-df458622c2cc_story.html
4 https://www.the-scientist.com/news-opinion/rna-extraction-kits-for-covid-19-tests-are-in-short-supply-in-us-67250
5 https://www.iso.org/news/2012/06/Ref1602.html