Editorial

Disruption of healthcare delivery and clinical trial operations during COVID-19: Lessons learned, planning for solutions

To say that there was a disruption of essential healthcare services during the COVID-19 pandemic would be a major understatement!

Even high-income countries, for example, Belgium, which spends 10% of their GDP on health care, struggled.[1] A qualitative survey in Belgium, involving 33 healthcare facilities of varied profiles (16 primary care, 6 solo, 4 monodisciplinary, and 7 multidisciplinary practices), showed a major change in healthcare organization during the pandemic, with a collective focus on COVID-19 patient management and disease containment. There was a resultant decrease in other chronic care management, with many activities put on hold.[1]

India's fractionated healthcare system with about 70% of care delivered by private setups (private corporate hospitals, nursing homes, polyclinics, and solo primary care practices) and heavily skewed facility density in metro/larger cities compounded the problem.

A systemic review published by Kapoor *et al.*[2] assessed seven studies that tracked disruption in healthcare services in India during lockdown between Mar 24, 2020, and May 30, 2020. Compared to prelockdown period, oncology showed 23%–54% (different cancer-related services), nephrology almost 50% (major impact on dialysis services), ophthalmic care 35%–98% (routine visits, elective surgeries, and emergency care), and orthopedics 55%–72% (outpatient, inpatient services, and surgeries) reduction in patient care services.

During COVID-19, clinical trials and their operations (with the possible exception of COVID-19-related studies) almost came to a grinding halt. According to ClinicalTrials.Gov, 1052 trials were suspended between March 01 and April 2020, out of which 905 were due to the pandemic.[3] During the same period, new subject enrollment in India reduced by 84%–97%.[4]

In a paper published in this issue, Chaudhari *et al.*[5] showed a significant reduction in scheduled trial visits and anti-rabies vaccination rate in a phase IV study involving postexposure prophylaxis for rabies. During lockdown, the visit compliance was 89%, compared to pre- (97% compliance) and postlockdown period (99% compliance) in 2020. This was for a potentially fatal disease prevention trial with high awareness of risk in the population!

The reasons for disruptions are similar in both clinical practice and trials – lack of accessibility to healthcare facilities and personnel due to travel restrictions, significant reduction in healthcare services, changed priorities with high attention to COVID-19, supply chain disruptions, and fear of contracting COVID-19 in the mind of patients to name some. In addition, in India, there was unprecedented reverse migration from cities to villages during the lockdown making patient contact and follow-up challenging.

The consequences of disruption to patient care are manyfold. Lack of continuity in standard of care (SOC), complications that go unnoticed, worsening of the disease under treatment, and negative psychological impact are some of them.

In clinical trials, new enrollment may be put on hold for the safety of participants; however, ongoing patients may face disruption in trial medication, SOC, disease/complications monitoring, and safety assessments.

After the initial shock, most countries started putting strategies in place to deliver health care under pandemic conditions. Telemedicine consultation, remote follow-up and education, and delivery of the medications closer to the home of the patients helped. South Africa scaled up their "Smart locker program" in every district wherein patients could access their medications in a contactless manner.[6] Many facilities in Belgium applied the "Chronic Care Model" by Wagner to better prioritize and manage high-risk patients.[1]

Learning from pandemics must be collated for better future planning. Strategies, such as telemedicine, stronger supply chains, decentralized and community-based care, better communication, travel assistance to patients for critical inperson visits, and ensuring and monitoring safety, are not

exactly new. However, during the COVID-19 pandemic, most healthcare facilities were unable to adjust quickly to changing circumstances – That is, managing high-priority pandemic cases yet retaining focus on other essential healthcare services.

Managing disruptions of this scale require advanced strategic planning and financial support. To accomplish these, trained manpower (Part of it, reserve) needs to be developed and maintained even during nonpandemic times with provision to scale up rapidly when the situation demands.

Governments, larger for-profit healthcare facilities, and clinical trial sponsors will need to plan for it and commit funding. There is a critical need to also support smaller healthcare facilities (many were closed in India during COVID-19) and clinical trial units that may not have the financial bandwidth to cope with a disaster of the scale of COVID-19!

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