Seizing the Moment 2020

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Introduction

Like a strong social support structure cushioning for individual's growth and resilience, Good Clinical Practices (GCP) offers a framework to develop research capacity. GCP was developed by International Council of Harmonization (ICH) to standardize practices in biomedical research that has been historically marred by deception, distrust, and controversies. It has guarded to a large extent against repeating Thalidomide-like disaster(s) of twentieth century by compelling the regulators to adopt of patient safety standards and find measures to gauge it within the study. Medical research by nature breeds skepticism due to the mere consequences of any method or interpretation gone wrong. Similarly, medicine itself is a treasure trove of knowledge yet to be discovered in so many ways. The combination of human curiosity and market forces are too formidable to be left on its own hence raising the regulatory bar for ensuring the ultimate scientific value for the society at large. GCP are a set of tools that has made it possible.

Majority of earlier medical research assumed the process itself as an outcome of the greater good that practice of medicine has often been perceived as. Majority of classical diagnostic methods relied on physicians' subjective observations that they begin to document forming what could be termed as the origins of evidence-based medicine. Physician belonged to the highest pedestal of honor in a society, the fact that many have still retained. Conquests and conflicts further provided insights as early records of infectious outbreaks such as malaria, plague, smallpox, and yellow fever. The industrial age coincided with emergence of commercialization of medical treatment indicating a shift away from traditional practices and the concept of healing per se. From the claim to invention of local anesthesia used in a tooth extraction that hasn't been fully settled to date to the Flexner report of earlier twentieth century, there were indications for a vacuum that existed in the race to achieve monetary glory and copy rights. The emergence of GCP itself is credited to the evidence of deception reported in past decades. Today, it's the bulwark against subject abuse in fact empowering them to seek clarifications and exercise autonomy before deciding to participate in a study. However, despite all this evolution, several medical inventions and drug patents are daily disputed in courts around the world with financial and societal costs running in tens of billions. It comes down to a culture of both scholarly and entrepreneurial biomedical research that was not available at any time in history. In fact, low-and-middle-income countries (LMICs) could exploit it to improve their health landscape and invariably tap into positive externalities associated with such a paradigm shift.

Estimates have been equivocal in categorizing LMICs to bear the brunt of global disease burden. Its neither surprising nor new. A report from International Federation of Red Cross (IFRC) concluded each global household with at least one family member with non-communicable diseases (NCDs) that commonly includes cardiovascular disorders, diabetes, cancers, and road traffic accidents leaving victims with lifelong disabilities.That would translate into ever-increasing disease burden helped by highest population growth rate ever recorded. Even such growth rates are skewed in favor of developing nations with limited resources to spend on public health and other social development. Emergence of new infections as the ongoing pandemic (SARS-CoV-1) with corresponding lack of preparedness further compounds the grim forecasts. For LMICs, the twentieth century public health challenges like infectious disease burden never lightened owing to persistent unsanitary living conditions that high-income countries (HICs) have been able to understand and subsequently overcome mainly due to rewards of industrialization. While financial resour-

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ces are often cited as the major handicap restricting development of solutions to health problems in LMICs despite record numbers graduating with higher degrees by research, one wonders why those researchers have been unable to contribute towards problem-solving for decades.

The state of medical research corresponding with disease burden in LMICs as summarized above raises key questions of how long the current situation is sustainable. Not for too long with emerging pandemics of zoonotic viruses every decade or two. There is no escape or "short-cut" either. Each problem comes with opportunities and set of solutions. Similarly, the abysmal state of medical research quality needs a strong promotion of GCP to encourage curious thinking for understanding local problems and possible methods to measure them. In case of Pakistan, one of the interesting development seen in international registry for registration of clinical trials (clinicaltrials.gov) is several randomized clinical trials registered since March 2020. It seems unlikely that any previous year would have that many within a short span of few months. That is a healthy trend to respond to a SARS-CoV-2 pandemic with an aim to muster whatever available resources to safeguard local population from a yet to be known scourge. Inevitably, it leads to the quality continuum been discussed here as GCP framework. More interestingly, various manuals of Drug Regulatory Authority of Pakistan cite GCP as their gold standard but was rarely practiced as now owing to local researchers trying herbal products to off-label compounds in randomized trials. The arrival of phase III, placebo-controlled vaccine trials has further boosted demand for GCP certifications. From March 2020, registered clinical trial have compelled institutions to expand their quality net around research protocols by wrapping it prominently in features that priorities subject rights such as the need for localized informed consent. It's a welcome departure from what was being observed in very recent past.

Similar to many countries with cellular-phone connectivity having skipped an entire generation of landline phones and telegraph infrastructure, LMICs have a more potent tool at disposal to promote a culture of authentic medical/health research that relies on public trust being built through demonstrable practice of GCP. Industrialized nations have probably learned it the harder way. Onus is on regulators in both academia and industry to incentivize this