Need for Nation-wide Regulatory Laws to Govern Privacy and Genomic Data in Healthcare

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The history of legislation related to the practice of medicine goes back to thousands of years, with elementary finds stemming from 2200 BC, as The Code of Hammurabi. Of late, the legislature related to medicine practice laws has seen a plight similar to other professions.[1] The divergence of conventional medicine into multitudes of medical specialities requires new confines by updating doctor and patient relationships.[2] The diverging trends in medical specialities are still expanding, powered by novel diagnostics such as genetic sequencing data and next--generational therapeutics including epidrugs i.e., miRNA inhibitors set a primary clinical stage within developing countries. Perhaps the more persuasive and compelling locale remains the practice of genomic sciences in all medical domains.[3] While biotechnology and bioinformatics need to associate genomic sciences, there is a desperate need to manage the medical practice with new legislature and regulatory guidelines both to avoid lawsuits and to fortify clinical decisions, as well as a wholesome redefinition of the patient-medic relationship.

The data yield from the genomic onslaught seems imminent, thus demanding bioinformatic strategies for physicians to decode, decipher, and protect human genomic signatures from hacking.[4]The sequencing markets are becoming galactical with an ever-increasing number of subjects being sequenced by novel techniques than ever before. Thus, there is more personal sequencing information related to basic racial traits, disease dynamics to psychiatric tendencies and genetic technologies. Surreptitious genetic testing can also steal/hack genetic information from DNA banks or online search engines leading to illicit use of information, including defamation of public figures, profiling for the organ industry, and unauthorised research.

All these scenarios provide seemingly useful genetic data, but they also open the door for opportunists to hack and misuse information, engage in racial profiling, exploit organ donation industry, manipulate insurance-related information, and possible eugenic approaches.

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The threat is more imminent for the developing world, which is struggling with basic literacy where neither the laws nor the preventive mechanisms exist. The developed world has already developed laws and regulations to guard genomic privacy exemplified by the Genetic Information Nondiscrimination Act (GINA), and the Health Insurance Portability and Accountability Act (HIPPA) while block-chain IT platforms have been developed to manage genomic data in recent times.[5]

By all accounts, genomic methods including various sequenc-ing methods, gene editing techniques like Cluster Regularly Interspaced Short Palindromic Repeats (CRISPR) and similar novel genomic therapeutics will impact the way healthcare ever functioned in our country. The patient-doctor and medic-to-medic data exchanges, as well as data storage along with confidentiality and sometimes legality of genomic forensic data in criminal scenes, will all require laws / regulatory guidelines but protecting the personal genome privacy should remain afloat alongside.[6] Research and real-time learning of disease trends / emerging information will remain a requirement in the field of medicine and neighbouring domains. The doctor-patient interface will require readjustments to include patient-doctor-diagnostic data-genomic search engine-researchers, where not only multiple stakeholders will require limit adjustments and right--sizing clinical applications towards new regulations as per prevailing customs and norms within the country. The human desire to improve breeding quality and to have perfected offsprings will prevail within any society regardless of culture, faith, and knowledge. Therefore, the science of eugenics will not fade away soon, and will attract partnering audiences to have the healthiest of children with all positive traits. Notwithstanding to the much-needed legality input, there remains the need to apply the most-desirable governance on the growing market of genetically modified foods (GMFs) and organisms (GMOs). These new life forms could be dangerously damaging the ecosystem with later emerging as a potentially alarming threat to mankind.[7]

Illicit genome editing with unchecked regulations and obligatory laws governing genomic sciences shall lead mankind to possible manipulation of an organism's genome. Medical professionals including genomic experts will further face two more issues including medicolegal opinion on DNA matching and implementing the role of direct-to-consumer genetic diagnostics. Emerging medicolegal needs seem to be heavily dependent upon evolving DNA techniques, but it remains prudent to acknowledge the limitations of these techniques. Alongside the evidence in the eyes of legal corridors must evolve by incorpo-

rating technical inputs from subject matter experts on matters such as secondary and tertiary DNA transfer, passer-by DNA, and the legal status of genomic techniques.[8] Similarly, direct-to-consumer (DTC) DNA methods have also emerged where speedy DNA identification has been suggested as a real-time possibility to track the accused and thus penalised. However, there are limitations tailed to the quality of DTC device, appropriate storage and conduct of methodology, the privacy of data, interpretation, non-existent regulations for ancestry tracing, and requirement of confirmatory analytics which can lead to uncertainty and challenges to be replied to any court of law.[9]

Today's fiction may be tomorrow's reality. Any human's DNA contains volumes of data which can be used for the good of mankind in limitless ways but then again, the same good fades away with misuse / non-permitted use in research work, racial profiling, personal privacy, illegal hacking to learn anybody's traits, defamation, insurance aspects, eugenics, and perhaps other psychological traits.[10]

In conclusion, genetic privacy has surfaced as a threatening concept of our times which must be addressed in parallel to the developed world by designing requisite country-specific guidelines by incorporating legal, medical, bioinformatic and genomic experts. Furthermore, these laws are required to be aligned with international developments on the subjects. Both medical and law enforcement agencies, along with legal teams, must endeavour to develop a working group leading to primary guidelines. Genomic data storage breaches and hacking can affect not just patient confidentiality, inappropriate DNA specimen-based legal decisions, illicit genomic data for family profiling, and potentially dangerous applications such as editing and synthesis with the science of eugenics.[11]

Genomic sciences management will be a far essential challenge for calibrating species of nature or outcome of laboratory or somewhere between the two. The latter though demands sanity, knowledge, and laws.

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