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EDITORIAL COMMENTARY

Whither genomic diagnostics tests in India?

Selecting the right drug for the right patient and tailoring treatment options based on the patient's genotype and mutational spectrum holds tremendous promise toward improving life and lowering the healthcare-related financial burden of the State. Although personalized medicine holds tremendous promise, the integration of genomic data into the clinic needs has to be standardized.[1] The US Federal Drug Administration (FDA), equivalent to India's Central Drug Standard Control Organization (CDSCO), is responsible for regulatory clearances and analytical and clinical data review of the diagnostic tests. The CLIA, or Clinical Laboratory Improvement Act, was passed in the US Congress in 1988, and establishes quality standards for laboratory operation, training, quality control, record keeping and inspection. In the US, private companies mostly license technology, assay and/or tests from an academic laboratory and offer the test in a CLIA lab environment as unregulated "homebrew tests."[2] The Center for Disease Control (CDC) and the Centers for Medicare and Medicaid Services (CMS) in the US, the agency that has the primary responsibility for operations of the CLIA program, has authority to regulate tests offered by individual laboratories as direct-to-consumer tests. Many tests offered through the CLIA lab are not approved by the FDA, and such tests are not intended for diagnostic purposes. From the regulatory standpoint, FDA in the US mandates that all tests need to be developed in the lab that sells them, and merely optimizing the test in the lab is not sufficient to qualify the test for diagnostic use.

What is the relevance of the US scenario in India? Let me explain.

Like in the US, with the promise of personalized medicine and its associated benefits to human health, many private players in India are attempting to provide genomic diagnostic tests either directly to consumers or through hospitals. But, the semblance ends there. Unlike in the US, proper guidelines and regulatory framework for developing and marketing genomic tests in India is absent. Although there are many laboratories in India that perform molecular diagnostics tests, there appears to be no evidence of standardization and/or quality control of the tests on offer. Additionally, most laboratories do not have trained manpower in providing genetic counseling to selected patients as a follow-up remedy. This is critical for proper benefits of the test. Attempts so far have been to port a marker or set of markers with known association with a disease in non-Indian populations and offer the test in India. It is not an exercise meant to reduce the State's burden on healthcare or meant as a societal or scientific exercise. Currently, there is very little stress on analytical parameters like the test's scientific and clinical validity and utility or healthcare benefits of the tests to the population at large. Additionally, the impacts of many of these complex genomic tests, over cheaper and less-cumbersome tests in reducing mortality, are also questionable. The process of introducing genomic diagnostics tests in India has largely been opportunistic. Private companies in India should follow the scientific rigor practiced by the US companies in bringing genomic tests to the market, but not the questionable pricing and commercial strategy often practiced by the US companies.

Affordability of these esoteric diagnostics tests is a subject in its own right. In a country like India, a small percentage of population can afford expensive genomic diagnostics tests. Does this mean we should not encourage these tests to be available in India? On the contrary, we must encourage young academic investigators to take this up as a challenge and come up with cheaper assays and associated instruments that will pave ways for offering complex genomic tests at an affordable price. It takes two to tango however and without active cooperation between the industry and the academia, this is going to prove futile. The industry must collaborate with academic investigators in making sure that the clinical trials of the genomic tests in the Indian population (where required) are properly and rigorously conducted. The academic investigator should then publish the results in peer-reviewed journals, following which the industry partner should plan for successful commercial launch and distribution of the tests. In this scheme of things, the third wing, the government must play a key and anchoring role in providing guidelines for the test's regulatory clearance and proper laboratory operation, quality control and inspection.

At a time when our public sector enterprises are increasingly giving up space to private players in the key sectors like health and education, leaving the regulation of genomic

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diagnostics in the hands of selected private players to self-regulate could prove expensive in the long run. The government must ensure that genomic tests are not sold at an exorbitant price by the private labs. The government must also encourage investigators to take up assay and instrument development/optimization as research topics by starting new research grant schemes. I, by no means, am advocating that all genomic tests should be provided by the government hospitals or government-authorized labs only. The role of the government is not to control the way tests are delivered but to provide regulatory guidelines to ensure that all citizens get access to safer tests conducted in an accredited laboratory that follows strict guidelines and sells tests at a price that is justified. The government must not shy away from putting stringent guidelines for the regulatory clearance of these tests and, at the same time, coordinate with other bodies to ensure speedy delivery of genomic tests to the public at large. The job of the regulator is not to stop the entrepreneurial energy in young innovators but to guide them in the right direction by providing proper regulatory framework and assistance.

The government has to strike a balance between encouraging growth of small and private enterprises and, at the same time, making sure that the private companies do not charge an unfairly large amount of money for the tests. The government should try to emulate the good things from the US; stringent test clearance principles, good regulatory guidelines and framework, but not the strategy that is slowly making healthcare practice in the US unaffordable to the majority.

Below are a few recommendations for all the relevant stakeholders in the genomic diagnostics arena in India.

Private players/industry:

1. Base genomic diagnostics tests' claims on analytical, scientific and clinical data validity and utility along with the tests' positive and negative predictive values
2. Engage with academic/clinical collaborators early on in developing, validating and optimizing tests
3. Realize that many tests may not make it outside of the research lab. Hence, be prepared to take financial risk
4. Understand that developing complex and esoteric genomic tests require time, money and expertise. Plan ahead and have clarity on who is going to pay toward development and commercialization of the tests
5. Get involved in developing genomic tests for the neglected/India-specific diseases.

Academic investigators:

1. Take up assay development and optimization, instrument development as academic projects
2. Apply for research grants jointly with private parties, with a clear understanding on how the test is going to be commercialized, if at all
3. Resist temptation of owning the intellectual property solely
4. Understand different ways in licensing a test to a commercial entity like getting royalties back from each test offered, an upfront transfer of rights fee and milestone-based upfront test development fee from the private company
5. Develop an understanding on how private companies work (you do not have to endorse their style but you need to understand their way of functioning).

Government:

1. Genomic diagnostics tests should be dealt under a separate subdivision within the "Medical Devices" division under the "molecular diagnostics umbrella" (i.e., differentiate diagnostics from therapeutics and devices)
2. Appoint a nodal officer to coordinate activities among various organizations/ministries within the government that deal with diagnostic tests (CDSCO and Indian Council of Medical Research in the Ministry of Health and Family Welfare; National Accreditation Board for Testing and Calibration Laboratories, Department of Science and Technology, Department of Biotechnology and Council of Scientific and Industrial Research in the Ministry of Science and Technology; Department of Pharmaceuticals in the Ministry of Chemicals and Fertilizers; and Department of Industrial Policy and Promotion in the Ministry of Commerce and Industry)
3. Release guidance from CDSCO for registration, regulation, distribution, control and licensing of genomic diagnostics tests
4. Release policy statements periodically as educational documents for laboratories engaged in providing complex genomic diagnostics tests to patients similar to the one released by the American College of Medicine Genetics and Genomics (ACMG) on next-generation sequencing data in detecting germline mutations[3]
5. Include one recognized expert on genomic diagnostics in the Drug Technical Advisory Board
6. Set up zonal diagnostics testing laboratories on the same line as the Central Drug Testing Laboratory (CDTL) or add extra capacity to the CDTL to conduct genomic diagnostics tests
7. Include special provisions for pricing of the molecular diagnostics tests in the charters of the National Pharmaceutical Pricing Authority (NPPA)
8. Come up with specific legislation to make sure that the genetic information of an individual is not exploited by employers and companies providing health insurance

similar to the provisions of the Genetic Information Non-Discrimination Act (GINA) in the US.[4]

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