

Direct-to-consumer Genetic Testing: Position Statement of the Society for Indian Academy of Medical Genetics (SIAMG)

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Background

With rapid technological advances, genomic testing has become widely available and affordable to the public. 'Direct-to-consumer genetic testing (DTC-GT)' refers to genomic/genetic testing offered to consumers by commercial service providers without the supervision and guidance of a health care professional, predominantly for the purpose of finding their ethnic origins, paternity, genomic variants that might affect disease pre-disposition, life style, or disease status, and management. Due to wider access to online advertisements and publicity gimmicks evoking the curiosity of consumers, there has been a rise in the demand and uptake of DTC-GT in India. The Society for Indian Academy of Medical Genetics (SIAMG) believes that DTC-GT without involving a health care professional causes more harm than good and the society strongly discourages the use of DTC-GT in any circumstance.

Present status

No strict regulations for DTC-GT services exist in India. Currently, worldwide more than 300 commercial organisations offer DTC-GT and information is easily available over the internet (organisations' websites or e-commerce websites) with unmoderated access, with or without the intermediation of a healthcare professional. These commercial organizations often make exaggerated claims and promises on benefits of these services by providing scientifically unproven information.


Society for Indian Academy of Medical Genetics position on direct-to-consumer genetic testing has discussed this issue among its executive committee members and has resolved that:

The SIAMG does not endorse DTC-GT and strongly dissuades the use of over-the-counter DTC-GT for healthcare purposes (for the diagnosis, predisposition testing, carrier testing and management) or in any other form of service delivery (paternity testing, ethnic origin, predisposition

to life style disorders, pharmacogenomics etc.) without a healthcare professional and/ or pre and post-test genetic counseling. SIAMG condemns the use of DTC-GT for testing of minors for carrier or disease predisposition testing.

Explanations

1. Genetic tests and interpretation of their results are complex and are associated with ethical, social and legal issues. Any form of genetic testing should be undertaken for an appropriate medical indication under a certified genetic healthcare professional after appropriate pre-test counselling and informed consent. Post-test counseling should be provided while providing the results back.
2. The clinical utility and validity of DTC-GT are questionable as they emphasize only on the genetic variants, totally disregarding the clinical signs/ symptoms, medical and family history, effects of environment, and lifestyle of the consumers. In India, there are no quality assurance guidelines for most of the genetic assays and pathogenicity prediction of the detected genetic variants and hence clinical implications of DTC-GT are extremely doubtful.
3. There is a huge scope for misinterpretation of the genetic results as neither the commercial organizations nor consumers understand the complexity of genomic assays in the absence of health care professionals. They may fail to realize that the genetic test performed may not be able to provide an etiological diagnosis for condition in question. Moreover, this might lead to a sense of false assurance, if genetic test has not detected any clinically relevant variant. DTC-GT may also generate undue anxiety if result is positive, as there is no healthcare professional to explain the implication of the results.
4. The consumers may not completely under-



stand the utility, implications and actionability of the detected genetic variants and thus may receive inappropriate medical advice which may cause immense psychological distress and discrimination. Such unsupervised and unwarranted testing can cause a huge burden on the healthcare system and genetic counsellors, who will be requested to interpret the complex genetic results.

5. Concerns over consumer data storage, privacy and sharing also exist.
6. Predictive testing in minors raises many ethical, legal and social concerns.

References

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The executive committee of SIAMG approved this statement on 10 August 2019
