

What do you think are the biggest hurdles in personalized medicine in India?

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Personalized medicine is highly interdisciplinary and requires people with varied skill sets to come together to deliver clinical decisions. While cost is most discussed, there are more fundamental issues that need to be resolved for successful implementation of personalized medicine in India. Following discussion focuses on personalized medicine with respect to cancer.

1. Defining responsibilities of molecular pathologists and their right to sign report: At present, majority of molecular pathologists in India are PhDs with significant experience in molecular biology. Molecular pathologist's pivotal role in cancer care is summarized in "image 1." She/he should suggest the most appropriate molecular test to the oncologist and give clarity on what the oncologist should expect from the results in terms of treatment, prognosis and sometimes accurate classification of cancer. She/he is also responsible for suggesting the best fitted molecular technique, be it sequencing by next-generation sequencing or quantitative polymerase chain reaction, etc. Finally, she/he should give report that is simple and comprehensible to the oncologist that paves the way for patient management. Molecular pathologist should also collaborate closely with histopathologists as most of the genomic tests follow prior tissue analysis. Needless to discuss their laboratory responsibilities which is to set up the complex molecular assays and quality control. There is no clarity on who should be explaining the genomic tests and its possible outcomes to the patient before the patient embarks on personalized medicine. One of the hurdles is, while PhDs are doing the work, conflicting reports keep appearing in the popular media on their right to sign reports.
2. Formal courses on biology of cancer, for MD oncology students: Clinical practice of personalized medicine requires deep understanding of signaling pathways that drive cancer.

Courses on cancer cell biology and short workshops should be designed to build clear understanding on how changes in signaling pathways describe the tumor profile. Basic cell biology and signaling pathways should be taught while woven in clinical cases. I did such workshop at OSMECON, Hyderabad, 2018, and the reviews were encouraging (<https://sites.google.com/view/molecularpathology/home/workshop/workshop-osmecon-2018-hyderabad>).

3. Seamless path to provide therapy: For a patient, once a course of investigation and treatment is determined, things get chaotic. The charges for genomic tests, charges for targeted therapy, patient enrollment in clinical trial, procuring drugs on compassionate ground, and all these variables require enormous time and resources. At each of these steps, the patient and the doctor deal with different entities. Overwhelming majority of cancer patients pay out of their pocket and charges of genomic tests, targeted therapy is significant. These charges add on the costs of clinical consulting, imaging, and pathology services. Hence, patients end up negotiating charges with diagnostic laboratories and targeted therapy dealers. For ongoing clinical trials, ICMR website for clinical trial registry is useful <http://ctri.nic.in/Clinicaltrials/login.php>.
4. Dialogue between molecular and histopathologist: Molecular pathologist should keep the histopathologist informed about the impending subsequent molecular tests that are to follow histology. This cannot be overemphasized in case of NSCLC lung adenocarcinoma. In the absence of good coordination, insufficient tissue amounts end up at molecular laboratory that leads to failed molecular result.

How to cite this article: Srivastava S. What do you think are the biggest hurdles in personalized medicine in India?. *Int J Mol ImmunoOncol* 2018;3:85.

Source of Support: Nil. **Conflict of Interest:** None declared.