

India's new health scheme: what does it mean for cancer care?



On Feb 1, 2018, the Government of India announced a major health-care initiative to improve the financial protection of India's most vulnerable populations—the Ayushman Bharat National Health Protection Mission. The scheme aims to cover the costs of hospital care and treatment for approximately 500 million people, representing the poorest 40% of India's population. Promoted as the “world's largest health-care initiative”, the government scheme provides up to 500 000 Indian rupees (US\$7150) per family per year for health-care expenditures. In this Comment, we focus on the implications and potential impact of this government health scheme in cancer care, as cancer is one of the fastest growing and most complicated diseases to manage.

In India, more than 75% of cancer care costs are paid out of pocket.¹ Adding to the financial burden is the fact that most patients move to metropolitan centres to access tertiary care. Expenditures for treatment, travel, and accommodation put enormous pressure on patients, often pushing families below the poverty line.² The new health scheme is an ambitious and important initiative, providing urgently needed funding for cancer care to reduce out-of-pocket expenditures. The scheme has the potential to revolutionise health care in India by substantially reducing financial constraints to accessing care and providing the economic drive to improve quality of care. Important features of the plan are that it is completely cashless and that pre-existing illnesses are covered. As of March, 2019, more than 15 000 hospitals have been enrolled in the scheme, with 65% of care provided by private hospitals. More than 1.4 million patients have received treatment with a total expenditure of 19 billion Indian rupees (\$273 million). 75% of this expenditure was for tertiary care. We consider three steps that might be essential for future success of the scheme in the context of cancer care.

The first step is to incentivise high-quality and high-value cancer care delivery. Ayushman Bharat provides India with a great opportunity to improve the quality of health-care delivery by linking reimbursements directly to adherence to evidence-based management guidelines. This is particularly important for cancer, for which treatment is more complex and expensive than for other conditions. Some parts of India's health-care

system are known to include rampant overutilisation of diagnostic and treatment services. The problem of overdiagnosis, overinvestigation, and overtreatment can be addressed by linking reimbursement to adherence to established evidence-based guidelines and the Choosing Wisely India recommendations—both from India's National Cancer Grid.³ Without evidence-based guidelines, feasible quality indicators, and mandatory data collection and reporting, public money could be seen as free money, which could further contribute to inappropriate, excessive, and unnecessary care. At the 2019 Annual Meeting of the National Cancer Grid in Mumbai, the leadership of Ayushman Bharat agreed to ensure that payments for services are tied to treatment packages that are consistent with guidelines. It is encouraging that the National Health Authority (which runs Ayushman Bharat) is keen on ensuring quality of treatment in addition to covering costs of care.

Current data suggest that since the launch of the scheme, there have been 152 000 medical oncology admissions, 44 000 radiation oncology admissions, and 17 000 surgery admissions. These numbers are concerning because they show that 70% of publicly funded treatment was spent on drugs. Of the 1575 hospitals in which cancer treatment will be reimbursed by this scheme, only 438 actually have multidisciplinary care with available medical oncology, radiation, and surgical services.

The second step is to promote improved public health care. Although the health scheme is important because it helps patients cover the costs of medical care, this is not a long-term solution. Ideally, the scheme should include mechanisms to strengthen public health-care infrastructure. The infusion of Ayushman Bharat funds into participating public hospitals is welcome. However, in isolation these funds are not sufficient to meaningfully improve the hospital infrastructure and quality of care provided to all patients. Most countries that have successfully improved health-care delivery have done so through the public health-care system; examples include Australia, Canada, Thailand, and the UK.

Lastly, Ayushman Bharat must not be seen as an end in itself. Delivering affordable and equitable cancer care in India will require substantial changes to demand and supply-side policies. This includes better price negotiation for all technologies, developing health



technology assessment mechanisms, identifying costs across whole pathways, developing new and context-appropriate models of care, and strengthening governance of clinical practice in both public and private sectors. India needs to revisit and revise its national cancer control programme with a focus on better overall care, not just access to new technologies.⁴ Ayushman Bharat offers an important opportunity—and responsibility—to improve care meaningfully for patients across the health system.

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The liquid biopsy: towards standardisation in preparation for prime time



The liquid biopsy holds potential as a more cost-effective, easier, and less invasive method for diagnosing and monitoring cancer, as well as predicting response, than currently available approaches (such as tissue biopsies or imaging scans). Circulating tumour cells (CTCs) and circulating cell-free DNA (cfDNA) are currently the most intensely investigated analytes, with some tests already approved in clinical practice (eg, the Cobas EGFR mutation test v2, Roche, Burgess Hill, UK). Despite the potential of the liquid biopsy for managing patient therapy, no widely accepted consensus has been reached regarding pre-analytical blood sample handling and technologies used for extracting cfDNA and isolating CTCs, or optimal workflows for their molecular analyses, all of which are required before liquid biopsies can become routinely used in the clinic. In this Comment, we discuss the current status of liquid biopsy testing in patients with solid tumours, and the variation in blood sample handling and isolation or extraction methods, focusing on cfDNA and CTCs.

Several pre-analytical variables can affect downstream data obtained from cfDNA analysis. The first is specimen type (plasma or serum). Plasma and serum constitute the non-cellular fraction of whole blood; however, serum is obtained by allowing whole blood to clot at room temperature before processing. This process results in substantial leukocyte and haematopoietic cell lysis,

diluting the concentration of circulating tumour DNA (ctDNA) present in cfDNA. To obtain plasma, whole blood is processed as soon as possible post-venepuncture, reducing contamination by genomic DNA and is, therefore, considered optimal for ctDNA analysis. The second, and arguably most crucial, pre-analytical variable is blood sample processing, further stratified by the type of blood collection tube and time to centrifugation, and the speed and number of centrifugations.

The type of blood collection tube is the most diverse pre-analytical variable. It is well documented in published literature that an increase in total cfDNA yield with increasing time before centrifugation is observed when blood is drawn into edetic acid (EDTA)-stabilising blood collection tubes, mainly because of leukocyte lysis. Therefore, it is recommended that time to processing is within 2 h of blood collection, minimising the risk of genomic DNA contamination and subsequent dilution of ctDNA.^{1,2} To circumvent the need for immediate blood processing, specialised preservative blood collection tubes are available, permitting longer-term storage (from 1 day to several days) at ambient temperatures (room temperature to 37°C), but at a higher cost than EDTA tubes. These blood collection tubes allow unprocessed samples to be transported before processing, with studies suggesting that preservative blood collection tubes prevent leukocyte lysis for up to 7 days at room