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Taking biotechnology to the patient: at what cost?

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Introduction

Enlargement of people's choices is one form of human development (1). To this extent, biotechnology as a treatment option for certain human ailments such as genetic disorders can be taken as an effort towards human development, as it definitely extends the range of choices available to the public. The issue of 'taking biotechnology to the patient' goes beyond mere technology development, which is a supply side activity that may not take into account the demand side requirements such as accessibility and affordability—two important attributes for the success of any intervention technique.

Availability in plenty of any commodity or technology has favourable implications for accessibility and affordability. However, healthcare devices/technologies differ from other economic commodities/services and are exemptions to the market rule 'higher the supply lower the price'. One witnesses the co-existence of high supply, poor access and high price in the field of medical care. Perhaps, supply creates its own (induced) demand.

Patients would be better off if the new healthcare technology is more effective and less expensive compared to the existing alternative technology. Taking it to the patients would result in health gains and resource savings. Alternatively, patients would be worse off if the new technology is less effective but more expensive than the existing one, as it would result in health losses besides eating away resources meant for alternative uses.

There would be a dilemma if the effectiveness of the new technology is unknown and uncertain and whose cost is not comparable with any existing technologies. Technologies such as genetic treatment of disorders like betathalassaemia fall under this category. Such technologies are costly and their full benefits are not really quantifiable (2) When a treatment increases cost, there is no explicit scientific or ethical definition of an acceptable cost– effectiveness ratio (3).

Public choice

Should the government allow, promote or provide such technology? The answer to the first part of the question,

i.e. allowing the technology, is 'yes' and the government can allow it because the technology in question is more effective than the existing one(s). What is hidden here is that it is not harmful to the patients who would undergo such treatment. Taking this technology to the patients simply means marketability.

The answer to the second part, i.e. promoting the technology, can be 'yes' or 'no' depending upon the prevalence of the disease condition for which the new technology is developed, or whether or not the technology fits into the essential clinical service package. If the disease in question is highly prevalent and/or the technology fits into the essential package, the government can promote it even if the technology is actually delivered by the private sector.

The technology accessible and affordable to patients. Duty exemption, cheap financing, bulk purchase by the government, insurance and subsidy can all make. On the contrary, if the disease for which the new technology provides solace is not widely prevalent or the technology does not fit into the essential service package, then the government does not have any justification to actively promote it. The third part, i.e. government providing the technology, is a complex one. There is no 'golden rule' concerning cost-effectiveness of government healthcare services. Moreover, there are measurement problems with respect to both cost and effectiveness of various healthcare interventions. Healthcare is often a joint product of multiple facilities and an estimate of the real cost may be rendered tricky. Similarly, the effectiveness of some healthcare interventions is not strictly comparable although utility measures such as quality adjusted life-years (QALY) and disability adjusted life-years (DALY) provide some basis for comparison. The government should provide only such healthcare that has public good (non-excludable and non-rival) or merit good (existence of information asymmetry) characteristics. These two terminologies are not well defined in practice either. Hence, the government should decide whether or not to provide the technology on a case-by-case basis. The decision under this circumstance becomes partly political-a comparison of the gain of investing in the new treatment with what would be given up (opportunity cost) by funding it.

The UK, for instance, has established the National Institute of Clinical Excellence (NICE), which requires manufacturers or sponsors of healthcare interventions to submit evidence on the clinical- and cost-effectiveness of many products and services (3).

Private choice

Technologies such as the cure for genetic disorders have the potential to make people 'sick' of higher expenditure, that too for an uncertain return. Since such interventions take away resources from alternative interventions/uses, total disease burden in the society may rather increase because resources available for cure of other illnesses are actually reduced. Even if the treatment works, one patient may get treated at the cost of two or more patients (with the same or other illnesses). Thus, the ultimate choice of the household in allocating resources for such ailments would depend on the relative 'value' of the sick individual within the household. The financing pattern of households to treat major ailments suggests that 29%-42% of people borrow money, 2%-5% sell assets, 15%-30% use past savings and only 15%-20% people use the current income (4). That is, seeking treatment for major illnesses induces financial burden on one-third of the population, denies investment in the case of one-fourth and eats away consumption resources in the case of one-fifth. These figures, however, do not indicate the number of people denied care. Hence, households too are exposed to numerous dilemmas in making personal choices.

The example of beta-thalassaemia

Beta-thalassaemia or Cooley's anaemia is an inherited disorder that affects the production of normal haemoglobin (5) Treatment options for *beta thalassemia* are:⁶ (i) regular blood transfusions; (ii) medications (chelation therapy); (iii) surgical removal of the spleen; (iv) daily doses of folic acid; (v) bone marrow transplantation.

The cost of bone marrow transplantation (BMT) is about Rs 0.6–1.2 million (2). A person has a 5%–15% chance that the transplant will not work and a 5%–20% chance of dying from complications of the transplant (7). Adjusting for failures and deaths, a person has a 65%–90% chance of getting cured. The effective cost of treatment per patient, given a 65% chance of cure, can be estimated a s Rs 0.9–1.9 million, while it is Rs 0.7–1.3 million for a 90% success rate. Given the fact that only 25%–30% of the patients are likely to find suitable donors, only 16,250–27,000 out of an estimated 100,000 patients in the country can be effectively treated. The total cost of treating 16,250–27,000 patients can be estimated as Rs 11.4 billion (Rs 0.7 million x 16,250)–Rs 51.3 billion (Rs 1.9 million x 27,500).

India has a wide range of options to consider if it wants to utilise the money (Rs 11.4-51.3 billion) cost-effectively. One of them is to use the entire money for the treatment of beta-thalassaemia through BMT. The second option is to utilise the money to provide an essential clinical service package to a part of the population or to treat high prevalence diseases that have cost-effective treatment options. The cost of providing essential service to one person is estimated as US\$ 8 (approximately Rs 384) (8). It means that India, if it is left with the option of utilizing Rs 11.4-51.3 billion cost-effectively, can provide an essential clinical service package to 29.7-133.6 million of the population. The option would be either to treat 27,000 patients for beta-thalassaemia saving 0.27 million life-years (assuming a survival period of 10 years) or provide an essential service package to 13.4 million people for 10 years. While the cost of saving one year of life is Rs 0.07-0.19 million for BMT, the cost is estimated as Rs 288 for AIDS education through media in Guinea (9). That is, with the same resources that save a year of life using BMT, the country can save 243-660 years of life through alternative interventions. The country may thus be benefited more if it provides AIDS education than treating betathalassaemia through BMT. There exist thousands of competing healthcare interventions addressing tens of thousands of ailments and BMT and beta-thalassaemia should be treated as one among them-nothing more, nothing less.

Should India discourage the use of such technologies in general? The choice can be left to households as long as it does not have harmful effects on patients. The role of the government is to facilitate such treatment options to those who are willing and able to pay for them and to regulate the choices that are available to the people.

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