Ethical issues in the care of persons living with haemophilia in India

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Abstract

The recent series of ad interim orders issued by the Bombay High Court under ordinary original civil jurisdiction following public interest litigation (PIL) on the provision of free clotting factor concentrates for persons living with haemophilia, especially those below the poverty line and emergency cases, highlights the need to think about the ethicality of various aspects of access to medicine and the rights of patients suffering from rare diseases from the public health perspective. The PIL (number 82/2012) (1) [Vinay Vijay Nair & Ors vs. Department of Health, State of Maharashtra & Ors), which calls for free treatment for all haemophiliacs who go to the designated hospitals, was followed by the issuance of five ad interim orders (July 19, 2012, October 22, 2012, November 6, 2012, January 24, 2013, and March 19, 2013).

Haemophilia is a rare genetic disorder

Haemophilia is the commonest form of inherited bleeding disorder, and the burden of the disease is the second highest in India after the USA. It is a rare and complex condition arising from congenital deficiencies of coagulation factors, ie factor VIII protein (haemophilia A) and factor IX protein (haemophilia B). The disorder results from defective gene mutation. It affects mainly males and is carried from mother to son. However, one in three cases of haemophilia occurs in the absence of a family history of the disease, and is possibly caused by a new genetic mutation. The severity of the disorder depends on the residual activity of the protein. The disorder is categorised as severe if the activity of the protein is less than 1% of the normal (<0.01 U/mL), moderate if it is 1%–5% of the normal (0.01–0.05 U/mL) and mild if it is 6%–30% of the normal (>0.06–0.30 U/mL). The disease is manifested as prolonged bleeding, especially at target joints, and the consequent occurrence of medical conditions such as acute haemarthrosis, intramuscular bleeding, chronic haemophilic arthropathy and septic arthritis (2). As haemophilia is a chronic disease, the patient is beset with a range of physical, social, emotional, and psychological problems.

According to the World Federation of Haemophilia (WFH), one out of every 10,000 people born is a person living with haemophilia (PWH). Considering this, the estimated number of haemophiliacs in India, which has a population of over one billion, would be approximately 1 lakh. However, as per the data provided by the Haemophilia Federation of India (HFI) to the WFH, only 13,314 patients are registered (3). This is a reflection of under-diagnosis and speaks of a dearth of services. Thus, there is an unacceptable gap in haemophilia care. The infusion of anti-haemophilic factors (AHF), ie clotting factor concentrates (CFCs), is the mainstay of therapy. However, since the cost of CFCs is exorbitant, on-demand therapy or episodic treatment is the common modality of treatment compared to prophylactic therapy, which is the standard treatment recommended by the WFH and the World Health Organisation. Most of the families of haemophiliacs cannot afford AHF unless they make a special effort and seek external help through social networks.

Due to the several public health challenges that need to be accorded high priority in a populous country like India, a low-density disorder such as haemophilia does not get the recognition it deserves. Comprehensive care for haemophilia is an exception rather than the rule in most parts of the country, as treatment facilities are available only at tertiary centres in cities (4). There is an almost complete absence of home care. Due to the high cost and shortage of AHF, patients receive infusions of AHF too late and the doses are too small. Others have to take recourse to rudimentary forms of treatment, such as the use of whole blood, fresh frozen plasma or lyophilised cryoprecipitate. The use of these blood products is considered extremely unsafe and is associated with a high prevalence of transfusion-transmitted infections. Due to the lack of access to medicines, haemophiliacs receive sub-optimal[1] or no treatment at all, which further complicates their condition and hastens death. Despite the fact that many haemophiliacs suffer from crippling disability induced by the disorder (5), these patients are not entitled to the benefits of the Persons with Disabilities Act. This article discusses the neglected as well as sensitive topic of patients with rare diseases, an issue which has not been given due attention in the mainstream discourse on medical ethics and patients' rights.

Care for haemophiliacs: ethical issues and challenges

The plight of haemophiliacs in low-income countries such as India presents certain challenges and raises ethical issues. These are summarised as follows.

- Even though haemophilia is the commonest form of inherited bleeding disorder, the general public still does not know of it or has only a vague idea. In addition, haemophilia disorder calls for specialised treatment. The dearth of haematologists in the public and private health sectors and inadequate laboratory diagnostic facilities are violative of the patients' autonomy as patients have the right to know about their ailment, the prognosis and right to get appropriate treatment.
- In general, the dearth of specialised training in the management of haemophilia care among frontline

healthcare providers like general practitioners seriously affects patient well-being and is in conflict with the ideal of responsible care.

- Patients with severe haemophilia usually bleed 30–35 times a year. The frequency of bleeding is likely to be higher in tissues previously damaged by uncontrolled haemorrhages. The patient requires 1000 IU of CFCs per episode of bleeding (6). Thus, to treat life-threatening bleeds and achieve optimal survival, on an average, a PWH requires 30,000 IU of CFCs at INR 10.50 per unit, in one year. The cost of 30,000 IU would be INR 3,15,000 This means that to access treatment products, the patient would have to spend an amount that is 8.04 times greater than India's average annual per capita income, which is INR 39143(7).
- Research has shown that 15%–35% of patients with severe haemophilia A develop neutralising antibodies against clotting factor concentrates (2). Known as "inhibitors", these do not respond to regular clotting factor replacement therapy. According to the WFH's global survey of 2012, 5.27% of Indian patients with haemophilia A have clinically indentified inhibitors, while the corresponding figure for those with haemophilia B is 0.16%. Other types of medicines are required to eliminate the factor VIII inhibitors to achieve haemostasis. The patient is given "bypassing" therapy, which includes activated recombinant factor VII (rFVIIa, eg NovoSeven, which costs the patient INR 43,000 per episode) and factor VIII inhibitor bypassing agent (FEIBA). However, in India, these medications are more costly on a per-unit basis. For example, FEIBA costs INR 30 per IU, so the cost per episode would be INR 30,000 because at least 1000 IU would be required. Similarly, the annual expense (for treating at least 30 annual episodes of bleeding) would be at INR 9, 00, 000 . Thus, the out-of-pocket expenditure associated with the treatment is 22.99 times higher than the average per capita income of Indian patients and, therefore, unaffordable.
- Due to the lack of access to treatment products and inability to pay, CFCs are infused in doses that are too small and also, by the time they are infused, it is too late. This has grave consequences for the health of patients. It compromises their quality of life, lowers their functional health status and gives rise to morbidities. It can even lead to premature mortality. The failure to provide access to medicines reflects a lack of justice, one of the core principles of bioethics.
- The disclosure of the status of women who are carriers of haemophilia to their family members and significant others requires careful consideration of the ethical principles of confidentiality and human rights issues. Such disclosure is a matter of personal choice, and is influenced by cultural and social norms. While it is important to respect the right to confidentiality, the principle of confidentiality is in conflict with the human rights of others in the case of inherited disorders, as it would create insurmountable problems for those who might inherit the disease. At the same time, being a carrier of haemophilia may have a profound psychosocial impact on a woman. The disclosure of her carrier status would have an adverse impact on her prospects of marriage or her reproductive choices, as there would be a risk of passing down the genetic defect to her offspring and of bearing an affected child with long term co-morbidities. Carriers are also at risk of both primary and secondary postpartum haemorrhage (8). Haemophilia is an X-chromosomal recessive disorder transmitted through asymptomatic heterozygous females to the male child (2). As it is genetically transmitted from carrier mother to son, it has gender sensitive implications as mothers may be deserted, stigmatised or held responsible for the birth of an affected child.
- The high prevalence of transfusion-transmitted infections among haemophiliacs (9) raises the issue of safe blood transfusion practices which needs to be revisited from a humanitarian and public health standpoint. Improving the quality of blood is a legal obligation and the Food and Drug Authority, Government of India, is expected to ensure strict surveillance of blood banks and regulation of blood transfusion medicine in terms of good laboratory and manufacturing practices. There is need for a complete overhaul of blood transfusion services in India (in the light of the National Blood Policy, 2002) to ensure that blood banks follow sound practices with a stringent donor deferral system. Enacting laws for the manufacture of safe blood is also of critical importance as patients have a right to safe treatment.
- In India, standard epidemiological methods are cost intensive for measuring the burden of rare disorders such as haemophilia. However, the disease registry maintained by HFI, a non-governmental organisation remains the only source for obtaining epidemiological data on haemophilia conditions (10). A public health intervention is also imperative for systematic surveillance and to obtain epidemiological data with robust quality control mechanisms like trained staff and a national patient registration number to avoid misclassification of patients, duplication of entries, under-reporting, data attrition due to mortality etc. The specific information on the morbidity, mortality, treatment outcomes and natural history of the disease enables cost-effective interventions, for example, to plan for the requirement for CFCs and provision of healthcare resources for the management of the disease.
- In the year 2012, a new scheme of medical social insurance, the Rajiv Gandhi Jeevandayi Arogya Yojana (11), was piloted in eight districts of Maharashtra. It covers families with an annual income of up to INR 1 lakh and implicitly recognises the need to provide free treatment products to people with haemophilia (list number M6S13.2), among several ailments. According to one of the provisions of the scheme, only those haemophiliacs who have been hospitalised for at least seven days are entitled to free treatment products. Haemophiliacs who require treatment for life-threatening bleeds in the emergency or outpatient department are excluded. This provision runs counter to

the very objective of the scheme. A large proportion of haemophiliacs are deprived of treatment and the inequity in access to healthcare is not addressed. In addition to the provision mentioned above, the scheme provides for a maximum of INR 1.5 lakh, which hardly suffices for the treatment of haemophiliacs, considering the severity, complexity and fatal nature of the disease. This clause needs to be reconsidered.

- The prevention and care of birth defects has been given due emphasis under the Action Plan for Global Strategy for the Prevention and Control of Non-communicable Diseases, 2008-2013 (12), and the recent launch of the Rashtriya Bal Swasthya Karyakram (RBSK) under NRHM in 2013, initiated by the Ministry of Health and Family Welfare (13). However, there is need to initiate a national programme on haemophilia. The absence of an appropriate policy is a major reason for the exclusion of haemophiliacs from health programmes. This, in turn, leads to further social marginalisation, which affects their quality of life.

Human rights and fundamental rights related to health

The question of access to medicine is closely related to the issue of justice in the context of patients' rights. A wide spectrum of human rights laws and conventions, including the Indian Constitution, guarantee all citizens the right to health. In 1946, the constitution of the World Health Organisation (WHO) stated, "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition." The right to health was then addressed in 1948 in the Universal Declaration of Human Rights [Article 25(1)], which laid the foundation for the international legal framework for the right to health (14). Article 12 of the International Covenant on Economic, Social and Cultural Rights provides an analytical framework that contains key elements of the right to health. Medical care in the event of sickness, as well as the prevention, treatment and control of diseases, are set forth as the central features of the right to health. Further, these features depend on access to medicine and, therefore, access to medicine forms an indispensable part of the right to health (15). Article 12 of the Universal Declaration on the Human Genome and Human Rights upholds the provision of the benefits of technological advancement to human beings for the betterment of their health, this being intrinsic to the individual's enjoyment of dignity and human rights (16).

Part III of the Indian Constitution (17) enumerates the various fundamental rights of the nation's citizens. However, the right to health and healthcare is not explicitly mentioned as a fundamental right. The right to health can be said to exist on the basis of the right to life guaranteed under Article 21. Similarly, the right to healthcare or the right to medical facilities, as well as access to these without discrimination, can be derived from this Article. Over the years, the meaning of the term "life" in Article 21 has been extended by various pronouncements of the Supreme Court. "Life" now denotes not only meaningful existence, but also robust health and vigour. According to Articles 41 and 47 of Part IV of the Indian Constitution (17), it is the State's duty to ensure that medicines are available to ailing and disabled persons; that they are affordable; and that they are physically accessible, without any discrimination against any section of society.

Application of Article 21 to the right to health of haemophiliacs

- Keeping in mind the various rights guaranteed under international covenants, the relevant provisions of the Indian Constitution and the plight of haemophiliacs in India, it is clear that the under-diagnosis of the disorder and barriers to access to the treatment represent a blatant violation of patients' rights. The patients' very right to life, guaranteed under Articles 21, 41 and 47 of the Indian Constitution, is jeopardised.
- Life-saving drugs are given the status of essential medicines on the basis of their relevance to public health, scientific evidence of their safety, their efficacy and cost-effectiveness. Access to essential medicines forms an indispensible part of the right to health under Article 21 and it is an urgent public health and ethical imperative. AHF are life-saving drugs, which find a mention in the national list of essential medicines and have been listed as such by the WHO (18). Moreover, if the country is to fulfil its role of a welfare state, it is imperative for the government to ensure prompt medical treatment, which includes treatment for rare diseases. The failure to provide medicines to PWH amounts to arbitrary discrimination and a denial of their right to treatment. The provision of medicines is a legal obligation as India is a party to several international conventions that bind it to make drugs available.
- Article 12 of the International Covenant on Economic, Social and Cultural Rights provides a framework for the right to health which is recognised by the Convention on the Rights of the Child. As haemophilia is an inherited disease, and the onset of the disease starts in childhood, therefore treatment for haemophilia is largely directed towards children. If a child receives sub-optimal treatment or no treatment (due to unaffordability of the medication), it is in contravention of the provisions of the Covenant. Children should be treated with an adequate quantity of CFCs to minimise the detrimental effects of joint and muscle bleeds to increase functional independence and thus, allow them to lead a normal social life.
- Article 12 of the Universal Declaration on the Human Genome and Human Rights provides and casts a duty on the state to conduct research in biology, genetics and medicine concerning the human genome to seek relief from suffering and improve the health of individuals and humankind. Genome wide linkage analyses in inherited bleeding disorder enables the pathophysiological understanding of clinically relevant phenotype-genotype correlation. The knowledge of causative gene mutations will facilitate genetic counselling in affected families as

well as identifying predicators of inhibitors (19). Such scientific evidence based information can be applied to a personalised treatment regime ensuring its cost-effectiveness.

- Haemophilia-induced disability, caused by prolonged bleeding in the joints and muscles, compounds the disease burden on the patient. Sub-optimal and delayed treatment ultimately causes permanent damage. The issue of the prevention of disability has been dealt with in Section 25 of the Persons with Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995 (PWD Act 1995:14) (20: p 12). In essence, the Act seeks to prevent disability through early detection and treatment. However, PWH are not covered by the provisions of this Act.
- Unlike the West, India does not have legislation such as the Orphan Drug Act and for this reason, multinational companies have a monopoly over the production of AHF (patent drug) leading to unregulated prices as production of these drugs is not lucrative for generic pharmaceutical companies. The Government of India must, therefore, pursue an aggressive policy for controlling the price of AHF under the Drug Price Control Order, invoke the compulsory licensing provisions[2] of the Patents Act, 1970. Further, it would be an added advantage if Government initiated plasma fractionation centres in public sector units to procure plasma derived medicinal products. This would go a long way in ensuring that AHF would be available at an affordable cost to the haemophiliac community.
- In 2005, the Haemophilia Federation of India (HFI) made an official complaint to the National Human Rights Commission (NHRC) about the blatant violation of the human rights of haemophiliacs. The NHRC came out with a series of recommendations in the year 2006. Among the notable recommendations were those which stressed the provision of anti-haemophiliac treatment products to patients and the launching of comprehensive haemophilia care programmes across the country. However, these recommendations are yet to be implemented.

In 2006, the HFI, Delhi filed a public interest litigation in the Delhi High Court, seeking the provision of free treatment products to haemophiliacs (PIL number 16326/2006; [*Haemophilia Federation of India vs Union of India*]) (21). Following successful negotiations, the High Court ruled that free AHFs be provided at three designated public tertiary hospitals of Delhi. This was followed by a spate of similar PILs in different states, such as Uttar Pradesh, Rajasthan and Karnataka. The ad interim orders of the Bombay High Court (orders on July 19, 2012, October 22, 2012, November 6, 2012 issued by a division bench comprising Chief Justice Mohit Shah and Justice Nitin M Jamdar and orders on January 24, 2013, and March 19, 2013 issued by a division bench comprising Chief Justice Mohit Shah and Justice Anoop V Mohta) (1) in response to a PIL seeking access to medicines and healthcare facilities for haemophiliacs in Maharashtra are a welcome development. The court has directed the state government to provide free CFCs to persons living with haemophilia, especially those below the poverty line and in emergency cases, free treatment to all haemophiliacs who come to the designated hospitals. The Maharashtra government has taken a few important steps in this direction. It has established day care centres for haemophiliacs on a pilot basis initially in four districts (Satara, Amravati, Nasik and Thane), and later extended to other districts (Mumbai, Ratnagiri and Pune). For this purpose, the Maharashtra government has allocated funds for the provision of free AHF through the National Rural Health Mission, Maharashtra (22: p 48).

However, since health is a state subject, the verdicts of the high courts following PILs in different states can be implemented only in those particular states. Clearly, this can provide only piecemeal solutions. To make AHFs available to the thousands of haemophiliacs spread across the country, the joint involvement of the states and the national government is necessary. If PILs are filed in the Supreme Court under Article 32 (17),[3] the Court's verdict will be binding on all states. Finally, the Indian State is duty-bound to develop a comprehensive policy for haemophilia care to address the unmet healthcare needs of haemophilia patients and ensure equity. The provision of 10,000–20,000 units of CFCs to every haemophiliac, as per the guidelines of the Indian Council of Medical Research, 2005, or the provision of a lower dose of prophylaxis (23) is imperative to avoid disability. There is also an urgent need to make prenatal diagnostic tests and genetic counselling services more widely available to obligate carriers as well as to possible carriers to avoid transmitting this disorder to the next generation.

Conclusion

The spate of PILs on the care of haemophiliacs across different states is testimony to the government's indifferent and lackadaisical approach to haemophilia patients. The answer to how to address the needs of haemophiliacs lies in heeding the principle of justice (ie equity) and patients' rights in the context of rare diseases. The Indian government will always face an ethical dilemma while deciding on the proportion of its scarce resources that should be allocated to the health problems of millions of people and on how much should be allocated to the problems of patients with rare diseases or "orphan diseases". However, justice demands the fair and equitable distribution of scarce resources. Therefore, it is imperative for the government to strike a balance and be constantly vigilant in a world of competing health demands. It is the responsibility of the government to issue policy directions to administer sufficient intellectual, financial and human capital to ensure viable standards of care and continuity of care to vulnerable groups of patients with rare diseases. This will certainly go a long way towards giving haemophiliacs access to medicines and safeguarding their right to health.

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Statement of authorship

The research work discussed in this paper was performed under the guidance of Kanchan Mukherjee. Uma Jadhav conceptualised the ethical and legal aspects of haemophilia in the light of the PIL order of Bombay High Court and wrote the draft of the manuscript. Anil Lalwani is a life member and current Secretary of the Haemophilia Society, Pune chapter, and contributed to the in-depth discussion of different facets of haemophilia.

Notes

[1] According to the WFH global survey of 2012, India had the lowest per capita consumption of CFCs worldwide. The figure for factor VIII was 0.020 and that for factor IX, 0.004.

[2] Compulsory licensing (CL) is an important option available to member countries of the World Trade Organisation as per the agreement on Trade Related aspects of Intellectual Property Rights to source affordable drugs for health emergencies. It is an instrument for addressing the pressing problem related to access to medicines, the pharmaceuticals market and pharmaceutical industry in India. CL enables a member state to license the use of a patented invention for itself or a third party "without authorisation" of the patentee.

[3] This Article pertains to the right to constitutional remedies and enables an individual to approach the Supreme Court directly for the enforcement of all fundamental rights.

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