Orthopaedic segment in India – from pandemic dormancy to a better future

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The world has been paralysed by corona virus variants for the past 2 years which has affected all the realms of activities of society. Its effect on the medical field was two-fold - on one side there was stress to handle the large inflow of highly contagious cases, while on the other, healthcare priorities got skewed towards COVID-19 care. Within a short timeframe after the first report of coronavirus-2 (SARS-CoV-2) in China in December 2019 (ref. 1), it has spread as an epidemic and progressed to a pandemic, percolating through the boundaries of countries. There was patient overflow in medical-care facilities across the world due to the escalation of symptomatic patients at each surge of new variants of the coronavirus. The highly contagious nature of the virus has put additional pressure of handling the situation with proper level of infection-control measures. Strategies of dealing with the pandemic have been implemented aggressively in all countries. The most notable change was a shift from patient-centred to public-centred healthcare. It was inevitable. but had put limits to specialty care, especially the elective services².

The pandemic management in India was in line with that practised globally. The government had to enforce complete lockdown for initial three weeks, in addition to the control of regional mass-mingling and strict implementation of personal protection measures like masks and hand-sanitizers. Nurses, paramedics and physicians were deputed in infection control. There was a strict order for minimization of elective services and the most prominent specialty among these is orthopaedics. The situation badly affected the outpatient clinics, emergency surgery, rehabilitation, resident training, personnel management and all sub-specialities of orthopaedics. The shift to public-centred healthcare led to shortage of healthcare professionals in orthopaedic hospitals. As a consequence, the scheduled surgeries and regular patient check-ups were cancelled. In addition, the service providers in this segment were forced to reduce outpatient numbers in clinics. Orthopaedic surgeons were not considered as frontline health worker to

contain infection. Thus they needed to stay away from work, causing economical and mental stress³.

This was the second blow to the Indian orthopaedic segment in last couple of years, the first being the price cap by the National Pharmaceutical Pricing Authority (NPPA) on total knee replacement implants. This move was brought in through a provision to regulate the selling price of medical devices under 'extraordinary circumstances' for public benefit, which resulted in a reduction of selling price between 59% and 69% (Table 1). The first instance of the price cap of medical devices in India was that of coronary stents in February 2017. Before the real effects of price cap of knee implants reflected in the business, the second wave of the COVID-19 pandemic fell upon us. Together they have caused significant damage to the orthopaedic segment during the past 20 months or so. Majority of international medical device manufactures had reported double-digit revenue loss in 2019-20 (ref. 4).

The huge price cut on knee implants is aimed at increasing the affordability and accessibility of the economically weaker strata to advanced treatments for a better quality of life. According to the World Health Organization, osteoarthritis was projected as fourth biggest cause of Indian population immobility by 2020. This is a huge burden to orthopaedic surgeons, considering the massive (over 1.3 billion) population⁵. The price cap on the knee implants may provide significant advantage to people considering the fact that over 1.5 lakh knee surgeries are performed each year⁶. However, from the manufacturer's side, this has resulted in a situation that it is profitable to sell only the base models with low innovation. The financial setback from the reduction of sales has limited the enthusiasm for research and development. It is obvious that the price capping is perceived negatively by the international medical device manufacturers, and they might consider withdrawal of the latest implants and technology from the market. This is likely to prevent access to the latest, high-quality and innovative implants for affordable patients. Another possibility is that the local manufacturers may try to reduce the quality of their products for profit, and there is also a chance of selling the implants in the grey market.

In the case of the healthcare providers, there is a likely chance that hospitals will increase the peripheral charges to make up for the losses, thereby reducing the cost advantage to the patient. Certain steps from the Indian Government have provided relief to the patients to a certain extent. It has been reported that out-of-pocket (OOP) spending (or the health expenditure through payments at the point of care) for an Indian is almost 60%, which ranks among the highest in the world⁷. This situation led the Government of India to initiate the Ayushman Bharat-Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) in order to reduce OOP spending for treatment. AB-PMJAY can be considered to be a step towards Universal Health Coverage (UHC), aiming at providing quality health services to all people without financial hardship. This programme provides health insurance cover of up to Rs 500,000 per family per year, and approximately 50 crore poor and vulnerable entitled families across the country are covered under it⁸. AB-PMJAY includes surgery, daycare treatment, cost of medicines, diagnostics, etc. A study conducted in 2019 found that only 9.84% of the beneficiaries in Bihar and 12.41% of the beneficiaries in Harvana were aware of AB-PMJAY9. However, around 59% of the beneficiaries were aware of the scheme in Tamil Nadu9. This highlights the need for creating awareness among the public. Further, the World Economic Outlook reports that the per capita GDP (nominal) income is nearly Rs 159,932 (US\$ 2191) in India, which translates to Rs 13,327 per month¹⁰. This amount is surely not sufficient for orthopaedic implant surgeries for 90 crore out of 130 crore people who are not covered under AB-PMJAY.

Recovering from setbacks

The true impact of price cap in the orthopaedic implant sector, and its scope and limitations could be assessed only when the field resumes its minimum quantum of

Table 1. Price control on knee implants

Type of knee implant	Mean MRP* (Rs before price capping)	Ceiling price, excluding goods and services tax (Rs after price capping)	Mean price reduction (%)
Cobalt chromium	158,324	54,720	65
Titanium and oxidized zirconium	249,251	76,600	69
High-flexion implants	181,728	56,490	69
Revision implants	276,869	113,950	59

^{*}MRP, Maximum retail price.

business after the COVID-19 pandemic. As mentioned above, price cap provides an apparent advantage to the patients when they buy the implants from the market. On the other hand, the manufacturers may try to limit implant improvement plans and the patients will be left with older models. The regulatory agencies will have to struggle to track the low-quality, low-cost implants distributed in the grey market.

In order to alleviate these shortcomings, orthopaedic healthcare needs holistic reforms for a better and affordable system. The need for reforms in orthopaedic speciality is further stressed by the elderly population (aged 60 years and above) which is projected to increase by nearly 41% in 2031, from 138 million in 2021, according to the National Statistical Office report¹¹.

Despite several steps for improvement and control measures by the Government in the Indian orthopaedic segment, the cost of orthopaedic surgery remains high. The high price associated with orthopaedic implants and devices is not due to import cost alone, but includes the dealers' commissions as well. For example, in case of total knee replacement implants, the final selling price is almost double¹². High orthopaedic surgery cost is obviously unaffordable to those in the low-income strata. The selling price escalation can be dealt with using technology and support of domestic implant manufactures. We suggest improvement in the following areas for accessible orthopaedic services to all.

Immediate recovery suggestions

The country is still under the threat of new variants of the corona virus, being combated with societal controls on one front and massive vaccination drive on the other¹³. However, the orthopaedic specialty has to get into action to provide care for the needy. Telemedicine is an good service modality for the specialties sidelined during COVID-19, particularly orthopaedics. In cases of quarantine and containment due to high

infection rate, tele-consultation provides a quick solution to needy patients. This will reduce crowding in hospitals. The Government of India has initiated a teleconsultation platform called 'eSanjeevani', where a patient can directly interact with the available doctors¹⁴. This modality has a promising future and seems affordable to the needy patients. However, there should be a legal provision to regulate consultation charges from time to time.

Patient-centred plans for long-term advantage

While planning the long-term actions for progress of orthopaedic care in the post-COVID-19 period, priority should be given to patient-centred healthcare. Providing implants and diagnostics at affordable rates will be highly helpful to those who are facing an economic crisis posed by the pandemic. Price-cap actions may be extended to other implants as well, but taking into consideration the financial consequences which can cripple the medium- and small-scale manufacturers. Other options of reducing the cost could also be explored.

Avoiding the middle operators and efficient management in the supply chain can considerably reduce the cost. According to data from the World Economic Outlook, the average income of an Indian is Rs 13,327 per month, which indicates that one person's income is not sufficient to undergo joint replacement surgeries. This shows the need for affordable surgical instruments and implant outlets. These affordable outlets are expected to serve quality instruments and implants, like the Pradhan Matri Bhartiya Janaushadi Pariyojana (PMBJP) Kendra, which has more than 1451 drugs and 24 surgical items included at present¹ In this direction M/s HLL Lifecare Limited, Thiruvananthapuram has come up with Affordable Medicines and Reliable Implants for Treatment (AMRIT) pharmacies in the country. The pan-Indian expansion of AMRIT pharmacies model must be promoted. Co-cordial relations among health professional will be required for better and wide utilization of the AMRIT pharmacies concept, which brings in price reduction by cutting down the commissions in the supply chain. These pharmacies are also profitable. According to the annual report of M/s HLL Lifecare limited, AMRIT business received a turnover of Rs 403.98 crores, at a growth rate of 45% (ref. 16).

Another experimental venture by M/s HLL Lifecare Limited is worth mentioning. Beating all the odds, they emerged in the pandemic period as a leader in supplying personal protective equipment (PPE) kits and pulse oximeters at an affordable cost. They started the 'HLL Pharmacy and Surgicals' outlet in the Government Medical College, Thiruvananthapuram, for providing surgical items at an affordable cost, by eliminating the middle players in the supply chain. The model is manufacturerto-customer type, bypassing the commissions to be paid at different intermediate levels of supply. This led to price discounts of 40% in the market, without sacrificing the profit to the company¹⁷. A similar model could be implemented in the orthopaedic implants segment. This could be a wise and practical step towards the reduction of MRP, and will potentially eliminate the need for price ceiling in the orthopaedic segment.

Along with the implants and surgicals, diagnosis is inevitable in orthopaedics. The essential diagnosis, including advanced radiological analysis must be done meticulously. High-quality diagnosis with certification is often expensive. According to a research report, the diagnostic services market in India is projected to grow at 27.5% for the next five years 18. The double-digit growth is likely to be driven by infusion of contemporary technology in medical diagnostic and pathological laboratories. The Indian diagnosis business is currently managed by unorganized small and independent laboratories, which needs better organization. The modern orthopaedic diagnostic tools such as X-ray radiography,

ultrasound, CT scan, MRI, etc. are by and large unaffordable for low-income patients. Government-owned diagnostic centres, run by efficient and performing Government agencies, will be a remedy to this 19. To make it more reachable to the intended strata, these centres must be primarily deployed at village/panchayat level. There must be good coordination with hospitals, doctors, surgeons and health professionals. Doctors must be encouraged to refer patients to these affordable centres for diagnosis. Advanced techniques of data management and communication can be introduced in these laboratories to make them more efficient and affordable. The centres may be linked with others hospitals using cloudbased universal health information systems, where electronic health records (EHRs), diagnostic test results, and medical scans can be stored. The hospitals can be enabled to retrieve the stored data using unique identification of a patient and a one-time password (OTP) sent to the patient's mobile phone. This will provide secure and better services, and reduce the overall cost of diagnosis. The centres must be encouraged to ensure quality diagnostic reports and cyber networking.

Solutions for reviving the domestic implants industry

The post-pandemic situation provides a good chance to take steps to revive the Indian implant Industry, as international companies are likely to reduce their presence in the Indian market due to device price-cap actions. The domestic manufacturers may be able to perform better and a little support from the Government will make them competent to produce world-class products. Common research and development platforms based on appropriate quality systems could be implemented as 'Orthopaedic Technology Park' or 'Medical Device Innovation Park'.

The 'Park' concept fosters the growth of domain-specific firms which are usually affiliated with educational institutions, wherein the knowledge is shared with a pool of talents to promote innovation, leading to large-scale commercial output. 'Medical Device Innovation Park' can be initiated by Government agencies (or philanthropic non-governmental organizations) and the State Government, based on the location of the project and infrastructure availability. Upon successful implementation of the initial few Orthopaedic Techno-

logy Parks, the public private partnership (PPP) model must be promoted for efficient management. Collaborative initiative will build co-cordial and long-lasting relationship among the participating agencies.

Implant distribution logistics also is an important activity in which the manufacturers should be able to supply their products even to remote areas of the country. It should be noted that the orthopaedic products prescribed by doctors are often specific, and the user/patient has no proper way to identify good quality products at affordable cost. Thus, the healthcare sector needs reforms in logistic handling system, which can help patients in speedy treatment and reduce overall expenses. The solution lies in the combined use of factors such as good collaboration with medical device suppliers, accurate inventory visibility and advance planning of implants requirement on immediate basis. This can be done by employing integrated process with forecasting algorithms and big-data analytics²⁰. The right technology will enable timely access of orthopaedic implants for the desired results.

Solutions for financial and infrastructural support

In the case of general healthcare, raising funds for implementing new ideas (aspects mentioned above) is quite challenging. This case is specifically applicable in orthopaedics. It may be difficult to invest public funds for experimental models. One potential source for fund raising is through Corporate Social Responsibility (CSR).

In the CSR concept, companies are socially accountable to themselves, the stockholders and public. The Government should make stipulation that companies spend a share of their funds in the orthopaedic domain as well. This is because poorly treated or inadequately managed orthopaedic cases can lead to long-term crippling condition and consequent loss of man-days. Also, a large share of the occupational hazards needs orthopaedic care. It has been estimated that 40.9% of Indians employed are in the age group of 60-64 years and 21.2% in the age group of 65 years and above¹¹. The large elderly Indian workforce participation in the employment sector is because of economy needs. Therefore, orthopaedic treatment has relevance in the employment sector as well.

Currently, various non-medical activities are ongoing in India under CSR, which

have benefitted the public at several levels. However, the COVID-19 pandemic has snatched economic wealth of the public. Thus it would be appropriate if some of the CSR fund is diverted to orthopaedic care, particularly in personnel skill development, infrastructure modernization and implementing insurance schemes.

Certain dedicated programmes on orthopaedic diseases, diagnosis and treatment can be envisaged under CSR funds. Various training programmes in collaboration with the Ministry of Skill Development and Entrepreneurship, Government of India, can be initiated for all manpower categories - from surgeons to paramedics. These programmes will broaden orthopaedic domain knowledge among participants and could be a potential source of employment. The state-of-the-art laboratories can be set up with skill stations, where trainees learn by practising on simulation exercises, mannequins, demonstration videos and presentations. The training must have interactive sessions, discussions, demonstration of skills, case studies, presentations and videos.

The state-of-the-art gadgets, particularly incorporating artificial intelligence, are revolutionizing the health sector. The emerging technology of 'internet of things' (IoT) encompasses various devices and instruments for medical care, and helps link and coordinate them in an effective and convenient manner. Several such devices with networking capability are already available and these should be more useful in caring for those with vulnerable health conditions. Wearable devices (like fitness bands, wireless blood pressure and heart rate monitoring devices, glucometer, etc.) can be used for constant tracking of health conditions of elderly patients²¹. The data generated from such devices can be stored in the secured cloud accessible to the healthcare professionals. By employing data-computing software, healthcare professionals can provide accurate and real-time diagnosis and treatment. The wearable devices distribution to elderly patients can be envisaged under CSR funds.

Another viable approach is to encourage the established hospitals and clinics to channellize the CSR funds for patient care, considering the need and financial status of the patients. Patients will be highly benefitted if support is available from the hospital itself for ambulatory assistive devices and orthopaedic surgery (such as hip, knee and shoulder replacement). Established healthcare providers can use CSR funds

for health insurance coverage and to meet hospital expenses of patients from the low economic strata.

The concept of City Health Project under the 'Smart India' mission

An ambitious programme could be envisioned to have a City Health Project which provides the appropriate infrastructure, environment and culture for better public health. Involvement of multinational companies with the Indian Government can be vital in such types of projects, where the companies can take the initiative to develop health facilities such as mobile medical centres (MMCs), community-based small health centres (CBHCs), elderly care homes (ECHs), local clinics, etc. 16. The objective of MMCs is to provide accessibility to quality healthcare services. Each MMC will have a team of orthopaedic specialists, nurses, laboratory technicians, a pharmacist and social workers. CBHCs can focus on improved survival outcomes through early management of trauma, birth defects, bone diseases and skeletal disabilities. ECHs can provide good healthcare facilities for the elderly, such as facilities for skill improvement, library, reading room, pharmacy, lifestyle modification centres, etc. The local clinics can be introduced for minor ailments and first aid, in addition to Primary Health Centres. These clinics must have provision for early diagnosis of communicable and non-communicable diseases.

Concluding remarks

India, much like other countries of the world, had stepped in proactively for the control of COVID-19, adopting a publiccentred healthcare approach. On the flipside, this has affected the elective health specialties, and we are hopefully looking forward to their recovery once the pandemic situation is controlled through steps like mass vaccination. For the orthopaedic segment, the pandemic gave an additional blow, over and above the aftermaths of the price cap on knee implants. Among the elective health specialties, orthopaedics should get prime importance because it deals with conditions leading to manpower loss and crippling ailments. Therefore, the orthopedic device segment should receive special consideration in the revival of patient-centred healthcare during the postpandemic period.

Government initiatives to control the price of implants and devices, and public medical care programmes have helped reduce the OOP expenditure burden of patients undergoing orthopaedic treatment. On the other side, device manufacturers are finding it hard to cope with price-control steps in the rapidly changing Indian medical device market scenario. Strengthening the orthopaedic device market and promoting device technology indigenization is the need of the hour, as it can directly affect the quality of patient care. This is the right time to stress on developing a domestic implant industry base, as the multinationals in this segment are likely to reduce their market share because of compromised profits. Various methods can be envisaged for supporting the Indian implant industry, like constituting centralized technology development parks and hand-holding for better supply chain and logistics. More number of certified and affordable diagnostic centres could be opened, and they can be networked with healthcare providers for quick and effective diagnostic decisions. These steps, in turn, will reduce the total OOP expenditure and can provide enhanced quality of life. The fund requirement towards these new concepts could be met, at least partially, by channellizing the industrial CSR funding. To be more futuristic, City Health Project may be envisaged as a long-term strategy.

These reforms may lead to accessibility to quality orthopaedic health services and good healthcare facilities to common people in India. The reforms, if implemented, can help realize 'the right to health' defined by the World Health Organization as 'the enjoyment of the highest attainable standard of health' and our 'Self-reliant India' campaign in future.

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COMMENTARY

Remembering the remnants of trout fisheries in the Nilgiris, Western Ghats, South India

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Trout fisheries first began in the Ooty region in the Nilgiris Mountains of South India during the late 1800s, followed by other cold-water regions in India. Trout fisheries are well established in North India but are not developed in South India. Efforts were taken to know the present status of the trout population in the montane regions of Ooty as it is a very pristine place for the trout species to flourish and investigations revealed that the trout stock is in an endangered state but proper conservative measures taken can help in its sustainable development.

The British in the late 1800s found the cool water streams of the Nilgiris region in South India suitable for trout culture. Hence initial attempts to establish trout in India were made in the Ooty region towards the end of the 19th century¹. It began with the introduction of brown trout (Salmo trutta fario) and Loch Leven trout (Salmo levensis) in 1863 by Francis Day, but failed even after four decades of effort². Later in 1909, Henry. C. Wilson introduced rainbow trout (Oncorhynchus mykiss) from New Zealand successfully along with a hatchery constructed in 1910. Decrease in size and number was noticed in 1913, indicating high fishing pressure. Attempts to improve the stock was done in 1920 with rainbow trout from Kashmir³ followed by introductions from Japan in 1968 with golden rainbow trout (Oncorhynchus mykiss aquabonita), brown trout, tiger trout (hybrid between brown trout and brook trout) and Sockeye salmon (Oncorhynchus nerka). The golden rainbow trout established itself as the dominant strain, while rest of the introduced species failed to establish. In 1974, 10,000-eyed ova of albino strain of rainbow trout was introduced⁴, but perished

due to fungal infection⁵. Stock improvement was again done in 1989 by introducing trout strains from Munnar and hybrids were formed, but no study has been made on the performance of these hybrids⁶. In 1997, the National Bureau of Fish Genetic Resources initiated a cross-breeding programme, but it failed due to untimely weather conditions with a poor success rate of 0.5% (ref. 7). Though the trout fisheries got established in the Ooty region, angling (trout fishing) evidence was available from 1966 to 1970 (refs 8, 9) and 1997 to 1998 (ref. 6), after which no reports were available in subsequent years.

Present status of trout fisheries in Ooty

In 2015 (after 16 years), fish biologists from Madurai Kamaraj University assessed the present status of trout fisheries in Ooty. The Assistant Director of Fisheries of Ooty revealed that angling activities have been banned from 2000 to avoid fishing exploitation. Every year, the Fisheries Department raises fingerlings and stocks them in the Upper Bhavani reservoir of

Ooty, but the rate of recovery is not known. Ripe brooders from the Upper Bhavani reservoir are caught and stripped for eggs and milt, which are then mixed for fertilization in specialized containers and then taken to the hatchery in the Avalanche Forest zone. The maximum number of wild trouts taken annually for breeding ranges from 300 to 500. Rainbow trout are now designated as 'wildlife fish' (importance of protection of this species is equivalent to that of the tiger) to save them from poaching. Wild stocks of the trout exist in less numbers in the Avalanche Lake and Mukurthi Reservoir, but breeding operations are not done in these waterbodies. Commercialization of trout is not practised in this geographical location. Records for the available years from 2011 to 2019 showed that a total of 633,340 eyed ova were produced, and the total number of fingerlings stocked was 462,350 and success rate was 73%. The produced fingerlings have been stocked along with the wild brooders and so stocking density is high in the Upper Bhavani reservoir. But recently in 2019, torrential rainfall and landslides have caused massive damage to the hatchery. The Upper Bhavani reservoir which