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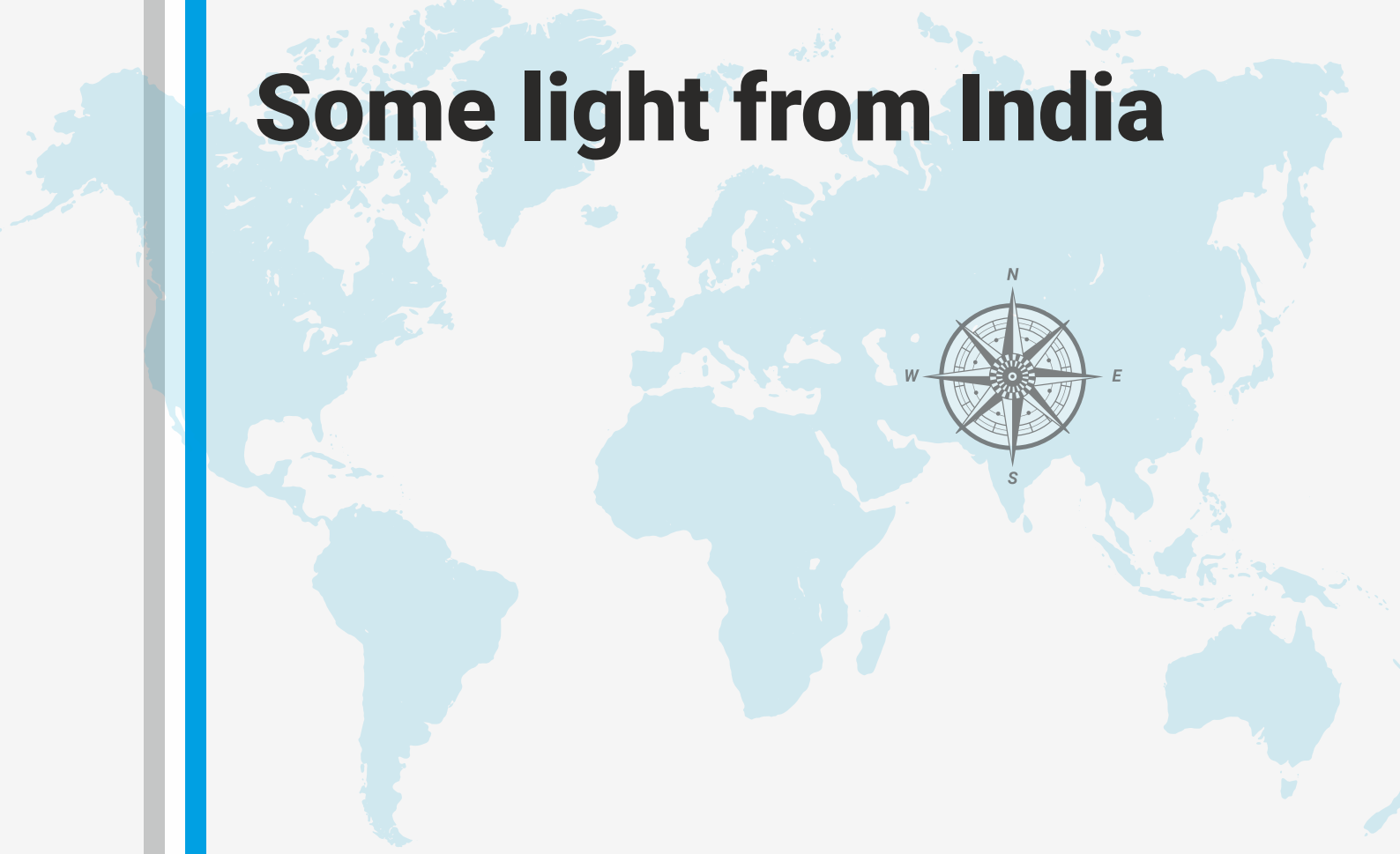
MEDICAL TECHNOLOGY ASSOCIATION OF INDIA

Policy choices which global leaders face in Healthcare:

Some light from India



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Navigating the Tariff Conundrum

- David Ricardo's Timeless Lesson

Excerpted from an article by Pavan Choudary*, published in The Hindu Business Line on July 21, 2024

In early 19th-century Britain, much of household spending went towards food grains, creating economic pressures that reverberated across society. The business landscape was split into two opposing factions: the landed, grain-producing aristocracy and the emerging industrialist (capitalist) class. As the population grew, so did demand and grain prices, leading even low-quality grain to sell at a premium. This inflation strained the common people and placed additional burdens on industrialists, who had to compensate their workers with higher wages, as food prices largely influenced labour costs.

Faced with soaring grain prices, industrialists turned to grain imports from other countries, providing essential relief to the populace but diminishing local landlords' profits. This new competition not only reduced landlords' earnings but also compelled them to improve the quality of their produce to match imported standards. Leveraging their influence in Parliament, however, landlords enacted the Corn Laws—a rigid system of high protectionist tariffs on imported grain which escalated further whenever foreign grain prices dropped, securing the landed gentry's profits.

Yet, following the Napoleonic Wars and a series of poor harvests, these high import duties revealed their flaws, exacerbating the suffering of ordinary citizens. Despite the evident distress, the landlord-dominated Parliament responded by raising tariffs even further, under the ironic belief that higher short-term duties would eventually drive-up local grain production! Instead, grain inflation soared to unprecedented levels, sparking a surge of petitions to Parliament from both the general public and industrialists. David Ricardo, England's foremost economist, emerged as a pivotal advocate for the "hardworking industrialists," championing a relentless campaign to reduce these prohibitive tariffs. His efforts ultimately persuaded the Parliament to repeal the Corn Laws, allowing affordable grain to enter Britain freely and offering lasting relief to its people.

Today, India's medical device sector

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echoes aspects of this historical lesson on tariffs and protectionism. Currently, around 80% of the medical devices used in India are imported, while domestic production is largely confined to items of limited engineering complexity or those intersecting with sectors where India is already strong. In these specific areas, India's manufacturing is performing well.

The basic custom duty on medical devices is 7.5% to 10% which is further compounded by healthcess ad valorem (5 percent), social surcharge (1 percent), making a final count of 13.75% to 16.5% in just import duties. Perhaps, the protectionist instinct driven by unsubstantiated claims in this sector, went over-board some time and that is why we have such high tariffs. The burden of custom duties is finally borne by the patient.

Compared to this in neighbouring South Asian countries the customs duty is around or below 5%. This disparity serves a useful benchmark and highlights a major risk: The increased likelihood of smuggling. Such illicit activities not only result in lost tariffs and taxes for the government but, more critically, expose patients to products that lack legal and service guarantees.

In pursuit of quality, affordability, and equitable competition, and to better align with regional tariff practices, India would benefit from reducing customs duties on medical devices that lack viable domestic substitutes in the short to medium term. Such a policy shift would attract foreign investment in research and development, manufacturing, and market expansion, ultimately enhancing the Indian healthcare sector while ensuring affordable, quality care for patients. ■

History of Healthcare Price Control and Way Forward

Excerpted from an article by Pavan Choudary, published in Express Healthcare on May 3, 2024

Pavan Choudary, Chairman of Medical Technology Association of India (MTaI) and a public intellectual, stresses that throughout history there have been many instances of governments wanting to control prices. In most of these instances, the often-well-intentioned price control has inadvertently hurt access or at least brought down the quality of the sector.

The attempt to control prices of medical services is not new. It dates back to several millennia.

The first medical technology was Religion. Because more than a couple of thousand years ago whenever a natural disaster occurred or a disease struck or even when lightning flashed or a thunder clapped, the question which the world asked was: ***Who did it?*** The answer which bubbled up - because how the question was constituted - was some God or Goddess. The remedy was some ritual, some mantras, some chants, some ceremony to appease the deity. The intermediary was the priest or the shaman, the pandit or the ojha. There were attempts by enlightened rulers to control their fees too!

Then in 500 BC in China and Greece, the question which people asked while facing incomprehensible natural phenomenon changed. From ***who did it*** to ***what caused it?*** This change in question changed the paradigm and caused a tectonic shift in the genre of the answers. The question ***what caused it*** paved the way for modern scientific thinking and led to the genesis of science, technology and medical technology.

The new medical technologist was the Physician. (It is interesting to note that

hospitals also owe their origin to pilgrimages – these establishments started as inns, hostels or hotels to rest the weary pilgrims on their way to their destination. Therefore, the common linguistic root of hospitals and hospitality.). With the growth of modern medicine, as the hold of religion started receding, these lodgings became centers of healing. Rulers now tried to control the prices of physicians and hospitals.

In some countries, like ancient India, businessmen gave away some of their profits to set up a center of healing to provide care to those in need. These hospitals ran as non-profit organizations as there weren't any businessmen whose business was hospital running alone. This historical antecedent gives rise to the lingering sentiment in some Indians that hospitals should still be run as non-profit enterprises.

The reason why medical service delivery/hospitals are among the first areas that governments seek to control prices is because worldwide medicine isn't the irreproachable profession it should have been and because of the information asymmetry in this space, the patient stays most vulnerable to exploitation.

Today, however, hospitals are usually the sole business of an entrepreneur offering not just basic care but healing, improving the quality of life and prolonging lives. These are complex organizations that require financial sustainability to continue operating effectively, bring the best manpower, provide access to latest medical technology and also make some profit in the process. Not to say that hospitals shouldn't do good, but they have to do well too because, they can't feed from an empty vessel.

For example, the price control after the Soviet era, where CIS countries, trying to address inflation or follow the diktat of self-reliance, brought in price controls on essential goods and services including medical services. This made suppliers unwilling or unable to provide goods at that mandated price, leading to shortages as demand outstripped supply. Price controls led to distortions in the market, inefficiencies, and reduced investment in production. At times, after announcing price ceilings, as a desperate counter measure the governments had to bring a price floor (a lowest guaranteed price of purchase by the government) or a subsidy to keep the production alive.

This is not to say that there is no proper way to reduce the financial burden of healthcare on patients. But it should be a holistic process like limiting diagnosis based on requirements, providing prescription efficiency and cost transparency data to patients, offering preventive care and screening programs aimed at early detection & management of chronic conditions, segregating hospitals into different tiers based on the quality of care they provide, etc. To ensure that any policy of such significance is not utopian, it should be brought in only after thorough consultation with the industry and the informed. ■

Can Price Control Create Treatment Bias?

Excerpted from an article by Pavan Choudary*, published in Express Healthcare on Jun 16, 2024

Levitt and Dubner in their book Freakonomics quote a medical study which found that obstetricians in areas with declining birth rates are much more likely to perform cesarean section deliveries than obstetricians in growing areas – suggesting that when incomes start falling doctors try to ring up more expensive procedures.

This is an example of a treatment bias.

Is it possible that the stent-price control could also be giving birth to treatment biases?

Just as a background – Stent prices were slashed in India by 85 per cent in 2017. This well-intentioned price control measure was aimed to ease the financial burden on patients undergoing angioplasty. The jury is still out if the major centers, to compensate for the income loss, just increased the interventional cardiologist's (hereafter cardiologist) fee, and hospital charges such as those for operating theater usage, nursing services, beds, medical supplies, food etc., thus bringing the price of the procedure to where it was with the higher priced stents! The overwhelming evidence is that they did. And this brought in bias in the Business Model, almost distorted it.

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Protagonists of this severe price control say that the measure at least made the hospitals start receiving through formal channels, the unaccounted money which was earlier going to cardiologists and that tier 2 and tier 3 towns saw some dip in procedure costs which the major centers evaded as described above. Referring to the multiplying volumes of angioplasty they also say that this is because angioplasty has become more affordable. Those who disagree contend that this is because the number of stents placed per person is increasing! The truth might be a mixture of the two contentions.

However, is a more deceptive treatment bias emerging due to stent price control? Are the diagnoses of blocked-calcified lesions increasing, which might explain the resurgence of Rotablators—a specialized burr used by skilled cardiologists to remove calcification. Although rotablation is vitally necessary for blocked-calcified arteries as a prerequisite for angioplasty and the Rotablator-pioneering company has taken great pains in training cardiologists on this sophisticated technique, there is no guarantee that a less skilled operator won't attempt to game the system – feigning just a single rotation of the drill to justify charging for it in the bill.

There is so much subjectivity in medical decision making that such price controls, more often than not, create a cascade of adverse unintended consequences which grow with time.

To truly make Indian healthcare more affordable, policymakers must – as an extension of the Hippocratic tradition – first ensure that their policy does no harm! Engendering treatment biases are harmful to the patients. Only through a comprehensive understanding of the ecosystem, keeping lessons drawn from historical precedents of price control in sight and consulting the stakeholders and the informed can India embark on a path towards a more resilient and equitable healthcare system. ■

It is interesting to study the trade margin rationalization (TMR) mechanism suggested in the Department of Pharmaceuticals, Government of India report of the Committee on High Trade Margins in the Sale of Drugs, 2016. The pilot TMR which was applied on anti cancer drugs in 2020 saved more than 118M dollars for the patient in the first year itself. The success of the pilot led to the mechanism being implemented for 5 medical devices- Pulse Oximeter, Glucometer, BP monitor, Nebulizer and Digital Thermometer, during the COVID pandemic, which also demonstrated consistently impactful outcomes.

How Globalized Standards Power the Economy and are Local Standards an Option?

Excerpted from an upcoming article by Pavan Choudary*, to be published

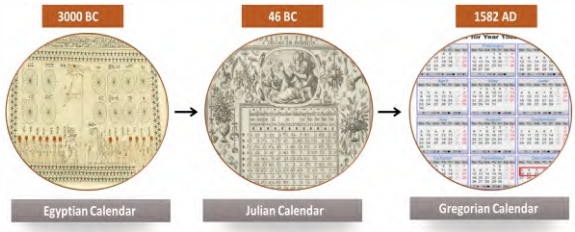
'Standards' are the common technical language for trade partners throughout the world. Standardization serves as the invisible yet powerful framework that drives efficiency, safety, and interoperability across industries and countries.

The foundational understanding for this, I had attempted to provide through my anecdotal LinkedIn post which detailed the challenges encountered by a German merchant in the 16th century, due to the existence of 112 different measures of length, 80 different measures of weight and 123 varying measures of volume in a small part of Germany itself. Industrialization and growth of free trade necessitated standardized practices and products. As industries expanded and the demand for complex devices increased, the need for consistency and interoperability became paramount. Consequently, standards evolved from individual enterprises to national, and eventually, international levels.

The History of some prominent standards:

The Julian and Gregorian Calendars: Harmonizing Time

Calendars are vital systems for dividing time into extended periods like days, months, or years, arranged in a specific order. They play a crucial role in regulating civil life, religious observances, and historical and scientific activities.



The figure above illustrates the condensed evolution of calendars over the centuries

They also address the crucial civilizational needs to measure periods for agricultural, business, or other purposes. The first practical calendar, evolving from these requirements, was the Egyptian calendar, which the Romans

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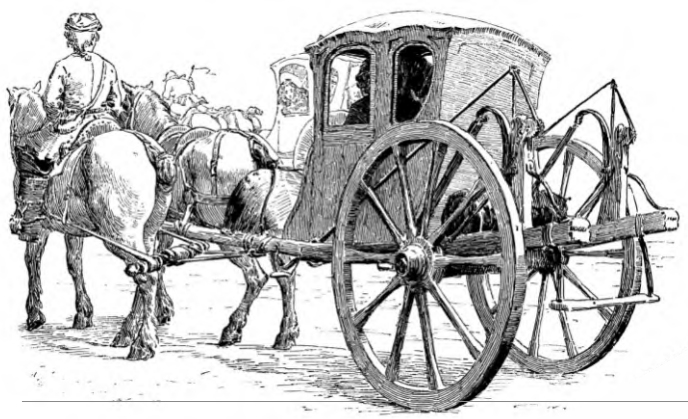
later developed into the Julian calendar in 45 BC. This calendar served Western Europe for over 1,500 years until the Gregorian calendar was introduced in 1582. This improvement provided a system drawing together religious festivals and seasonal activities, and was almost universally adopted. This is an example of successful universalization of a standard. Now let us see what happens when standards stay fragmented and regionalized.

Left or Right handed drive: Unresolved Global Divide

The distinction between left- and right-hand driving is another example of varying standards across the world. Approximately 35% of the global population drives on the left with the steering on the right (Right Hand Drive), This is so mainly in countries that were once part of the British Empire. Historically, left-side driving or riding whether on chariots or horseback were common because it allowed right-handed swordsmen to defend themselves more effectively. Additionally, mounting horses from the left side was easier and safer, reinforcing this practice.

Figure below shows Chariot with Left-handed (Right sided) driving



However, in the late 1700s, practical considerations led to a shift in some countries. In France and the United States, charioteers driving large wagons with multiple horses, sat on the left rear horse (Left Hand Drive) to keep their right arm free for whipping. This led to traffic moving to the right so drivers could sit closer to the center of the road and feel more in control of their vehicle or mount. Over time, many countries adopted right-sided driving, but former British colonies retained the left-side standard.

Left and Right Driving Countries

Figure above shows World map of countries with left and right-side driving

Today, several issues arise from differences in left- and right-hand driving. Cars are typically designed for either left-hand or right-hand driving, with controls and visibility optimized accordingly. Trading of vehicles between countries with different systems can require costly modifications, such as moving the steering wheel and pedals. The need to modify vehicles for different driving systems create trade barriers, reduced market competition, and result in higher prices for consumers. Regulations related to the trade of vehicle are more complex and costly. At borders between countries with different driving systems, the infrastructure has to accommodate the transition, such as crossover bridges or

complex traffic management systems, which further increases the cost.

Driving licenses and regulations vary between countries with different driving systems, creating additional hurdles for international drivers.

Electric Plugs: 15 different routes to power

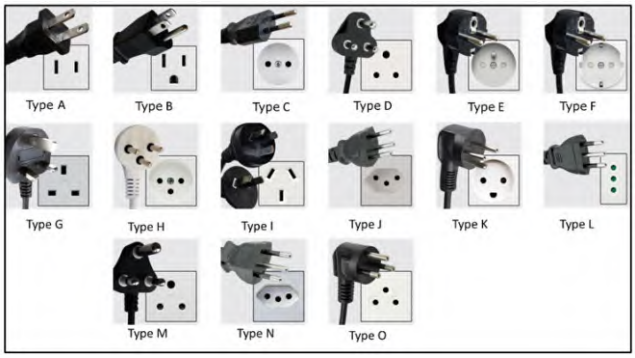
The modern electrical outlet, a convenience often taken for granted, has undergone significant development since its early days of do-it-yourself wiring and light-bulb socket plugs.

Early light bulb socket which was also used as a socket for other appliances

The first 2-pin plug & socket were invented to mitigate hazards associated with using light bulb sockets

As electricity came to homes through the bulb, before the invention of 2- or 3-pin plugs, electrical equipment was connected directly to light bulb sockets. Electricity was supplied to homes via these sockets, and the method to power on or off involved hooking into or unhooking from the socket. Consequently, all appliances were designed with a light bulb-like powering system that required hooking and unhooking for operation. There was no concept of switches or pinned plugs at that time. For instance, early washing machines had to be plugged in by connecting to the light bulb socket. The abrupt start of these machines often led to accidents, particularly for women whose hair could get caught in the machinery. This safety hazard was a significant factor in the widespread adoption of pinned plug sockets.
The first pinned plug originated in Britain in 1880s and had two pins. The most significant advancement came from Philip F. Labre in 1928, who added a third ground prong to the plug to reduce electrical shock risks. This ground prong provides an alternative "path of least resistance" for electricity to flow to the ground, bypassing the person. Labre's design, featuring two prongs for live and neutral wires and a grounding prong, became the model for modern outlets. Variations in plug designs and socket types worldwide, such as different-sized prongs in the US and various shapes in Europe and Japan, reflect the continued evolution of electrical outlets.

There are currently 15 types of electrical plugs used worldwide: Type A, B, C, D, E, F, G, H, I, J, K, L, M, N, and O. Each type varies in design, voltage, and frequency standards.



The global diversity in electrical plugs presents significant challenges for manufacturers, travellers, and consumers. Products designed for one type of plug may not be easily sold in countries using a different type, limiting market access and consumer choice. Manufacturers need to produce different

versions of their products to fit various plug types, increasing production and logistics costs. Travelers need to carry multiple plug adapters to use their electronic devices in different countries, which is inconvenient and adds to travel costs. Additionally, not all adapters work perfectly with all types of plugs, leading to potential damage to devices or difficulty in using electrical appliances. The need for multiple adapters and different plug designs contributes to electronic waste, as these items are often discarded after travel or when moving to a new country.

The Global Need for Standardization

The journey of standardization, from the Julian calendar to modern electrical outlets, highlights the importance of creating uniform systems to manage the complexities of daily life. These standards facilitate consistency, safety, and efficiency, reflecting the continuous efforts to adapt and improve in response to changing needs and technological advancements. The transition from left- to right-hand driving and the diversity in standardized electrical plugs further highlight how important is standardization for fostering global interoperability and safety. Harmonized standards ensure compatibility, enhance efficiency, and facilitate international trade and travel. Another praiseworthy example of standardization is that of containerization in shipping. Many experts say that standardizing container size has been one of the greatest catalysts for globalization.

Similarly, in the healthcare space, medical devices should adhere to the same standards worldwide. This would facilitate the standardization of training globally, crucial for doctors and healthcare workers who are often internationally mobile and need to operate devices proficiently anywhere. With more than 20% of the global non-native healthcare workforce being of Indian origin and the government's plan to export 300,000 healthcare workers annually, it is essential for these professionals to be fluent with globally standardized medical devices. This would also benefit internationally mobile patients and boost medical tourism. Embracing standardization, particularly in healthcare, will drive global progress, and ensure that we meet evolving healthcare needs with consistency and efficiency. ■

The Medical Technology Association of India (MTaI) is a leading association of research-driven medical technology companies with strong focus on innovation and manufacturing. As a foremost industry body for MedTech in India, MTaI is recognized as a thought leader in the healthcare sector.

All the time stressing on the three hallmarks of healthcare – Quality, Consistency and Patient Safety, MTaI's primary objective is to enhance access to high-quality healthcare while ensuring industry's long-term viability.

MTaI has consistently collaborated with the government, healthcare professionals and other stakeholders to bring cutting edge research and recommendations to the fore.

The association's members currently operate 14 large manufacturing facilities and 15 state-of-the-art research and development centers across India. Each year, they train over 250,000 physicians and healthcare professionals, equipping them to deliver superior patient care.

Through its ongoing engagement with government stakeholders, MTaI works to streamline regulations, attract foreign and domestic investment, and ensure patient access to quality medical devices. The association upholds ethical business practices and aims to foster an environment where MedTech companies can find a space commensurate to their contributions to healthcare.

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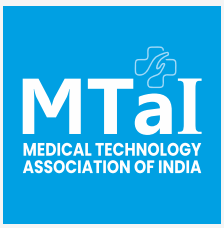

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