Received February 20, 2020, accepted May 8, 2020, date of publication May 19, 2020

A Model for Priority Setting in Health Technology Innovation Policy

By J. Sharma[1,2]; J. Bunders[2]; T. Zuiderent-Jerak[2]; B. Regeer[2]

[1] CEO, AP Med Tech Zone & Executive Director, Kalam Institute of Health Technology, Visakhapatnam, India.
[2] Athena Institute, Vrije Universiteit Amsterdam.

ABSTRACT

Health Technology Assessment focuses on the equal appraisal of health technologies introduced into the market. This has made regulators and the governance of innovation reactive and dependent on the initiatives that innovators take for technology development, thus making it supply-driven. The policy-makers' role has become one of appraising technologies that are already developed rather than guiding the development agenda. This severely limits the possibility to ensure that health technologies sufficiently address major issues such as the burden of disease, trade deficit, and health inequalities. It places governments outside of the actor arena that co-shapes technologies in the early stages, restricting the involvement in facilitating whether to scale up or not. It makes it hard to achieve health technology governance practices that maximally contribute to ensuring technological developments that address public concerns. What is the potential of the framework for changing this dynamic and how can evidence shape technology development agendas without falling into the traps of regulator lock-in or social engineering? The methodology presented in this study takes the first important steps toward an evidence-based framework for priority setting to guide innovations, particularly in the health and social sectors.

Keywords – *Assessment, health technology, medical technology, regulation, innovation, development, priority setting.*

INTRODUCTION

The appraisal of health technologies introduced in the market is of utmost relevance for healthcare governance. One of the greatest challenges that governments face is aligning the agenda of technology development with social indicators like the burden of disease and macro-economic indicators like trade. However, the role of evidence-based policy restructuring in guiding medical device development has remained an overlooked possibility. Understanding the necessities and gaps in medical device development could have major consequences for sectoral advancement and its benefits to the society instead of being locked in a supply-driven mode. As the current COVID-19 pandemic painfully shows, it is also necessary to take into account a country's capacity for self-sufficiency in terms of manufacturing the devices used in their territories and becoming more independent from importing medical devices and the economic impacts of such import. The pandemic shows that countries across the world, lower-middle-income countries (LMICs) as well as high-income countries (HICs), have all become largely dependent on the import of medical devices and that self-sufficiency by no means is a concern for emerging economies alone. This study aims to provide an evidence-based framework for priority setting in guiding innovations by developing a practical

model that can be implemented using country-specific data that reflects the actual territorial needs and can be related to the countries' economic capabilities. A set of composite indicators have been identified and used for the priority setting exercise. Firstly, the quality of human life is a major indication of national economic progress and human development index.[1] The corollary of Gross Domestic Productivity as a human health welfare index is an indication of national health,[2] both economic and contextual. One major parameter for the identification of wellness of populace is public health data records.[3] All countries have their specific manner of maintaining public health records[4] and analysis methodologies[5] to use evidence from such records.

While minor variations in the analytical tools might be present, one common consensus among all government structured health analytics is the importance of mortality records.[6] Of the common parameters of assessing disease-affected livelihood, the Quality-Adjusted Life-Year is a generic measure of disease burden, including both the quality and the quantity of life lived. The Institute of Health Metrics and Evaluation (IHME) at the University of Washington published a report titled *WHO Global Burden of Disease (GBD)* which considered Disability-Adjusted-Life-Year (DALY) as the point of consideration for disease-affected livelihood.[7,8]

To consolidate the data of the major disease burden for India, this study focused on interpolating the diseases that are of immense concern. Each disease has a large number of diagnostic, therapeutic, rehabilitative, and palliative procedures meant for combating the condition. While the diseases are classified under the International Classification of Disease (ICD-11) by WHO, the interventions to tackle such diseases are listed under the International Classification of Health Interventions also by WHO. The interventions are thereafter dependent on various health technologies, and while pharmaceutical products often come with varied alternatives, most medical devices do not have an alternative for the patient nor operationally for the care provider. For example, while several lines of drug therapy exist for non-communicable diseases such as renal failure or diabetes, there are no alternatives to a dialysis machine, a dialyzer, a glucometer, or an insulin pump. There lies an important distinction between medical devices, with both devices and drugs being health technologies.

Furthermore, by conceptually combining the evidence from the burden of disease estimates for a country to the export-import trade data on medical devices, a model list could be enumerated to estimate which medical devices could be developed in a country, which would be reflective of its health as well as economic impact. This reasoning was applied in this study to India's context. As a country, India currently imports >80% of its medical device needs.[9] This ranges across all healthcare paradigms as well as all domains of devices.[10] It greatly affects the healthcare cost attributed primarily to capital expenditure on commodities as essential as health technologies.[11] The overall medical devices market in India is estimated to be USD 7 billion,[12] however the country imports over 80% of its needs, making medical technology acquisition costlier which negatively impacts the healthcare costs. The medical device market in India is growing at a 15.8% CAGR (compound annual growth rate) and is postulated as the fourth largest potential globally.

The methodology described in this paper, using a model that could cross-pollinate information from both disease burden and trade deficit has several advantages. Firstly, avoidable death or disabilities from disease or ailments that could be possibly cured by medical technology is an effective indicator of meaningful technological and scientific progress. Secondly, the import dependency on such devices including life-saving ones has a direct impact on the country's trade deficit impacting its macro-economic growth and therefore societal progress. Needless to say, United Nations in its 17 Sustainable Development Goals has given equal importance to these by keeping poverty elimination as Goal 1; Good Health and well-being as Goal 3; and Industry, Innovation, and Infrastructure as Goal 9.

Aligning these goals for priority setting in medical technology innovation could, therefore, result in health improvement and economic sustainability. This would also help realign the trade and export-import decision-making processes to encourage domestic manufacturing, which is increasingly important in light of world-wide outbreaks of infectious diseases. To the best of our knowledge, this study presents the first-ever attempt in correlating these

essential principles to establish a pathway for medical technology development and drive innovation policy to improve healthcare access, economic sustainability, and societal impact.

METHODS AND RESULTS

In this section, the creation of a model or methodology to enumerate the priority list of medical devices that need to be developed is explained. The methodology is also a part of the results themselves, given that this study focuses, first, on the creation of a model and then application of the model to do the priority listing. For this reason, the authors opted to merge the methods and the results in the same section.

To estimate disease burden, the main causes of mortality compared over a decade for India, estimated by the IHME was used and are tabulated below (see Table 1). Trends from 2005 to 2015 signify that while there has been a substantial decline in mortality due to neonatal complications, mortality due to metabolic disease and/or lifestyle diseases has overtaken the mortality due to communicable diseases – a classic trend across developing economies.

TABLE 1. Top 10 Causes of Death in 2015 and Percent Change From 2005 (Data from Institute of Health Metrics and Evaluation, India)

Cause of Death	2015 (rank)	2005 (rank)	% change
Ischemic heart diseaseHeart Disease	1	1	(+) 16.7%
Chronic Obstructive Pulmonary Disorder	2	2	(+) 4.3%
Cerebrovascular diseaseDisease	3	3	(+) 7.3%
Lower Respiratory Infection	4	5	(–)(-) 22.6%
Diarrheal diseaseDisease	5	4	(–)(-) 31.7%
Tuberculosis	6	6	(–)(-) 30.7%
Diabetes	7	11	(+) 34.8%
Chronic Kidney Disease	8	10	(+) 20.6%
Neonatal prePre-term birthBirth	9	7	(–)(-) 39.5%
Road injuriesInjuries	10	9	(–)(-) 2.7%
Neonatal encephalopathy	11	8	(–)(-) 31.0%

Table 2 signifies similar parameters in the disability or morbidity estimates since mortality can be indicative but does not singularly affect GDP or macro-economic progress in a population.

TABLE 2. Top 10 Causes of Disability in 2015 (Data from Institute of Health Metrics and Evaluation, India)

2015 Rank	Disability Causes
1	Iron Deficiency Anemia
2	Low Back and Neck Pain
3	Sense Organ Diseases
4	Depressive sDisorders
5	Musculoskeletal Disorders
6	Migraine
7	Skin Diseases
8	Diabetes
9	Anxiety Disorders
10	Chronic Obstructive Pulmonary Disorders

The aspects under study were disease models which required significant medical device intervention, hospitalization, or otherwise. To outline the relevant causative factors and disease conditions, the major disease burdens were classified as communicable and non-communicable. The top five from both were enlisted and relevant treatment procedures that required technological interventions were detailed.

Concomitantly each of the medical devices used for diagnosis and treatment were mapped for each of the therapies corresponding to the diseases. Further, the segmentation of medical devices was charted by bringing in common devices used for these diseases. This had a relationship of one-to-many (e.g., cardiac and pulmonary diseases require more than one medical device) but also of many-to-one (hollow fiber membrane finding application in dialysis, oxygenator, ECMO and the like) (Figure 1).

Table 3 entails the communicable diseases list and technological interventions required to tackle such disease conditions. Table 4 enlists the non-communicable diseases and their diagnostic methods involving technological

interventions that are critical to disease treatment or mitigation.

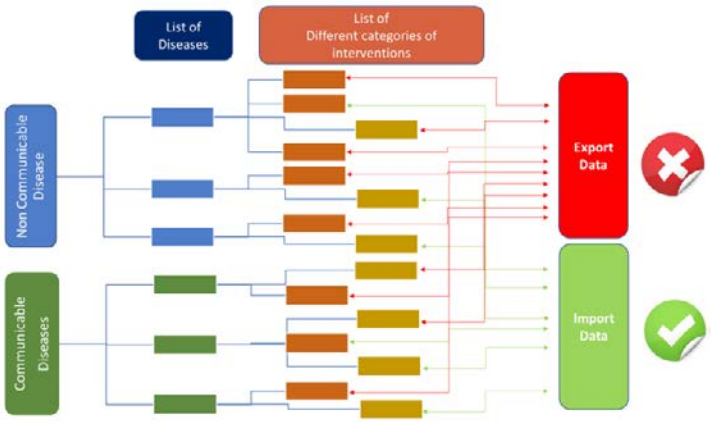

FIGURE 1. Model flow diagram of Burden of Disease to Categories of Interventions to Medical Devices Involved. Starting from the left: (1) Make a list of non-communicable and communicable diseases in order of highest burden (see Tables 1 and 2). (2) Identify diagnosis methods and device-related interventions for the top 5 diseases (see Tables 3 and 4). (3) Create a consolidated list of essential medical technologies (see Table 7) by combining the priority lists of medical and diagnostic devices for communicable and non-communicable diseases (Tables 5 and 6). Next, starting from the right: (4) Tabulate export and import data of categorized medical devices (see Table 8). (5) Consolidate high import and low export-dependent devices (see Table 9) as they require the increase or improvement in internal manufacturing capability to create self-dependency, higher affordability, and greater access.

TABLE 3. Classification of Communicable Diseases and their Corresponding Technological Dependencies

Rank	Communicable Disease or Infectious Disease	Diagnosis Methods and Device-Related Interventionsdevice related interventions and uses
1	Malaria, dengue, parasitic infections like filariasis, and hookworm infestation	Microscopic examination Rapid diagnostic tests Molecular testing Antibody testing (IgG and IgM) Fecal matter testing with PCR assays Endoscopy of intestinal tracts DNA testing Surgery Serological techniques
2	Diarrheal diseases along with amoebiasis and cholera, and similar gastroenteritis, and typhoid	Microscopic examination Cyst search in fecal matter Serological techniques DNA testing Rapid dipstick urine testing Swab samples Laboratory examinations Endoscopy and colonoscopy Blood culture Stool culture Bone marrow culture Widal testing Typhidot medical testing (for detection of IgG and IgM antibodies)
3	Tuberculosis, and fever-associated complications like influenza and leptospirosis	LED microscopic examination Commercial culture and DST Testing TB and drug resistance using Xpert MTB/RIF assay Diagnosis and screening of active tuberculosis in people living with HIV, using lateral flow urine lipoarabinomannan assay Detection of resistance to second-line anti-tuberculosis drugs using molecular line probe assays Diagnosis of pulmonary TB using loop-mediated isothermal amplification Detection of resistance to isoniazid and rifampicin using molecular line probe assays Latent TB infection testing (TST or IGRA) Ultrasound imaging Sputum cultures Mantoux tuberculin skin tests Nucleic acid amplification tests Adenosine deaminase tests Serology, virus isolation and culture, antigen detection, RNA detection by PCR endoscopy Examination using flashlight X-ray Examination using tongue depressors Serum tests Blood tests Kidney function tests Liver function tests ELISA tests PCR tests Microscopic agglutination tests

Rank	Communicable Disease or Infectious Disease	Diagnosis Methods and Device-Related Interventionsdevice related interventions and uses
4	Jaundice and hepatitis, and similar diseases which affects the liver	Blood tests Urine tests Fecal tests LFT Ultrasound imaging Computerized tomography scan Magnetic resonance imaging scan Endoscopic retrograde cholangiopancreatography with the help of X-ray Liver biopsy LFT Hepatitis A, B, D, and C marker tests
5	Venereal diseases like STDs (gonorrhea, syphilis, HIV, etc.,)	Blood tests Urine samples Fluid samples Diaphragm or cervical cap Male condom Female condoms Cervical cap

DST = drug susceptibility testing; HIV = human immunodeficiency virus; LED = light-emitting diode; PCR = polymerase chain reaction; STDs = sexually transmitted diseases; TB = tuberculosis.

Data were collected by taking into account the top five communicable and top five non-communicable diseases which account for the most lives lost as per the latest data available.

With the perspectives of disease paradigm enlisted on priority, our methodology brought in the next component of these diseases and their possible intervention to prevent prevalence or provide treatment. Matching was done between diseases and relevant medical devices of the relevant intervention procedure from the prior lists removing overlapping entities if any. Table 5 lists the priority medical and diagnostic devices in communicable diseases subset, while Table 6 details the priority medical and diagnostic devices list for non-communicable ones. By merging the two previously referred lists and removing overlapping entities, a common list of essential medical technologies was created as shown in Table 7, consolidating this entire dataset. This list is referred to as the "priority list of medical and diagnostic devices on the

TABLE 4. Classification of Non-communicable Diseases and their Corresponding Technological Dependencies

Rank	Non-Communicable Disease	Diagnosis Methods and Device-Related Interventionsdevice related interventions and uses
1	CAD or IHD and their abnormalities	CAD and IHD diagnosis and monitoring using ECG Holter monitoring Event monitoring Cardiac stress testing Ultrasonic imaging of the heart using echocardiography Nuclear stress testing (radioisotopes injected into the bloodstream) Heart CT scan (CT coronary angiogram), which requires high-speed CT scanner Coronary catheterization (diagnosis and interventional purpose, invasive) Intravascular ultrasound Intracoronary optical coherence tomography Fluoroscopy
2	COPD, lower respiratory tract infection, and asthma	Spirometry Chest radiography CT scan Complete blood count Arterial blood gas analysis Other pulmonary function tests
3	Cerebrovascular disease and strokes	Carotid angiogram CT scan Magnetic resonance imaging scan ECG Cerebral angiogram Vertebral angiogram
4	Diabetes and obesity-associated disorders like hypertension	Glycated hemoglobin (A1C) test Random blood sugar test Fasting blood sugar test Oral glucose tolerance test
5	Iron deficiency and protein malnutrition	Complete blood count (using microscope or analyzers) Endoscopy (to check for internal bleeding in the upper gastrointestinal tract) Colonoscopy (to check for internal bleeding in the lower gastrointestinal tract) Ultrasound imaging

CAD = coronary artery disease; CT = computed tomography; COPD = chronic obstructive pulmonary disease; ECG = electrocardiogram; IHD = ischemic heart disease.

disease burden context." This formed half of our dataset for this study.

A second dataset was also created, referred to as the priority list in medical devices from the perspective of trade using export-import data as available in the public

TABLE 5. Priority List of Medical and Diagnostic Devices Communicable Diseases

Communicable Disease	Priority List of Medical Devices
• Malaria, dengue, parasitic infections like filariasis, and hookworm infestation • Diarrheal diseases along with amoebiasis and cholera, and similar gastroenteritis, and typhoid • Tuberculosis, and fever-associated complications like influenza and leptospirosis • Jaundice and hepatitis, and similar diseases which affect the liver • Sexually transmitted diseases (gonorrhea, syphilis, human immunodeficiency virus, etc.)	• Microscopes • Rapid diagnostic test kits • Antibody testing (IgG and IgM) kits • Fecal matter examination kits • Complete Blood Testing kits (viz. kidney function test, liver function test) • DNA and protein-based test assays • Devices for serological techniques and Widal tests • Kits for biopsy including fluid and tissue • Endoscope, Colonoscope, Duodenoscope, and Sigmoidoscope • Ultrasound imaging Devices • X-ray imaging devices • Computed tomography scanner • Magnetic resonance imaging scanner • Female condom and cervical cap

TABLE 6. Priority List of Medical and Diagnostic Devices Non-communicable Diseases

Communicable Disease	Priority List of Medical Devices
• Malaria, dengue, parasitic infections like filariasis, and hookworm infestation • Diarrheal diseases along with amoebiasis and cholera, and similar gastroenteritis, and typhoid	• Microscopes • Rapid diagnostic test kits • Antibody testing (IgG and IgM) kits • Fecal matter examination kits • Complete Blood Testing kits (viz. kidney function test, liver function test) • DNA and protein-based test assays
• Tuberculosis, and fever-associated complications like influenza and leptospirosis • Jaundice and hepatitis, and similar diseases which affect the liver • Sexually transmitted diseases (gonorrhea, syphilis, human immunodeficiency virus, etc.)	• Devices for serological techniques and Widal tests • Kits for biopsy including fluid and tissue • Endoscope, Colonoscope, Duodenoscope, and Sigmoidoscope • Ultrasound imaging Devices • X-ray imaging devices • Computed tomography scanner • Magnetic resonance imaging scanner • Female condom and cervical cap

CAD = coronary artery disease; CT = computed tomography; COPD = chronic obstructive pulmonary disease; ECG = electrocardiogram; IHD = ischemic heart disease.

TABLE 7. Priority List of Medical and Diagnostic Devices on the Disease Burden Context for both Communicable and Non-communicable Diseases

Priority Common Medical and Diagnostic Devices
• Microscopes
• Rapid diagnostic test kits
• Antibody testing kits (IgG and IgM)
• Examination kits for fecal matter
• Complete blood tests (viz. kidney function tests, liver function tests)
• DNA and protein-based test assays
• Serological techniques and Widal tests
• Kits for biopsy including fluid and tissue
• Endoscope, colonoscope, duodenoscope, and sigmoidoscope
• Ultrasound imaging devices and probes (including intravascular ultrasound)
• X-ray imaging device
• CT scanner (including heart CT scanner)
• Magnetic resonance imaging scanner

Priority Common Medical and Diagnostic Devices
• Female condom and cervical cap
• Heart monitoring devices (ECG, Holter monitor, and event monitor)
• Echocardiogram device
• Nuclear stress test (radioisotope)
• C-arm (for cerebral angiogram, vertebral angiogram, carotid angiogram)
• Stents (drug eluting for angioplasty, cerebroangioplasty)
• Balloon catheters (angioplasty, cerebroangioplasty)
• Spirometer
• Mechanical ventilators and accessories
• Nebulizers and accessories
• Disposable resuscitators
• Portable oxygen units
• Automatic insulin pumps
• Syringes with needles
• Sutures and surgical instruments
• Blood bags and accessories
• Portable oxygen concentrators

CT = computed tomography; ECG = electrocardiogram.

domain. This list looked at medical devices apropos their HS codes. The Harmonized Commodity Description and Coding System, also known as the Harmonized System (HS) of tariff nomenclature is an internationally standardized system of names and numbers to classify traded products.

The entire export and import data of categorized medical devices were tabulated as per recent import figures compared against the past few years of export (Table 8). It was postulated that threshold or higher exports indicated self-dependency, higher affordability, and greater access. By opposition, the extreme or high import dependency denoted greater costs and lower accessibility. Figure 2 illustrates the two types of scenarios mentioned, A and B, respectively. The consolidated high import and low export-dependent devices (driven from the illustrative scenario B) were then highlighted and tabulated into segments that required an increase or improvement in internal manufacturing capability. Table 9 forms the other half of the dataset of the study from the trade perspective.

Further, two of the aforesaid priority lists (Table 5 and Table 9) were overlapped in a Venn diagram format, creating an intersection area of the priority list. The outcome

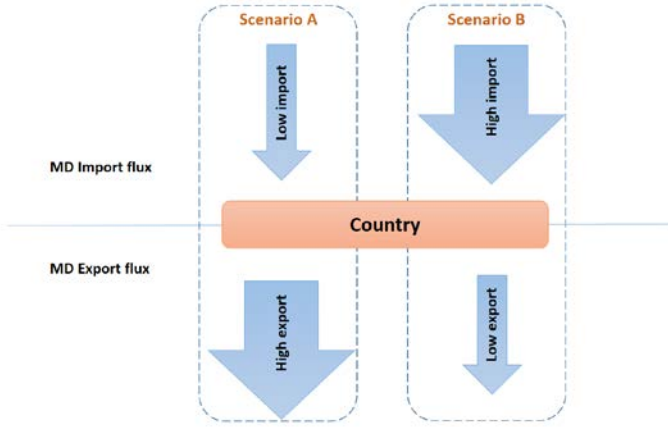

FIGURE 2. Diagram of the import and export data relationship in a country. Scenarios A and B are depicted, as resulting in a lower medical device (MD) cost and higher accessibility (Scenario A) and greater MD device cost and lower affordability. Illustrative scenario B is the focus model of the trade data in this study.

of this entire exercise (Figure 3) was then subjected to expert discussion. The expert group included public health experts, epidemiologists, academia, research scientists, and user specialists.

Using the listed medical devices in the priority list that qualified expert group approval, these medical devices were mapped to their current domestic manufacturing

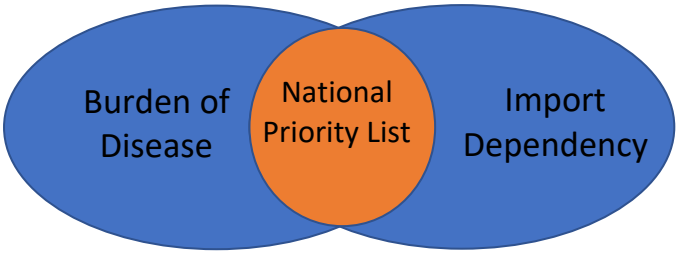

FIGURE 3. Consolidated modeling of the priority lists from the burden of disease and trade dataset to arrive at the national priority list.

TABLE 8. High Import Category of Medical Devices (Year 2014 – 2015, reference Directorate General of Foreign Trade, Government of India)

S No.	HS Code	Commodity	EXPORT - Year 2013-14 (million USD)	EXPORT - Year 2014-15 (million USD)	IMPORT - Year 2013-14 (million USD)	IMPORT - Year 2014-15 (million USD)
1	90189099	Other surgical instruments and appliances (including veterinary)	59.50	56.08	235.32	246.98
2	90185090	Ophthalmic surgical instrument and appliances	11.09	12.57	117.76	139.15
3	90272000	Chromatographs and electrophoresis instruments	5.03	5.04	104.34	132.97
4	90181990	Other electro - diagnostic apparatus	83.52	68.01	89.84	93.36
5	90181300	Magnetic resonance imaging apparatus	3.23	5.37	74.23	84.48
6	90181290	Other electro - diagnostic apparatus	30.10	83.65	68.31	80.02
7	90213100	Artificial joints	0.68	1.97	63.21	78.50
8	90221200	Computed tomography apparatus	0.52	0.67	70.84	65.03
9	90273010	Spectrometers	1.84	2.52	71.74	59.43
10	90271000	Gas analysis apparatus	4.27	11.00	46.96	58.10
11	90221490	Other X- ray machines for medical uses	84.13	40.14	53.77	52.71
12	90189019	Other diagnostic instruments	17.34	43.94	55.27	51.34
13	90223000	X-ray tubes	20.83	32.78	31.88	43.36
14	90189044	Endoscopes	4.32	6.17	31.14	40.09
15	90184900	Other instruments and appliances, USD in dental science	5.26	5.14	32.80	36.76
16	90189029	Other surgical tools	15.86	12.94	39.35	36.31
17	90221900	Apparatus based on use of x-rays, for other use including radiography/ radiotherapy apparatus	0.86	1.39	32.68	35.70
18	90183100	Syringes, W/N with needles	27.02	30.06	32.92	34.06
19	90183920	Cardiac catheters	1.66	4.22	33.75	32.24
20	30063000	Preparation material for X-ray exams; Diagnostic reagents designed to be administered to patient	8.55	7.96	23.07	23.62

capability. This was named as the Priority List of Health Technology and was used as a key approval criterion by a public agency for providing financial support for further research.

As some devices in the list could have domestic production viability for some of its components but would be completely dependent on exports for other components, it was also critical to understand which critical parts of components needed additional or focused research. To understand the key components of these technologies, two-day technology consultation was organized. This was named as "FIRST" (Formative Industry Leaders Research Institutes Start-up Partners Technology Meet) to identify essential components for focused research. The technology consultation included innovators, researchers, academia and industry, in which the shortcomings were highlighted and the technology development pathway discussed.

As part of the consultative process, a list of 108 Core Technology Components was identified. The list was then submitted to the concerned agencies within the government that provide funding for technology research. Requests for proposal for these were subsequently released by the

TABLE 9. Priority List of Medical and Diagnostic Devices from a Trade Deficit Perspective

S. No.	HS Code	Medical and Diagnostic Device Category
1.	90272000	Chromatographs and electrophoresis Instruments
2.	90221200	Computed tomography apparatus
3.	90221900	Apparatus based on use of X-rays, for other use including radiography/ radiotherapy apparatus
4.	90273020	Spectrophotometers
5.	90189011	Instrument and apparatus for measuring blood pressure
6.	90183220	Hollow needles for injection, aspiration, biopsy and transfusion
7.	90192010	Oxygen therapy apparatus
8.	90278010	Viscometers
9.	90278030	Instruments and apparatus for measuring the surface or interfacial tension of liquids
10.	30062000	Blood-grouping reagents
11.	90275010	Photometers
12.	90275030	Polarimeters
13.	90189024	Surgical tools, chisels, gauges, elevators, osteotome, craniotomy, bone cutters, etc.
14.	90229020	Radiation generation units
15.	90189033	Hemofiltration instruments
16.	90189097	Nephrostomy/lithotripsy instruments

public funding agency under the categories established as part of Priority List of Medical Devices for Research. The categories include: (1) Biochemistry, (2) Immunology (3) Hematology, (4) Histopathology, (5) Molecular Biology, (6) Genetics, (7) Imaging, (8) Catheters, (9) Ultrasound, (10) Neonatal Equipment, (11) Ventilators, (12) Renal Care, (13) Sutures and Scaffolds, (14) Non-cardiac Implants, (15) Endoscopy, and (16) Muscular dystrophy treatment.

The list elaborates three distinct categories of research priorities.

1. Health Technologies that are not domestically engineered and add to substantial import, high economic costs, and extremely relevant clinical utility.
2. Health Technologies that forms solutions for diseases that have not had solutions globally, such as muscular dystrophy and their research would be of both national as well as global significance.
3. Health Technologies that focus on disease/clinical conditions reflective of LMICs/specific geographies and whose research would not be priorities in any other geography – such as snake bites.

DISCUSSION

This study aimed to provide an evidence-based framework for priority setting to guide innovation in the healthcare sector. By analyzing a combined dataset of the top ten diseases that account for the most lives lost and trade impact in India, this study specifically developed a method to determine a priority list of medical devices to address both the rising burden of diseases and growing trade deficit in the medical technology sector. Traditionally, the role of policy-makers has been to focus mainly on appraising technologies that are already selected by the innovators for research due to knowledge or engineering capabilities available with the innovators. Therefore, the policy maker's role has been reactive and necessarily not reflective of actual healthcare needs. This methodology allows the policy maker's approach to shifting from being merely reactive to actively driving the agenda of technology development. To do this, it is necessary to find, based on data, what the sectoral needs for development are. To the best of our knowledge, this study is the first to develop a transparent and intuitive method to establish the National Priority List of Medical Devices Research. The results of this study are twofold. Firstly, the formulation of the model can be considered a result in itself. Secondly, the medical device list that resulted from the application of the model/method developed for India is another result.

For the first set of findings, such as the method/model creation, it is important to consider that given its intuitive steps it can easily be adapted to other national settings, for LMIC or even HICs. Similar models could also be applied in other contexts besides the medical device sector, after further testing, like for instance, in agriculture.

In this study, a group of 10 diseases (top five communicable and top five non-communicable diseases) was selected. For other broader studies, this number can also be higher, thus resulting in different scale of results.

Despite the high incidence of communicable diseases, non-communicable diseases account for more than half of the health crisis and are more life-threatening in nature in India.[13] The comparative weight of the type of diseases (communicable versus non-communicable) could also be taken into account when developing national priorities for research. To the best of the author's knowledge, the only comprehensive study to estimate summary measures of population health for the world, by cause, is the Global Burden of Diseases, Injuries, and Risk Factors (GBD) enterprise, which was updated by WHO for the years 2000 and WHO estimates were subsequently updated for the year 2004.[7] Later, WHO developed a comprehensive and consistent set of DALY estimates for years 2000–2012 for population, births, all-cause deaths and specific causes of death as well as WHO estimates for some specific diseases and analyses carried out for the Global Burden of Disease 2010 study. Thus, using data on causes of premature death, loss of health and disability in different populations' mortality and disability, other than a disease, would be valuable to enrich the model itself and the resulting list of priority medical devices. Thus, this methodology could be further improved depending upon the contexts and breadth of the application intended.

CONCLUSION

The findings of this study outline extrapolative projections for the future for population health,[14] based on certain demographic and trade assumptions. We use the word assumption with measured responsibility because irrespective of the plausible uncertainty, this is only an application of epidemiological data and its convergence with macro-economic indicators. This is expected to impact a generation of indigenous manufacturing and innovation that are need-driven, market-driven, as well as highly relevant for self-reliance in the context of pandemics. In turn, such innovation policy could guide the government to make strategic resource allocation, positively impact healthcare indicators besides improving manufacturing and employment. Similar models for other sectors/programs that require to be fueled by innovations is suggested for further research.

Governance of innovation has been influenced by very few methods and decision making is reactive to the understanding of technology at the point of product submission. Such proactive methods, one described through this study, could initiate a wider dialogue on resilient innovation policy which has become so much more pressing in times where all nations simultaneously experience enormous dependencies on the import of crucial medical devices.

REFERENCES

1. Eißel D, Rokicka E, and Leaman J. Welfare State at Risk: Rising Inequality in Europe: Springer International Publishing; 2013.
2. Amiri A and Ventelou B. 2012 Granger causality between total expenditure on health and GDP in OECD: Evidence from the Toda–Yamamoto approach. Econom Lett 2012;116(3):541–44.
3. Kelman CW, Bass AJ, Holman CDJ. Research use of linked health data — a best practice protocol. Aust N Z J Pub Health 2007;26(3):251–55.
4. Kim JY. Data for better health—and to help end poverty. Lancet 2012;380(9859):2055.
5. Pope C and Mays N. Qualitative Research: Reaching the parts other methods cannot reach: an introduction to qualitative methods in health and health services research. BMJ 1995;311(6996):42.
6. Murray CJL and Lopez AD. Alternative projections of mortality and disability by cause 1990–2020: Global Burden of Disease Study. Lancet 1997;349(9064):1498–504.
7. Murray CJL, et al. Disability-adjusted life years (DALYs) for 291 diseases and injuries in 21 regions, 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet 2012;380(9859):2197–23.
8. Lim SS, et al. A comparative risk assessment of burden of disease and injury attributable to 67 risk factors and risk factor clusters in 21 regions, 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet 2012;380(9859):2224–60.
9. Mahal A and Karan AK. Diffusion of medical technology: medical devices in India. Exp Rev Med Dev 2009;6(2):197–205.

10. Mahal A, Varshney A and Taman S. Diffusion of diagnostic medical devices and policy implications for India. Int J Technol Assess Health Care 2006;22(2):184–90.
11. Thatte U, et al. Evidence-based decision on medical technologies in Asia Pacific: Experiences from India, Malaysia, Philippines, and Pakistan. Value Health 2009;12(s3):S18–S25.
12. Chakravarthi I. Medical equipment industry in India: Production, procurement and utilization. Indian J Pub Health 2013;57(4):203–207.
13. Kinra S, et al. Sociodemographic patterning of non-communicable disease risk factors in rural India: a cross sectional study. BMJ 2010;341:c4974.
14. Chan M. From new estimates to better data. Lancet 2012;380(9859):2054.