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Health Economic- Industrial Complex	Healthcare Digitalization	Tuberculosis Control	Healthcare System Reforms	Path to Universal Health Coverage
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Dear colleagues and friends!

This is the first issue of *The BRICS Health Journal*, dedicated to the major global political event – the 16th BRICS Summit, during which the 14th Meeting of BRICS Health Ministers will be held in Moscow in October 2024.

BRICS, a consortium of nations established in 2006, currently includes Brazil, Russia, India, China, and South Africa, with Egypt, Iran, the United Arab Emirates, Saudi Arabia, and Ethiopia joined this year. The BRICS countries cover about one-third of the Earth's land surface and represent over 40% of the world's population.

Given the organization's vast scale, establishing a unified information space is critically important. The foundation of a joint medical journal is crucial, as it will serve as a platform for spreading medical knowledge in accordance with the latest global scientific advancements. We are honored with the historic mission of creating this journal!

Healthcare and medicine transcend borders. *The BRICS Health Journal* will serve as a meeting place for experts, practitioners, and researchers to share their experience in overcoming the challenges they face. The Ministry of Health of the Russian Federation and Sechenov University

play a key role in creation of *The BRICS Health Journal*. By involving a highly professional editorial team and adhering to international publishing standards, we aim to ensure our journal's high standing in the global ratings.

The BRICS Health Journal is a long-term project aimed at providing BRICS medical communities with a platform for sharing the expertise of leading experts across various fields of public health and medicine. The journal will act as a media channel, broadcasting the perspectives of the BRICS countries to a global audience.

We are confident that this new journal will bring together health experts, doctors and researchers from different continents, enabling them to make the most effective decisions – decisions that will undoubtedly save lives on our planet!

Editor-in-Chief

Minister of Health of the Russian Federation

Mikhail A. Murashko

A handwritten signature in blue ink, appearing to read 'M. Murashko', with a stylized flourish at the end.



Dear colleagues!

We are pleased to present you the first issue of *The BRICS Health Journal* proposed by the Minister of Health of the Russian Federation and supported by all countries of the BRICS.

The honor of publishing this journal has been entrusted to Sechenov University. With a history spanning 266 years, the university continues to preserve and enrich the legacy of both Russian and global medical education. Numerous international specialists, fortunate enough to have studied here, proudly consider Sechenov University their Alma Mater. The university's teaching staff, which has always been the pillar of Russian medicine, generously shares invaluable experience and knowledge with young persons who have chosen the noble and responsible profession of a doctor.

Modern medical education is inextricably linked with scientific advances. To facilitate the exchange of experience and the latest achievements in medicine, and to engage young people in the scientific and publication process, Sechenov University has initiated several publishing projects. The Sechenov Medical Journal and The

National Health Care (jointly with the Ministry of Health) have already gained renown not only in Russia but also in other countries, and are indexed in the global Scopus scientific database.

The new journal – *The BRICS Health Journal* – will be led by an expert team headed by the Minister of Health of the Russian Federation, Mikhail Murashko.

We hope that the new journal will serve as a valuable platform for accumulating the most up-to-date information in global medicine, contribute to the development of healthcare and medical science, foster cooperation between the BRICS countries, and ultimately improve public health.

*Deputy Editor-in-Chief
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The Brazilian health economic-industrial complex perspective: health as a strategic option for BRICS development*

Carlos A. Graboïs Gadelha, Mônica Felts de La Roca Soares, Felipe Kamia

*Text originally published as a chapter of the book Health is Development – Saúde é Desenvolvimento, in Portuguese¹. The text was revised, updated, and expanded for this article aimed at an international audience.

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ABSTRACT

The Health Economic-Industrial Complex (HEIC) is recognized as a fundamental pillar for the Welfare State, essential for ensuring universal health access and reducing the vulnerability of Brazil's Unified Health System. This paper argues that the HEIC must be positioned as a key vector in the national development strategy, linking the reconstruction of Brazil's economy with social development, science, technology, innovation, and environmental sustainability. These strategies collectively work towards building a dynamic, just, and democratic Brazil. Furthermore, it presents how Brazil, under Lula Presidency, incorporated HEIC in a set of public policies aiming to strengthen the production and innovation in health to increase the Brazilian Health System resilience and increase health access to Brazilian population. Furthermore, the paper explores how the principles of the HEIC can be adapted to the BRICS context. By leveraging this model, BRICS nations can address global health disparities and enhance their capacity to produce vaccines, treatments,

¹ Gadelha CAG, Gimenez DM, Cassiolato JE, eds. Saúde é Desenvolvimento: O Complexo Econômico-Industrial da Saúde como Opção Estratégica Nacional. Rio de Janeiro: Fiocruz – Centro de Estudos Estratégicos Antonio Ivo de Carvalho; 2022. ISBN: 978-65-87063-21-8. [in Portuguese].

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diagnostics, and other critical health technologies. Ultimately, this paper advocates for the bold reimagining of the HEIC as a transformative force in BRICS countries capable of driving structural changes in both national and global health landscapes, promoting a healthier, more equitable, and sustainable society.

Key Words: Health Policy; Global Health; Sustainable Development; Technological Innovation; Health Economics

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The economy at the service of life

Health can – and should – become a new vector for Brazil's development in the 21st century. It has the potential to address economic, social, and environmental challenges. In the past, the focus was on steel, oil, and automobiles. Today, however, the Health Economic-Industrial Complex (HEIC) emerges as a strategic bet for the country. It offers a pathway to resume growth and overcome social regression and structural dependency.

The painful experience of the COVID-19 pandemic, which resulted in the loss of over 680,000 lives, highlighted the limited way in which the relationship between the economy and society has been treated in the national debate. The Unified Health System (in Portuguese: Sistema Único de Saúde, SUS) and the Welfare State have proven to be valuable societal achievements that can solidify as a great opportunity for Brazil's development, going beyond compensatory measures.

In its bicentennial of independence in 2022, Brazil was under immense socio-economic pressure. The economy did not grow, the environment was increasingly degraded, the state was disorganized, and the basic needs of the population were not met. This situation brought back the challenge of thinking about how to build a national project that promotes economic growth, equity – both social and regional, and environmental sustainability.

Lula's third term presidency (since 2023) is reconstructing the Brazil he had left in his second term that ended in 2010. The scenario left by Bolsonaro's presidency (2019–2022) was devastating. Amid a context of profound global transformations, Brazil was engulfed in an intense economic, social, and environmental crisis. In a country that once ranked among the six most important economies in the world, hunger skyrocketed to 33.1 million people by 2022 [1], with unemployment figures around 10 million².

Furthermore, the increasing precariousness and underemployment affected a growing number of families. These were the most visible consequences of the low economic dynamism and the sharp deindustrialization of the Brazilian economy. This economic decline was accompanied by the advance of deforestation, ecosystem contamination, and biodiversity loss.

In 2023, 24.4 million people in Brazil were lifted out of hunger, marking a significant achievement in the country's ongoing battle against food insecurity. This milestone reflects the success of targeted social policies

² Instituto Brasileiro de Geografia e Estatística (IBGE). PNAD Contínua. Rio de Janeiro: Instituto Brasileiro de Geografia e Estatística (IBGE) website. Published 2022. Accessed August 15, 2024. (in Portuguese). <https://www.ibge.gov.br/en/home-eng.html?lang=en-GB>

and programs implemented by the Brazilian government, which focus on reducing poverty and ensuring that the basic needs of the most vulnerable populations are met. These efforts are part of a broader strategy to rebuild social welfare systems and restore dignity to millions of Brazilians, reinforcing the nation's commitment to eradicating hunger and promoting inclusive development³.

This article proposes that the economy should support the material conditions necessary for sustaining life, both for people and the planet. To improve the quality of life, the national productive system must have the technical and scientific capacity to meet society's demands. Development and innovation drive the structural changes needed to guarantee universal access to social rights and ensure environmental sustainability.

Putting the economy at the service of life allow us to overcome the false dichotomy between the social, environmental, and economic dimensions. It directs the economy towards generating income, investments, and qualified jobs to support a prosperous, just, and democratic society. A sustainable society, committed to well-being, is only possible with a national economic and material base that supports this vision of a democratic society.

This perspective concretely guided the formulation of an agenda to support public policies for the development of the HEIC, integrating the national economic system with the organization of the SUS and Welfare system. The goal is to contribute to a national development project that simultaneously pursues economic dynamism, environmental sustainability, and social well-being, while engaging in global processes grounded in sovereignty, solidarity, and the right to life for different peoples and regions.

As we move forward in this article, the subsequent sections will delve deeper into the role of the HEIC in driving Brazil's development strategy. The next section will explore the significant social, economic, and environmental transformations shaping the global and national contexts; furthermore, how these impact Brazil's SUS. We will examine the critical role of the state in fostering innovation and economic resilience within the HEIC by discussing policy proposals that align with Brazil's long-term development goals. Lastly, we will expand the discussion to a broader international perspective, highlighting how the principles of the HEIC can be integrated into the BRICS framework to address global health disparities and promote equitable access to health technologies across member states.

Health Amid Social, Economic, and Environmental Transformations

Brazil and the world are undergoing a series of transformations that could significantly impact health. These transformations include demographic and epidemiological shifts, the fourth industrial and technological revolution, growing globalization and financialization, and the risk of economic stagnation. Additionally, changes in the labor market, climate change, and biodiversity loss are also contributing factors. In the context of a crisis in the international economic system and escalating geopolitical tensions, these changes have deepened social and territorial inequalities, as well as economic and technological asymmetries. Furthermore, they have profoundly impacted health systems, leading to unavoidable effects on the SUS.

³ 24.4 milhões de pessoas saem da situação de fome no Brasil em 2023. Ministério do Desenvolvimento e Assistência Social, Família e Combate à Fome (MDS) website. Published April 25, 2024. Updated April 25, 2024. Accessed August 15, 2024. [in Portuguese]. <https://www.gov.br/mds/pt-br/noticias-e-conteudos/desenvolvimento-social/noticias-desenvolvimento-social/24-4-milhoes-de-pessoas-saem-da-situacao-de-fome-no-brasil-em-2023>

In the coming decades, according to the IBGE⁴, the country will undergo profound demographic and epidemiological changes. In around twenty years, the population is expected to reach around 230 million inhabitants, and the number of people over 60 years old will increase from 25 million to 50 million, representing more than 21% of the population. Within this group, the population over 80 years old will reach nearly 9 million people.

The increase in population longevity represents significant societal achievements, but it also brings about social, technological, and economic challenges that inevitably project future commitments for the state. The demographic transition will result in increased demand on the welfare system, especially in the healthcare systems, in a country where the population already faces serious issues related to nutrition, housing, sanitation, employment, transportation, and access to basic citizenship rights.

Epidemiological complexity will deepen in the coming decades, with the increasing prevalence of chronic diseases in the overall disease burden. However, this will not be a linear transition, as communicable diseases, external causes, and health emergencies will continue to exert pressure on the SUS [2, 3]. These trends together create a scenario of growing epidemiological complexity, reshaping the demand for healthcare attention, promotion, and prevention in the 21st century⁵.

The profound demographic and epidemiological changes are occurring in parallel with the advancement of the fourth industrial and technological revolution. The use of biotechnology, artificial intelligence, big data, genetic editing, additive manufacturing, nanotechnology, and the Internet of Things forms a block of innovations that decisively impact the health field, bringing both significant threats and potential opportunities.

The recent global technological transformations, driven by the Fourth Industrial Revolution, have deepened the economic and technological asymmetries between nations, highlighting the persistence of the center-periphery pattern. In the field of health, these changes present significant challenges to the sustainability of SUS. The increasing external dependency of the HEIC reflects a structural vulnerability that could undermine the country's ability to ensure a universal, equitable, and comprehensive health system – as envisioned by the principles of SUS.

Given this scenario, it is crucial to understand how the dissemination and direction of technical progress in health, influenced by global economic and geopolitical factors, directly affect Brazil's ability to develop effective public policies for universal access to health. The analysis of technological asymmetries reveals that nations dominating the global technological standard also exert geopolitical dominance that extends to social policies – particularly health policies. Therefore, overcoming these structural barriers is essential for advancing SUS and building a resilient and sustainable health system in the Brazilian context [4].

The interconnectedness enabled by 4.0 technologies involves the incorporation of new fields of knowledge and sectors of activity within the HEIC, driven by an intense movement of automation based on networks of intelligent machines. The spread of digital technologies has led to the blurring of boundaries between sectors and fields of knowledge, causing a radical shift in the systemic nature of the economic space and capital accumulation in health.

⁴ Instituto Brasileiro de Geografia e Estatística (IBGE). Projeções da população: Brasil e unidades da federação: revisão 2018. Rio de Janeiro: Instituto Brasileiro de Geografia e Estatística (IBGE) website. Published 2018. Accessed August 15, 2024. [in Portuguese]. <https://www.ibge.gov.br/estatisticas/sociais/populacao/9109-projecao-da-populacao.html?edicao=21830&t=publicacoes>

⁵ Lima NT, Gadelha C. Non-communicable diseases: a challenge for global cooperation. SDG Action website. Published June 14, 2021. Accessed August 15, 2024. <https://sdg-action.org/non-communicable-diseases-a-challenge-for-global-cooperation/>

New technological possibilities for health promotion, prevention, and protection highlight a true cross-cutting process of "creative destruction" in the health field, posing a significant challenge for the SUS to be solidified as a universal system. In the realm of work and employment in health, activities related to the HEIC, particularly care, and attention services will continue to be major generators of qualified jobs. However, new occupations will emerge, and the existing ones will be transformed, what will incorporate new skills. The training of health professionals will need to become increasingly interdisciplinary, with a particular focus on equipping them to operate new digital technologies that enhance attention and humanized care in health services.

The recent set of transformations also decisively impacts the world of science, technology, and innovation in health (ST&I in health). The widespread diffusion of 4.0 revolution technologies opens the possibility for new forms of knowledge production, rooted in trans disciplinaryity and oriented towards the challenges of health and sustainability, reinforcing the centrality of ST&I to the economy, well-being, and sustainability. At the same time, the challenge of funding basic research activities, which are fundamental for the advancement of scientific knowledge, remains.

Understanding the challenges posed by this set of social and technological transformations on the SUS and HEIC – in a realistic and pragmatic way – requires considering the concrete context in which they occur. On the international stage, the geopolitical context is one of climate emergency, the deterioration of the global cooperation environment, deepening financialization, the expansion of the power of large transnational corporations, in addition to increasing inequalities, asymmetries, and inequities.

The escalating tensions between blocs led by the U.S., China, and Russia point to the emergence of a multipolar international order, particularly after the COVID-19 pandemic. In the international economy, we see an unprecedented deepening of the power of financial institutions alongside the rise and expansion of digital monopolies. This trend is evident in the market concentration among giant companies – like Google, Amazon, Facebook, and Microsoft –, and in the fact that just three investment fund management institutions – BlackRock, Vanguard, and State Street – are the largest individual shareholders in approximately 90% of the world's top 500 companies.

This movement significantly impacts health. Health-related activities, including primary care, have become crucial expansion fronts for large global corporations, manifesting a process where industrial logic invades all productive spheres – including services – in line with the perspective that has guided the development of the HEIC since its inception.

In this context, the dominance of scientific, technological, and innovation capabilities is intensifying. Approximately 88% of health-related patents come from just ten countries. The U.S. and China alone account around 53% of health patents under the Patent Cooperation Treaty and 44% of health 4.0 patent families. This asymmetry in the production of scientific knowledge and technological innovations in health, coupled with a weakened productive base, tends to translate into inequities in access to healthcare, as evidenced during the pandemic [5], updating the perspective for the contemporary context of technological transformation and the challenges faced by universal health systems and Brazil's SUS.

In the COVID-19 Pandemic, the Secretary-General of the United Nations stated that "the global political and economic system is not delivering vital global public goods: public health, climate action, sustainable de-

Table. Main ongoing transformations and their impacts on the health field

Transformations	Impacts on the Health Field
Demographic transition and health needs	The situation of epidemiological complexity will deepen. Longevity and aging of the population with increasing weight of chronic diseases in the burden of disease and strong presence of communicable diseases and external causes.
Revolution 4.0	Radicalization of the systemic health space and the introduction of innovations open challenges and opportunities for the organization of health systems and for universal access.
Financialization	Risk of the R&D strategy moving away from welfare, dismantling the innovation of universal, equitable, and integral access. Increasing tension between the collective and individual dimensions of health.
Conglomeration	The large concentration and centralization of capital in economic conglomerates translate into little diversity and high asymmetry in the production and innovation base for health.
Science, Technology, and Innovation in Health	Centrality of ST&I to respond to health challenges. Global discussion on new forms of scientific production focused on social and sustainability challenges.
Transformations in the World of Work	Health will remain as a great front for generating quality jobs. Potential for substantial transformation in health occupations, requiring more interdisciplinary training, including that of professionals from other areas to work in health.
Increased geopolitical disputes and appreciation of the territory	Health as a factor of sovereignty. Regional, national, and local productive and innovation capacity in critical areas, such as health, gains relevance.
Climate change	Intense climate events, emergence of new pathogens and other effects of climate change should put health systems in a state of permanent health crisis.
Growth of inequalities, asymmetries and inequities	Increased hunger, precariousness, climate injustice intensifies health vulnerabilities (social determinants of health). Asymmetry in knowledge, productive capacity and innovation become inequities in access to health.

velopment, peace"⁶. Despite multilateral access mechanisms like the Covax Facility being crucial for ensuring vaccination in low-income countries, the technological-industrial asymmetry has resulted in a disproportion in the very right to life, as highlighted in an editorial by the journal *Lancet* [6]. By the end of 2021, while countries with productive capacity like Brazil and the European Union had fully vaccinated more than 70% of their populations, low-income countries without health production capacity had vaccinated less than 5% of their populations [7].

"Inequality defines the era we live in" [4]. While the richest 1% captured 38% of the global wealth growth over the past 25 years and accounted for 15% of global carbon emissions between 1990 and 2015, the poorest 50% received only 2% of the wealth⁷ and contributed to just 7% of emissions⁸. Economic inequalities are closely linked with social vulnerability and climate injustice, each one influencing and being influenced by the others.

Amid the growing inequalities, an environmental consciousness is emerging and solidifying. The signing of the Paris Agreement and the launch of the Sustainable Development Goals demonstrate how global economic, social, and political actors are moving to address the "contradictory dynamic between the expansion and accumulation of capital and the system's inherent tendency to generate asymmetries, exclusion, inequality, loss of social legitimacy, and unsustainability" [8].

The transformations presented, summarized in Table, pose significant challenges for the realization of universal health access in Brazil. If these global movements are not understood and integrated into the field of so-

⁶ Guterres A. Encarar a pandemia da desigualdade. Um novo contrato social para uma nova era. Conferência Anual da Fundação Nelson Mandela, Nova York. Naciones Unidas website. Published July 18, 2020. Accessed August 15, 2024. (in Portuguese). <https://www.un.org/es/coronavirus/articles/tackling-inequality-new-social-contract-new-era>

⁷ World Inequality Lab (WIR). World Inequality Report 2022. World Inequality Lab website. Published 2022. Accessed August 15, 2024. <https://wir2022.wid.world/>

⁸ Oxfam. Confronting Carbon Inequality: Putting Climate Justice at the Heart of the COVID-19. Recovery. Oxfam website. Published September 21, 2020. Accessed August 15, 2024. <https://oxfamlibrary.openrepository.com/bitstream/handle/10546/621052/mb-confronting-carbon-inequality-210920-en.pdf>

cial policies and development, the result will be the perpetuation of a compensatory pattern of public policies, while the reality escapes a strategic, structural, and efficient approach that harnesses the opportunities of the new technological paradigms in progress.

Analyzing the cited trends is essential not only to forecast the future of health, but also to guide present actions in development policies. Brazil's ability to respond to the challenges in health and the SUS requires reflection and the construction of a "new state" that places the economy in the service of life, equipped with the capacity to promote economic, social, and environmental development.

The National State will continue to play a fundamental role. It is necessary to analyze the historical-structural process that shaped past policies and contextualize it to understand the degree of freedom and the capacity to execute structural policies in the present. Institutional arrangements and instruments should be considered to articulate measures that: stimulate investment; design economic subsidies for strategic projects; create and participate in national companies; actively and assertively use purchasing power by treating the domestic market as a national asset and a control of foreign capital entry; among others.

The National State must be capable of formulating and implementing systemic and structural policies – contextualized and coordinated across various territorial scales – to address the different territories and regions of the country. The sociocultural and environmental diversity present in Brazil is a potential source of diverse knowledge and solutions for national problems.

The most challenging step is to adopt a perspective that captures the interdependent nature of production and societal organization models with the environment. Strengthening the SUS, as it becomes a national challenge, can mobilize the utopian energies necessary to support the construction of a Welfare State in Brazil [9, 10].

The economic dimension of productive transformation is crucial for achieving this goal. The reconstruction of a technology-intensive national economy and industry should be viewed as a central aspect to ensure that accessing social rights does not remain a privilege for a minority, whether by providing the material support for universal health access or through the economic dynamism that this project generates.

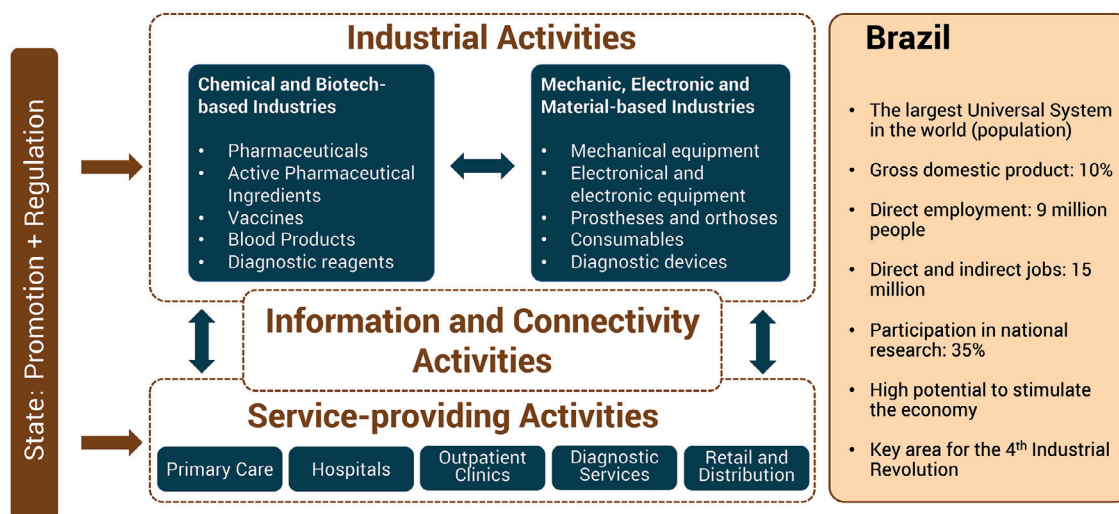
The next section presents how the perspective of the HEIC, which places the economy in the service of life, can underpin a process of structural change that promotes economic dynamism, social inclusion, and environmental sustainability amidst the challenges and opportunities generated by contemporary transformations.

The Perspective of the Health Economic-Industrial Complex

The 1988 Federal Constitution approved a significant expansion of social rights in Brazil, particularly relevant being the universalization of the SUS, which importance was highlighted during the COVID-19 pandemic. The successful public actions in defense of life – especially the immunization of the population – increased the perception of the social value of public institutions such as SUS, the largest universal health system in the world. However, there is still much progress to be made to ensure universal, comprehensive, and equitable access for all Brazilians.

The perspective being advocated, which has been developed at Fiocruz over the past twenty years, highlights the analytical and political interdependence between the economic, social, and environmental dimensions of development [8, 11, 12].

FIG. Contemporary Morphology of the Health Economic-Industrial Complex: A Systemic Approach in Health Production and Technology



According to the conception of one of Brazil's greatest social thinkers, Celso Furtado, development is a process of structural change in which the introduction of innovations transforms the productive and technological base to meet the growing needs of society [13]. Without productive transformation and technological innovation, access to citizenship rights will remain restricted to a privileged minority of the population. The scientific and technological base, along with economic and productive autonomy, are pivotal to ensure access to essential rights, as evidenced in the context of the pandemic.

In the research program of the HEIC, health is viewed as a clear and prominent space for the reproduction of capitalist dynamics in its tense articulation with life, politics, and society, overcoming fragmented and sectorized views that sometimes treat it as an externality (or merely as human capital), or as a specific and insulated field of social policies. The COVID-19 pandemic underscored the importance of treating health as a space for development – economic, social, and environmental –, overcoming false and linear dichotomies between these spheres.

The morphology of HEIC presented below (fig.) represents a systemic approach to health production and technology, integrating various industrial and service-providing activities under the coordinated promotion and regulation of the state. This complex includes industries based on chemicals, biotechnology, mechanics, electronics, and materials, which produce a wide range of essential health products such as pharmaceuticals, active pharmaceutical ingredients, vaccines, blood products, and diagnostic reagents. These industries are interlinked with service activities, including primary care, hospitals, outpatient clinics, diagnostic services, and retail and distribution networks, all of which are supported by advanced information and connectivity systems.

Brazil has the largest universal health system in the world and a powerful productive and innovative health system that mobilizes about 10% of the gross domestic product; furthermore, the health system represents one-third of the scientific and research effort and is strongly aligned with 4.0 technologies. It is also a privileged space for generating investment, income, and jobs, accounting for approximately 10% of occupations [14] and 25 million direct and indirect jobs [5].

However, the development of the HEIC has not kept pace with the growing health needs of Brazilian society. The commitment to ensuring universal, comprehensive, and equitable access in a country of continental dimensions creates a demand proportional to the challenge of guaranteeing health promotion, prevention, and care on a national scale, which far exceeds the installed national productive and technological capacity.

The analysis of the evolution of health trade relations in Brazil highlights a structural trend of increasing mismatch between the health needs of the population and the productive base that supports them. This reality, however, does not arise spontaneously in the country. On the contrary, it is a result of a passive and subordinate integration into the international geopolitical landscape, which dynamics lock peripheral countries in a path of dependence in the process of generating and use of knowledge. Inequality and capitalist polarization manifest in the formation (or reaffirmation) of an essentially asymmetric and unequal global order.

As emphasized in the tradition of Latin American social thought, economic and social backwardness are interconnected. This idea is now recognized by many schools of thought, including Harvard's complexity school and the neo-Schumpeterian approach. Economic and social backwardness can be understood as distinct dimensions of the same problem: underdevelopment. This issue manifests internationally as asymmetries between countries and nationally as structural heterogeneities.

The reproduction of a primary-exporting and poorly diversified economic structure limits growth potential and makes social policies vulnerable to external relations. External constraints are structural, with the balance of payments being the major expression of dependence and technological backwardness [15]. On the other hand, this simultaneously reflects in chronic labor market issues and the vulnerability of social policy, confining the social sphere to its compensatory functions, without the capacity to become a dynamic element.

Although the economy may experience growth cycles – as seen during the industrialization periods of the 20th century and more recently in the 2000s – the structural problems related to technological and productive dependence persistently manifest, exacerbating the condition of economic and social vulnerability.

The pandemic crisis made this perspective clearer in the health field. The fragility of the national productive-technological base became evident during this time. This fragility resulted from the deindustrialization process and the pronounced re-primarization of the Brazilian economy over the past five years. The shortage of basic products highlighted the unsustainability of this position of dependence.

It is unsustainable not only from an economic development standpoint, but also as a matter of sovereignty and health security. The insufficiency of the productive-technological base, resulting from the specialization of production in lower value-added products, explains the country's difficulty in overcoming the technological asymmetry in relation to the global economy; besides that, it is reflected in the inequality and segmentation of access to health goods and services, creating objective obstacles to the expansion of SUS. In other words, the possibility of "consuming without producing" is not compatible with a democratic society where social rights are shared by all.

This discussion must be expanded to consider the development of the economic, productive, and technological base in health – the Health Economic-Industrial Complex – as a structural factor for the sustainability of SUS and for transforming the prevailing development pattern in the country.

From the perspective of the HEIC, the intentionality of agents, the actions of society, and the role of the state have a decisive weight in transforming the pre-existing conditions. Without this, the productive system and social structure may remain locked in the past. It is not merely about understanding that economic growth and income distribution contribute to social policies or that these are functional to economic development through the provision of externalities. Rather, it is about considering how capitalist dynamics reproduce within welfare systems, conditioning public policies.

Considering Brazil's continental dimensions and the strength of its domestic market to drive diversification and the internalization of dynamic productive sectors, the decisive question arises: what economic, industrial, social, and political base simultaneously conditions the establishment of dense welfare and technological development structures?

A new type of development is necessary, one that is dynamic and strongly oriented toward social equity and environmental sustainability. To achieve this, countercyclical and compensatory policies are necessary, but insufficient. Considering the current crisis and challenges, profound structural transformations are required to create space for the expansive forces that are currently severely restrained, to the detriment of the vast human improvement possibilities offered by scientific and technological advances.

Health as a Vector for Brazil's Development in the 21st Century

Health is a universal right of citizenship, enshrined in the Brazilian Constitution, while also is a central arena for economic interests and the exercise of global geopolitical power. To face the SUS challenges as a universal system, a bold project and a new set of public development policies tailored to the challenges of the current historical moment is necessary.

In the face of the profound transformations underway, a universal, equitable, and comprehensive system requires an increasingly sophisticated productive and technological base that can address all aspects of care and serve the entire population. The systemic nature of health production and access demands public policies that consider the interdependence between social, industrial, environmental, and ST&I policies, as well as the construction of new instruments to coordinate the multiple interests present in the health sector.

It is the coordination by the state that strategically guides the development of the HEIC, regulating the private sector, strategically engaging where the market competes in high technology and high-value products, and where the market has no immediate interest – despite public interest.

There is a need to move towards a dynamic, systemic, and strategic vision that captures the opportunities for national development by articulating social demand with the domestic market and leveraging the economic power of SUS.

Development entails a profound transformation of the productive structure which, when oriented toward universal access in a country as vast as Brazil, can become a major front for development. Caring for people, reflected in the expansion and qualification of healthcare, can become a driving force for the expansion of industrial and service sectors, allowing for the densification of the productive fabric and aligning the productive-technological structure with the social demand for health. Given the scale of SUS, these new areas of activity, being intensive in qualified labor and following sustainable technological pathways, have the poten-

tial to be at the core of development policies, promoting spillovers and structural changes.

It is within this dimension that the development of the HEIC emerges as a crucial space for a profound change in the national development pattern. When strengthened with production, technology, science, and innovation, generating income and qualified jobs, SUS can serve as a platform with the scale and dynamism needed to sustain long-term development in Brazil. The great strategic challenge is precisely to enable an articulated expansion and transformation of the entire health productive system; simultaneously, it's necessary to meet the expansion of universal actions and services, and the development of the national productive and innovation potential.

Well-being, caring for people, and caring for the environment can be the key to sustaining structural changes in Brazilian society. The Brazilian state and SUS institutions must build the capacity to act in a complex, systemic, and strategic manner, oriented towards the needs of the population.

Theoretical and political formulations based on narrow views see the Welfare State as an expense. These views contribute to the chronic underfunding of the SUS and to a merely compensatory perspective of its role. The SUS is a powerful universal system that operates from basic care to high-tech procedures. It runs programs that are internationally recognized, developing and producing knowledge, products, and services for the entire Brazilian population.

Among countries with universal health systems, Brazil has the lowest proportion of public funding for health actions. While in European countries at least 70% of these actions are funded by national governments, in Brazil, public health spending is around 40%. It is both possible and desirable to overcome this contradiction by promoting the expansion of public funding through actions that strengthen national production and enable a virtuous arrangement for the development of the HEIC aimed at universal access.

It is time for boldness, to take the risks of new approaches, and, progressively and collectively, to seek a vision that provides the foundation for a new development project that incorporates a profound change in the state's mode of operation. This is the essential condition for society not to be misled by one-size-fits-all solutions and to – once again – embrace utopias and transformative energies with a view to build a dynamic, just, and democratic country.

Health can and should lead this great front of transformation, which requires expanding the paradigms to treat the health sector as a strategic bet for the country in driving structural changes. Just as oil, steel, and automobiles were engines of development in the 20th century, health has the potential to be one of the vectors of expansion in the 21st century in Brazil, embodying a model of society capable of addressing climate change, the need for income and job growth, innovation, and the strengthening of national production. To achieve this, it is essential breaking conceptual paradigms, daring to take risks, embracing diversity and contradiction at all levels, and integrating different areas of knowledge and public policies.

Health Economic-Industrial Complex in action: Driving Healthcare Transformation in Brazil

The Brazilian Government, since the beginning of Lula administration, adopted the HEIC perspective that Health is Development. The Ministry of Health has been engaging with multiple institutions and actors, public

and private, to revisit policies of previous administrations, recreate and improve the health industrial and innovation policy, adapting to the old and the new challenges of the XXI century.

For this purpose, President Lula launched, in September 2023, the National Strategy for the Development of the HEIC. The Strategy aims to guide public and private investments in local production and innovation in health to reduce vulnerability and expand access to the Unified Health System (SUS). It is based on the diagnosis that the development of productive capacity in health in Brazil to meet the health needs of the population constitutes an engine of national development, generating investment opportunities, income generation and the creation of quality jobs. On the launch of the strategy, President Lula declared: "What is happening today is the realization of a dream that we have been dreaming for a long time. It is more than a program to create a health industry, we are creating a country ... Brazil decided to become a great nation by defining sovereignty as a country that prioritizes the quality of life."

The Matrix of productive and technological challenges in health is the main guide of the National Strategy for the Development of HEIC, signaling to society and the group of economic agents involved in production and innovation in health the strategic challenges to improve the resilience of the SUS and expand access to health in Brazil. The matrix is presented in two blocks:

1. SUS preparedness for health emergencies, including those associated with climate change, and
2. SUS critical diseases and conditions.

The strategy encompasses five structuring programs: Partnerships for Productive Development Program (Programa de Desenvolvimento Produtivo, PDP, in Portuguese); Local Development and Innovation Program (Programa de Desenvolvimento e Inovação Local, PDIL, in Portuguese); Program for Preparation in Vaccines, Serums and Blood Products; Production and Technological Development Program for Neglected Populations and Diseases; and Program for the Expansion and Modernization of the Infrastructure of the Economic-Industrial Health Complex.

Each program involves different areas, actors, and instruments to achieve the objective of expanding national production, facing the challenges of the SUS, and expanding Brazil's sovereignty in the development and production of inputs, medicines, vaccines, and other health products, aiming to promote universal access to health.

Among the main advances are the updating of the regulatory framework of the Partnerships for PDP and the creation of the PDIL. The PDPs were a successful example of public-private partnerships between public laboratories and private companies to expand access to strategic products for the SUS and strengthen the Brazilian HEIC. The Ministry of Health of Brazil guarantees access to the public market to the partnership for 5 to 10 years, provided there is a technological transfer of the product in question from the private partner to the public. The PDIL, on the other hand, is the new program created to use the purchasing power of the State to foster the development of innovations and productions in health in the Brazilian territory.

The Strategy for the Development of the Economic-Industrial Health Complex is articulated with the New Industry Brazil, the new Brazilian industrial policy, which seeks to drive the country's neo-industrialization and ecological transformation. The strengthening of HEIC to reduce the SUS's vulnerabilities and increase health access is one of the six missions established by the new Brazilian industrial policy.

To fulfill this mission, the New Industry Brazil set the mobilizing targets to domestically produce 50% of the country's needs in medicines, vac-

cines, medical equipment, and other health technologies by 2026, and 70% of health needs by 2033. These goals emphasize the importance of enhancing Brazil's productive capacity to support the SUS and ensure health sovereignty.

The adoption of the HEIC perspective contributed to improving expectations and confidence in the private and public sector, resulting in the largest public investment in Brazilian HEIC in the history. These Investments are facilitated through the PAC (Programa de Aceleração do Crescimento in Portuguese) HEIC, which focus on reconstructing Brazil's infrastructure to health technology production and innovation.

To coordinate this set of initiatives, the Brazilian government recreated the Executive Group of the HEIC, an interministerial governance group led by the Ministry of Health, with the participation of public and private entities and civil society. The executive group is the locus for the institutional coordination of HEIC policies, articulating with the different actors and institutions related to innovation and production in health, including regulatory and financing institutions.

These initiatives position the HEIC as a key driver of sustainable development, with the potential to generate high-quality jobs, foster innovation, reduce territorial inequalities and increase Brazil's global competitiveness.

Health Economic-Industrial Complex approach: A Strategic Opportunity for BRICS

The adoption of HEIC perspective, that posits that health is development, presents a compelling model to BRICS nations to address the disparities in global health technology access. The BRICS countries – with their unique combination of emerging economies – have the potential to lead a transformative movement of local production and R&D in health technologies. By integrating the principles of HEIC perspective, considering the specificities of each BRICS countries, can enhance their collective capacity to produce vaccines, treatments, diagnostics, and other essential health technologies, thereby reducing their dependence on external sources and ensuring greater health sovereignty.

Brazil's experience in coordinating public policies based on the HEIC perspective offers valuable insights that can be adapted to the BRICS context. By focusing on the development of local and regional production capacities, the BRICS nations can collectively strengthen their health systems, ensuring that even the most vulnerable populations within their borders have access to critical health technologies. This approach aligns with the broader objectives of BRICS to promote equitable and sustainable development across member states.

The BRICS countries, known for their scientific and technological advancements, can use the HEIC perspective to bridge the innovation gap between developed and developing nations. Moreover, by fostering cooperation in research and development and promoting technology cooperation among member states, BRICS can enhance their collective capacity to respond to global health emergencies. This collaboration would not only improve health outcomes, but also would drive economic growth by creating jobs, stimulating local industries, and fostering innovation within the BRICS countries.

Final considerations

The strengthening of the HEIC should be recognized as a fundamental pillar for Brazil's development, ensuring universal health access, and re-

ducing the vulnerabilities of the Unified Health System (SUS). As the BRICS countries seek to address disparities in global health technology access, they can adopt the principles of the Brazilian experience, enhancing their capacity to produce vaccines, treatments, diagnostics, and other health technologies, reducing dependence on external sources and ensuring greater health sovereignty. This approach not only strengthens the health systems within BRICS nations, but also fosters economic growth by stimulating local industries and driving innovation.

By fostering cooperation in research, development, and technology transfer, BRICS can collectively respond to global health emergencies. This collaboration not only improves health outcomes, but also positions BRICS as a more influential force in global health governance, challenging existing inequities and advocating for equitable access to health technologies on a global scale.

In conclusion, adopting the HEIC perspective that health is a vector of development, can promote a transformative agenda that builds a dynamic, just, and democratic future, ensuring health equity and sustainable development for all.

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Digital transformation of healthcare in the Russian Federation

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ABSTRACT

The history of creating and using various information and communication technologies for medicine and healthcare in Russia dates back to the 1950s–1960s, when the first scientific research was launched in the USSR and the first practical developments and proprietary technologies were created. The creation and application of the first software products was aimed at the collecting and automating statistical reports and partial automation of auxiliary departments, such as accounting, personnel departments, etc. In the early 2000s, Russia began to form a commercial market of specialized software for medicine and healthcare. In 2011, by order of the President and with the active participation of the professional community, the Russian Ministry of Health and Social Development launched a federal project to create a “Unified State Information System in Healthcare”, which became the starting point for the mass introduction of various information systems in the healthcare sector of the Russian Federation. In 2019, the federal project “Creation of a unified digital health care circuit based on Unified State Information System in Healthcare” was launched in Russia as part of the “Healthcare” national project. The implementation of the projects in 2011–2024 allowed to achieve high rates of application of medical information systems, as well as to move to projects on digital transformation of the industry, including the introduction of artificial intelligence technologies and various digital services and assistants for patients, doctors, and managers. The article presents a brief history of the development of digital projects, the current key directions in developing information technologies for healthcare and the results achieved so far.

Key Words: health digitalization; digital health; artificial intelligence; decision support systems; electronic health records; telemedicine

Overview of the healthcare system of the Russian Federation

The healthcare system of the Russian Federation is one of the largest and most complex in the world. According to official data, the population of the Russian Federation in 2020 was 147.2 million people, of whom 75% live in urban areas and 25% in rural areas^{1,2}. The working age population was 82.7 million (56.4%), the population under working age was 27.4 million (18.7%), and the population over working age was 36.6 million (24.9%).

Healthcare in the Russian Federation is represented by three systems: state, municipal, and private³. The dynamics of several indicators characterizing the healthcare system of the Russian Federation, including population by years, is presented in Table 1.

The total number of healthcare organizations in the Russian Federation in 2019 was 26.3 thousand organizations. As can be seen from Table 2, the number of hospitals is decreasing as well as the number of hospital beds. The total number of hospitals in 2018 was 5,257, and only 259 were of a private form of ownership. The number of outpatient healthcare organizations has been increasing since 2010 at the expense of private healthcare organizations³.

Table 1. Some data characterizing the dynamics of health indicators of the Russian Federation

Indicator	2000	2010	2017	2018	2019
Population, million people	146.3	142.9	146.9	146.8	146.7
Number of hospitals, thousand	6.3	5.4	5.3	5.3	5.1
Number of outpatient healthcare organizations, thousand	21.3	18.6	20.2	20.2	21.2
Number of physicians, thousand people	680.2	680.9	697.1	703.7	714.6
Number of nursing staff, thousand people	1,563.6	1,537.9	1,525.2	1,491.4	1,491.3

Table 2. Data on the dynamics of the number of healthcare organizations in the Russian Federation³

Healthcare organizations of the Russian Federation	2010	2016	2017	2018
State and municipal hospitals	6,084	5,091	4,999	4,938
Private hospitals	115	205	241	259
State and municipal outpatient healthcare organizations	12,173	14,117	14,465	14,424
Private healthcare organizations	2,753	4,168	4,837	4,866

¹ Российский статистический ежегодник. 2020: Статистический сборник/Росстат. / Russian Statistical Yearbook. 2020: Statistical book/Rosstat. Moscow, 2020. 700 p. ISBN 978-5-89476-497-9. (In Russian). Accessed September 12, 2024. https://rosstat.gov.ru/storage/mediabank/Ejegodnik_2020.pdf

² Всероссийская перепись населения 2020 года / Russian Population Census (In Russian). Accessed September 12, 2024. <https://rosstat.gov.ru/vpn/2020>

³ Здравоохранение в России. 2019: Статистический сборник/Росстат. / Healthcare in Russia. 2019: Statistical book/Rosstat. Moscow, 2019. 170 p. ISBN 978-5-89476-470-2. (In Russian). Accessed September 11, 2024 <https://rosstat.gov.ru/storage/mediabank/Zdravoohran-2019.pdf>

The total number of physicians in the Russian Federation in 2019 was 714.6 thousand (48.7 physicians per 10,000 people), and the number of nursing personnel was 1,491.3 (101.6 per 10,000 people). The dynamics of changes in the number of healthcare personnel in the Russian Federation are presented in Table 1.

Healthcare expenses in the Russian Federation are financed by public and private funds. Public funding is formed by the Compulsory Health Insurance Fund, payments by constituent entities of the Russian Federation for the non-working population, as well as federal and regional budgets. Private expenses are formed by payments by citizens, as well as payment for healthcare provided within the framework of voluntary health insurance. In total, in 2020, total healthcare expenses in the Russian Federation amounted to 6 trillion rubles, of which public expenses were 65% (3.34 trillion rubles), and private 35% (2.66 trillion rubles) [1, 2].

Pioneering research and development in healthcare information technology

The first studies in the field of information and communication technologies and their application in medicine and healthcare began in the 1950s and 1960s, mainly based on large Soviet research institutes and scientific centers. At that time, several research teams were created that studied methods of collecting and processing data using computer systems and automation tools. The Soviet scientific school of medical cybernetics was formed and began to develop [3]. The first developments in the field of telemedicine technologies have appeared in several areas at once – from analyzing electrocardiogram results to using them in the space industry [4, 5].

By the end of the 1970s, the Union of Soviet Socialist Republics (USSR) had accumulated the first experience in creating and using automated control systems and information processing tools. A department of computer technology and automated control tools was created based on the USSR Ministry of Health, and the main computing center began its work, ensuring the functioning of the country's automated healthcare management system. The first healthcare institution management systems were launched, for example, the "Automated control systems of a medical university" and the "Medical information system of a multidisciplinary hospital" [6, 7].

Research teams have accumulated a large reserve in terms of designing and developing various software solutions, including those intended for diagnostics, monitoring, and assessing the health status of patients. In particular, the first clinical decision support systems based on expert knowledge bases were developed [8].

In the 1980s, the first geographically distributed systems began to appear, in which several medical organizations operated at once. These developments began to demonstrate signs of complex solutions, including data collection and automation of both treatment and diagnostic processes, and elements of management decision support at various levels: from the heads of structural divisions to industry planning and management. The use of fairly powerful computing complexes at the time, such as the Unified System of Electronic Computing Machines and System of Mini Computers as well as the first personal computers, began. At this time, specialized scientific and practical conferences began to be held regularly to discuss projects and research results [6].

In the early 1990s, amid the active development and relative cheapening of personal computers, the use of computers and the creation of local area networks became available to a wider range of healthcare organiza-

tions. At the same time, the first operating systems with a graphical control interface appeared, as well as accessible means of creating software, which led to a significant simplification of both the software development processes and its development by users: physicians, nurses, managers of any level [9, 10].

The creation of the first software products was mainly aimed at collecting and automating statistical reports, and partial automation of auxiliary departments, such as accounting, human resources departments, etc. As the compulsory health insurance system was being established, many developments appeared in the field of forming registers and information exchange with insurance companies. Gradually, computer systems found their application in treatment and diagnostic processes. It started with the automation of registries and accounting of incoming patients and then moved on to maintaining records in electronic health records.

In the early 2000s, a commercial market for specialized software for medicine and healthcare began to form in Russia. Creative teams and small commercial companies, often numbering up to 10 people, began to develop the first versions of medical information systems with the capabilities of complex automation, maintaining electronic health records (EHR), and accounting and generating statistical and financial reports.

The number of companies and the solutions they offered began to grow rapidly. By 2007, there were already over 50 such developers. However, despite the wide variety of solutions offered, the actual level of their use and deployment in practical healthcare was quite low. Projects for the implementation of various information systems were launched by proactive managers and financed from their own, rather limited funds.

In 2009, the level of practical application of information and communication technologies was low. Less than 20% of healthcare organizations used various medical information systems, most often implementing them fragmentally in individual departments or for a limited range of processes. Less than 7% of healthcare organizations kept any records in the EHR, most often of a statistical and accounting nature. The most acute problem of that time was an acute shortage of hardware, only 10% of medical workers could have access to a computer, and only 7% of the available computers had an Internet connection [6].

In 2008, the Department of Information Technology and Communications was created in the Ministry of Health and Social Development of the Russian Federation, which began developing state policy in the field of digital healthcare. Since 2009, federal initiatives in the field of digitalization have been launched, and a regulatory and methodological framework has been prepared for the implementation of a federal project to introduce information systems in the healthcare sector.

Creation and development of the Unified State Information System in the field of healthcare in 2011-2018

In 2011, on the instructions of the President and with the active participation of the professional community, a project was initiated to create the "Unified State Information System in Healthcare" (in Russian: Edinaya Gosudarstvennaya Informatsionnaya Sistema Zdravookhraneniya, EGISZ), the basic principles of which were defined by the order of the Ministry of Health and Social Development of Russia No. 364 of 28.04.2011⁴.

⁴ Приказ Минздравсоцразвития России №364 от 28.04.2011 г. "Об утверждении Концепции создания единой государственной информационной системы в сфере здравоохранения" / The Order of the Ministry of Health and Social Development of Russia No. 364 of April 28, 2011 "On approval of the Concept for creating a unified state information system in healthcare". (In Russian). Accessed September 12, 2024 <https://minzdrav.gov.ru/documents/%207200-prikaz-minzdravsotsrazvitiya-rossii-364-ot-28-aprelya-2011-g>

In 2011-2012, due to state funding, basic conditions for the creation of infrastructure and implementation of information systems in the healthcare sector were created in the constituent entities of the Russian Federation. The project activities included the mandatory purchase of computer equipment, creation and protection of local area networks, acquisition, and implementation of medical information systems of healthcare organizations, as well as state information systems in the healthcare sector of the constituent entities of the Russian Federation. The work was coordinated with the help of regularly updated methodological recommendations, during the development of which the regulator interacted with industry experts and companies developing the solutions being implemented.

By 2014, all constituent entities of the Russian Federation had completed the 1st stage of the project implementation. As a result, the transition to personalized registration of rendered medical services became possible, the minimum necessary conditions for the deployment of EHRs were provided, and the introduction of the first digital services for citizens, such as, for example, making appointments online, began.

A significant driver for the development of digitalization of healthcare in the Russian Federation was the release of Federal Law No. 242-FZ of July 29, 2017, which defined the key legal framework for the implementation of information systems in the healthcare sector, including the status of the EGISZ, "Other Information Systems" and other components. This law also created the opportunity for the development and further regulation of the use of telemedicine technologies, the transition to electronic document management, and information exchange in the healthcare sector⁵.

Another important document was the Resolution of the Government of the Russian Federation Resolution N 555 of May 5, 2018, which established the legal basis for the functioning of the EGISZ, its architecture, and key requirements, presented the composition of the components, requirements for providing access and collecting the necessary information⁶. It was thanks to this document and subsequent targeted funding that the basic components of the EGISZ were created. They currently comprise the main source for coding and storing data on the operation of the Russian healthcare system – the Federal Register of Regulatory and Reference Information, the Federal Register of Healthcare Professionals (in Russian: Federal'nyi Registr Meditsinskikh Rabotnikov, FRMR), the Federal Register of Healthcare Organizations (in Russian: Federal'nyi Registr Meditsinskikh Organizatsii, FRMO), the Federal Electronic Registry, the Federal Integrated Electronic Health Record, etc.

In 2013-2018, the 2nd stage of the EGISZ development was implemented. This stage was aimed at developing the infrastructure created in 2011-2012. The healthcare authorities of the constituent entities of the Russian Federation, development companies, and system integrators were given an ambitious task to ensure increased efficiency of healthcare management by automating all major treatment, diagnostic, and auxiliary processes and collecting data on the work of healthcare organizations in

⁵ Федеральный закон от 29.07.2017 № 242-ФЗ "О внесении изменений в отдельные законодательные акты Российской Федерации по вопросам применения информационных технологий в сфере охраны здоровья" / Federal Law of July 29, 2017 No. 242-FZ "On Amendments to Certain Legislative Acts of the Russian Federation on the Application of Information Technologies in the Sphere of Healthcare". (In Russian). Accessed August 27, 2024. <http://publication.pravo.gov.ru/Document/View/0001201707300032>

⁶ Постановление Правительства Российской Федерации от 5 мая 2018 г. N 555 "О единой государственной информационной системе в сфере здравоохранения" / The Resolution of the Government of the Russian Federation of May 5, 2018 N 555 "On the Unified State Information System in Healthcare". (In Russian). Accessed September 12, 2024. <http://static.government.ru/media/files/Sgy0w5b7VRX0WBZeBIHnwI6co7vid2am.pdf>

digital form. Another important task of this stage was the creation of convenient services for citizens. In just a few years, almost all state healthcare organizations and healthcare authorities in the constituent entities of the Russian Federation launched their websites with detailed information on the provision of medical care in the region, online and through the Unified State Public Services to make an appointment with a physician appeared everywhere, electronic queuing systems were implemented in many clinics, and information terminals for making an appointment and obtaining certificates were installed in clinics.

One of the key areas of basic healthcare digitalization in 2013-2018 was the transition from paper-based document management to maintaining electronic health records. The key objective of implementing EHR was to reduce the labor costs of health workers, including maintaining medical records, patient health records, certificates, appointments, prescriptions, conclusions and other documents.

As federal and regional projects were implemented, the work to improve regulatory and technical regulation continued. On December 24, 2018, The Ministry of Health issued Order No. 911n, which defined the basic requirements for medical information systems of healthcare organizations and state information systems in the healthcare sector of the constituent entities of the Russian Federation, including a list of processes to be automated using the relevant software products, as well as requirements for information exchange and information security⁷.

Thus, the created regulatory framework and the results of the implementation of various information systems achieved in the constituent entities of the Russian Federation provided the opportunity for the total collection of a huge amount of data on the healthcare system, personnel and financial support, and the results of medical care. The process of transition to EHR was launched throughout the country, various software products were created to support management decision support and, most importantly, digital services for citizens were created.

Creation of a Unified Digital Circuit in Healthcare in 2019-2024

In 2019, within the framework of the "Healthcare" national project, the federal project "Creation of a Unified Digital Circuit in Healthcare Based on the Unified State Health Information System" was launched in Russia. It marked a fundamental change in the attitude towards information systems and the role assigned to them by the regulators and the expert community. In 2011-2018 the implemented solutions were intended to create an infrastructure for the implementation of healthcare information systems and state information systems in the healthcare sector of the regions of the Russian Federation. The project to create the Unified Digital Circuit in Healthcare was formulated as preparation for the digital transformation of healthcare. The key difference and the main objective of this stage was a significant increase in the efficiency of the Russian healthcare system through in-depth development and implementation of unified platform solutions and new technologies, such as telemedicine, artificial intelligence, remote monitoring, and de-

⁷ Приказ Министерства здравоохранения Российской Федерации от 24.12.2018 № 911н "Об утверждении Требований к государственным информационным системам в сфере здравоохранения субъектов Российской Федерации, медицинским информационным системам медицинских организаций и информационным системам фармацевтических организаций" / The Order of the Ministry of Health of the Russian Federation of December 24, 2018 No. 911n "On approval of the Requirements for state information systems in healthcare of the constituent entities of the Russian Federation, medical information systems of medical organizations and information systems of pharmaceutical organizations". (in Russian). Accessed September 12, 2024. <http://publication.pravo.gov.ru/Document/View/0001201906190017>

cision support systems based on raw data. The state project included federal-level activities: the creation of a regulatory framework, issuance of methodological documents and regulations, development of the EGISZ and regional-level activities: developing the digital contour of each subject of the Russian Federation, taking into account the specifics of the region, population, climatic conditions, and structure of the healthcare system.

Each subject of the Russian Federation, in coordination with the Russian Ministry of Health, developed individual programs for the creation of the Unified Digital Circuit in Healthcare in the subjects of the Russian Federation. The implementation and control of the projects were carried out according to strict roadmaps, including various areas and final indicators developed taking into account regional characteristics.

The projects were implemented in priority areas:

1. Development of functional capabilities and integration of healthcare information systems and state information systems in the field of healthcare of the constituent entities of the Russian Federation, including a gradual transition to centralized solutions that are fully integrated and automatically exchange data with each other without re-entry.
2. Development of services for patients. In this area, the main focus was on improving the convenience and functionality of the patient's personal "My Health" account on the Unified Portal of State and Municipal Services, ensuring interaction between citizens and the healthcare system, the development of telemedicine technologies and remote medicine, and monitoring the health status of patients with chronic non-communicable diseases.
3. Development of intelligent systems, including the active implementation of business intelligence technologies, medical devices with artificial intelligence technologies, systems for supporting clinical decision-making, and tools for forecasting and monitoring the work of the healthcare system in a variety of areas and data sections.

The key achievements in the creation of a single digital circuit in the Russian healthcare sector were:

- Implementation of digital services for patients: the maximum availability of various products and services to increase convenience and satisfaction from interaction with the healthcare system, including remote appointments with a doctor, remote registration of a compulsory health insurance policy and registration with a clinic, receiving electronic medical records in a personal account, remote monitoring of health status, telemedicine consultations, etc.
- Implementation of digital services for healthcare professionals: elimination of paper-based document flow, reduction of time spent on processing medical records, including various reports, use of artificial intelligence technologies, voice assistants and other digital services in the provision of medical care.
- Transition to data-driven management – automated processing and analysis of primary data collected from the healthcare information systems of healthcare organizations and EGISZ services, including with the use of artificial intelligence (AI) technologies, increased transparency and improved monitoring and evaluation of the performance of healthcare organizations, introduction of promising management tools and approaches, such as predictive analytics and management decision support based on digital twins.

Level of development of digital healthcare in the Russian Federation

Development of federal services

The federal services of EGISZ are the basis for strategic planning and development of the Russian healthcare system and are also used regularly by employees of the Ministry of Health and authorized organizations to support operational management decision-making. In total, the EGISZ includes 22 services and components that provide a unified information exchange and management decision support.

The key service of the EGISZ is the FRMO, which contains detailed structured data on all healthcare organizations in the country, including their structural subdivisions, buildings, equipment, licenses for clinical activities, and much more. Currently, the FRMO contains data on 76,200 medical organizations, of which 23,300 are state-owned and 52,900 are private organizations.

The FRMR, which includes detailed information on the staffing of the industry, including detailed social data, information on education and advanced training, data on the workplace, and much more. Currently, the FRMR contains information on 2.577 million healthcare professionals, of which 768 thousand are specialists with higher medical education. In addition, the FRMR includes information on 163.7 thousand pharmaceutical workers.

Federal nosological registers are intended to automate the collection, processing, and analysis of data on patients suffering from relevant diseases to organize the provision of medical care, including the provision of medicines. Such registers include registers of persons with HIV, tuberculosis, rare (orphan) diseases, COVID-19 and other diseases.

As part of the development of digital transformation, work is underway to create the “Healthcare” domain. The core of the “Healthcare” domain, according to the planned areas of development of the architecture of the unified digital platform in healthcare, consists of:

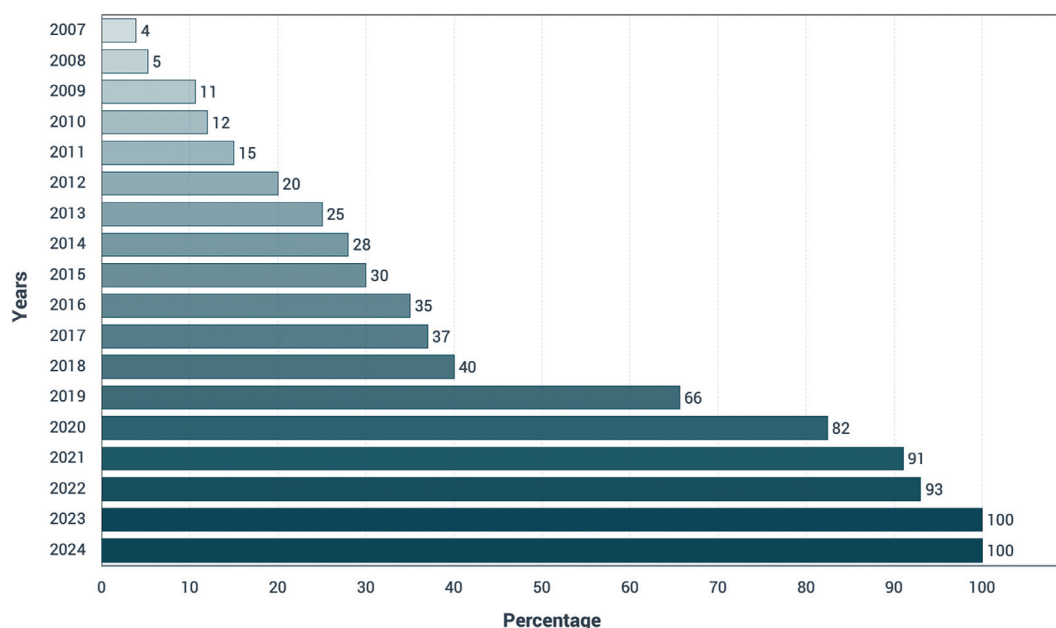
- The Unified Patient Register based on the Unified Register of Insured Population and information from related agencies, consolidating patient information into a master register; universal patient identifier for the entire healthcare system, used by all domain participants;
- Digital health profile of a patient, consolidating information on the state of health, medical services provided and enabling the creation of services aimed at organizing the provision and improving the quality of medical care;
- Digital twin of a medical professional, created based on the FRMR, consolidating all information on healthcare professionals;
- Digital twin of a healthcare organization created based on the FRMO, consolidating all information on healthcare organizations;
- Digital twin of processes created based on clinical guidelines and processes of medical care organization and accompanying processes.

The above services are accompanied by unified normative and reference information and are built on a unified data model.

Implementation of healthcare information systems in healthcare organizations

The implementation of several federal projects and initiatives in 2011-2024 attracted substantial public investment in infrastructure and implementation of healthcare information systems, which ensured that healthcare organizations were equipped with computer equipment, including

Fig. 1. Dynamics of the use of healthcare information systems in healthcare organizations of the Russian Federation, % of the total number



automated workstations for healthcare professionals, server capacity, information storage and protection facilities, system-wide software, etc.

All 100% of public healthcare organizations and their structural subdivisions have the necessary computer equipment and connection to unified secure data transmission networks. 1.028 million automated workstations are equipped with electronic signatures and connected to secure access to healthcare information systems. Moreover, other services have been created for medical professionals.

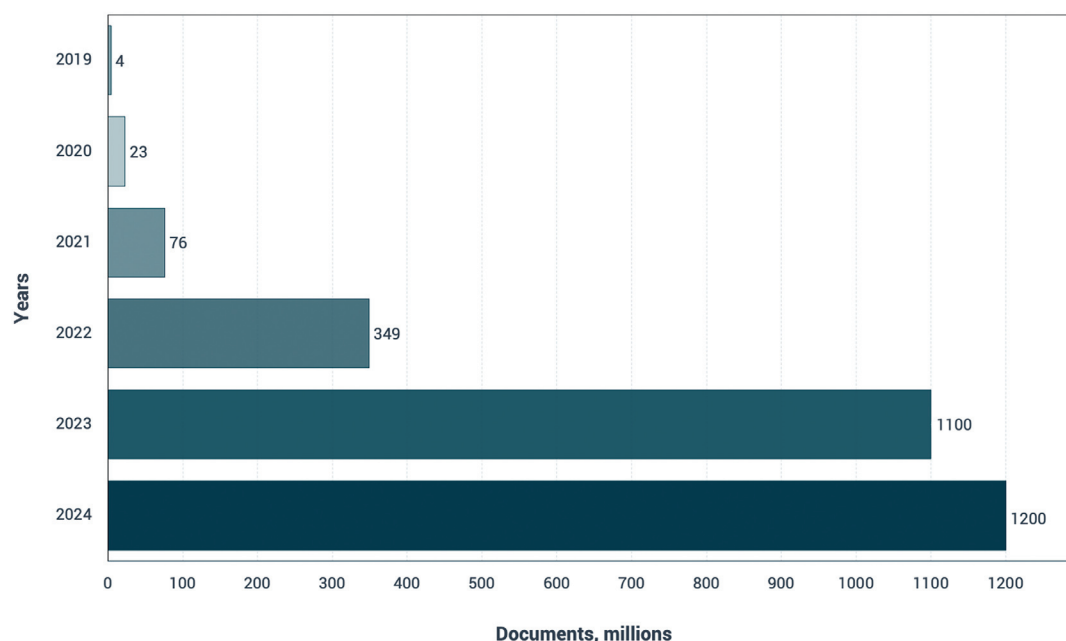
By the end of 2023, 100% of public healthcare organizations use various healthcare information systems for maintaining electronic health records, physicians' work schedules, automating diagnostic and treatment units, generating statistical, financial and management reporting (Fig. 1).

Information exchange in the healthcare system

The basis of automated information exchange between various information systems and components of the EGISZ is a structured electronic medical document (SEMD), created on the basis of the international HL7 standards stack. Since 2019, 113 types of SEMD have been developed in Russia, which provide at least 80% of the needs of healthcare organizations for paperless medical document flow in all types of clinical activities, and 24 of them were created in 2023. The creation of new SEMDs and corresponding federal reference books for coding metadata and clinical information is carried out on an ongoing daily basis.

Thus, the Russian Federation provides automated collection and transfer of data via secure communication channels from the Ministry of Health of the Russian Federation to state information systems in the field of healthcare of the regions of the Russian Federation, and from them to the federal services of the EGISZ. Aggregated data is actively and continuously used for operational and strategic planning and management of the

Fig. 2. Dynamics of transfer of electronic medical documents to the federal service "Register of Electronic Medical Documents" EGISZ



industry at all levels, from the heads of healthcare organizations to the federal minister of health, and the volume of transferred data is constantly increasing. Thus, in 2019, 4.2 million electronic medical documents were transferred, in 2023 – more than 1 billion documents. Over the first nine months of 2024, more than 1.2 billion documents have already been transferred between the regions of the Russian Federation and the federal services of the EGISZ, the average daily volume of transferred data exceeds 3.6 million documents (Fig. 2).

Seamless information exchange is provided and gradually develops both within the healthcare sector and with related organizations and executive authorities. For example, 100% of state healthcare organizations provide information interaction with medical and social expertise institutions, for which the Federal Register of Electronic Medical Documents service of the EGISZ is used. Since March 2022, interdepartmental interaction with the National Guard of Russia has been introduced, which is currently carried out exclusively electronically in terms of transferring information on passing a medical examination to obtain the right to bear arms. It has made it possible to strengthen the control and responsibility of healthcare organizations for the accuracy of the transmitted information. Over the first 8 months of 2024, 502,248 birth records were registered in the registry offices based on electronic birth certificates generated by healthcare organizations, through the service on the Unified Portal of State and Municipal Services or through a direct visit to the Multifunctional Public Services Center.

Development of digital services for citizens

Digital services for citizens are implemented to increase patient-centricity, ensuring the convenience of citizens' interaction with the healthcare system, and the possibility of their involvement in caring for their health.

Digital services allow for early diagnosis of diseases, timely prevention of deviations from clinical recommendations during treatment and the organization of continuous monitoring of each patient, interdepartmental interaction, the use of telemedicine technologies, the creation of electronic services and services for citizens in the personal "My Health" account on Unified Portal of State and Municipal Services, providing citizens with digital services for remote dispensary monitoring using medical devices with a data transfer function.

Services are being created to involve citizens in caring for their health, to increase the transparency and efficiency of the healthcare system, to increase the satisfaction of patients, as well as the availability and convenience of receiving healthcare services by providing them in electronic form in compliance with the one-stop principle, ensuring the security of personal data and an equal level of quality of healthcare services regardless of the place of residence of citizens in the territory of the Russian Federation.

The central place in this area is occupied by the patient's personal "My Health" account on the Unified Portal of State and Municipal Services. By August 2024, 44.39 million citizens used the services and services of this information resource. Over 96% of healthcare organizations ensure continuous transfer of information from electronic health records to patients' accounts. As a result, 75.97% of the Unified Portal of State and Municipal Services users have access to their electronic medical documents, and when new medical records or examination and treatment results are received, patients receive corresponding push notifications, so the patient always knows that new data has appeared in his electronic health record.

The service of making appointments with physicians via the Internet is extremely popular, and it can be used not only on the Unified Portal of State and Municipal Services, but also on regional portals, at special information kiosks installed in clinics, and using mobile applications. As a result, 80.95% of appointments were made by citizens remotely.

Since December 2022, the State Information System of Compulsory Health Insurance has been maintaining a Unified Register of the Insured Population, containing more than 50 million digital compulsory health insurance policies based on a barcode, which frees citizens from the need to carry policies on physical media. Services related to the registration of a compulsory health insurance policy have also been digitized.

Implementation of telemedicine technologies

In the Russian Federation, a regulatory framework has been created for the implementation of telemedicine technologies, which has provided the opportunity for remote interaction between physicians, as well as the opportunity for consultations between patients and their legal representatives with physicians.

The goals of telemedicine consultation "doctor-patient" are prevention, collection, and analysis of the patient's medical history and complaints, assessment of the effectiveness of treatment and diagnostic measures, monitoring the patient's health, and deciding on the need for an in-person appointment. Diagnosis and treatment are not permitted during telemedicine consultation.

Remote monitoring of a patient's health status can only be carried out using medical devices registered by the Federal Service for Surveillance in Healthcare (Roszdravnadzor).

A significant driving force for the wider use of telemedicine was the COVID-19 pandemic, during which these technologies became one of the

most valuable aids in reducing the burden on healthcare organizations, reducing unnecessary patient visits and thereby reducing the risk of spreading infection. Since 2019, the number of telemedicine consultations conducted in the regions of the Russian Federation has increased more than 11 times, and the number of telemedicine consultations conducted by specialists from federal centers of the Ministry of Health of the Russian Federation on complex cases has increased 5 times.

The most popular nosologies for telemedicine consultations are oncology, pediatrics and cardiovascular diseases, as well as obstetrics and gynecology. According to the results of 2023, more than 8.1 million consultations were conducted in the state healthcare system of the Russian Federation, including consultations, conclusions on the results of diagnostic studies, as well as remote monitoring of patients' health. Specialists from federal centers of the Ministry of Health of the Russian Federation conducted more than 205 thousand physician consultations using telemedicine technologies.

Implementation of personal medical assistants

One of the most important areas of industry development was the federal project "Personal Medical Assistants", the purpose of which was to digitally transform the dispensary monitoring of patients with chronic non-communicable diseases. The project includes the creation of services and medical devices for remote dynamic monitoring of the health of citizens. Its implementation is carried out in several areas at once:

- creation of a unified national system for the circulation of medical data in the field of remote monitoring of a patient's health
- creation of conditions for the implementation of remote monitoring of patients with chronic diseases living in remote areas, including the Far Eastern Federal District, the project is currently being implemented in the Magadan Region
- creating conditions for maximum preferences for domestic developers of IT solutions and manufacturers of medical devices, stimulating the development of the microelectronics industry and personal medical devices for citizens.

The initial stage of the implementation of the "Personal Medical Assistants" initiative is carried out in the form of a pilot project for remote monitoring of the health of patients with arterial hypertension and diabetes mellitus using the "Personal Medical Assistants" platform under an experimental regulation.

The participants of the project are the Ministry of Health of Russia, the State Corporation Rostec, national medical research centers of the Ministry of Health of Russia, medical organizations of 8 subjects of the Russian Federation (Irkutsk, Magadan, Novosibirsk, Ryazan, Samara and Tyumen regions, the Republic of Tatarstan, Khanty-Mansiysk Autonomous Okrug – Yugra) and the Federal Medical and Biological Agency of Russia, and Roszdravnadzor.

As of September 2024, a regulatory and methodological framework has been formed, a prototype of the Personal Medical Assistants platform has been created and is functioning, and information interaction of the Personal Medical Assistants platform with medical devices and healthcare information systems of healthcare organizations has been implemented. Requirements for medical devices have been defined and some Russian developments are being tested, for example, the INME-01 tonometer (manufacturer: Altonika), the HemoDin-GSM tonometer (manufacturer: AKSMA LLC), and the Satellite® Online glucometer (manufacturer: ELTA LLC).

By September 2024, more than 23,000 patients have been taken under remote monitoring, including 21,262 people under monitoring for arterial hypertension and 1,930 people for diabetes. By the end of 2024, it is planned to conduct a clinical and economic assessment of the effectiveness of remote monitoring in order to decide on replicating the results of the pilot project from 2025. At the same time, an interim analysis of the results, carried out by experts from the National Medical Research Center of Cardiology and the National Medical Research Center of Endocrinology, has already shown a positive effect.

Implementation of artificial intelligence technologies

According to the national strategy for the development of AI in the Russian Federation for the period up to 2030, the implementation of AI in the healthcare system is a priority task⁸. The goal of active use of AI is to improve the efficiency and quality of medical care, automate data processing, and support clinical and management decision-making.

By September 2024, Roszdravnadzor has registered 37 medical devices using AI technologies. Of these, 30 medical devices were created by Russian development companies and have been given priority for implementation in national healthcare.

By the end of 2023, 84 regions of the Russian Federation had launched projects to implement AI-based medical devices. The basis for the implementation of AI is data on the state of human health, including data from studies on fluorography, radiography, mammography, computed tomography, contained in the regional subsystems "Electronic Health Record" and "Digital Archive of Medical Images".

In the city of Moscow, as part of the implementation of an experiment on the use of innovative technologies in the field of computer vision for the analysis of medical images, 59 AI solutions are operating, 14 of which have marketing authorization as medical devices issued by Roszdravnadzor [11].

Voice services with artificial intelligence have been implemented in healthcare organizations to optimize the work of call centers; these services allow you to conduct a dialogue with a patient using a virtual assistant, make an appointment with a physician, and call patients with reminders.

Scientific medical research centers are creating data sets in the following areas: cardiology, oncology, pathomorphology, radiology, and critical obstetric conditions. A solution with AI for detecting colorectal cancer has been created, which allows reducing the risk of colon cancer by 90% due to early detection.

Conclusion

In December 2024, the implementation of the federal project "Creation of a single digital healthcare circuit based on the EGISZ" will be completed, within the framework of which the digitalization of healthcare in the Russian Federation has moved to a fundamentally new level. A common information technology infrastructure has been created and is actively used. The EGISZ has been created and is functioning at the federal level, state information systems in the field of healthcare are functioning in all regions, and 100% of state and municipal healthcare organi-

⁸ Указ Президента Российской Федерации от 10.10.2019 № 490 «О развитии искусственного интеллекта в Российской Федерации» / Decree of the President of the Russian Federation of 10.10.2019 No. 490 "About the development of artificial intelligence in the Russian Federation". (In Russian). Accessed September 12, 2024. <http://publication.pravo.gov.ru/Document/View/0001201910110003>

zations have switched to operation in healthcare information systems and maintaining electronic health records.

The full implementation of digital technologies in healthcare has allowed the Russian Federation to achieve significant practical results in terms of the efficiency of processes for organizing and providing medical care.

Daily work of physicians in healthcare information systems allows doctors and nurses to switch to paperless electronic healthcare records, use time during appointments more efficiently, get instant access to digital archives, use systems to support clinical decision-making and artificial intelligence, voice input services, which significantly reduces medical errors and improves the quality of medical care.

The emphasis on developing patient services allows citizens to quickly and conveniently find the information they need, make an appointment, receive a telemedicine consultation, or use a remote health monitoring service.

The introduction of data-driven management technologies allows managers to see detailed information about the resource and personnel provision of the industry, to make operational and strategic decisions based on data and forecasts, including in the visual form of analytical dashboards. All this makes the work of managers more efficient, which is extremely important in the conditions of personnel and financial shortages.

In 2025-2030, the Russian Federation will implement the next stage focused on the comprehensive digital transformation of all key processes, from the treatment and interaction of patients with the healthcare system to the work of doctors, nurses and healthcare organizers. The Order of the Government of the Russian Federation of April 17, 2024 No. 959-r approved the strategic direction in the field of digital transformation of healthcare, which includes the following projects: platformization and creation of "digital twins", the "Healthcare" domain, artificial intelligence, personal medical assistants, and information security⁹.

The goal of the strategic direction until 2030 is to achieve a high level of "digital maturity" of the participants in the implementation of the strategic direction through the accelerated transition of the healthcare sector of the Russian Federation to electronic document management, decision-making based on raw data and the use of "digital twins" of processes, the widespread use of artificial intelligence, increasing the quantity and quality of digital services provided to citizens in the field of healthcare and remote health monitoring.

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⁹ Распоряжение Правительства Российской Федерации от 17 апреля 2024 г. № 959-р «Об утверждении стратегического направления в области цифровой трансформации здравоохранения» / The Order of the Government of the Russian Federation of April 17, 2024 No. 959-r "On approval of the strategic direction in digital transformation of healthcare". [In Russian]. Accessed September 12, 2024. <http://publication.pravo.gov.ru/document/0001202404190016>

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Current challenges and future development of India's healthcare system' towards tuberculosis free India – research evidence and programmatic initiatives

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ABSTRACT

Tuberculosis (TB), the single most infectious killer deserves special attention in a focussed manner, to reduce morbidity and mortality. We describe the challenges in the four pillars of TB control: detect or diagnosis, treat, prevent, build and elaborate the success stories, listing out newer and advanced tools like artificial intelligence, whole genome sequencing, clustered regularly interspaced short palindromic repeats based technologies, one health approach and cost effectiveness strategies for an all-round reduction in TB control. Special problems posed by paediatric and extra-pulmonary TB are dealt with. Post TB lung sequelae, reverse zoonosis and behavioural modification that can influence catastrophic costs are explored. Use of molecular and genomic methods of TB detection has revolutionized TB care with increased sensitivity of diagnosis, and timely detection of drug resistance, saving many a precious lives. Undoubtedly, the need of the hour would be shortening TB treatment duration and comprehensive preventive strategies that simultaneously decrease both the incidence and prevalence of TB. The various schemes and initiatives undertaken by the Government of India including the Pradhan Mantri TB Mukht Bharat Abhiyaan – “TB free India” stand as a unique solution in the wake of eliminating TB. India has been extending its success stories to other countries as well, by creating platforms for multilateral research and multinational implementation. This manuscript gives a concise and comprehensive outlook of process involved in TB elimination, amalgamating the research evidences with the programmatic initiatives, enlisting the existing challenges, envisaging the current achievements, providing a road map for TB elimination.

Key Words: TB programme; NTEP; TB; mycobacteriology; ATT

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Introduction

Tuberculosis (TB) has regained its status as the single most infectious killer after the COVID-19 pandemic¹ globally with, 7.5 million new cases of tuberculosis were diagnosed in 2022, with a little over half of these cases affecting the male gender and 12% contributed by the paediatric population as per the World Health Organization (WHO) report 2023. Tuberculosis accounted for 1.3 million deaths and 4.1 Multidrug Resistant Tuberculosis (MDR-TB) patients¹. India accounted for 23,58,664 cases newly diag-

¹World Health Organization. Global Tuberculosis Report 2023. World Health Organization website. Accessed August 6, 2024. <https://iris.who.int/bitstream/handle/10665/373828/9789240083851-eng.pdf?sequence=1&isAllowed=y>

nosed with 90638 (4.2%) deaths during 2022. MDR-TB accounted for 63801 (5.18%) of the population, with a notification to treatment rate of 95.3% (22,48,816 cases)². Pursuing the Sustainable development goals globally, we could achieve only 8.7%, 19% and 49% decline in the incidence, mortality and reduction in catastrophic costs respectively³.

The chronic and indolent nature of the disease, with the ability to resist drug pressure while modifying its metabolism, makes *Mycobacterium Tuberculosis* (*M.tb*) formidable [1]. The very challenge in TB management stems from the fact that Pulmonary TB though the most common form, detected with certainty still requires multi-drug therapy even for pan-sensitive organism, with the therapy spanning for months, which is long and cumbersome due to immune evasion [2].

Dealing with such a panoramic predator, challenges are inevitable for the National TB Elimination Programme that has strategically categorized TB control into four domains: Detect Treat, Prevent and Build, through innovative solutions and comprehensive interventions to gear up to expectations of TB elimination by 2025⁴. In the following sections, we discuss these challenges in the same four domains and the solutions offered through research evidences and programmatic implementation for successfully eliminating TB disease.

Diagnostic challenges

For a bacterium that has spent centuries with the human race, dating back to the Vedas where it is termed “Raja Yaksha” or the king of diseases, confirmatory diagnosis becomes the foremost challenge. Luckily, pulmonary TB remains the commonest form of TB in an immunocompetent patient detected by Sputum smear and currently by molecular methods. Complexities increase when it comes to diagnosing TB among immunocompromised individuals, extra pulmonary forms and paediatric population where tissue invasion predominates extracellular forms and hence not captured by the conventional and simple sputum examination. Delay in diagnosis needs to be addressed by upfront molecular diagnosis. Once this is achieved, resistance testing and species identification becomes the next hurdle. To anticipate credible results, transport of specimens has to be given attention apart from point of care tests developed to overcome the rough terrains and inaccessible area.

Development and validation of open real-time polymerase chain reaction assay for tuberculosis diagnosis and treatment follow up

While the gold standard for TB diagnosis is still mycobacterial culture, which is a long drawn process, quick and precise techniques are being developed. With Real Time Polymerase Chain Reaction (RT-PCR) machines available in the farthest regions as part of SARS CoV-2 testing strategy in the country, a study has been designed to make use of these Kits for rapid diagnosis and prognosis of TB. A comprehensive RT-PCR assay is also used for *Mycobacterium Tuberculosis* (*M.tb*) viability and detection apart from differentiation from its counterparts, the Non-Tuberculous Mycobacteria and the other M. Tb Complex members, along with viability (Fig. 1).

² Central TB Division M of H and FW. India TB Report 2023 [Internet]. New Delhi, India; 2023. Accessed August 6, 2024. <https://tbcindia.gov.in/showfile.php?lid=3680>

³ World Health Organization. Sustainable Development Goals 2017: Target 3.3. Communicable diseases. World Health Organization website. Accessed August 6, 2024. https://www.who.int/data/gho/data/themes/topics/sdg-target-3_3-communicable-diseases

⁴ Central TB Division, Ministry of Health with Family Welfare. National Strategic Plan for tuberculosis: 2017-25 elimination BY 2025. Central TB Division website. Published March, 2017. Accessed August 6, 2024. <https://tbcindia-wp.azurewebsites.net/wp-content/uploads/2023/05/National-Strategic-Plan-2017-25.pdf>

FIG. 1. Algorithm showing testing for tuberculosis using the open Real Time Polymerase Chain Reaction system.

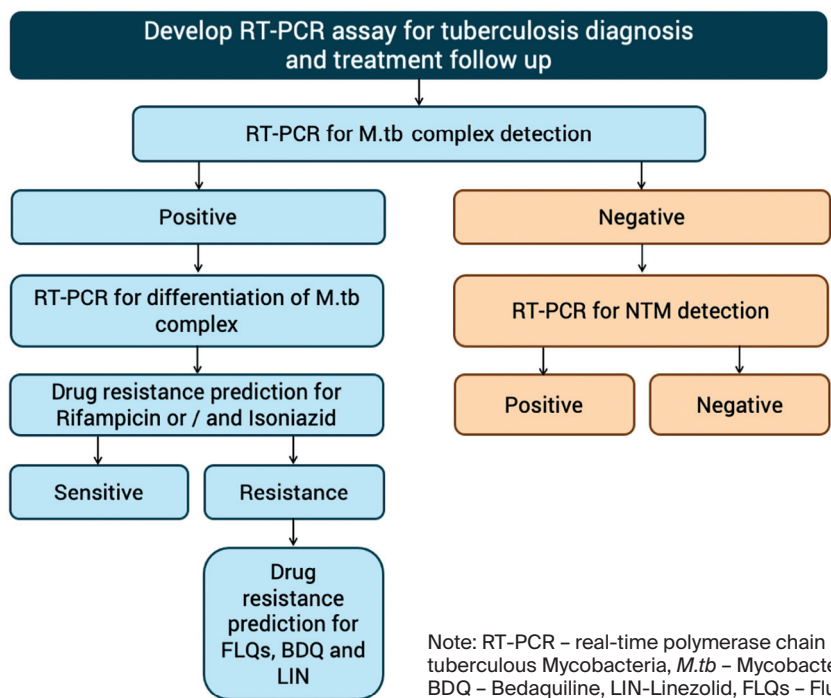
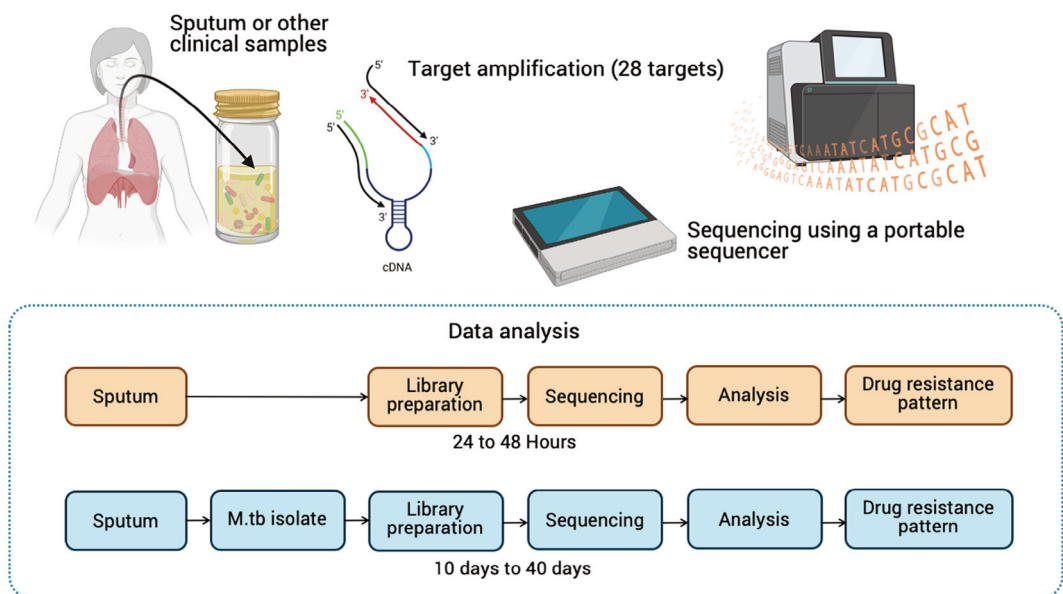
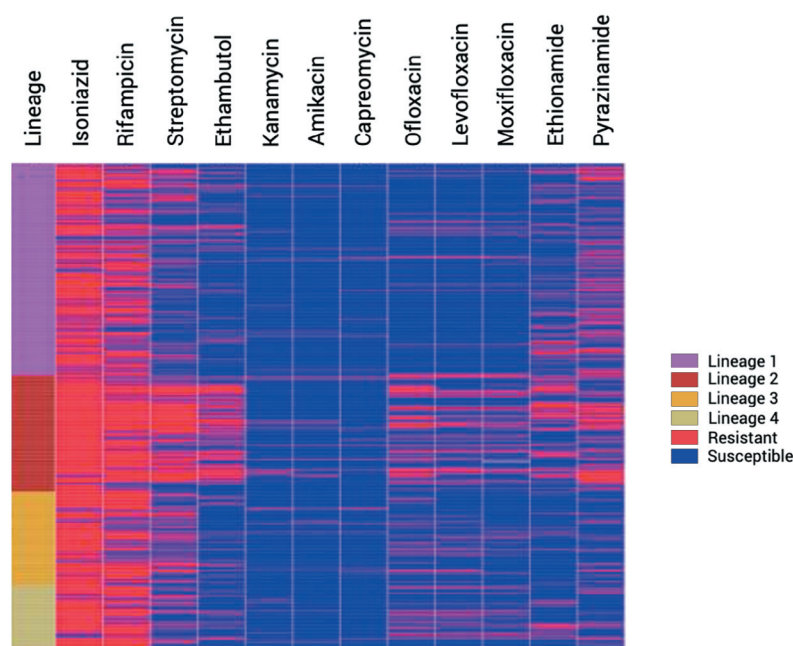


FIG. 2. Targeted next generation sequencing for culture free detection of drug resistance.



Culture free detection of extended drug resistance, non-tuberculous mycobacteria (NTM) speciation by in-house primers using portable nanopore sequencer becomes a boon for detection of rapid drug resistance as shown in (fig. 2) [3, 4].

FIG. 3. Indian catalogue of mycobacterium tuberculosis drug resistance mutation along with lineage of Mycobacterium Tuberculosis from India



Whole genome sequencing

Whole genome sequencing of *M.tb* offers the most comprehensive solution to genomic-based drug susceptibility testing, allowing identification of all mutations that may be associated with resistance (and sensitivity) to first-line, second-line, and new or repurposed antituberculosis drugs within a single platform. This also provides valuable data to establish genetic relatedness between strains of *M.tb*, which is necessary for understanding of potential transmission linkages. To address the concerns pertaining the region-specific resistance, and following WHO's recommendation, Indian Council of Medical Research – National Institute for Research in Tuberculosis (ICMR-NIRT) has developed the first 'Indian catalogue of Mycobacterium tuberculosis Mutations and their Association with Drug Resistance' from drug-resistant TB strains collected from across the country. This has been periodically updated for better surveillance (Fig. 3).

Though whole genome sequencing is quite comprehensive, direct sequencing of sputum samples is sometimes challenging due to low amounts of *M.tb* Deoxy Ribonucleic Acid (DNA) [5, 6]. Confirmation of this can be seen in Fig 4.

Challenges in transport of specimens

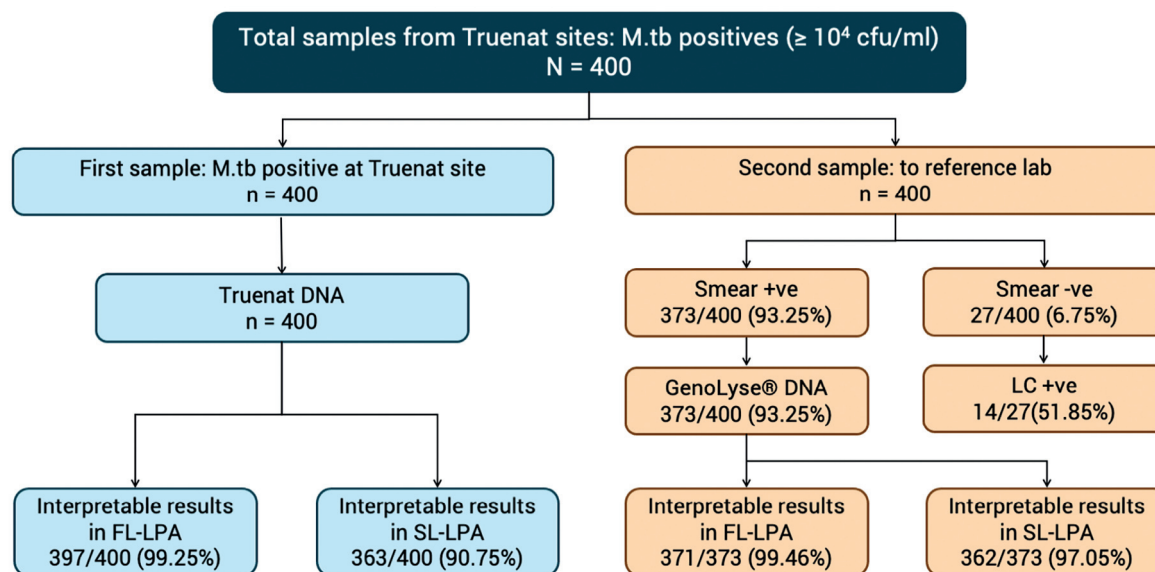
Transport of sputum samples for molecular testing from the periphery to Nucleic Acid amplification test (NAAT) / line probe Assay (LPA) centres may sometimes take more than 10 days in difficult terrains. This problem is obviated by using the principle of LPA testing using Trueprep DNA (Fig. 4).

Treatment challenges

Challenges to therapy include the following:

- The long duration of TB therapy, adverse drug reactions, and Drug-drug interaction has increased the attrition rates, leading a considerable number of patients, not completing therapy in the prescribed

FIG. 4. Deoxyribonucleic acid collected from samples are transported, to perform line probe assay in intermediate reference laboratories – an innovation to curb infectivity and sample transport challenges.



Note: FL-first line, SL-second line, LPA-line probe assay, LC-liquid culture, cfu – Colony-forming unit, +ve – positive, -ve – negative.

period, not only progressing to failure but also adding on to the pool of emerging drug-resistant cases. Shorter and oral regimens are the need of the hour, which would directly translate to better cure rates.

- Lack of social support and catastrophic cost take a toll on patients continuing misery, with an ardent urge to resume their work that drives the attrition rates. Shortening TB treatment has been a global priority, but careful attention should be given to recurrences.
- TB mortality and post TB lung disease or Tb sequelae cripples not only the patient family but the overall economy and productivity of the community as such.

The evolution and legacy of tuberculosis treatment shortening

For a long time until the 1950's, there was no medication for TB except for admitting the patient in a sanatorium that translated to requirement of 23,000 beds. Of those admitted, there were 50% deaths, 30% – naturally cured, leaving 20% chronically smear positive [7]. To overcome the requirement of sanatorium and explore the efficacy of domiciliary treatment, the first ever randomized trial was started by Tuberculosis Chemotherapy Centre (currently ICMR-NIRT) in September 1956, headed by Professor Wallace Fox, comparing anti-tuberculosis therapy (ATT) given at home versus same therapy with admission in the TB Sanatorium, coordinated by WHO [8]. This was the first ever global non-inferiority trial conducted in India, that showed that treatment at home was not only Non-inferior (86% vs 92%), with comparable rates of recurrence being 7% in home and 10% at sanatorium respectively, but also with no additional risk of transmission at home, revolutionising TB treatment with the psychosocial support of the family [8]. Mycobacterium Tuberculosis has a peculiar characteristic called the Lag Phase, where the bacilli do not grow after exposure to ATT, even after 2-3 days also called the post antibiotic

Table. The evolution of tuberculosis chemotherapy through dedicated research for the last five decades.

Study number	Years	Conclusive findings
Home San study [8]	1956-1959	Rx at home was as effective as sanatorium Rx. Diet was of minor importance not only concerning immediate response to treatment but also to in the occurrence of relapse. There was no evidence that the close family contacts of patients treated at home incurred an increased risk of contracting tuberculosis.
VA [11]	1961-1963	Twice weekly regimen of streptomycin and INH was as effective as daily treatment with PAS+INH. Cost was also less.
IX [12]	1970-1972	Twice weekly oral regimens of PAS+INH were comparable to that of a standard daily regimen of PAS and INH.
XII [9]	1974-1977	The findings with the non-rifampicin regimen Z7 (Pyrazinamide given daily) are highly encouraging. Rifampicin makes an important contribution to the efficacy of regimens in patients who have initial resistance to INH and streptomycin as well. Steroids have no role in short course chemotherapy.
XVIII [10]	1995-1998	Regimens containing ofloxacin of duration of 4&5 months were found to be highly effective with relapse rates of 4% and 2% when the regimens were 4 and 5 months respectively.
XXA [13]	2001-2005	In HIV-TB, a 6 months regimen was equivalent to 9 months. Intermittent anti-tuberculosis therapy at the end of treatment except that Acquired rifampicin resistance was prevalent in both the arms and bacteriological relapses were more in the 6 months regimen in HIV.
XXII [14]	2004-2006	4-month thrice-weekly regimens of gatifloxacin or moxifloxacin with isoniazid, rifampicin and pyrazinamide, were inferior to standard 6-month treatment, in patients with newly diagnosed sputum positive pulmonary TB.
XXIII [15]	2006 - 2008	In HIV -TB, once daily regimen of Nevirapine failed to be non-inferior to an Efavirenz based regimen co-administered with rifampicin containing anti-tuberculosis therapy.
XXIV [16]	2008- 2018	A moxifloxacin based 4 months regimen given with the standard 4 drugs daily and followed up for 24 months was non-inferior to a six months intermittent regimen of anti-tuberculosis therapy.
XXV [17]	2008-2016	A daily regimen in HIV with pulmonary TB was more efficacious than an intermittent regimen, especially reducing emergence of Acquired rifampicin resistance, but at the expense of increased incidence of hepatotoxicity which was manageable.

Note: HIV – human immunodeficiency virus, INH – Isoniazid, PAS – Para Amino salicylic acid. TB – tuberculosis.

effect⁵. This property was capitalised for initiating intermittent therapy that would reduce cost as well as toxicity. In the journey towards shortening TB treatment, the trial of 5-months and 7-months regimen containing rifampicin showed cure rates of 100% with recurrence rates of 9–12% [9]. Table provides the sequence of trials in pulmonary TB towards enhancing cure rates and the salient findings deduced in each of them. India was one of the first to introduce quinolones into TB therapy, aimed at shortening TB treatment to less than 6 months in the early 90s [10]. This study showed that a daily regimen with addition of ofloxacin given for 4 and 5 months had a relapse rate of 4% and 2% respectively [10].

However, with the advent of human immunodeficiency virus (HIV), regimens required a strategic alignment taking into account the ease of bacillary dissemination in a vulnerable immune compromised environment leading to extra pulmonary forms, disseminated TB and atypical presentations [18]. The most dreaded complication of intermittent ATT therapy was Acquired rifampicin resistance in the phase of immune-compromisation, first reported in thrice weekly rifampicin, that was not offset by the initiation of antiretroviral therapy alone [13, 19]. This compelled researchers to perform the trial comparing daily vs intermittent therapy of

⁵ Toman K, Frieden TR. Toman's tuberculosis: case detection, treatment, and monitoring : questions and answers / edited by T. Frieden, 2nd ed. World Health Organization website. Published 2004. Accessed August 6, 2024. <https://iris.who.int/handle/10665/42701>

ATT of 6 months along with prompt introduction of ART. This trial stands even today as the only global evidence of a direct comparison of daily vs intermittent therapy where it was found that a daily regimen for 6 months was necessary for enduring success rates and preventing MDR-TB in HIV despite antiretroviral therapy initiation [17]. Shortening TB treatment to four months in HIV seronegative pulmonary TB patients with addition of Moxifloxacin was introduced. This trial, with a cure rate of 91% at the end of treatment and relapse rate of 4% at 24 months, became one of the early pieces of evidences to prove that shortening of TB treatment to under six months was a possibility [16]. This regimen is currently being tried in a pragmatic mode before programmatic implementation.

In the domain of MDR-TB trials, ICMR-NIRT participated in two landmark trials; one was the first triple regulatory trial in Multidrug resistant TB was the Standardized Treatment Regimen of Anti-tuberculosis Drugs for Patients with MDR-TB (STREAM) stage 2, multinational multicentric trial sponsored by vital strategies and Medical Research Council London. From a cumbersome period of 18–24 months, which had a severe attrition rate, this trial brought down the time period to 6–9 months, a great advancement in MDR-TB regimens. This was the Food and Drug Administration licensing trial for Bedaquiline and established its safety beyond 6 months in the Indian population. With Bedaquiline, playing the “captains knock” in all regimens used in Drug resistant TB, this trial assumes greater importance. Apart from Treatment shortening, the trial offered a fully oral regimen which is currently the shorter regimen (slightly modified) in the national programme [20]. The other (unpublished data) trial offers a simplified treatment for pre-extensively Drug resistant TB and in-tolerant MDR TB treatment further by giving just 3 drugs (Bedaquiline, Pretomanid and modifying doses of Linezolid) for 6 months and the results are gratifying, achieving cure rates of above 90% at the end of treatment. With linezolid toxicity especially after 2 months causing drug interruption, this dosage modification gives a dual advantage of ensuring safety with ease of drug intake.

Various modalities are being tried to provide a reliable four months regimen in drug sensitive TB, that includes stratified medicine approach [21, 22], multi-arm, multistage design, adaptive sample size⁶ and use of newer drugs [23], all of them aiming to provide a relapse free survival from TB in the long run.

One of the strategies used by Indian physicists to achieve effective shortening maintain the relapse free survival is by using high dose rifampicin as a surrogate for rifapentine. A dose of 25 mg per kilogram (kg) of rifampicin given along with other ATT produces a viable option towards effective TB treatment shortening, as it has the same efficacy of higher doses while possess comparative toxicity as the conventional regimen of 10 mg/kg [24].

Achievements in extra pulmonary tuberculosis

Extra pulmonary Tuberculosis is another physician’s enigma with peculiar attributes that include difficulty in establishing microbiological proof in specimens, paradoxical reaction or immune reconstitution inflammatory syndrome that mimics failure and drug resistance [25]. Overall, 440 150 patients with extra pulmonary tuberculosis (EPTB) were notified across different states in the year 2022, of which 28 to 32 % was

⁶ Nicholas Paton, National University Hospital, Singapore. Two-month Regimens Using Novel Combinations to Augment Treatment Effectiveness for Drug-sensitive Tuberculosis (TRUNCATE-TB). National Library of Medicine website. Published March 21, 2018. Updated August 14, 2023. Accessed August 6, 2024. <https://www.clinicaltrials.gov/ct2/show/NCT03474198?term=NCT03474198&draw=2&rank=1>

contributed by the paediatric population⁷. EPTB varies from lesser morbid lymph node TB, debilitating spinal, pleural TB to severe life-threatening forms such as tuberculosis meningitis, and tuberculous pericarditis. The burden of EPTB, especially based on different organs, is largely unknown nor are they clear cut definitions of treatment outcomes. Monitoring the treatment response is another challenging area in EPTB.

Challenges in Diagnosis of extra pulmonary tuberculosis

The rapid molecular diagnostic tests such as NAAT play the crucial supportive role for faster diagnosis in EPTB. Multicentric evaluation of Truenat (MolBio Diagnostics, India) showed that the sensitivity and specificity was 73.7% and 90.4% respectively against GeneXpert (Xpert *M.tb* rifampicin, Cepheid) with highest sensitivity in pus samples (89%) and highest specificity (92%) in cerebrospinal fluid samples by Truenat, similar to GeneXpert was observed [26]. Pauci-bacillary nature of EPTB, varied presentations, expertise for taking samples, quantity of the samples available for testing, infrastructure and expertise required for testing these samples are some for the reasons for diagnostic challenges. A study from central part of India showed that median time of health system for EPTB was 7 (0.6–16.4 weeks), shortest for tuberculosis meningitis and longest for abdominal TB [27]. Strengthening the knowledge of health care staff and awareness of the Index TB guidelines for EPTB⁸, training module of EPTB (2023)⁹ and the standard treatment workflow for EPTB which describe the algorithms of EPTB management¹⁰ is vital for early diagnosis or appropriate referral for further management.

Though ATT recommended for EPTB is similar to pulmonary TB, A longer duration is required for TB Meningitis and osteoarticular TB due to penetration issues. An important study carried out by the tuberculosis Research Centre formerly the tuberculosis research centre was the TB spine study with patients followed up to 15 years post treatment completion that demonstrated that effective chemotherapy had a success rate of 96% with surgery required only among those with neurological complication and more than three vertebrae involved [28]. Multicentric tuberculosis meningitis – KIDS trial done in Chennai, Pune and Malawi showed that high dose rifampicin (R30mg/kg) improved neurocognitive outcomes in children with tuberculosis meningitis [29]. The recently concluded trial from Chennai showed that Ofloxacin containing four-month regimen was non-inferior and safe for adults with lymph node TB [30]. Optimal regimen and the duration of ATT in different forms of pulmonary TB is still an area to be explored.

Paediatric tuberculosis present status and current challenges

Paediatric tuberculosis remains a public health problem [31, 32]. Children younger than 5 years are particularly susceptible to this severe TB and can serve as reservoirs for future disease outbreaks and are important group for TPT (Tuberculosis Preventive therapy) as well [33–35]. Diagnostic issues, safety concerns ethically exclude paediatric population from very many trials that makes evidences

⁷ Central TB Division M of H and FW. India TB Report 2023 [Internet]. New Delhi, India; 2023. Accessed August 6, 2024. <https://tbcindia.gov.in/showfile.php?lid=3680>

⁸ Central TB Division, Ministry of Health and Family Welfare, Government of India. Index TB guidelines: Guidelines on extrapulmonary tuberculosis for India 2016. Central TB Division website. Accessed August 6, 2024. <https://iris.who.int/bitstream/handle/10665/278953/IND-tb-guidelines-eng.pdf?sequence=5&isAllowed=y>

⁹ Central TB Division, Ministry of Health and Family Welfare, Government of India. Training module on extrapulmonary tuberculosis 2023. Central TB Division website. Accessed August 6, 2024. <https://tbcindia.mohfw.gov.in/2023/06/06/training-module-on-extrapulmonary-tb/>

¹⁰ Indian Council of Medical Research, Ministry of Health and Family Welfare, Government of India. Training module on extrapulmonary tuberculosis: Standard treatment workflow. Central TB Division website. Accessed August 6, 2024. https://main.icmr.nic.in/sites/default/files/STWsDownload/Adult_Extr_Tuberculosis/Adult-Extrapulmonary-Tuberculosis-all.pdf

Sparse [35]. The recent Shorter Treatment for Non-severe TB in African and Indian Children (SHINE) trial was one of the few trials in children which showed a shorter four months regimen to be non-inferior to the conventional 6 months regimen among non-severe TB [36, 37].

Challenge in tuberculosis diagnosis in paediatric population

The paucibacillary nature of the disease, challenges in sample collection in young children, and the limitations of currently available microbiological tests restrict bacteriological confirmation of TB in children [38]. Recent WHO guidelines recommend the use of novel rapid molecular assays as initial diagnostic tests for TB and endorse alternative sample collection methods for children¹¹. The poor reliability of current paediatric diagnostics has made clinicians rely heavily on clinical judgement and radiological evidence, both being non-specific. One of the ways to reduce reliability on expectoration in the paediatric population is to evaluate methods for *M.tb* detection in urine, stool and saliva collected from the children with presumptive TB and to compare the yield of *M.tb* detected which is now an ongoing study at ICMR-NIRT, the secondary outcome of interest is to determine the sensitivity of *M.tb* detection methods using stool and urine for screening the prevalence of TB disease among children with respiratory distress.

Nutrition and tuberculosis

Nutritional support has been an integral component of patient-centred care to improve TB treatment outcomes in the presence of disease-induced cachexia with undernutrition being a common comorbidity including India. The “RATIONS” (Reducing Activation of Tuberculosis by Improvement Of Nutritional status) study was a field-based, cluster-randomised controlled trial assessed the effects of nutritional support on tuberculosis mortality, treatment success, and other outcomes. Patients received nutritional support in the form of food rations (1200 kcal and 52 g of protein per day) and micronutrient pills for 6 months in the drug-susceptible tuberculosis and 12 months in the multidrug-resistant tuberculosis group. The median weight gain was 4.6 kg (IQR 2.8–6.8), but 1441 (54.8%) of 2630 patients remained underweight. At 2 months, 1444 (54.0%) of 2676 patients gained at least 5% of baseline weight. Weight gain, particularly in the first 2 months, was associated with a substantially decreased hazard of tuberculosis mortality. Nutritional support has been an integral component of patient-centred care to improve TB treatment outcomes [39].

Socio-behavioural component of tuberculosis control and elimination

Studies in India and globally point out to depression and unhealthy alcohol use as important socio-behavioural factors, determining non-adherence and leading to poor TB treatment outcomes. In recent studies, 48–59% of people starting TB treatment in India had probable moderate-to-severe depression, with more than one-quarter having persistent depression at the end of TB treatment [40, 41]. In a meta-analysis of global

¹¹World Health Organization. Global Tuberculosis Report 2021. World Health Organization website. Published 2021. Accessed August 6, 2024. <https://www.who.int/publications/i/item/9789240037021>

studies [42] and in Indian studies [43–45]. Depression at TB diagnosis is strongly associated with medication nonadherence and unfavourable TB treatment outcomes (odds ratio 4.1, 95%CI 2.4–6.9, evident from the meta-analysis by Ruiz-Grosso P, 2020 [42]. Similarly, people with TB have high Unhealthy Alcohol Use prevalence globally has been reported as 30% by Necho M, 2021 and in India it ranges from 15–61% across six studies [46–52] and the odds ratio of an unfavorable TB treatment response has been 2.0, (95%CI 1.6–2.5) in a meta-analysis by Ragan EJ 2020 [46].

More intensive integration of mental and behavioral health services and scaling up of differential counselling and care services for persons with TB to address gaps in psycho- social needs of persons with TB, would help obviate this problem and ensure adherence to treatment [48].

Health economic evaluation of regimens and ways to reduce catastrophic cost – National Institute for Research in Tuberculosis

Towards achieving, zero catastrophic cost for tuberculosis affected families

Catastrophic Health expenditure (CHE) is defined as out-of-pocket expenditure for health care that exceeds a specified proportion of household income (10% to 40%), with the consequence that the household may have to sacrifice the consumption of other goods and services necessary for their wellbeing¹² [53, 54]. The India's National Strategic Plan (NSP) for elimination of TB 2017 to 2025 is committed to zero catastrophic cost for TB patients.

Catastrophic expenditure in tuberculosis

Study from ICMR-NIRT reported that on an average, a patient suffering from TB incurred out of pocket expenditure, while shopping for diagnosis and treatment, Rupees (Rs.) 2052 in terms of direct cost, Rs. 934 in terms of indirect cost and the collective total cost was Rs. 986 [55, 56]. When projected to the country with the current prevalence, the amount works out to Rs. 30 billion per year for the country, despite free diagnosis and treatment offered to patients. For daily wage labourers, the mean number of work-days lost due to TB was 83 days. Every year, more than 170 million workdays are lost to the national economy on account of TB, amounting to Rs billion. In addition, 67% of rural and 75% of urban patients borrowed money on account of the TB illness. The average debts incurred because of TB including treatment was Rs 405 for rural and Rs.762 for urban patients. The proportion of various costs to annual family income was for direct cost 13%, indirect cost 26%, total cost 40% and debts 14%. The pre-treatment direct cost incurred by patients was Rs.50.

Active case finding as a measure to reduce tuberculosis catastrophic expenditure

Currently active case finding is yet to be a strategy under the TB control programme. A study from ICMR-NIRT, of the 336 individuals, 110 were diagnosed through active case finding and 226 through passive case finding showed a total of 29% of patients diagnosed through passive case finding and 9% of patients diagnosed through active case finding experienced catastrophic costs due to TB [57]. Active Case Finding inter-

¹² World Health Organisation. The World Health Report 2000: Health Systems: Improving Performance. World Health Organization website. Published 2000 Jun 14. Accessed August 6, 2024. <https://www.who.int/publications/i/item/924156198X>

ventions for TB began in India a decade before and since then it has expanded and acquired importance in the national strategic plan for TB elimination in 2025. The WHO end TB strategy adopted a target of achieving 'no tuberculosis affected household face catastrophic costs due to tuberculosis' by 2020.

Economic aspects of shortening the duration of tuberculosis treatment

Consistent efforts to mitigate the burden of treatment for drug-resistant tuberculosis as well as reducing costs, has resulted in shorter regimens (STREAM stage 2) [58-60]. From the cost perspective, the study by Ryckman and colleagues suggests that shortened duration yielded the most savings for both rifampicin-sensitive and rifampicin-resistant TB in three high burden countries [61]. It is important that the studies highlight that shortening TB treatment duration could be an important strategy to achieve the TB elimination goals together while also achieving sufficient economic gains [62-64]. The shorter duration was the most important driver of medium term savings with novel regimens, followed by increased treatment adherence.

Post-tuberculosis lung diseases present status and current challenges

Though ATT drugs help to sterilize the lesions through bactericidal activity, Scarring is the rule and if extensive can derail the entire lung parenchyma, that could cripple even a cured patient, which has assumed center stage and termed Post TB Lung Diseases (PTLD), defined as "Evidence of chronic respiratory abnormality, with or without symptoms, attributable at least in part to previous tuberculosis" [65]. With mortality more than 4 times higher in TB patients compared to matched controls in general population, PTLD needs to be drastically reduced [66]. The first challenge is to have a succinct definition which is lacking currently. In recent days, Host directed therapies including anti-fibrotic agents are tried to prevent or reduce PTLD, by decreasing inflammatory cell death, matrix destruction and fibrosis of the lung [65, 67]. Standard guidelines have to be framed after overcoming the challenges stated so that we can appropriate prioritise PTLD and reduce on the catastrophic cost further creating recovery as a whole rather than merely achieving bacterial quiescence.

Challenges in tuberculosis preventive therapy

TB infection is present in over half of the population in India. But to convince a population of millions, especially when asymptomatic, without the certainty of breakdown of a disease pose major hurdles in initiating TPT therapy. The National TB elimination programme hence is using a tiered approach, initially dealing with the high-risk groups and slowly ramifying to cover other population based on available evidence.

Randomised controlled clinical trial for tuberculosis preventive therapy in human immunodeficiency virus

This trial was done among People living with HIV /AIDs who were screened for TB and were given either 36 months of daily Isoniazid alone or 6 months of a combination of Ethambutol and Isoniazid, with appropriate initiation of antiretroviral therapy as per prevailing guidelines. Both regimens were similarly effective in preventing TB, when compared to his-

torical incidence rates, but with a trend towards better control with the longer regimen with negligible emergence of Isoniazid resistance [68].

Accelerating testing for tuberculosis infection and initiating preventive therapy is critical to achieving the goal of END TB strategy envisioning a world free of tuberculosis by 2035. This will require constant innovation, locally driven solutions to address the diverse and dynamic tuberculosis epidemiology and persistent programme monitoring and evaluation. As new tools, regimens and approaches emerge, midcourse adjustments to policy and practice must be adopted. Key programmatic challenges regarding the TB preventive therapy includes the potential burden of latent tuberculosis infection, identifying persons for TB preventive therapy, development and adoption of new diagnostic tools and TB preventive therapy acceptance, adherence and completion [69].

The 3-month once-weekly isoniazid-rifapentine regimen recommended by WHO for tuberculosis preventive treatment is being rolled in countries including India. It has higher treatment completion rates and lower risk of hepatotoxicity than isoniazid preventive treatment. However, trials showed higher frequency of adverse drug reactions including flu-like syndromes and dizziness, and also uncommon Grade 3 or 4 adverse events like hypotension, syncope, bronchospasm [70] requiring further evaluation. It would also be prudent to rule out TB as much as possible before initiating TPT therapy.

Pragmatic trials have been initiated in ICMR-NIRT to evaluate the effectiveness of preventive regimens in drug resistant TB. Levofloxacin drug given daily for six months is planned to be studied as preventive treatment among MDR TB contacts. Similarly, delamanid is studied as a potential drug among contacts of pre-XDR (Extremely Drug Resistant) TB patients.

Currently National TB Elimination Programme has rolled out adult Bacillus Calmette Gue'rin revaccination strategy for population with high risk like Elderly, malnourished, smokers, alcoholics and Diabetics is another step by the National TB Elimination Programme.

Pragmatic studies of national importance

The model directly observed therapy short course project – a game changer for programmatic implementation

The Governments of India and Tamil Nadu along with the world health organization and United States agency for international development conceptualized the idea of Model dots project between 1998 to 2002. They showed on the field that Directly Observed Therapy Short course with administration of the standard 4 drugs in intensive phase and isoniazid and rifampicin for four months, decreasing culture positive TB from 1.3% to 11.3%. The most salient feature was also the mortality survey which showed a four times higher risk among TB compared to matched controls of the same ages with incomplete treatment, failure and age above 45 years, proving to increase the risk of mortality due to TB¹³.

National tuberculosis prevalence survey

The National TB Prevalence survey in India, conducted from 2019 to 2021, was a comprehensive endeavour to estimate the true burden of tu-

¹³ National institute for research in Tuberculosis (ICMR). Genesis and achievements – A Monograph: Model Dots Project (1994-2014). September 2014. Accessed August 6, 2024. https://www.nirt.res.in/pdf/AR/MDP_GENESIS%20AND%20ACHIEVEMENTS_A%20MONOGRAPH_2014.pdf

berculosis at the national level. This robust survey funded by the Central TB Division and supported by technical assistance from the WHO and various Indian research institutions, utilized a cluster sampling design to cover a population of over 3.54 million across the country. The findings revealed a prevalence of microbiologically confirmed pulmonary TB among individuals aged 15 and above at 316 per 100,000 population, with notable variations among the 20 surveyed states/state groups for the year 2021. The prevalence to notification ratio was observed as 2.84 highlighting a significant gap in case detection and notification. The prevalence of TB infection among the surveyed participants was 21.6%. Additionally, the survey informed that 64% of the symptomatic population did not seek healthcare services. These insights have significantly informed India's efforts to combat tuberculosis through evidence-based interventions [71].

Reporting adverse drug reaction during tuberculosis management in India

Adverse drug reactions can lead to cryptic non-adherence contributing unfavourable response to TB therapy through cryptic non-adherence¹⁴ [72]. The increasing use of complex regimens for drug-resistant TB globally, the concomitant use of antiretroviral therapy in patients with HIV-associated TB, and the imminent release of new classes of medicines to treat TB on the market make the requirement for pharmacovigilance in TB even stronger. Understanding the need, WHO has come out with a framework namely active TB drug-safety monitoring and management¹⁴ in 2015, that refers to active and systematic clinical and laboratory assessment of patients on treatment with new anti-TB drugs, novel MDR-TB regimens or XDR-TB regimens to detect, manage and report suspected or confirmed drug toxicities¹⁴. The National TB Elimination Programme prioritizes pharmacovigilance at Drug Resistant TB Centres and the Adverse Drug Reactions Monitoring Centres established under Pharmacovigilance programme of India are linked with the Drug Resistant TB centres, so as to improvise adverse drug reactions management and appropriate reporting¹⁵.

Capacity building

Therapeutic anti-tuberculosis therapy drug monitoring

Though not routinely required, therapeutic anti-TB drug monitoring help in dose optimization to improvise success rates [73, 74]. This is especially true in pulmonary TB when sensitive bacilli persist despite adherence to ATT and comorbidities where malabsorption is inevitable [75]. There is a need for expansion in the programme as it plays a critical role in diagnosing and differentiating simple malabsorption from emergence of Drug resistance.

National tuberculosis biorepository

ICMR-NIRT has set up a large TB Biorepository in its Thiruvallur campus, inaugurated by the honourable Prime minister of India on 25th

¹⁴ World Health Organisation. Active TB drug-safety monitoring and management (aDSM). World Health Organization website. Accessed August 6, 2024. [https://www.who.int/teams/global-tuberculosis-programme/diagnosis-treatment/treatment-of-drug-resistant-tb/active-tb-drug-safety-monitoring-and-management-\(adsm\)](https://www.who.int/teams/global-tuberculosis-programme/diagnosis-treatment/treatment-of-drug-resistant-tb/active-tb-drug-safety-monitoring-and-management-(adsm))

¹⁵ Central TB Division, Directorate General of Health Services, Ministry of Health with Family Welfare. Technical and Operational guidelines for TB Control in India 2016. Central TB Division website. Accessed August 6, 2024. <https://tbcindia.mohfw.gov.in/wp-content/uploads/2023/05/5585665076Index-TB-Guidelines.pdf>

February 2024. The Biorepository stores large numbers of various types of biological specimens including whole blood, DNA, RNA, urine, saliva, sputum, *M.tb* isolates and peripheral blood mononuclear cells collected from well-characterized cohorts of TB patients, their household contacts, as well as community controls, enrolled and followed-up in various clinical trials, multicentric cohort studies and research projects of ICMR-NIRT, thus serving as an extremely valuable and much needed resource for the TB research community to support advances in diagnostics and biomarker research. The samples are stored appropriately in -80° freezers and liquid nitrogen storage tanks. All the storage equipment is equipped with temperature monitors capable of real time temperature logging and alerting users via SMS as well as emails when temperature deviations are noticed. The specimen inventory is managed through a cloud-based software. The Biorepository is manned by skilled staff who are trained in Good clinical and laboratory Practice and International Air transport Association guidelines. The Biorepository has all safeguards and safety devices including access control, Closed circuit cameras, smoke detectors, oxygen monitors, fire extinguishers and backup generators. This facility will be a boon to the TB research community within and outside the country to accelerate basic and translational research to support global TB elimination efforts.

Other collaborative activities spear headed by Indian Council of Medical Research

ICMR along with WHO South East Asian Region (SEAR) office collaborated with 10 SEAR member states to implement a common platform titled 'Regional Enabler for the South-East Asia Research Collaboration for Health'. This SEAR RESEARCH Platform has been established to formulate and implement public health research projects and conduct capacity-building activities based on common national health priority areas. The other activity for capacity building in the same platform with regard to diagnosis is the "Capacity building for Advanced TB diagnostics in SEAR countries" organised by ICMR-NIRT and McGill's University for effective application of diagnostics in TB care.

Future technologies and strategies proposed for implication

Research: clustered regularly interspaced short palindromic repeats system. CRISPR-Cas technology

Among the many technologies evolving in a rapid manner to address these gaps, CRISPR-Cas is one of the promising technologies. It uses the Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) system. For diagnostic tool development, the CRISPR-Cas system, particularly Cas 12/Cas 13 enzyme is used to detect specific genetic signature from mycobacteria. The methodology as such involves designing a CRISPR RNA (crRNA) that guides the Cas enzyme to the target DNA or RNA sequence and upon recognition of the site, the Cas enzyme gets activated and cleaves the reporter molecule producing a detectable signal such as Florescence signal that can be read on a plate reader or captured as a band immune-chromatogram strip. ICMR-NIRT is in the early stages of developing a CRISPR-Cas based mycobacterial detection tool and has submitted for process patent. This tool is being developed for detection of TB in sputum and urine samples.

Research: direct drug susceptibility testing – commercial version

The microscopic observation drug susceptibility (MODS) assay is the only WHO approved non-commercial direct susceptibility testing method which is a growth-based assay system proven to be an in-house low-cost assay which simultaneously detects *M. tb* and their susceptibility to first-line anti-TB drugs. Bob Gilman and Luz Caviades introduced the MODS assay at the Universidad Peruana Cayetano Heredia in Lima [76] and WHO recommends this assay as a non-commercial and direct drug susceptibility testing technique [76, 77]. An attempt was made to miniaturize the conventional MODS into a 96-well plate method (M-MODS). This effort created an avenue to reduce the quantity of liquid media used to ten times lower and the data showed almost identical sensitivity of over 95% to that of the conventional methods used (MODS, MGIT960) in determining the presence of *M. tb* in sputum sediments (n=20). The turnaround time was again identical between M-MODS and MODS. Furthermore, this assay method M-MODS has the advantage of including more drugs and a greater number of specimens tested in a single plate with ten times lesser volume of reagents. In addition, the commercialization of this format (M-MODS) is plausible, and the optimal quantity re-hydrant was also determined in the preliminary work.

Future developments in paediatric tuberculosis in India

Drug trials focusing on shorter regimen for both DS-TB and DR-TB are underway. In addition, PK studies looking at the optimal dosage of anti TB drugs are also being conducted. Increased funding from the public and private sectors, improved stakeholder collaboration, and increased investment in paediatric TB-specific basic science, vaccine, diagnostic, and implementation research are all essential to improve the health of children with TB [78, 79].

Zoonotic and zoo-anthropotic tuberculosis

Tuberculosis is one of the important Zoonotic disease with Bovine TB not amenable to either vaccines or any other treatment. Culling or slaughtering of the concerned animal, is the only way to eliminate transmission, which the poor farmer cannot afford. Diagnosis is by using.

Tuberculin skin test for detecting the presence or exposure of the pathogen. The Institute was the first to report *Mycobacterium Orngis* in India among the wild ungulates. The One Health approach is globally gaining momentum as well due to possibility of reverse Zoonosis.

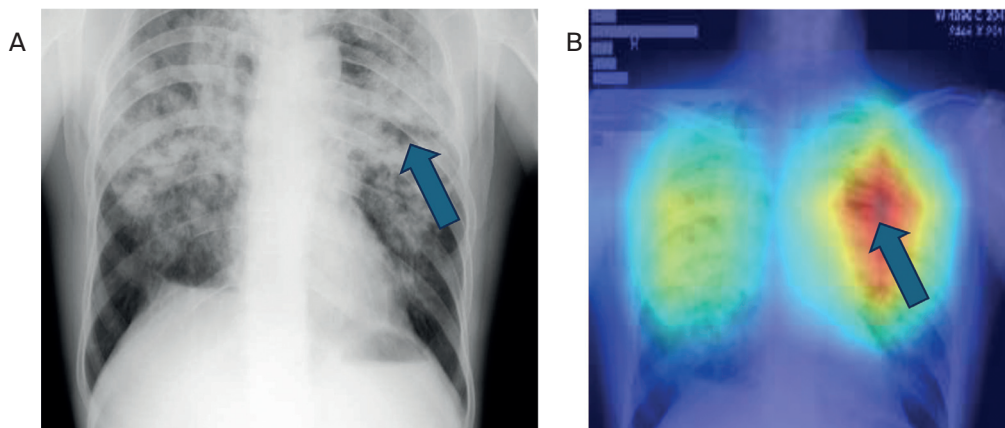
Artificial intelligence incorporation for early detection

Innovative TB health technology sharing platform is a periodical scientific exercise and exploration conducted at the ICMR headquarters with Central TB Division that brings the stakeholders for a first-hand information about the status of these products to facilitate validation and apply in field conditions. The two artificial intelligence tools currently explored are the Xray Computed aided Detection in Chest X-ray (fig. 5) and Cough artificial intelligence tool for prompt detection and early initiation of therapy working to prevent secondary transmission.

Evaluation of the artificial intelligence model performance for line probe assay first line and 2nd line reporting

LPA is used to diagnose drug resistant TB cases. There are two types of LPA: First Line (FL) and Second Line (SL). FL-LPA picks up drug resistance to First Line Anti TB Drugs (Isoniazid and Rifampicin) while SL-LPA

FIG. 5. Xray of the lungs (A) and heat mapping (B)



Note: Heat mapping to reveal the extent of severity of lesion showing the increased activity on the left side where the infiltration is breaking into a cavity, suggesting a more ominous lesion compared to the right – tool indigenously being developed by Indian Council of medical research with Centre for development of advanced computing courtesy CDAC and ICMR-NIRT.

detects drug resistance to Second line Anti TB drugs (Fluoroquinolones and second line injectable). The LPA testing process is an output of a complex interaction between a series of probes (reagents) and specific segments of TB bacterial DNA called genotypes (wild types and mutations) which are visible as dark bands of varying intensities against a white background. Each individual patient's LPA test result is captured over a special slender paper strip with 27 bands, which is interpreted by lab technicians and microbiologists to infer sensitivity to various drugs. Multiple LPA test strips are serially pasted on to an LPA Hain's sheet and are interpreted manually in the laboratory using a reference paper card.

Other exploratory objectives in the near future include:

- Markers of recurrence and predictors of paradoxical reaction in immunocompromised;
- Markers for detection of extrapulmonary TB;
- Point of care tests for drug resistance testing for newer drugs and expanding mutation catalogues;
- climatic influence on TB (fig. 6).

Programmatic initiatives on tuberculosis elimination

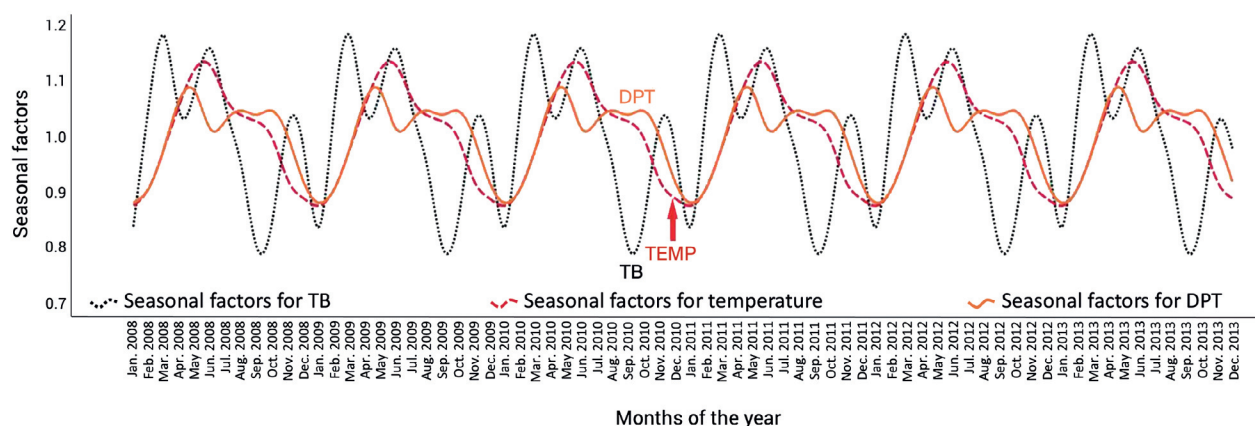
Pradhan Mantri Tuberculosis Mukht Bharat Abhiyaan

This is a unique community engagement program that adopts TB patients, providing support in various forms, from nutritional support, vocational assistance to support for diagnostics etc., for a period of six months to three years while the patient is on treatment for TB, aiming to create awareness and reduce stigma by involving the community in the treatment cascade¹⁶.

Jan Andolan – A People's Movement. This movement envisage reaching out to the population at large, focusing on improved active/passive case finding efforts for early diagnosis, prompt treatment initiation, and ensuring successful treatment across both public and private sectors.

¹⁶ Pradhan Mantri TB Mukht Bharat Abhiyaan. Central TB Division website. Accessed August 6, 2024. <https://tbcindia.mohfw.gov.in/pradhan-mantri-tb-mukht-bharat-abhiyaan/>

FIG. 6. Influence of climate on tuberculosis transmission (adapted from [80])



Note: The role of temperature, dew point temperature (DPT), and relative humidity have bearing on the survival on the *M.tb* and may influence tuberculosis (TB) disease's progression from latent stage infection to active, supported by higher dew point temperature and moderate temperature in summer and monsoon season.

Support for the patients come from own family caregivers introduced in 2023, from TB vijeta or TB champions who share their struggle and success stories, how hey overcome the obstacle of TB disease and Ni-kshay Mitras – The Donors, which has substantially supported the TB programme with nearly 1 lakh 60 thousand Ni-kshay Mitras committing to assist around a million patients, raising an estimated \$146 million per year.

Ni-kshay Poshan Yojana (Nutritional Support Scheme through Direct Benefit Transfer)

The National TB Elimination Programme (NTEP) in India has been providing Rs.500/- per month to all notified TB patients from the day of notification until the time treatment outcome is achieved in India since 2018¹⁷. Currently, NTEP provides Rs.3000/- at Rs.1500 at two different instances during the treatment – at notification and 84 days later till 6m duration. Rs.500/- per month will be added in case someone needs an additional amount. As on date, the NPY incentives have been disbursed to ~9.8 million beneficiaries, amounting to more than Rs. 28,120 million i.e., approx. USD 336,315,200.

Ayushman Arogya Mandir Health and Wellness Centres (HWCs) (integration of health services) integrating TB services with the various platforms of National Health Mission, Ministry of Health and Family Welfare is one of the key strategies proposed in the National Strategic Plan (2017-2025) of NTEP.

The NTEP framework in collaboration with the HWCs aims to integrating and strengthening TB services like TB case finding, Referral for Testing, Case management, advocacy, counselling, Treatment support and monitoring, TB preventive treatment and interventions to ensure community participation. Multiple batches of Community Health officers were trained by Central TB Division, State TB cells and District TB office on how to integrate TB services in HWC and about how to efficiently exercise the same.

¹⁷ Ministry of Health and Family Welfare. Nikshay Poshan Yojana (Nutritional Support to TB Patients). myScheme website. Accessed August 6, 2024. <https://www.myscheme.gov.in/schemes/npv>

Operational challenges and their rectification

NTEP aims to eliminate TB as a public health problem in India¹⁸. Despite significant progress, several challenges impede the programme's success. One of the primary challenges is in detecting TB, particularly regarding diagnosis. According to the National TB Prevalence Survey, 60% of symptomatic individuals do not seek care, indicating a significant gap in awareness and accessibility to TB diagnostic services. Additionally, the timely and adequate supply of NAAT consumables, crucial for rapid and accurate TB diagnosis, is essential for effective case detection. Community engagement for active case finding also remains a challenge, necessitating effective strategies to improve case detection rates.

In terms of treatment modalities, interrupted supplies of drugs are a significant issue. Continuous and reliable drug supply chains are vital for uninterrupted treatment. Many TB cases remain undiagnosed or untreated, highlighting the need for strengthened surveillance and follow-up mechanisms. Timely direct benefit transfer disbursements to patients are often delayed, and timely financial support is necessary to ensure patients adhere to their treatment regimens.

Preventing TB within the programme also faces challenges, particularly in identifying and motivating the eligible population for adult Bacillus Calmette Gue'rin vaccination and TB preventive therapy. Efforts must be intensified to expand coverage and acceptance of these preventive interventions.

Capacity building of NTEP staff is another significant challenge. Continuous training and capacity building are required to enhance their skills and knowledge in TB management and ensuring regular and comprehensive training programs is essential for the effective implementation of NTEP. Additionally, strong advocacy and sustained engagement with various government and non-government departments are necessary for a coordinated response to TB. Collaborative efforts can help address the multifaceted challenges of TB elimination.

Differentiated tuberculosis care-prioritization in preventing deaths among tuberculosis cases

NTEP has implemented a range of measures to address factors contributing to increased morbidity and mortality among individuals with TB¹⁹ [81]. One notable initiative is the adoption of a differentiated TB care approach in 2021, which involves the provision of comprehensive evaluation and supportive treatment services at various healthcare levels. It aims to reduce death among TB patients by prioritizing patients who are high risk of death for special care including hospitalization currently being practiced in 20 states.

Conclusion

Research and implementation, Governmental and non-governmental organisations, patients and health staff require to work like Hand and glove to achieve this task of TB elimination. End TB task is achievable with countries and organisations coming together to work for the welfare of the TB community. This kind of philanthropic collaboration for ending TB knows no boundaries. A multidisciplinary approach with innovations centered around patients perception of disease would make the earth breath freely, bereft of TB.

¹⁸ Central TB division. National TB Elimination Programme. Central TB Division website. Accessed August 6, 2024. <https://tbcindia.mohfw.gov.in/>

¹⁹ Ministry of Health and Family Welfare. Nikshay Poshan Yojana (Nutritional Support to TB Patients). myScheme website. Accessed August 6, 2024. <https://www.myscheme.gov.in/schemes/npv>

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Health system strengthening in China: progress, challenges and ways forward

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ABSTRACT

China's health system reform, launched in 2009, has been a comprehensive effort to enhance healthcare accessibility and quality while addressing the challenges of escalating costs, an aging population, and the rise in non-communicable diseases. The reform has achieved near-universal health insurance coverage, leading to reduced out-of-pocket expenses and improved financial protection for citizens. It has also focused on public hospital reform, aiming to improve management efficiency, eliminate financial dependency on drug sales, and introduce new payment models to curb over-prescription. Strengthening primary care has been a cornerstone, with investments in infrastructure and workforce to enhance local healthcare services and introduce a family doctor system for continuous care. The Essential Medicines Program has made medications more affordable and accessible. Despite these advancements, challenges such as service delivery fragmentation, quality of care inconsistencies, and health financing issues persist. The Healthy China 2030 vision, building on these reforms, aims to further integrate health services, enhance governance, and promote preventive care to achieve a more equitable and sustainable healthcare system. The article underscores the importance of robust governance, financial investment, and policy innovation in realizing health reform goals and offers lessons for other nations facing similar health system challenges.

Key Words: Universal Health Coverage (UHC); Health System Reform; Primary Health Care; Public Hospital Reform; Healthy China 2030

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Introduction

Health system strengthening has become a critical priority for global health, especially in achieving Universal Health Coverage (UHC) and advancing Sustainable Development Goals (SDG). Globally, health systems face increasing pressure from challenges such as rising healthcare costs, an aging population, and the growing prevalence of non-communicable diseases (NCDs). Countries across the globe are grappling with these challenges as they seek to balance cost containment with improving the quality and accessibility of healthcare. The World Health Organization (WHO) and global health policymakers emphasize the importance of robust health systems to ensure equitable access to quality health services, financial protection against the rising cost of health care, and improved health outcomes for all populations [1]. UHC, which ensures that all individuals have access to essential health services without financial hardship, is a cornerstone of global health improvement efforts. Strengthening health systems is essential to meet these goals, ensuring equitable access to quality care and addressing both existing and emerging health threats.

China's health system reform, launched in 2009, represents one of the most ambitious and wide-reaching efforts to address these global health system challenges. Facing escalating healthcare costs, inadequate access to care, and deep disparities between urban and rural populations, the Chinese government initiated a series of reforms aimed at creating a basic healthcare system that provides equitable access to all citizens. The goal of these reforms was not only to contain costs but also to ensure that the majority of the population could access essential health services without falling into poverty due to medical expenses [2]. This marked a significant shift from earlier decades when healthcare was predominantly market-driven, leading to unequal access and increased out-of-pocket payments for patients.

China's health system reform offers valuable insights for other nations facing similar challenges. Its success in rapidly expanding health coverage and reorienting its healthcare delivery system towards primary health care provides a potential model for countries seeking to strengthen their own health systems. Moreover, China's experience underscores the importance of strong governance, substantial financial investment, and a willingness to experiment with policy innovations in achieving health reform goals.

This article aims to explore the progress China has made in strengthening its health system, the ongoing challenges it faces, and the future directions of its health reforms. By examining China's journey through the lens of global health system strengthening, this article will draw lessons that can inform health reform efforts in other countries.

Progress in Health System Strengthening

In 2009, China initiated an overall health system reform to achieve universal health coverage. The primary objective of China's health reform was to establish a basic healthcare system that would provide affordable and equitable access to essential services for the entire population. The reform sought to address several key issues: the rising cost of healthcare, the inequality in access to care between urban and rural areas, and the financial burden of Out-of-Pocket (OOP) payments that led to medical impoverishment for millions of citizens [3, 4]. By creating a healthcare system that covered all citizens, the reform aimed to improve equity, accessibility, and affordability, ensuring that all Chinese people could receive basic health services without falling into poverty.

Table 1. Three phases of China's health system reform since 2009

Phase	Years	Goals
First	2009–2011	The focus was on establishing foundational elements of the health system, including basic medical insurance system, national essential medicine system, strengthening primary health care, ensuring equal access to basic public health services, piloting public hospital reforms
Second	2012–2015	This phase emphasized expanding coverage and strengthening healthcare services by accelerating the establishment of universal health insurance coverage, improving the essential medicine system and primary care services, promoting public hospital reforms
Third	2016 onwards	This phase focused on modernizing and integrating the healthcare system, introducing tiered service delivery system, modern hospital management system, full implementation of universal health insurance, pharmaceutical supply system, and comprehensive regulatory system

The health system reform can be divided into three distinct phases, each with evolving priorities and goals (Table 1). The overall health system reform including the following key measures.

Expansion of Social Health Insurance

One of the most remarkable achievements of China's health reform has been the rapid expansion of social health insurance. By 2015, over 95% of the population was covered by one of the three major health insurance schemes: The Urban Employee Basic Medical Insurance, the Urban Resident Basic Medical Insurance, and the New Rural Cooperative Medical Scheme (NCMS). Specially, NCMS was introduced to address the healthcare needs of rural residents, who had been largely underserved prior to the reforms. By 2015, it had become one of the largest healthcare insurance schemes globally, providing rural populations with affordable access to both outpatient and inpatient services [5]. In 2016, URBMI and NCMS were merged into one scheme, i.e. Urban and Rural Resident Basic Medical Insurance. This near-universal coverage represented a massive leap forward in terms of healthcare access [6].

Strengthening Primary Care

Recognizing the need to reduce the overreliance on hospitals and provide more localized and preventive care, the government made significant investments in strengthening primary care. Primary care facilities, especially in rural areas, were previously underdeveloped, lacking both infrastructure and qualified health workforce. To address this, the reform focused on building new community health centers, upgrading existing facilities, and increasing the number of trained healthcare providers at the primary care level [7].

Since 2009, the government invested heavily in improving the capacity of primary care institutions. This included not only the physical infrastructure but also human resources, with efforts to train and recruit more doctors, nurses, and community health workers. The goal was to make primary care the first point of contact for patients, reducing the burden on overcrowded hospitals and providing more continuous and coordinated care [4].

Moreover, to improve service delivery, China introduced a family doctor system, in which general practitioners lead teams to provide comprehensive and continuous care for enrolled residents. This model, aimed at increasing patient trust in primary care, has shown promising results in areas such as chronic disease management and preventive care [6].

Public Hospital Reform

Public hospitals are central to healthcare delivery in China, and their reform has been a key component of the overall health system strengthening strategy. Historically, public hospitals faced several challenges, including inefficiencies in management, financial dependency on drug sales, and overprescription driven by profit incentives. The reform focused on addressing these inefficiencies and improving the governance of public hospitals [8].

A major aspect of the public hospital reform was the introduction of governance structures that allowed hospitals greater autonomy in management while holding them accountable for performance outcomes. One of the significant measures was the removal of the 15% mark-up on drug sales, which had previously incentivized hospitals to overprescribe medications in order to increase profits⁶. This reform helped to realign hospital incentives towards better patient care, rather than profit generation.

Additionally, new payment models were introduced, shifting from a fee-for-service system that encouraged overuse of services to more efficient mechanisms such as case-based payments and global budgets. These models were designed to contain costs while ensuring that hospitals could provide high-quality care [9].

Equalization of essential public health services

Since the commencement of health system reform in China in 2009, the provision of essential public health services has been pivotal, with a focus on enhancing population health and reducing disparities in health service access. The funding for these services has been predominantly public, with a structured mechanism that ensures a steady increase in financial support. This includes a per capita subsidy model that has seen significant increments, thereby expanding the range and depth of services offered. The service package itself has evolved to encompass a broad spectrum of health interventions, starting with foundational services like vaccinations and maternal and child care, and progressively incorporating comprehensive care for the elderly, chronic disease management, and targeted health education.

A critical aspect of the reform has been the emphasis on equity, aiming to bridge the gap in essential public health service delivery between urban and rural populations. This has been addressed by bolstering the primary health care infrastructure in rural areas and ensuring widespread accessibility to services [10].

Essential Medicines Program

The Essential Medicines Program was a cornerstone of China's health reform. Prior to the program's implementation, access to affordable and effective medication was a significant barrier for many people, especially in rural areas. High drug prices and overprescription of expensive medications were common, exacerbating the financial burden on patients. To combat this, the Essential Medicines Program aimed to provide a standardized list of essential drugs that were available at lower, regulated prices across the country [11].

The program made essential medicines more affordable and available in public healthcare facilities. This policy ensured that healthcare providers, particularly at primary care levels, prescribed these essential medications as the first line of treatment, reducing reliance on more expensive drugs that were often promoted for profit motives. By eliminating the 15% drug mark-up in public hospitals and health centers, the govern-

ment was able to curb overprescription, improve medication affordability, and make sure that critical drugs were accessible to patients across China.

Integrated healthcare system reform

China's integrated healthcare system reform focuses on promoting collaborations between institutions at different levels to enhance service efficiency and accessibility. Four types of health service entities have been developed: urban medical groups, county medical communities, specialized medical alliances, and telemedicine collaboration networks. These alliances serve as platforms for resource integration, institutional cooperation, and seamless service delivery. By the end of 2022, over 18,000 medical alliances had been established nationwide, with telemedicine networks covering all cities and counties.

To improve the continuity and convenience of services, China has introduced family doctor contracted services. These teams, with a focus on comprehensive health management, provide integrated services, including prevention, treatment, care, rehabilitation, and health education to contracted residents, particularly key populations such as children, perinatal women, the elderly, and patients with chronic conditions like hypertension and diabetes. More than 70% of these key populations are now covered¹.

In addition, China is advancing digital health to support universal health coverage. The integration of digital tools into the healthcare system includes the creation of Regional Health Information Platforms, enabling mutual recognition and data sharing among institutions. Over 8,000 hospitals are connected to this platform, with 17 provinces sharing electronic medical records and 204 cities allowing the mutual sharing of test and examination results¹. Through digital health and telemedicine, high-quality services are now more accessible to patients in grassroots, remote, and rural areas.

Major Achievements of the Reform

The implementation of these key reform measures has led to substantial progress in strengthening China's healthcare system, particularly in terms of healthcare access, financial protection, and improved outcomes.

Continuous development of healthcare resources

China has experienced a rapid growth in healthcare resources in the recent decades, particularly in terms of health personnel. According to the China Health Statistics Yearbook 2023, the number of practicing doctors grew from 1.6 million in 2000 to 4 million in 2023¹. Registered nurses also increased from 1.3 million to 5.6 million during the same period¹. The number of general practitioners per ten thousand people increased from 0.81 in 2012 to 3.28 in 2022¹. Together, these figures reflect significant improvements in healthcare capacity. Alongside the growth in healthcare personnel, the expansion of healthcare facilities has also improved access to medical services by promoting the standardized construction of primary healthcare institutions and continuously enhancing their ability to diagnose and treat common diseases, as well as their public health service and health management capabilities. Currently, 90% of urban and ru-

¹ National Health Commission of the People's Republic of China. China Health Statistics Yearbook 2023. Peking Union Medical College Press; 2023. Accessed September 10, 2024. <https://www.stats.gov.cn/sj/ndsj/2023/indexeh.htm>

Table 2. China's progress in health system strengthening

Indicator	Years					
	2000	2005	2010	2015	2020	2023
Population aged 65 and above (%) ²	6.9	7.8	8.6	10.0	12.6	14.3
Number of health professionals per 1000 population ³	3.6	3.5	4.4	5.8	7.6	8.0 (2021)
Sustainable Development Goals 3.8.1 ⁴	47	57	66	76	81 (2019)	81 (2021)
Life expectancy at birth ²	72	74	76	77	78	78.6
Total Health Expenditure (billion CNY) ⁵	458.7	866.0	1998.0	4097.5	7217.5	9057.6
Total Health Expenditure as proportion of Gross Domestic Product (%) ⁵	4.6	4.6	4.9	6.0	7.1	7.2
Out-of-Pocket as proportion of total health expenditure (%) ⁵	59.0	52.2	35.2	29.3	27.7	27.3

ral households can reach the nearest medical point within 15 minutes⁵. Furthermore, China's total health expenditure has consistently risen, increasing from 458.7 billion CNY in 2000 to over 9 trillion CNY in 2023, demonstrating a significant financial commitment to healthcare⁵ (table 2). This upward trend in spending is well-documented in studies, which indicate that investment in healthcare has contributed to improved service availability and quality across the country.

Increased Utilization of Health Services and Improved Health Outcomes

The expansion of health insurance coverage and the strengthening of primary care have contributed to an increase in the utilization of health-care services. More people, particularly those in rural areas, now have access to essential medical services, leading to earlier detection of diseases and improved management of chronic conditions [12]. China has made great progress in SDG indicator 3.8.1, i.e. essential health service coverage. According to WHO statistics, the indicators increased from 66 in 2010 to 81 in 2021, well above the regional average⁴ [13].

China's focus on preventive care, vaccination, and health education has also yielded significant improvements in public health outcomes. Additionally, chronic disease management programs, such as those for diabetes and hypertension, have helped patients manage their conditions more effectively, reducing complications and improving overall quality of life. Life expectancy has increased from 74.8 in 2010 to 78.6 in 2023⁵.

Reduction in Out-of-Pocket Expenses

One of the most significant achievements of China's health reform has been the dramatic reduction in out-of-pocket healthcare expenses. Before the reforms, patients were paying an unsustainable portion of their health-care costs, with OOP expenses accounting for approximately 60% of total health expenditure in 2000. This high financial burden often drove households into poverty, particularly when facing major health emergencies [9].

² The World Bank. World Bank Open Data [online database]. World Bank Group website. Updated September 10, 2024. Accessed September 10, 2024. <https://data.worldbank.org>

³ National Health Commission of the People's Republic of China. China Health Statistical Yearbook 2022. Accessed September 10, 2024. <http://www.nhc.gov.cn/mohwsb-wstjxxzx/tjtjn/202305/6ef68aac6bd14c1eb9375e01a0faa1fb.shtml>

⁴ World Health Organization, World Bank. Tracking Universal Health Coverage: 2023 Global monitoring report. The World Bank Open Knowledge Repository website. Accessed September 10, 2024. <https://openknowledge.worldbank.org/handle/10986/40348>

⁵ National Health Commission of the People's Republic of China. China Health Statistics Yearbook 2023. Peking Union Medical College Press; 2023. Accessed September 10, 2024. <https://www.stats.gov.cn/sj/ndsj/2023/indexeh.htm>

Table 3. The Sanming Model: A Milestone in China's Health System Reform

Focussing	Proposed solutions
Addressing Governance and Financial Investment	The local government placed a strong emphasis on healthcare reform, with senior leaders taking primary responsibility for its success. The government consistently increased its investment in healthcare, achieving an average annual growth rate of 12.1% in health expenditure. In addition, long-term public hospital debts were resolved in alignment with regional health plans.
Adjusting the Purchasing Mechanism	The Sanming model implemented several reforms to improve the purchasing mechanism. These included reducing inflated prices for drugs and medical consumables, standardizing diagnostic and treatment procedures, and adjusting the pricing of medical services. These measures were designed to ensure that healthcare institutions remain focused on public welfare without imposing additional financial burdens on the population. The model also explored the integration of medical resources at the county level through the establishment of county medical communities. Moreover, it introduced packaged payment systems in the health insurance schemes and encouraged healthcare institutions to shift from a treatment-centered approach to a health-centered model, with a focus on health education and chronic disease management.
Reforming Financial Incentives	One of the key reforms was the decoupling of physician income from hospital profits. Instead, a new compensation system was introduced, comprising a base salary plus a bonus determined by a point system that rewarded the quality of care and the achievement of strategic targets. This reform encouraged a shift towards value-based healthcare services, aligning financial incentives with the delivery of high-quality care.
Placing People's Health at the Center	The Sanming model emphasized a patient-centered approach by establishing health management centers and disease management centers in hospitals and PHC institutions. These centers train health management physicians and disease managers to provide comprehensive and continuous health services, including pre-hospital health management, in-hospital diagnosis and treatment, and post-hospital disease management.
Key Achievements	The Sanming model has achieved substantial cost reductions without compromising clinical quality or operational efficiency. It has demonstrated that, with appropriate governance structures and financial incentives, public hospitals and PHC institutions can deliver cost-effective, high-quality services. The central government has recognized the success of the Sanming model, encouraging the adoption of its principles in health system reform across the country.

Note: PHC – Primary health care.

By expanding public health insurance schemes and regulating drug prices through the Essential Medicines Program, China successfully reduced OOP expenditures to less than 30% by 2016. This has greatly alleviated the financial strain on individuals and families, allowing more people to seek medical care without the fear of incurring catastrophic costs [9]. The reduction in OOP expenses has been particularly beneficial for low-income and rural populations, who were previously the most vulnerable to medical impoverishment. The poverty alleviation efforts also greatly contributed to the financial protection for the poor group [13].

One of the most significant achievements in China's health system reform is the implementation of the Sanming model. This model addressed critical challenges in health system reform by focusing on comprehensive changes in governance, financial incentives, and service delivery. Frequently cited as a benchmark for public hospital reform across China, the Sanming model has demonstrated how systemic transformations can enhance both cost efficiency and the quality of care. This case study is demonstrated in table 3.

Key Challenges in Health System Strengthening in China

China's health system reforms have made substantial progress in expanding coverage and improving access to healthcare, but several challenges continue to impede the realization of a fully efficient, equitable, and sustainable health system. These challenges primarily stem from the fragmentation in service delivery, issues related to the quality of care, health financing constraints, and governance gaps. Addressing these challenges is critical for the long-term success of the reforms and the achievement of UHC.

The healthcare system lacks sufficient integration and coordination, falling short of meeting the public's need for continuous and comprehensive services. The collaboration mechanisms between specialized public health institutions, primary healthcare facilities, and hospitals still need further improvement. This results in overcrowded hospitals, longer wait times, and unnecessary admissions, with a hospital-centric model that undermines primary care's role in managing less severe cases and providing preventive services, adding strain to the overall system [4, 7]. The healthcare system also has limited connectivity and insufficient sharing of personnel, technology, equipment, data, and information, further hindering cohesive functioning. There is an ineffective integration of medical treatment, prevention, rehabilitation, care, and elderly services, and insufficient coordination between different levels of the system [6]. As a result, the system struggles to effectively address issues like chronic disease management, and its overall efficiency needs improvement.

The quality of healthcare services needs improvement and still falls short of meeting the public's expectations for 'accessible and satisfactory care'. China is among the countries with the greatest progress in healthcare quality and accessibility worldwide. However, there is still significant room for improvement in service quality. Compared to developed countries, China's healthcare workforce, particularly in primary care, still has significant gaps in qualifications and training, leaving many providers ill-equipped to deliver comprehensive care [14]. In particular, the regional disparities in healthcare quality and the need to enhance primary healthcare services have affected patient choices for medical care.

Rising healthcare costs and the fragmented nature of China's health insurance schemes have raised concerns about the system's long-term financial sustainability. The aging population and increasing prevalence of non-communicable diseases like diabetes and hypertension are placing additional strain on healthcare spending for both individuals and the state [15]. Demand for advanced medical technologies further escalates costs. Additionally, the fragmentation of insurance schemes, each with distinct rules and benefits, creates inefficiencies and disparities. For instance, rural residents typically receive fewer benefits and face higher out-of-pocket expenses compared to urban employees, resulting in unequal access to care [5].

Ways forward

The future of China's healthcare system is poised for significant transformation, with the overarching goal of achieving the Healthy China 2030 vision. This long-term strategic plan is designed to propel the country towards a more equitable and efficient healthcare landscape, addressing the multifaceted challenges of modern healthcare delivery. The following sections outline the key areas of focus that will shape the evolution of China's healthcare system in the coming years.

Healthy China 2030 Vision

The Healthy China 2030 strategy represents a comprehensive approach to public health, with a clear focus on reducing health disparities and ensuring that all citizens have access to quality healthcare services. This vision is underpinned by the understanding that health is a fundamental human right and an essential component of social and economic development.

One of the key objectives of the Healthy China 2030 plan is to manage the rising tide of chronic diseases, which have become a significant bur-

den on the healthcare system. This will involve a shift towards preventive care and PHC, with an emphasis on early detection, health education, and disease management. The strategy also highlights the importance of promoting healthy aging, given the country's rapidly aging population. This will require a reorientation of healthcare services to better meet the needs of the elderly, including the provision of geriatric care and the development of age-friendly health policies.

Moreover, the vision extends beyond the traditional scope of healthcare to encompass environmental health, food safety, and lifestyle improvements. Recognizing the impact of these factors on population health, the strategy calls for a holistic approach that integrates health considerations into all aspects of public policy. This includes efforts to improve air and water quality, ensure the safety of the food supply, and promote healthy lifestyles through public education campaigns and community initiatives.

Further Integration of Health Services

A critical aspect of the future direction for China's healthcare system is the further integration of health services. This involves strengthening primary care as the foundation of the healthcare system and enhancing the referral systems between primary, secondary, and tertiary care. The aim is to create a seamless continuum of care that allows patients to navigate the healthcare system with ease and receive the appropriate level of care based on their needs.

One key area of focus is the integration between medical services and public health, particularly for the management of NCDs. Policy recommendations in this area could include the establishment of comprehensive care models that bridge the gap between clinical treatment and preventive public health measures. This could involve the development of community-based health centers that not only provide primary care but also offer health education, screening programs, and lifestyle modification support to prevent and manage NCDs such as diabetes, hypertension, and cardiovascular diseases. This holistic approach can help in early detection, effective treatment, and better long-term management of these conditions, thereby reducing the burden on the healthcare system.

The integration of health services and social care for the elderly is another vital aspect of China's healthcare policy. As the population ages, there is a growing need for services that cater to the unique health and social needs of older adults. Policy recommendations should emphasize the development of integrated care systems that combine medical care, long-term care, and social support services. This might involve creating geriatric care units within hospitals, establishing home care services that provide both medical and social care, and promoting the use of assistive technologies to help elderly individuals maintain their independence. Furthermore, policies should consider the role of family and community in providing care, supporting the development of community-based programs that encourage intergenerational interaction and social engagement. By integrating health and social care, China can ensure that its elderly population receives the comprehensive support they need to maintain their health and quality of life.

To facilitate the integration of health services discussed above, it will require the development of robust information systems that facilitate communication and coordination among different healthcare providers, residents and the community. It will also necessitate the training of a healthcare workforce that is equipped to work in interdisciplinary teams and provide comprehensive, patient-centered care. In addition, the cre-

ation of a unified national health financing system is envisioned to reduce fragmentation and ensure that all citizens have access to affordable and high-quality healthcare services.

Enhancing Governance and Accountability

The Chinese government, recognizing the pivotal role of health in the nation's development, must reaffirm its political commitment to prioritizing health and integrating health considerations into all policies. This commitment should be reflected in the formulation of a national health strategy that centers on the well-being of the people. By adopting a "health in all policies" approach, the government can ensure that health considerations are taken into account across various sectors such as education, environment, and urban planning. This holistic approach will not only improve the governance of the health system but also enhance accountability by setting clear goals and metrics for health outcomes, which can be tracked and reported on regularly.

To enhance the governance and accountability of the health system, China should promote the integration of medical services, health insurance, and pharmaceuticals, drawing on the successful experiences of Sanming model. This coordination mechanism approach can streamline the healthcare delivery process, improve the efficiency of resource allocation, and ensure that patients receive coordinated care. By aligning the interests of providers, insurers, and pharmaceutical industry, this model can help to control healthcare costs, reduce inefficiencies, and enhance the quality of care. It also necessitates the establishment of mechanisms for data sharing and joint decision-making among these stakeholders to ensure transparency and accountability.

Effective governance and accountability in the health system require the involvement of multiple stakeholders, including the private sector, as well as community and resident participation. This inclusive approach ensures that diverse perspectives are considered in health policy and service delivery. By engaging private healthcare providers, the system can benefit from innovation and competition, which can drive improvements in quality and efficiency. Community and resident involvement, on the other hand, can help to tailor services to local needs and empower individuals to take charge of their health, embodying the concept that individuals are the first responders for their own health. This participatory approach also fosters a sense of ownership and responsibility among all stakeholders, which is crucial for maintaining the accountability of the health system.

Conclusions

The journey of China's healthcare system reform illustrates a remarkable transformation that has been underway for decades. The progress made is evident in the expansion of health insurance coverage, the establishment of a basic public health service system, and the significant strides in reducing health disparities. The commitment to managing chronic diseases and promoting healthy aging through the Healthy China 2030 strategy is a testament to the country's long-term vision for public health. As we look to the future trajectory of health system strengthening globally, the lessons from China's reforms are invaluable. The future of healthcare lies in collaborative efforts, innovative solutions, and a steadfast commitment to the health and well-being of all citizens.

The experiences drawn from China's health system strengthening can be summarized as follows:

First, placing health at the center and prioritizing PHC is fundamental to constructing a high-quality and efficient healthcare service system. The implementation of the Healthy China Strategy, a major initiative by the Chinese government, represents an essential response to the key challenges in the health sector. This strategy is a significant measure to advance the high-quality development of health system. Regardless of the resources available, adopting a "people-centered" approach and emphasizing the enhancement of PHC will enhance public participation and support, which in turn fosters further development.

Providing people-centered integrated care is the core function of a high-quality, efficient health system. The health service entities and family doctor contracting services integrate various aspects of healthcare, including disease prevention, diagnosis, treatment, nutrition, rehabilitation, nursing, and health management. These services ensure the provision of comprehensive and continuous healthcare to the public.

Strengthening the whole-process management of key diseases serves as a critical entry point for health system strengthening. Focusing on specific diseases and linking specialist services with health management offers an effective means to build an integrated service system. This approach makes it easier for healthcare professionals to understand, engage with, and contribute to the health system reform, thereby facilitating the integration of the healthcare system.

Creating shared and aligned interests around health improvement is essential for the sustainability of an integrated health system. System integration involves connecting previously fragmented institutions and resources. For such integration to be sustainable and continue evolving, it must be driven by shared and aligned interests, such as bundled payment mechanisms for health service providers.

Finally, application of information technology plays a crucial supporting role in building an integrated healthcare system. The application of information technology across the supply, demand, and management sides of health services has proven effective in shaping a new people-centered health governance model. By leveraging information technology, the health system can be integrated, allowing for the provision of "comprehensive and full-cycle health services" to the public.

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Profiling the unique passage of South Africa's health system reforms towards realisation of universal health coverage

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ABSTRACT

Thirty years into democracy, South Africa's health system is rated as the best-developed on the African continent and is geared towards closing the divide between the public and private healthcare sectors, but the country still faces immense social, economic and health inequities which thwart the fulfilment of universal health coverage. In tracing the journey of South Africa's health system development to highlight persistent challenges and future directions for solutions, key issues such as the various negative determinants of health, the burden of disease, patients' experience of care, the paucity of strategic health information, and the dearth of human resources for health, surface as a tableau of polycrisis. Integrated, multi-sectoral approaches to promote health as a human right, well-governed implementation of policy to holistically address gaps in service delivery and data management, and authentic community participation in monitoring health system performance can support action for reform to improve its quality, responsiveness, efficiency and resilience.

Key Words: health rights, policy and information; service delivery; disease burden; health promotion; human resources for health

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South Africa's experience of health system strengthening for universal health coverage

Representing almost half of the world's population, the shared commitment of Brazil, Russia, India, China, and South Africa (BRICS) to national, regional and global achievement of universal health coverage (UHC) is a seminal effort in health co-operation. Reflecting on South Africa's health system challenges and future directions can provide important footholds for motivating such collaboration, and lay a foundation for jointly addressing fundamental problems and finding solutions to address slow progress.

With the expansion in 2024 of the BRICS membership to include five new countries (Egypt, Ethiopia, Iran, Saudi Arabia and the United Arab Emirates), this grouping represents about 45% of the global population, with the original five member states accounting for about 27% of the world gross product¹.

BRICS countries accounted for three of the top 10 countries with tuberculosis (TB) diagnoses in 2020, including South Africa (0.33 million), and globally, Human Immunodeficiency Virus (HIV) is the only primary communicable disease with a prevalence rate still increasing in BRICS countries [1].

South Africa has the largest economy on the African continent, with its Gross Domestic Product (GDP) amounting to just over US\$ 373 billion in 2024². South Africa also has Africa's highest expenditure per capita on health care, estimated at about US\$ 584 per capita in 2021³, with expenditure having risen from US\$ 121 per capita in 2002, representing an average annual growth rate of 7.75% in this period. In 2021 it was estimated that South Africa spends at least 8.3% of its GDP on health³ a relatively high level by developing country standards. The country's healthcare system is also rated as the best on the African continent, ranking 49th out of 89 countries in the 2024 Global Healthcare Index⁴. According to the World Health Organization's UHC service coverage index, South Africa's index score was 0.71 out of a possible 1 in 2021; this is slightly above the world average of 0.68, and considerably above the 0.44 average for Africa.

Tracing the historical roots of South Africa's health system, Coovadia, et al. [2] noted that 15 years after democracy, and despite the State's endeavours towards progressive realisation of the right to health, the country was still grappling with massive health inequities, reflecting racial dif-

¹ BRICS. Brics to add Argentina, Egypt, Ethiopia, Iran, Saudi Arabia and UAE as new members. BRICS-plus website. Published August 24, 2024. Accessed September 11, 2024. <https://www.brics-plus.com/post/brics-to-add-argentina-egypt-ethiopia-iran-saudi-arabia-and-uae-as-new-members>

² Galal S. GDP of African countries 2024, by country. Statista website. Published July 8, 2024. Accessed September 12, 2024. <https://www.statista.com/statistics/1120999/gdp-of-african-countries-by-country/>

³ World Health Organization Global Health Expenditure database. Current health expenditure (% of GDP) – South Africa. World Bank Group website. Accessed September 12, 2024. <https://data.worldbank.org/indicator/SH.XPD.CHEX.GD.ZS?locations=ZA>

⁴ 2024 Global Healthcare Index. 2021 GHS Index Country Profile for South Africa. Accessed September 12, 2024. <https://ghsindex.org/country/south-africa/>

ferences in living conditions and healthcare access, varying health status between provinces, rural and urban settings, and men and women. Manifesting the post-apartheid health policy vision for an integrated, comprehensive national service, with free Primary Health Care (PHC) delivered via a district health system as the foundation for public health sector services, has been constrained by factors such as inadequate human resource capacity and planning, poor stewardship, leadership, and management, the impacts of the HIV epidemic on the public health system, and restricted spending in the public health sector [2].

Analysis by Zondi and Day⁵ of South Africa's UHC coverage trends and related information gaps indicates that the country did reasonably well in increasing population coverage between 1998 and 2019 – expanding access to the range of health services and reaching more of the population, with a general reduction in inequity. However, quality and operationalisation challenges have persisted, and although information systems improved steadily in scope and data quality over the period, much more is required to support the realisation of UHC.

Rispel, et al.⁶ summarised progress made in providing quality health care during 25 years of democracy, notably an enabling legal and policy environment, numerous quality-improvement initiatives, increased life expectancy of the population, and reduced mortality rates. This progress is juxtaposed with gaps in ethical leadership, management and governance, as well as a human resources for health (HRH) crisis, contributing to poor quality of care and avoidable loss of lives. They note that malpractice and medical litigation are threats to the realisation of the right to health care, that fragmentation of interventions limits their impact, and that health information system gaps hamper the measurement and monitoring of improvements. To ensure high-quality UHC the country, their recommendations were to enhance governance and leadership for quality and equity; revolutionise the quality of care; invest in and transform human resources; and measure, monitor and evaluate policy implementation.

During the country's health system evolution over 30 years, the terrain of challenges has become increasingly broad and complex within a context of persistent socio-economic disparities, having escalated to a multiplicity of challenges which urgently requires an integrated whole-systems approach to ensure effective UHC. This juncture presents an inflection point for steadfastly confronting these challenges towards realising tangible health benefits for everyone in the country, throughout their life course, as a moral and constitutional obligation.

Learning from South Africa's health system transformation

The President of the South African Medical Research Council recently mapped the contemporary multiplicity and severity of these challenges⁷, describing “a relentless burden of infectious and non-communicable diseases”; inadequately resourced, under-skilled and demotivated staff to provide health care for a growing population, resulting in suboptimal quality

⁵ Zondi T, Day C. Measuring National Health Insurance: towards Universal Health Coverage in South Africa. In: Moeti T, Padarath A, editors. South African Health Review 2019. Published 2019. Accessed September 12, 2024. https://www.hst.org.za/publications/South%20African%20Health%20Reviews/05%20SAHR_2019_Measuring%20National%20Health%20Insurance.pdf

⁶ Rispel L, Shisana O, Dhai A, Dudley R, English R, Grobler GP, et al. Achieving high-quality and accountable universal health coverage in South Africa: a synopsis of the Lancet National Commission Report. In: Moeti T, Padarath A, editors. South African Health Review 2019. Published 2019. Accessed September 12, 2024. https://www.hst.org.za/publications/South%20African%20Health%20Reviews/06%20SAHR_2019_Achieving%20a%20high%20quality%20health%20system.pdf

⁷ Sobuwa Y. SAMRC president highlights dire state of South Africa's health sector: calls for urgent reforms. Health-e News website. Published September 5, 2024. Accessed September 12, 2024. <https://health-e.org.za/2024/09/05/samrc-president-highlights-dire-state-of-south-africas-health-sector-calls-for-urgent-reforms/>

of care in key programmes; deficient health management, and a crisis of health governance. Broken equipment and sub-standard infrastructure, medicine shortages, and poor infection control at facilities both cause and are exacerbated by public-sector medico-legal claims that require expenditure from much-needed health budgets on settling court cases. We elaborate on several of these issues in the following sections.

Social determinants of health

Addressing the social determinants of health is essential for achieving UHC, as non-medical factors such as poverty and access to basic services, education, housing and employment play a critical role in shaping health outcomes. These determinants create structural barriers that limit access to health care, especially among the country's most vulnerable population. High levels of unemployment and income inequality restrict the ability of many South Africans to afford healthcare services, even in a system that offers free primary health care. According to the latest Quarterly Labour Force Survey, the rate of unemployment in South Africa in June 2024 was estimated to be 33.5%, and this figure rises to almost 43% when those who have given up trying to find work are included⁸. Adverse housing and living conditions are also a factor, particularly in informal settlements where overcrowding, poor sanitation and limited access to clean water contribute to higher rates of communicable diseases such as TB and waterborne illnesses. Improving healthcare access alone will not resolve the many inequities that are deeply rooted in such socio-economic conditions, and it is against this backdrop that the South African public health system is functioning.

Infectious diseases

Tuberculosis remains a leading cause of death in the country, claiming an estimated 54 200 lives in 2022, and with around 280 000 falling ill with the disease – a reduction from 552 000 cases in 2015⁹. HIV co-infection is a major contributor to TB incidence, which complicates diagnosis and treatment, and usage of preventive therapy remains suboptimal, particularly among child household contacts of people with living with TB⁹.

South Africa is the epicentre of the global HIV pandemic, with approximately 7.8 million (12.7%) people living with HIV (PLHIV)¹⁰. The country has the largest treatment programme in the world and this has reduced mortality, incidence and prevalence over recent years. In 2022, among people aged 15 years and older, 90% were aware of their HIV status, 91% who were aware of their status were taking treatment, and 94% of those on taking treatment were virally suppressed¹⁰. This compares with 85-71-87 in 2017¹⁰ against the UNAIDS 95-95-95¹¹ targets to fast-track epidemic control. The previously declining trend in life expectancy at birth has been reversed, with life expectancy increasing by 5.75 years from 55.8 years in 2000 to 61.5 years in 2021¹². Despite this significant achievement, in mid-2023 only 75% of those diagnosed with HIV are on treatment, and of

⁸ Maluleke R. Quarterly Labour Force Survey – Q2: 2024. Statistics South Africa website. Published 2024. Accessed September 11, 2024. <https://www.statssa.gov.za/publications/P0211/Presentation%20QLFS%20Q2%202024.pdf>

⁹ Tomlinson C. In-depth: What new WHO TB numbers mean for SA. Spotlight website. Published November 10, 2023. Accessed September 10, 2024. <https://www.spotlightnsp.co.za/2023/11/10/in-depth-what-new-who-tb-numbers-mean-for-sa/>

¹⁰ Human Sciences Research Council. The Sixth South African National HIV Prevalence, Incidence, Behaviour and Communication Survey, 2022 (SABSSM VI). Accessed September 13, 2024. <https://hsrc.ac.za/news/sabssm-vi/>

¹¹ Joint United Nations Programme on HIV/AIDS. Understanding Fast-track: Accelerating action to end the AIDS epidemic by 2030. Accessed September 13, 2024. https://www.unaids.org/sites/default/files/media_asset/201506_JC2743_Understanding_FastTrack_en.pdf

¹² World Health Organization. Health data overview for the Republic of South Africa. World Health Organization website. Accessed September 13, 2024. <https://data.who.int/countries/710>

those previously initiated on antiretroviral therapy, an estimated one million people disengaged from treatment¹³.

Case management for patients' continuity of care and treatment adherence is therefore a key area for attention, along with combination prevention strategies to maintain HIV-negative status, integrated and community-based services, the Welcome Back treatment re-engagement campaign, enhanced adherence counselling, and adherence support groups. HIV self-screening and index contact testing are modalities that improve case-identification.

There is a need to prioritise the health and rights of adolescent girls and young women and key populations, as they are disproportionately affected by HIV due to various socio-economic factors, including gender inequalities, poverty, and lack of access to education and health care. In 2021, 65.7% of HIV-positive adults older than 15 years were women, while HIV prevalence among young women (aged 15–49 years) was double (24.5%) that of their male counterparts (12.1%)¹⁴. The prevalence of HIV among some key populations is higher than in the general population¹⁴. Targeted prevention efforts should therefore focus on young people and deploy appropriate communication channels, platforms, influencers and messaging to lower the rate of new infections and enable improved linkage to care and adherence to treatment.

Non-communicable diseases and obesity

The mortality rate and disease burden of non-communicable diseases (NCDs) gives cause for deep concern, especially noting the experience of NCDs comorbidities aggravating the risk of severe COVID-19 illness. South Africa has the highest prevalence of obesity in Sub-Saharan Africa [3], and is an epidemic affecting just under one third (31%) of South African men, two thirds (68%) of South African women, and 13% of children under the age of five^{15,16}, heightening their risk of heart disease, stroke, hypertension, diabetes, cancer, gallbladder disease, osteoarthritis, gout, fatty liver, and breathing problems, among other illnesses. Statistics South Africa data show that obesity-related diseases were the fifth-highest cause of mortality in the country, and deaths due to cardiovascular disease, cancer, diabetes and chronic lower respiratory diseases increased by 58.7% from 1997 to 2018¹⁷. Moreover, a 2023 systematic review and meta-analysis of obesity, hypertension and diabetes prevalence among South Africa's HIV-positive population [4] indicates that the country is experiencing “a syndemic of NCDs among PLHIV” – a daunting predicament, given its 14.75% HIV prevalence¹⁸.

NCDs such as diabetes and its comorbid conditions (e.g. renal failure, amputations and blindness) place a heavy financial and organisational burden on the country's already strained health system arising from in-

¹³ Section27. One in four people with HIV not on treatment, according to new estimates. Published April 5, 2024. Accessed September 10, 2024. <https://section27.org.za/2024/04/one-in-four-people-with-hiv-not-on-treatment-according-to-new-estimates/#:~:text=It%20is%20calculated%20that%20in,were%20thus%20previously%20on%20treatment>

¹⁴ South African National AIDS Council (SANAC). Gender Assessment of the HIV Response – South Africa. SANAC website. Accessed September 13, 2024. https://sanac.org.za/wp-content/uploads/2024/01/Gender-Assessment-of-the-HIV-Response-South-Africa_Low-Res.pdf

¹⁵ National Department of Health (NDoH), Statistics South Africa (Stats SA), South African Medical Research Council (SAMRC), and ICF. South Africa Demographic and Health Survey 2016. Pretoria, South Africa, and Rockville, Maryland, USA: NDoH, Stats SA, SAMRC, and ICF; 2019. Accessed September 14, 2024. <https://dhsprogram.com/pubs/pdf/FR337/FR337.pdf>

¹⁶ World Obesity Organisation. Global Obesity Observatory. Economic impact of overweight and obesity in South Africa. Accessed September 10, 2024. https://data.worldobesity.org/country/south-africa-197/#data_economic-impact

¹⁷ Statistics South Africa. Rising non-communicable diseases – a looming health crisis. Published October 17, 2023. Accessed September 10, 2024. <https://www.statssa.gov.za/?p=16729>

¹⁸ Human Sciences Research Council. New HIV survey highlights progress and ongoing disparities in South Africa's HIV epidemic. 27 November 2023. Accessed September 10, 2024. <https://hsrc.ac.za/press-releases/hsc/new-hiv-survey-highlights-progress-and-ongoing-disparities-in-south-africas-hiv-epidemic/>

creased demand for extensive and efficient acute and chronic care services¹⁹. The direct cost to South Africa's health system of those diagnosed with diabetes is R2.7 billion (notwithstanding the costs associated with advanced organ damage, long-term disability and other diabetes-related complications, and the indirect toll of loss of jobs and income)¹⁹. The cost of diagnosing and treating all cases would be R21.8 billion a year, rising to R35 billion in real terms by 2030 – not including those in the population who are pre-diabetic (which was found to be 67% of all men and women in 2016²⁰).

Despite policy and regulation in the form of the National Department of Health's 2015–2020 and 2022–2027²¹ National Strategic Plans for the Prevention and Control of Non-Communicable Diseases, Strategy for the Prevention and Control of Obesity in South Africa 2023–2028²², and the Health Promotion Levy²³, key factors that perpetuate the country's diet-related NCD epidemic are the commercial determinants of health, combined with the country's economic and social disparities in terms of access to healthy food.

Further policy measures to reduce overweight and obesity through healthier diets are stronger regulation on food package labelling, increasing the threshold percentage of the Health Promotion Levy and extending this tax to pure fruit juices, banning junk-food advertising to children, and blocking the establishment of fast-food outlets near schools. Introducing strengthened tobacco and vaping legislation (in line with South Africa having signed the WHO Framework Convention on Tobacco Control²⁴), as well as legal measures to curb health harms wrought by hyper-consumption of alcohol, would also constitute progressive action to stem the NCD burden through more comprehensive prevention interventions.

Systems for strategic health information

According the World Health Organization, “the goal of a health information system is often narrowly defined as the production of good-quality data. However, the ultimate goal is more than this – it is to produce relevant information that health system stakeholders can use for making transparent and evidence-based decisions for health system interventions”²⁵ and building health system resilience.

Building resilient health systems and tracking their performance requires robust data systems and management. Reliable evidence is needed to ground UHC policy in three key aspects: population coverage, service coverage, and coverage with financial risk protection, all with an equity focus [5]. While rights-based approach to UHC requires that it be fully inclusive, the quest for equity necessitates attention on the most vul-

¹⁹ Hofman KJ, Goldstein S. Diabetes is South Africa's second-biggest killer disease: hiking the sugar tax would help. Daily Maverick. Published November 1, 2023. Accessed September 10, 2024. <https://dev.dailymaverick.co.za/article/2023-11-01-lets-hike-the-sugar-tax-to-urgently-help-reduce-diabetes-sas-second-biggest-killer-disease/>

²⁰ National Department of Health (NDoH), Statistics South Africa (Stats SA), South African Medical Research Council (SAMRC), and ICF. South Africa Demographic and Health Survey 2016. Pretoria, South Africa, and Rockville, Maryland, USA: NDoH, Stats SA, SAMRC, and ICF; 2019. Accessed September 14, 2024. <https://dhsprogram.com/pubs/pdf/FR337/FR337.pdf>

²¹ South African National Department of Health. National Strategic Plan (NSP) for the Prevention and Control of Non-Communicable Diseases (NCDs) 2022–2027. Pretoria: NDoH; 2022. Accessed September 13, 2024. <https://bhekisisa.org/wp-content/uploads/2022/06/NCDs-NSP-SA-2022-2027-1.pdf>

²² South African National Department of Health. Strategy for the Prevention and Control of Obesity in South Africa, 2023–2028. Pretoria: NDoH; 2023. Accessed September 10, 2024. https://www.health.gov.za/wp-content/uploads/2023/05/Obesity-Strategy-2023-2028_Final_Approved.pdf

²³ South African Revenue Service. Health Promotion Levy on Sugary Beverages. Rates and Monetary Amounts and Amendment of Revenue Laws Act 14 of 2017 (see from page 46). Government Gazette. Published December 14, 2017. Accessed September 13, 2024. <https://www.sars.gov.za/customs-and-excise/excise/health-promotion-levy-on-sugary-beverages/>

²⁴ World Health Organization. WHO Framework Convention on Tobacco Control. Geneva: WHO; 2003. Accessed September 14, 2024. <https://iris.who.int/bitstream/han>

²⁵ World Health Organization. Framework and Standards for Country Health Information Systems. Second edition. Geneva: WHO; 2008. Page 10. Accessed September 14, 2024. https://www.afro.who.int/sites/default/files/2017-06/AHO_Country_H_Infos_Systems_2nd_edition.pdf

nerable populations, prioritising those with the least access to care, and the currently available data are inadequate for this purpose.

Access to good-quality data housed in a single, comprehensive data repository for monitoring and evaluating progress towards attainment of health-related goals is crucial for the successful attainment of UHC²⁶. Historically, it has been noted that whilst much data are collected, they are mostly not processed or not used at an appropriate level and tend to be of an administrative nature²⁷.

While there are effective reporting platforms, primary collection of the data used, including medical records, is reliant on paper-based systems. Management of these paper-based records in compliance with relevant policies and procedures has been a significant challenge within the South African context, leading to incomplete documentation, large-scale duplication, and generally poor quality of the data being fed into electronic reporting systems, with the upshot being reports that do not accurately reflect factual realities. To resolve these issues, there has been a gradual roll-out of electronic health records, with varying levels of implementation across provinces. Interoperability and interface between the different systems remains a challenge, hindering the seamless flow of information across levels of care.

Key developments aimed at strengthening the health information system in South Africa include the development of a District Health Management Information Systems policy and adopting implementation of South Africa's National eHealth Strategy²⁸, which is central to achieving a well-functioning, patient-centred, electronic national health information system based on agreed scientific standards of interoperability.

The current National Digital Health Strategy 2019–2024²⁹ aligns with the country's National Development Plan (NDP)³⁰ and the intended health system transformation towards UHC. Strategic interventions include strengthening leadership capacity for digital health; appropriate multi-stakeholder engagements and collaboration; sustainable interventions and funding; strengthened governance structures and oversight mechanisms; the development of appropriate digital applications for improving health services; the development of a Human Resources Information System, establishing a robust physical and network infrastructure; effective and safe sharing of health information across health systems and services; and an integrated information architecture and interoperability.

Other priorities include digitising health systems, expanding mobile health (or mHealth) for community-based interventions, and building health workers' digital capacity and technology skills.

The National Department of Health's commitment to achieving UHC was foregrounded in its response to the Central Chronic Medicine Dispensing and Distribution programme's paper-form data entry processes leading to inefficiencies and a lack of transparency between stakeholders. To address these challenges, the electronic Synchronised National

²⁶ English R, Masilela T, Barron P, Schönfeldt A. Health Information Systems in South Africa. In: Padarath A, English R, editors. South African Health Review 2011. Durban: Health Systems Trust; 2011. Accessed September 14, 2024. https://www.hst.org.za/publications/South%20African%20Health%20Reviews/sahr_2011.pdf

²⁷ Bradshaw D, Mbofo L. Informatics Support. In: Harrison D, Neilson M, editors. South African Health Review 1995. Durban: Health Systems Trust; 1995. Accessed September 14, 2024. <https://www.hst.org.za/publications/South%20African%20Health%20Reviews/sahr95.pdf>

²⁸ Masilela TC, Foster R, Chetty M. The eHealth Strategy for South Africa 2012–2016: how far are we? In: Padarath A, English R, editors. South African Health Review 2013/14. Durban: Health Systems Trust; 2014. Accessed September 13, 2024. <https://www.hst.org.za/publications/South%20African%20Health%20Reviews/2%20The%20eHealth%20Strategy%20for%20South%20Africa%202012-2016%20-%20how%20far%20are%20we%20-%20SAHR2014.pdf>

²⁹ South African National Department of Health. National Digital Health Strategy for South Africa 2019–2024. Pretoria: NDoH; 2019. Accessed September 11, 2024. <https://www.health.gov.za/wp-content/uploads/2020/11/national-digital-strategy-for-south-africa-2019-2024-b.pdf>

³⁰ Presidency of the Republic of South Africa – National Planning Commission. National Development Plan 2030: Our future – make it work. Pretoria: NPC; 2011. Accessed September 11, 2024. https://www.gov.za/sites/default/files/gcis_document/201409/ndp-2030-our-future-make-it-workr.pdf

Communication in Health system was developed and implemented. This introduced a digitised and streamlined process across provinces for on-line patient registration; selection of approved medicine collection points; pre-programmed selection of medicines and dosages based on approved provincial medicine formularies; transmission of electronic prescriptions to courier pharmacy service providers; barcode scanning and management of patient medicine parcels, and automated reporting at various levels within the health system. The insights for good practice gained from this roll-out can support sustainable implementation of healthcare technology in South Africa.

Since the COVID-19 pandemic, the development of health information and digital systems has accelerated in South Africa. However, there are ongoing challenges with many health reporting systems not being interoperable, which results in data inconsistencies, problems with identifying patients through the continuum of care, and poor quality and accuracy of data. It is important to implement digital health platforms that enable interoperability among the various fragmented health information systems, such as those for clinical management, laboratory services, demographic administration, programme monitoring, tuberculosis, vaccination services, differentiated models of care, mHealth, and other sub-systems to improve quality, cohesiveness and functionality and to reduce duplication and cost.

Despite the existence of the earlier eHealth strategy³¹ and the National Department of Health commissioning a National Health Normative Standards Framework for eHealth in South Africa (which provided a foundational basis for interoperability as articulated in the eHealth strategy), development in the health information systems sector has occurred in silos and as the need arises for completion of various task- and programme-based services. These legacy systems have made it difficult to implement an overall integrated digital information system that can serve the needs of the patient, the healthcare worker, and the Department of Health.

Other challenges needing prioritisation are the secure sharing of data between different systems, more equitable access to high-quality telecommunications infrastructure, patient confidentiality, and the development of procedures and systems for identity verification of users of the health system.

In 2014, the first steps towards roll-out of the country's Health Patient Registration System (HPRS) in 700 Primary Health Care facilities in the 10 pilot National Health Insurance districts were initiated. As the patient's entry-point into the health system, the HPRS is a central, standardised, automated system that maintains a Master Patient Index of all people who use public-sector healthcare services to improve their quality and continuity of care, as well as national health system efficiencies. The vision is to draw down information about each individual patient from various linked health data systems and collate this into a single electronic health record inspired digitalisation. The outcome is a holistic picture of the person's healthcare interactions, clinical history, tests and diagnoses, medication prescriptions, other forms of treatment, and referrals, thus enabling healthcare providers to rapidly assess the patient's health pathway. Ensuring the interoperability of data systems creates a shared health information exchange that streamlines the patient's experience of accessing care, and reduces the facility's administrative time and costs.

³¹ Masilela TC, Foster R, Chetty M. The eHealth Strategy for South Africa 2012–2016: how far are we? In: Padarath A, English R, editors. South African Health Review 2013/14. Durban: Health Systems Trust; 2014. Accessed September 13, 2024. <https://www.hst.org.za/publications/South%20African%20Health%20Reviews/2%20The%20eHealth%20Strategy%20for%20South%20Africa%202012-2016%20-%20how%20far%20are%20we%20-%20SAHR2014.pdf>

Currently, the HPRS has been introduced in 3 150 facilities, with more than 60 million registered users and 35 million with verified identity documentation³². Implementation of the HPRS contributes to South Africa's health infostructure and is highly advantageous for health system governance towards meeting the needs of healthcare users. More accurate data drawn from integrated systems, shorter timeframes between end-of-reporting periods, and timeous data feedback loops for programme management, all help to improve health service delivery and ensure universal health coverage.

Like all modern health systems, South Africa's health system functions sub-optimally if management decisions (at all levels) are not based on objective evidence and information. There have been wide-scale improvements in both the quality and quantity of information available over the past two decades. An example of this is the Health Systems Trust's *District Health Barometer*³³, which provides a vast range of cross-sectional and longitudinal information, with comparisons among districts and provinces on key health performance indicators. The 2019/20 edition of the Barometer reported on the computation of a UHC service coverage index³⁴, which is discussed later in this article. One of the key issues highlighted was the inadequacy of current data systems to capture the full scope of NCDs across various populations. NCDs such as diabetes, hypertension and cancer require long-term monitoring, yet much of South Africa's health data collection remains fragmented, with reliance on paper-based systems in rural areas and a lack of integration between public- and private-sector data. This leads to data gaps, particularly on vulnerable communities where NCD prevalence is high but under-reported, thus complicating efforts to measure the true extent of service coverage, impacting treatment access and health outcomes.

However, there are significant opportunities for development. The increasing implementation of digital health systems, such as the District Health Information System and the HPRS, creates the potential for more accurate and timeous data collection. Expanding these systems for a stronger focus on NCDs could greatly improve the ability to track service coverage. Additionally, leveraging mHealth initiatives to reach rural populations can enhance data collection and service delivery, ensuring that more individuals living with NCDs are included more accurately when measuring UHC service coverage.

Health research to inform UHC

An important source of strategic information to guide policy and measure progress towards UHC is research. In 2013, following the adoption of a resolution to promote UHC the previous year, the World Health Report addressed the theme of 'Research for Universal Health Coverage'³⁵, advocating for good-quality research to inform strategies for service provision. The report also highlighted that individual studies have the potential to improve access to health services and suggested strategies

³² South African Government. Accelerating Health System Strengthening and National Health Insurance (NHI) Implementation. 2nd Presidential Health Compact 2024–2029. Pretoria. Published August 22, 2024. Accessed September 13, 2024. <https://www.stateofthenation.gov.za/assets/downloads/Second%20Presidential%20Health%20Compact%202024-2029.pdf>

³³ Massyn N, Peer N, English R, Padarath A, Barron P, Day C. District Health Barometer 2015/16. Durban: Health Systems Trust; 2016. Accessed September 14, 2024. https://www.hst.org.za/publications/District%20Health%20Barometers/District%20Health%20Barometer%202015_16.pdf

³⁴ Day C, Gray A, Cois A. Universal Health Coverage – the service coverage index at district level. In: Massyn N, Day C, Ndlovu N, Padayachee T, editors. District Health Barometer 2019/20. Durban: Health Systems Trust. Published December 2020. Accessed September 14, 2024. <https://www.hst.org.za/publications/District%20Health%20Barometers/DHB%202019-20%20Section%20A,%20chapter%206%20-%20Universal%20Health%20Coverage.pdf>

³⁵ World Health Organization. The World Health Report 2013 – Research for universal health coverage. Geneva: WHO; 2013. Accessed September 11, 2024. https://iris.who.int/bitstream/handle/10665/85761/9789240690837_eng.pdf?sequence=2

for enabling research and innovation [6]. South Africa boasts a robust and diverse health research ecosystem, with numerous academic institutions, research organisations, and governmental and non-governmental entities contributing to the knowledge base. The country also has several policies and entities that co-ordinate research at national level, such that South Africa's journey towards UHC has been significantly informed and shaped by ongoing research efforts and strategic use of the information emanating therefrom.

The impact of research is most evident in the country's HIV programme. South Africa has been recognised as a global leader in this regard, and nearly every aspect of the programme is informed by locally generated research which is also internationally relevant. Most studies have investigated the effectiveness of various service delivery platforms which have been adopted to ensure the highest coverage among people living with HIV.

Despite these strengths and past successes, there are ongoing challenges in translating research findings into policy and practice, and a significant distance between researchers, policymakers and implementers, which hinders decision-making at all levels of the health system. There is also a lack of sufficient capacity, human resources and finance to meet the country's research needs. Several focus areas, such as non-communicable diseases, are disproportionately under-resourced and thus under-researched, leading to weak adoption of some prevention, treatment and care interventions and providing services at scale.

Strategic information reporting and research has become increasingly dependent on 'big data' available in various information systems. The adoption of data privacy regulations, specifically the Protection of Personal Information Act (POPIA) [7] has made it increasingly difficult to access data [8]. This has been largely due to varied interpretations of the Act and lack of guidance in its implementation. Although there have been efforts to address the challenges related to POPIA, these have been unsuccessful. For instance, the Academy of Science of South Africa recently led efforts to develop a POPIA Code of Conduct for Research, but this was returned by the Information Regulator and its progress has stalled.

Patients' experience of care

The Ritshidze ('Saving Our Lives') Project focuses on community-led clinic monitoring of health service outcomes and processes in South Africa for appropriate, respectful and responsive health service delivery. Recent Ritshidze reports have highlighted that public health facilities are not providing services at the standards set forth in national guidelines nor fulfilling the expectations of users. Findings from national December 2023³⁶ and February 2024³⁷ reports present evidence that key populations continue to experience hostile and discriminatory attitudes by staff; that people without identity documents are denied services; and people who miss appointments are made to wait longer and loudly chastised in public areas of the facility. Frequent medicine stock-outs, long waiting times, lost patient files and poor protection of patient confidentiality make visiting a clinic a tortuous experience for those seeking health care.

In terms of key programme service delivery, Ritshidze authors emphasise that tuberculosis control must be strengthened, and that more

³⁶ Ritshidze Project. Ritshidze Report: South Africa – State of health. Published December 2023. Accessed September 10, 2024. <https://ritshidze.org.za/wp-content/uploads/2023/12/National-Community-Meeting-07.12.23.pdf>

³⁷ Ritshidze Project. State of healthcare for key populations. 3rd edition. Published February 2024. Accessed September 10, 2024. <https://ritshidze.org.za/wp-content/uploads/2024/02/Ritshidze-State-of-Healthcare-for-Key-Populations-2024.pdf>

must be done in the realm of HIV treatment literacy and viral load suppression by thoroughly implementing guidelines for treatment adherence, differentiated models of care, and multi-month dispensing. Department of Health staff should be properly trained on patient re-engagement procedures and implementation of 'Undetectable = Untransmittable' messaging, along with assessments to improve their capabilities for implementing index contact testing and HIV prevention modalities. All Operation Phuthuma-supported sites with waiting times longer than three hours should be evaluated, and specific improvement plans should be developed for each facility to reduce these times to less than two hours.

Human resources for health

Assessing progress towards universal health coverage in BRICS, Marten, et al. [9] note that although reforms create an entitlement to a broad range of services, delivery will not be possible without additional staff. South Africa has the lowest doctor-patient ratio of 0.9 per 1000 when compared to other BRICS countries³⁸. The situation is exacerbated by the maldistribution of health professionals between the private and public sectors, as well as uneven allocation of public-sector health professionals between the provinces³⁹.

For example, the 2030 HRH Strategy estimated⁴⁰ that in 2019, there were only seven medical specialists per 100 000 employed in the public sector compared to 69 per 100 000 in the private sector. In the public sector, the Western Cape Province was found to have 25.8 medical specialists per 100 000 population compared to only 1.4 per 100 000 in Limpopo.

Nurses play a critical role in achieving UHC in South Africa, but the profession faces significant challenges. Despite being the largest group of health providers, concerns about nursing shortages, declining interest, a lack of caring ethos, and a disconnect between nurses' needs and those of the communities they serve persists. Key issues needing attention include nursing education reforms, ethics, quality of care, and the work experiences of nursing managers, particularly at PHC clinics. Workforce concerns – such as the competence of new entrants, student selection, and agency work – also have a negative impact on professionalism and quality of care.

Community Health Workers (CHWs) are pivotal to achieving UHC and are featured in South Africa's National Development Plan⁴¹. Their significance was demonstrated during the COVID-19 pandemic when South Africa became the first country to implement mass community screening using CHWs⁴¹. However, CHWs face several challenges, including lack of formal recognition, tenuous employment, and limited access to training, certification, and career pathways. Accurate data on their deployment is also lacking. Similarly, clinical associates remain underutilised, with only 130 of 220 registered associates employed in the public sector in 2013, despite the country's healthcare personnel shortages. Additionally, work-

³⁸ Motsoaledi A. Discussion: Health Minister Aaron Motsoaledi comments on sector challenges. eNCA. Published September 7, 2024. Accessed September 7, 2024. <https://www.enca.com/top-stories/discussion-health-minister-aaron-motsoaledi-comments-sector-challenges>

³⁹ The state of SA's healthcare system 30 years on. Interview with Dr Mvuyisi Mzukwa, Chairperson of the South African Medical Association (SAMA). eNCA. Published May 4, 2024. Accessed September 7, 2024. <https://www.enca.com/videos/state-sas-healthcare-system-30-years>

⁴⁰ South African National Department of Health. 2030 Human Resources for Health Strategy: Investing in the Health Workforce for Universal Health Coverage. Pretoria: NDoH; 2020. Accessed September 14, 2024. <https://www.health.gov.za/wp-content/uploads/2023/06/2030-HRH-Strategy-Final.pdf>

⁴¹ Madikizela L, Matlala M, Mosikare O. Leveraging Community Health Workers for intensified case-finding: experience from South Africa's COVID-19 response. In: Goven-der K, George G, Padarath A, Moeti T, editors. South African Health Review 2021. Durban: Health Systems Trust; 2021. Accessed September 14, 2024. https://www.hst.org.za/publications/South%20African%20Health%20Reviews/Chapter18_SAH21_04022022_OD.pdf

force data management issues, reported as early as 2010, continue to hamper effective healthcare planning.

Human resources for health in relation to health system responsiveness was the focus of the 2018 *South African Health Review*⁴², which recommended enhancing HRH technical capacity and expertise in the National Department of Health to provide strategic leadership and support for the entire health system; recruitment of public servants with the right skills, competencies, ethos and values; and the equitable allocation of staff to rural and underserved areas, as well as an inclusive approach to planning that incorporates higher education institutions and other stakeholders to ensure greater coherence between health worker training and service delivery platforms.

Leadership and governance

Leadership and governance are widely recognised as critical entry points for strengthening health systems and achieving national and global health goals. The 2008 World Health Report⁴³ highlighted leadership reforms as one of the four essential sets of reforms needed for health systems to address existing health challenges more effectively.

South Africa's health system faces numerous challenges, including tensions between the National and Provincial Health Departments, with a key issue being that policy formulation is often disconnected from the realities of on-the-ground planning and delivery, through insufficient blending of top-down expertise with bottom-up experience. Governance at local level for PHC health service delivery is particularly important, as this stratum is where communities' needs, characteristics, experiences and preferences can be identified and met through public participation and engagement, and the objectives of a people-centred health system and positive health outcomes fulfilled.

Leadership, implementation and operational challenges also persist at district level. District Health Management teams have limited influence over policy, strategy and budgets, and decisions regarding workforce planning and staff appointments are made at higher levels. There is also a lack of mechanisms for district-level feedback to inform national policies, and district managers often fail to consistently use data for evidence-based decision-making, particularly in areas of planning and performance management⁴⁴.

Rispel⁴⁵ avers that to repair South Africa's health sector transformation fault-lines, "addressing the leadership, management and governance failures requires political will; meritocratic appointment of public service managers with the right skills, competencies, ethics and value systems; effective governance at all levels of the health system to enforce laws; appropriate management systems; and citizen involvement and advocacy to hold public officials accountable." Enabling environments for conscientious health service delivery can be established through strong political volition and leadership that supports local stakeholders, community structures, non-governmental capacity, civil society health activists, and the persistently unsung and poorly sustained body of CHWs.

⁴² Rispel LC, Padarath A, editors. *South African Health Review 2018*. Durban: Health Systems Trust; 2018. Accessed September 14, 2024. <https://www.hst.org.za/publications/South%20African%20Health%20Reviews/SAHR%202018.pdf>

⁴³ World Health Organization. *The World Health Report 2008: Primary health care now more than ever*. Accessed September 14, 2024. <https://iris.who.int/handle/10665/43949>

⁴⁴ Gilson L, Daire J. Leadership and governance within the South African health system. In: Padarath A, English R, editors. *South African Health Review 2011*. Health Systems Trust, Durban. Accessed September 14, 2024. <http://www.hst.org.za/publications/south-african-health-review-2011>

⁴⁵ Rispel L. Analysing the progress and fault-lines of health sector transformation in South Africa. In: Padarath A, King J, Mackie E, Casciola J, editors. *South African Health Review 2016*. Durban: Health Systems Trust; 2016. Accessed September 14, 2024. <https://www.hst.org.za/publications/South%20African%20Health%20Reviews/2%20Analysing%20the%20progress%20and%20fault%20lines%20health%20sector%20transformation%20in%20South%20Africa%20.pdf>

In terms of the legal framework for ensuring patients' rights of access to quality health care, the 1997 White Paper on Transforming Public Service Delivery⁴⁶ sets out the eight Batho Pele ('People First') principles to govern responsive service provision, and the National Patients' Rights Charter⁴⁷ was introduced in 2008 by South Africa's National Department of Health in accordance with section 27(1)(a) of the Constitution. It could be argued that gaps between principles and practice are evident in patients' experience of care, as described earlier.

The need for co-created solutions

To address this confluence of crises, several authors advocate for enhancing the quality, accessibility and affordability of Primary Health Care services within a well-functioning District Health System, because efficient and cost-effective disease prevention, early detection and treatment, consistent care, rehabilitation and appropriate palliation, enable improved access to quality services and reduce escalation to tertiary services⁴⁸ [10]. Others urge for more regulatory interventions that address the various determinants of health in order to lower demand for health services, and symphonic application of health promotion so as to mitigate South Africa's growing burden of infectious and non-communicable diseases – and in turn, to curb their related social and financial costs⁴⁹.

A call for inter- and multi-sectoral collaboration and eradication of disciplinary silos is common to much of the UHC-focused literature, and integrated agency for progress towards a salutogenic environment is essential for achieving health system transformation from disease-focused to people-driven health care. This approach befits the adoption of a systems lens to the health sector challenges in South Africa.

The World Health Organization's Health Systems Framework⁵⁰ – comprising the six building blocks of service delivery; health workforce; health information systems; access to essential medicines; financing; and leadership and governance – enables precise categorisation of health sector policies, and implementation and monitoring thereof. However, it does not accommodate other sectoral influences and actions, nor those that influence health promotion and protection, service uptake or the various determinants of health.

It is therefore important to parse the component crises prevailing in South Africa's health system along with the broader context of other systemic and structural factors that have a bearing on health, in order to discern the dynamic interplay of these connections. For example, *Sanders*, in his seminal book entitled *The Struggle for Health* [11] identifies the economic and political forces of globalisation and neo-liberal capitalism as existential threats that shape the health outcomes of communities; these determinants undermine equal access to quality health services.

⁴⁶ Republic of South Africa. Transforming Public Service Delivery White Paper (Batho Pele White Paper). Government Gazette Vol. 388, No. 18340, 1 October 1997. Accessed September 14, 2024. <https://archive.gazettes.africa/archive/za/1997/za-government-gazette-dated-1997-10-01-no-18340.pdf>

⁴⁷ South African National Department of Health. Patients' Rights Charter. Pretoria: NDOH; 2008. Accessed September 12, 2024. <https://knowledgehub.health.gov.za/system/files/elibdownloads/2023-04/PATIENTS%252520RIGHTS%252520CHARTER%252520-%252520Eng.pdf>

⁴⁸ Naledi T, Vallabhjee K, Mosam A, Heywood M. What would it take to turn National Health Insurance into universal healthcare? Daily Maverick. Published July 30, 2024. Accessed September 14, 2024. <https://www.dailymaverick.co.za/article/2024-07-30-what-would-it-take-to-turn-national-health-insurance-into-universal-healthcare/>

⁴⁹ Goldstein S, Vallabhjee K, Naledi T, Mosam A, Heywood M. For universal healthcare and NHI to succeed, SA needs effective health promotion programmes and institutions. Daily Maverick. Published August 18, 2024. Accessed September 6, 2024. <https://www.dailymaverick.co.za/article/2024-08-18-for-universal-healthcare-and-nhi-to-succeed-sa-needs-effective-health-promotion-programmes-and-institutions/>

⁵⁰ World Health Organization. Monitoring the building blocks of health systems: A handbook of indicators and their measurement strategies. Geneva: WHO; 2010. Accessed September 10, 2024. <https://iris.who.int/bitstream/handle/10665/258734/9789241564052-eng.pdf>

A systematic approach is therefore required to address the country's disease burden and health system challenges within the context of globalisation and neo-liberal capitalism, combined with the structural stressors of increasing unemployment and poverty, inequality, infrastructure, energy and logistics failures, mismanagement of public finances, and severe human resources for health shortages. This approach prepares the ground for systemic changes that underpin ethical and effective health governance to honour the social contract and transcend the unevenness of health system responses to multi-dimensional challenges – targeted efforts to address risks and leverage opportunities, build capacity, apply better fiscal policies, ensure efficiency and accountability, and institute emergency response systems, all focusing on system resilience and sustainability.

Four lessons for other countries

South Africa's experience in pursuing UHC offers several valuable lessons for other countries, particularly those grappling with health inequities and resource constraints.

The first key learning is the importance of political will and policy commitment. South Africa's National Health Insurance framework reflects the government's clear intent to achieve UHC, demonstrating that even in countries with deep socio-economic divides, significant health system reforms can be driven by bold, top-down policy initiatives. This commitment can inspire other nations to prioritise health as a fundamental right and to invest in long-term strategies for expanded access to healthcare.

A second lesson is that South Africa's globally recognised HIV treatment programme, which reaches millions of people, is a model that highlights how targeted health interventions can be scaled to improve coverage for other conditions, such as NCDs.

A third critical lesson is the need for health data system integration. South Africa's implementation of digital health platforms shows how technology can improve health governance, data collection, and service delivery. Countries seeking to improve health outcomes should focus on developing robust, interoperable digital systems to ensure accurate measurement and monitoring of UHC progress, enabling real-time, data-driven decision-making.

The fourth lesson inheres in the importance of addressing health workforce challenges, which are faced by many other countries. Ensuring adequate training, equitable distribution, and retention of healthcare workers, particularly in rural areas, is crucial for delivering quality services.

Fulfilling the right to health in an ecology of wellbeing

Achieving optimal standards and innovation for a homogenous South African health system require a culture of servant stewardship for pooling of skills, resources and experience. Public and private healthcare sector collaborative efforts should prioritise health promotion and disease prevention, while addressing all aspects of service delivery shortcomings as well as health information system and digital health solutions.

Practical steps in this direction would entail establishing a National Health Commission and/or an independent Health Promotion and Development Foundation to prioritise 'health in all policies' and health promotion financing, with health literacy and health education being systemised and invigorated at facility level. These bodies should also consider structured incorporation of indigenous knowledge systems, including traditional medicine and communitarian values.

Intersectoral collaboration mechanisms such as KwaZulu-Natal Province's Operation Sukuma Sakhe can be emulated, adapted and scaled up to implement co-ordinated, sustainable strategies that enable consistent use and delivery of high-quality health and other public services premised on the District Development Model; this model calls for collaborative planning on the basis of a detailed, technically driven consultative process within all levels of government and with communities and stakeholders – resulting in a single strategically focused 'One Plan' for each district and metropolitan space in the country. Grafted upon this, forging multisectoral partnerships to generate research evidence and data sets can support formulation and refinement of UHC-orientated health policy and its implementation.

From our perspective, a more integrated approach to health data management is needed to ensure uniform standards across the public and private health sectors. Strengthening digital health infrastructure, ensuring interoperability across platforms, and focusing on equity-driven metrics will be critical for providing a more accurate picture of South Africa's progress towards UHC. Regular, standardised national health surveys that incorporate socio-economic indicators will also enable a more accurate reflection of service coverage across the country.

The global context of South Africa's journey towards UHC also presents opportunities for international collaboration to improve the health of large populations and support global health governance, especially among BRICS nations, which collectively have significant experience in addressing similar healthcare challenges. By continuing to strengthen its digital infrastructure, focus on health workforce development, and address gaps in service delivery, South Africa is poised to emerge as a leader in UHC implementation within the region.

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Public mental health – the Indian perspective

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ABSTRACT

The global burden of mental disorders is already substantial and increasing disconcertingly each year. In India, the prevalence of mental disorders is estimated to be 10.6%. There is a significant treatment gap and a limited number of mental health professionals. Every country needs a robust public mental health system to address this burden. India has developed a comprehensive public mental health infrastructure across all levels of healthcare. The National Mental Health Programme, which has evolved since its inception in 1982, is a key component of this system. Additionally, India has a National Mental Health Policy and a Suicide Prevention Strategy. The recently introduced National Tele Mental Health Programme has transformed mental healthcare in the country. Ayushman Arogya Mandirs, located at Primary Health Centres and Sub Health Centres, are providing comprehensive primary health care, including mental health services. Despite these advancements, India faces several challenges in mental healthcare, including population size, geographical diversity, cultural variations, stigma, multiple stakeholders, a shortage of mental health professionals, and budget constraints. Efforts are ongoing to address these issues. New areas such as Artificial Intelligence, climate change, and perinatal mental health are being explored. The public mental health setup in India could serve as a model for other countries.

Key Words: programmes; mental illness; public health; challenges; mental health

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Introduction

Mental disorders are highly prevalent. According to the Global Burden of Disease study, mental disorders have risen to become the 6th leading cause of health loss worldwide, up from 9th place in 1990 [1]. In 2021, 13.9% of the global population experienced mental disorders. Depressive and anxiety disorders are among the top causes of Disability-Adjusted Life Years (DALYs), ranking 12th and 23rd, respectively. These conditions also show the most significant increase in DALY rates from 2010 to 2021. The global age-standardized suicide rate was 9.0 per 100,000 population in 2019¹. In India, the suicide rate is 12.4 per 100,000 population².

The prevalence of depressive disorders in BRICS nations is 4.09%, exceeding the global average of 3.91%. In terms of absolute numbers, India, China, Brazil, and Russia rank 1st, 2nd, 4th, and 6th respectively for the highest number of individuals affected by depression. Collectively, BRICS nations account for approximately 44% of the global burden of depression [2].

According to the National Mental Health Survey [3], 2016, the estimated prevalence of mental disorders among individuals over the age of 18 in India, excluding tobacco use disorders, was 10.6%. The lifetime prevalence of these disorders in the surveyed population was 13.7%.

Treatment gap and limited mental health professionals

Between 76% and 85% of individuals with mental, neurological, and substance use conditions do not receive adequate care, with the treatment gap exceeding 90% in many low- and middle- income countries³. In India, the National Mental Health Survey [3] revealed a treatment gap of 28% to 83% for mental disorders and 86% for alcohol use disorders.

Globally, there are 1.7 psychiatrists and 1.4 psychologists per 100,000 population⁴. In India, however, the median number of psychiatrists is just 0.2 per 100,000 population, significantly below the required levels. The number of psychologists is even lower, at only 0.03 per 100,000 [4].

Sustainable development goal and mental health

The 2030 Agenda for Sustainable Development, adopted by all United Nations Member States in 2015, provides a shared blueprint for peace and prosperity for people and the planet, now and into the future. At its heart are the 17 Sustainable Development Goals (SDGs), which are an urgent call for action by all countries – developed and developing – in a global partnership. Goal 3 is related to health – Ensure healthy lives and promote well-being for all at all ages⁵. Within the health-related sustainable development goals, two targets are directly related to mental health and substance abuse:

Target 3.4 “By 2030, reduce by one third premature mortality from Non communicable diseases through prevention and treatment and promote mental health and well-being”⁵.

¹ Suicide worldwide in 2019: global health estimates. Geneva: World Health Organization; 16 June 2021. Accessed August 5, 2024. <https://www.who.int/publications/i/item/9789240026643>

² Accidental Deaths & Suicides in India 2022. New Delhi; National Crime Records Bureau; 2022. Accessed July 4, 2024. <https://data.opencity.in/dataset/6af5e9d7-9de5-4689-9fe3-3418790bb0d5/resource/493c904b-d83b-48bc-bf55-678594ffffff/download/170161156012adsi2022publication2022.pdf>

³ mhGAP operations manual: mental health Gap Action Programme (mhGAP). Geneva: World Health Organization; 8 January 2018. Accessed August 5, 2024. <https://www.who.int/publications/i/item/mhgap-operations-manual>

⁴ Mental health ATLAS 2020. Geneva: World Health Organization; 8 October 2021. Accessed August 5, 2024. <https://www.who.int/publications/i/item/9789240036703>

⁵ Sustainable Development Goals. The United Nations: Department of Economic and Social Affairs. Accessed August 5, 2024. <https://sdgs.un.org/goals>

Table 1. Objectives and components of the District Mental Health Program

Objectives		Components	
1.	To provide mental health services including prevention, promotion, and long-term continuing care at different levels of district healthcare delivery system	Service Provision	Management of cases of mental disorder and counselling at various levels in district
2.	To augment institutional capacity in terms of infrastructure, equipment, and human resource for mental healthcare	Capacity Building	Manpower training and development of prevention, early identification, and management of mental disorders
3.	To promote community awareness and participation in the delivery of mental health services.	Awareness Generation	Information, Education and Communication (IEC) activities for early identification and reducing stigma
4.	To broad-base mental health into other related programs		

Target 3.5: “Strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol”⁶.

From the discussion above, it is evident that mental health should be a major concern for BRICS nations. Various service delivery models exist for managing mental disorders, with the Public Health Delivery model being particularly significant. In this article, the authors outline the Public Mental Health system in India, which could serve as a model for other countries.

The public mental health setup in India

India was one of the first nations in the world to have a National Mental Health Programme (NMHP) which was launched in 1982 with the following objectives:

- To ensure the availability and accessibility of minimum mental health-care for all in the foreseeable future, particularly to the most vulnerable and underprivileged sections of the population;
- To encourage the application of mental health knowledge in general healthcare and in social development; and
- To promote community participation in the mental health service development and to stimulate efforts towards self-help in the community⁷.

The model of service delivery in NMHP was through Primary Health Centres and Community Health Centres. However, this was not successful. It was later felt that District will be a better unit to provide mental health serves. The District Mental Health Program (DMHP) was launched under NMHP in the year 1996⁸. The main goal of DMHP was to provide Community Mental Health Services and integration of mental health with General health services through decentralization of treatment from Specialized Mental Hospital based care to primary health care services. The DMHP has objectives and components presented in Table 1.

As per DMHP Guidelines⁸, one psychiatrist, one clinical psychologist, one psychiatric social worker, one psychiatric nurse, one community nurse, one monitoring and evaluation officer and case registry assistant and one ward assistant are the staff of the District Mental Health Pro-

⁶ Sustainable Development Goals. The United Nations: Department of Economic and Social Affairs. Accessed August 5, 2024. <https://sdgs.un.org/goals>

⁷ National Mental Health Programme (NMHP). Ministry of Health and Family Welfare, Government of India. Accessed August 6, 2024. <https://nhm.gov.in/index1.php?lang=1&level=2&sublinkid=1043&lid=359>

⁸ District Mental Health Programme. Accessed September 1, 2024. https://mohfw.gov.in/sites/default/files/56464578341436263710_0_0.pdf

Table 2. The service provision at various levels as per District Mental Health Program

Primary health centre	Community health centre	District hospital
• Outpatient department • Counselling • Pro-active case finding • Mental health promotion • [Manpower: 2 community health workers]	• Outpatient department • Inpatient for emergency psychiatry cases • Counselling • [Manpower: +1 medical officer, clinical psychologist/psychiatric social worker]	• Outpatient department • Inpatient ward – 10 bedded facility • Outreach services • Sensitization & training of health personnel

gramme Team. The DMHP has currently been approved for 767 districts across the country. Under DMHP, the service provision at various levels is as described in Table 2.

There is also a public private partnership model in DMHP. It is being utilized for following activities:

- Advocacy and local Information, Education and Communication in districts & states.
- Day care/residential/ long term residential continuing care centres.
- Supplementation of innovative mental health services.
- Training/sensitization of health workers.
- Hiring of private psychiatrist/ clinical psychologist/psychiatric social worker psychiatric nurse on contract.
- Ambulance services.

The NMHP was re-strategized in 2003⁹ to include two schemes as tertiary care component, modernization of state mental hospitals and up-gradation of psychiatric wings of medical colleges/general hospitals. 25 Centres of excellence have been sanctioned to increase the intake of students in Post graduate departments in mental health specialties as well as to provide tertiary level treatment facilities. Further, the government has also supported 19 government medical colleges/institutions to strengthen 47 Post graduate departments in mental health specialties.

Achievements of District Mental Health Programme in 2023-24

- Outpatient department (OPD) services: 9,495,530 patients were catered in mental health OPDs in the districts during April 2023 to March 2024.
- Inpatient services: 319,065 patients admitted for mental health disorders in district hospitals.
- Outreach activities/OPDs conducted by DMHP teams: 45,995 outreach activities were conducted by DMHP Teams
- Patients attended through Outreach activities and OPDs: 1,190,804 patients/ beneficiaries were attended through outreach activities or OPD sessions.
- Let's talk campaign was initiated in schools and colleges on occasion of world suicide prevention day on 10th September 2023.

Some best practices followed by the states in India

Telangana. The state has adopted integration of perinatal mental health as part of comprehensive Ante Natal Care (ANC). Screening tools by Auxiliary Nurse Midwife (ANM) are introduced in the mother and child protection card and the MCH portal has included the indicators of the same for reporting. ANC counselling cards integrated with elements on mental health.

⁹ National Mental Health Programme. Ministry of Health and Family Welfare, Government of India. Accessed August 6, 2024. https://dghs.gov.in/content/1350_3_NationalMentalHealthProgramme.aspx

Tamil Nadu. "Mental Health Thursdays," known as "Mana Nala Viyazhan." Dedicated to raising awareness about mental health among the health care workers on a regular (weekly) basis through messages shared on WhatsApp.

Odisha. Mobile Mental Health Units (MMHU) for providing doorstep mental health care services to the Persons with Mental Illness (PwMI). Fixed day visits to CHC, PHC, HWC for providing mental health care services.

Karnataka. Various initiatives undertaken by the state are as follows:

- Mano-chaitanya program: Super Tuesday clinics, a fixed day strategy for mental health services across all public health facilities;
- Manasa-dhara program: day care program for those recovering from mental illness being run under a registered NGO;
- assisted home care/care at doorsteps for psychiatric disorders by community volunteers.

India also has a separate National Mental Health Policy¹⁰ which was released in October 2014 with the following goals:

1. To reduce distress, disability, exclusion morbidity and premature mortality associated with mental health problems across lifespan of the person.
2. To enhance understanding of mental health in the country.
3. To strengthen the leadership in the mental health sector at the national, state and district levels.

The policy calls for universal access to quality services, equitable distribution, community participation, rights-based approach, intersectoral coordination, use of appropriate technology and a holistic approach to mental health.

It is fully implemented, and its principles have been incorporated in the National and District Mental Health Programmes and Mental, Neurological and Substance Use Package of services at Ayushman Bharat Health & Wellness Centres.

In 2022, the National Tele Mental Health Programme (Tele MANAS) was also launched with the following aim and objectives¹¹.

Aim: to provide universal access to equitable, accessible, affordable and quality mental health care through 24x7 tele-mental health counselling services as a digital component of the NMHP across all Indian States and Union Territories with assured linkages.

Objectives:

- To exponentially scale up the reach of mental health services to anybody who reaches out, across India, any time, by setting up a 24x7 tele-mental health facility in each of the States and UTs of the country.
- To implement a fully-fledged mental health service network that, in addition to counselling, provides integrated medical and psychosocial interventions including video consultations with mental health specialists, e-prescriptions, follow-up services and linkages to in-person services.
- To extend services to vulnerable groups of the population and difficult to reach populations.

As of July 23, 2024, 36 States/ UTs have set up 53 Tele MANAS Cells and have started telemental health services¹². The service is available in

¹⁰ National Mental Health Policy of India. Ministry of Health and Family Welfare, Government of India. October 2014. Accessed August 6, 2024. https://nhm.gov.in/images/pdf/National_Health_Mental_Policy.pdf

¹¹ National Tele Mental Health Programme of India. Ministry of Health and Family Welfare, Government of India. Accessed August 6, 2024. <https://telemahas.mohfw.gov.in/aimobjectives>

¹² Mental health programmes. Press Information Bureau. Ministry of Home Affairs. Accessed August 6, 2024. <https://pib.gov.in/PressReleaseIframePage.aspx?PRID=2039067#:~:text=As%20on%2023.07,handled%20on%20the%20helpline%20number>

20 different languages. More than 1 million calls have been handled on the helpline number since inception with an average of 3500 calls per day¹³.

The Government of India also rolled out Comprehensive Primary Health Care¹⁴ under the Ayushman Arogya Mandir approach. The approach covers Mental, Neurological and Substance use disorders. As per the guidelines¹⁵ of the same, a five-pronged approach is being used to enable the integration of mental health care in primary health care:

1. Community level health promotion interventions and improving mental health literacy that enables an understanding of mental health, common symptoms, risk factors/causes of disorders, treatment, reduction of stigma and discrimination, and of techniques such as psychological first aid, and self-care.
2. Early identification, referral to community health officer for screening and home & community based follow up by frontline worker team.
3. Screening by community health officer through the use of a standard screening tool, psychosocial management and enabling referral.
4. Diagnosis and initiation of treatment by the medical officer at the primary health centre (PHC) levels.
5. Reduction of treatment gap (psychosocial and pharmacological) by facilitating access to treatment by referral to higher level centres (PHC and other referral centres), initiation of treatment and ensuring regular supplies and treatment adherence.

In addition to the above programmes, India also has a National Suicide Prevention Strategy¹⁶ which has the following objectives:

- Reinforce leadership, partnerships and institutional capacity in the country.
- Enhance the capacity of health services to provide suicide prevention services.
- Develop community resilience and societal support for suicide prevention and reduce stigma associated with suicidal behaviors.
- Strengthen surveillance of suicide and evidence generation.

India has a strong legislative mechanism with regards to mental health. The Mental Health Care Act of India, 2017 is a progressive act and follows a rights-based approach in line with the United Nations Convention on the Rights of Persons with Disabilities¹⁷. The Rights of Persons with Disabilities Act, 2016 also covers mental illness as a disability¹⁸.

Challenges in Indian mental healthcare setup

Mental health service delivery in India faces numerous challenges, many of which are also encountered by other nations. These challenges are listed below.

1. Population. With a population of 1,210,854,977 as per the 2011 census, India's large numbers strain the healthcare system, including mental health services. The demand for healthcare often overwhelms the available resources.

¹³ In a significant milestone achieved under the National Tele Mental Health Programme of India, the Tele-MANAS Helpline receives over 10 lakh calls since its launch in October 2022. Press Information Bureau. Ministry of Health and Family Welfare. Accessed August 6, 2024. <https://pib.gov.in/PressReleasePage.aspx?PRID=2022057>

¹⁴ Comprehensive Primary Health Care. National Health Systems Resource Centre. Accessed August 6, 2024. <https://nhsrindia.org/practice-areas/cpc-phc/comprehensive-primary-health-care>

¹⁵ Operational Guidelines Mental, Neurological and Substance Use (MNS) Disorders Care at Health and Wellness Centres. Accessed September 1, 2024. https://aam.mohfw.gov.in/download/document/Final_MNS_Operational_Guidelines_-_Web_Optimized_PDF_Version_-_19_11_20.pdf

¹⁶ National Suicide Prevention Strategy. Ministry of Health and Family Welfare, Government of India; 2022. Accessed September 1, 2024.

¹⁷ The Mental Healthcare Act, 2017. Accessed September 1, 2024. https://mohfw.gov.in/sites/default/files/Mental%20Healthcare%20Act%2C%202017_0.pdf

¹⁸ The Rights of Persons with Disabilities Act, 2016. Accessed August 6, 2024. <https://depwd.gov.in/acts/>

2. Geography. India's vast expanse, with its numerous states and districts, complicates the management of national health programs from a centralized location. Additionally, many areas are situated in difficult and remote terrains, making service delivery more challenging.
3. Cultural Variation. India's cultural diversity adds complexity to mental health care. Cultural differences, even within small geographical areas, and the presence of over 1,500 'mother tongues' make it challenging to tailor mental health programs to meet diverse cultural needs effectively.
4. Lack of mental health professionals. As highlighted earlier, the low per capita number of mental health professionals poses a significant challenge to effective service delivery.
5. Stigma. Mental health conditions are often stigmatized, with cultural explanations leading people to seek help from faith healers rather than mental health professionals. Myths and misconceptions about mental health disorders and their treatment further exacerbate this issue.
6. Disintegration of the Family System and Westernization. The traditional Indian family system, which provided substantial support, is shrinking. The decline of joint families and the increasing influence of Western lifestyles have led to higher stress levels and diminished support systems. This shift has resulted in more individuals with severe mental illness being institutionalized, with challenges in community reintegration.
7. High expectations and Pursuit of material success. The pursuit of material success has also increased stress and reduced focus on personal health. Expectations, self-imposed and from external sources, lead to over ambition. The constant exposure to social media creates unrealistic benchmarks for success and happiness. All this leads to increased stress and burnout, creating a base for mental disorders. The Indian society is currently struggling with these issues as well.
8. Skewed Multidisciplinary Approach. Effective mental health care requires a multidisciplinary approach involving psychiatrists, psychologists, psychiatric social workers, and psychiatric nurses. Biopsychosocial model is the best model to understand and manage mental disorders. However, there is an over-reliance on psychiatrists and the medical aspects of mental health, with insufficient emphasis on other professionals. Training and educational programs for these other roles are also lacking.
9. Budgetary Challenges. Mental health funding constitutes about 1% of the total health budget. As per a 2019 article [4], the approximate conservative estimated total cost on government to implement the Mental health care Act is 94,073 crore rupees. On a positive note, there has been an upward trend in budgetary allocation
10. Multiple Stakeholders. The mental health sector involves numerous stakeholders, including various ministries (health, social justice, education, women and child development), non-governmental organizations, human rights commissions, and professional bodies. Coordinating among these diverse groups for planning and implementing mental health initiatives can be complex and challenging.

Steps taken to overcome the challenges

1. Including mental health in the Comprehensive Primary Health Care¹⁹ approach ensures services reach all areas of the country, including remote regions far from hospitals. Community frontline workers, such as

¹⁹ Comprehensive Primary Health Care. National Health Systems Resource Centre. Accessed August 6, 2024. <https://nhsrcindia.org/practice-areas/cpc-phc/comprehensive-primary-health-care>

Multi-Purpose Workers and Accredited Social Health Activists, can address cultural issues effectively.

2. Integrating traditional medicine systems (Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa Rigpa, and Homeopathy) into mental health-care has increased community acceptance. Yoga, in particular, has gained widespread acceptance both in India and globally.
3. The Tele MANAS provides services to remote areas of the country. Any region with phone access can now connect with a mental health professional.
4. E-Sanjeevani, the National Telemedicine Service of India, promotes digital health equity to achieve Universal Health Coverage. It facilitates quick and easy access to doctors and medical specialists via smartphones, including psychiatric services.
5. The hub-and-spoke telehealth model in mental health allows centrally located providers to offer specialized care to medically underserved areas through telehealth.
6. Various programs, such as NMHP and DMHP, focus on awareness activities aimed at reducing stigma and dispelling myths and misconceptions related to mental health.
7. To address the shortage of psychiatrists and psychologists, efforts are ongoing to train Medical Officers, Nurses, Social Workers, and Counsellors in mental health under the DMHP and Ayushman Arogya Mandirs-PHC & Sub Health Centres. Innovative approaches like Digital Training are also being implemented.
8. The National Medical Commission of India, the regulatory body for medical education, has significantly increased the number of post-graduate seats in Psychiatry over the last few years.

Way forward

These are important times for mental health in India. The Ministry of Health and Family Welfare has steadily increased its focus on mental health. Various societal groups, including NGOs, celebrities, professional organizations, and human rights associations, have been advocating for advances in mental health service delivery. The dialogue on mental health has gained momentum across different sections of society.

India has embraced technology wholeheartedly. The widespread availability of internet connectivity, smartphones, and affordable mobile connections has led to innovative approaches in service delivery and training. The country had the world's second-largest internet population at over 1.2 billion users in 2023. Of these, 1.05 billion users accessed the internet via their mobile phones. Estimates suggest that this figure would reach over 1.2 billion by 2050²⁰. Artificial Intelligence is also being explored as a tool for enhancing mental healthcare. Chatbot based tools are being developed. Various mental health smartphone apps have been developed providing mental health screening and diagnostic tools, counseling services, health promotion and consultation services [5].

There has been a steady shift from hospital-based mental healthcare to community-based care, with efforts towards 'de-institutionalization.' Many mental hospitals have moved beyond the colonial mindset and approach. The rights of persons with mental illness are being given due importance, and rehabilitation services, such as halfway

²⁰ Basuroy T. Mobile internet users in India 2010-2050. Statista, Jul 18, 2023. Accessed August 6, 2024. <https://www.statista.com/statistics/558610/number-of-mobile-internet-user-in-india/>

homes, skill development, and employment opportunities, are being expanded.

The focus has also shifted to a lifespan approach. The mental health of children and adolescents is being specifically addressed, with the School Mental Health Programme being strengthened [6]. The geriatric population is included in various mental health care approaches. Women's mental health, especially perinatal mental health, has become a focus area [7]. Various corporate organizations are also addressing the mental health of their employees. Additionally, the mental health aspects of climate change and disasters are being prioritized.

The authors would also like to emphasize the restoration of family as a support system as an important strategy to promote mental health as well enhance care for persons with mental illness. The family provides buffer, guidance and support to its members going through stress. The sharing of resources and emotional availability plays a huge preventive role. Further, if one develops a mental disorder, the family provides support, ensures adequate treatment and helps the person recover from their problems.

Further, efforts should be made to create community based self-help groups. These groups provide a supportive network where individuals can share experiences, offer mutual support, and work collectively towards better mental health. Such groups can be instrumental in reducing stigma, normalize the mental health issues, promote empowerment and self-efficacy, build social connections, provide an emotional outlet and complement the professional help, all this in a very accessible cost-effective manner.

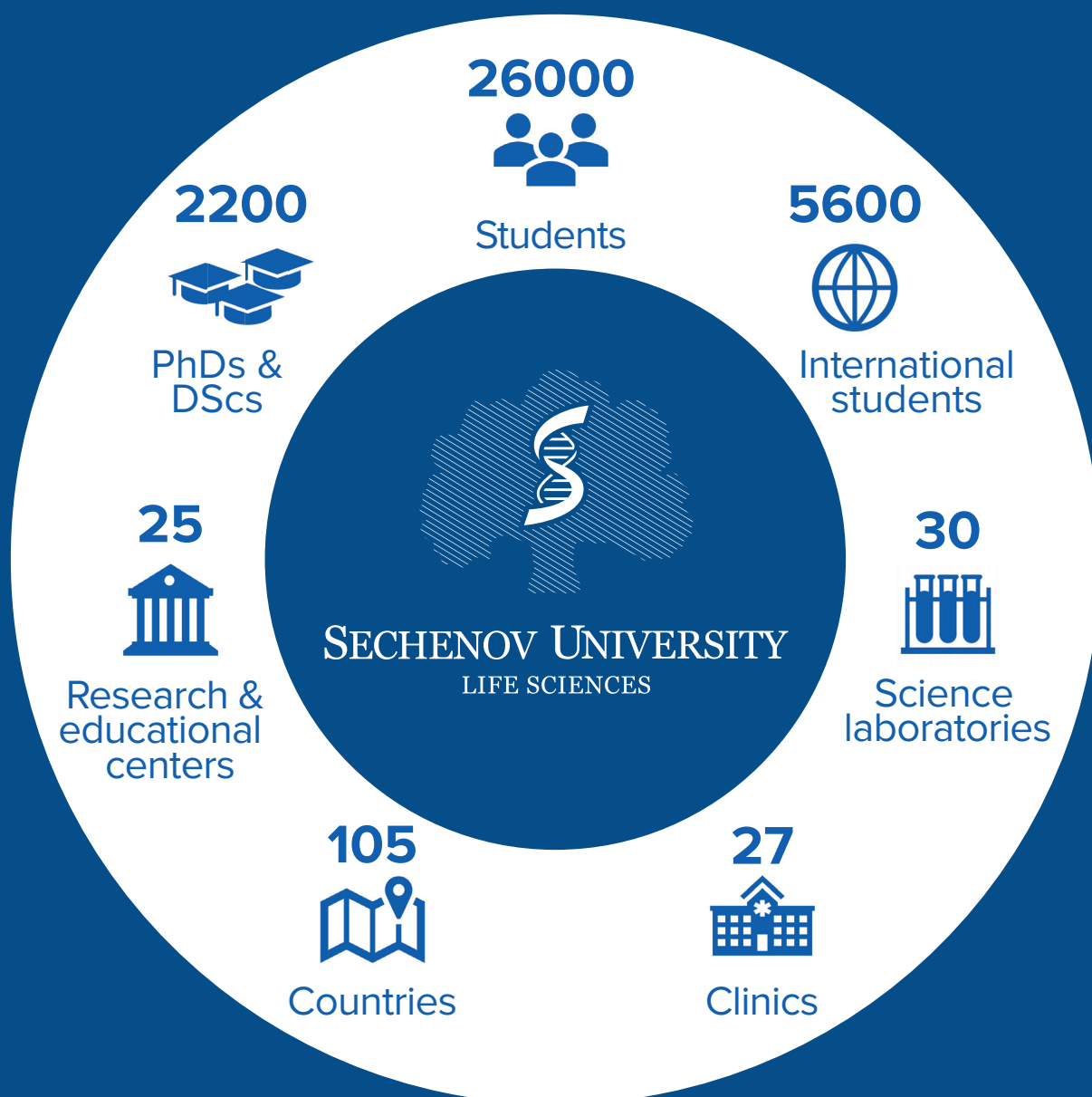
India still has a long way to go to achieve the goals envisioned in various programs, but efforts are increasing every year. It is believed that India's Public Mental Health Model can serve as a guide for other nations.

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