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Healthcare Innovation Lifecycle and Policy Ecosystem: Insights from India

Author:
Kanchan Mukherjee,
Professor, Centre for Health Policy, Planning and Management, School of Health Systems Studies, Tata Institute of Social Sciences, Mumbai.

Address for Correspondence
Prof. Kanchan Mukherjee,
Professor, Centre for Health Policy, Planning and Management
School of Health Systems Studies
Tata Institute of Social Sciences
V.N. Purav Marg, Deonar
Mumbai-400088.
E-mail: kanch@tiss.edu.

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Abstract: Purpose: Healthcare innovations are one of the drivers of healthcare sector growth in India. Innovation policies are challenging because of the uncertainty regarding the outcome of the innovations. Hence, there is a need to understand the interface between policies and healthcare innovations to identify gaps and propose timely recommendations. Accordingly, this study uses the Indian healthcare start-up sector as a case study to analyse the above linkages, gaps and propose recommendations. Methodology: Quantitative data from the Start-up India portal along with qualitative data from key informant interviews have been analysed to draw insights. Findings: Healthcare start-ups have made significant contributions to the economy and healthcare sector, but there are gaps and room for improvement especially in the areas of awareness, funding and mentoring. Conclusions: Based on the study findings a conceptual framework has been created for understanding the nature of gaps and their linkages in the healthcare innovation lifecycle.

Key Words: Healthcare Start-up, Innovation, Entrepreneurship, Health Technology, Emerging market economy, COVID-19

Introduction:
Health is one area where the progress of science and technology in the last century has been most remarkable. At the same time, it has been dramatically uneven across and within countries, and disease areas and the COVID-19 pandemic have exposed the healthcare system's vulnerabilities globally. The global healthcare industry was worth USD 8.45 trillion prior to the COVID-19 pandemic, and global healthcare spending is expected to reach USD 10 trillion by 2022,[1,2] despite a decrease in spending by 2.6% in 2020 due to this pandemic.[3] This decrease in healthcare spending, which happened due to lockdown and social distancing measures, resulted in greater use of virtual platforms and technology for health monitoring. The pandemic thus reflects two sides of the same coin-crisis and opportunity. While strains the healthcare sector infrastructure, human and financial resources and exposing social inequalities, it also acted as a catalyst for change across the ecosystem and stimulated innovation and entrepreneurship to deal with the health crisis. Favoured by policy push, the pandemic has resulted in the creation of many new health technologies, which emerged as start-ups focused on addressing the challenges faced by the healthcare sector. However, despite the importance of this start-up sector in terms of revenue and employment as well as a policy priority, there is very little published literature focusing on healthcare start-ups and start-up policies. A review of articles on the Scopus database using the keywords start-up AND healthcare AND policy revealed only 18 documents. Among these published documents, six were from emerging market economies (four from India and two from China). While one study was from a low-income country (Uganda), the remaining were from developed economies. However, none of these 18 studies looked at the entire spectrum of healthcare start-ups or start-up policies in their countries. Hence, this paper addresses this important gap in the literature and provides insights on the interlinkages between healthcare start-ups and policy and provides recommendations for researchers, innovators and policymakers.

Given the current global health crisis and its impact on the economy, the role of innovation and entrepreneurship through healthcare sector start-ups in addressing this crisis and responding to the 'new normal' is critical. In this context, the healthcare start-up sector in India has been selected as a case study. India has been selected based on its economic, epidemiological and entrepreneurship indicators. Economically, India belongs to an emerging market economy and is an important global investment destination. Epidemiologically, it has been severely affected by the COVID-19 pandemic but has also shown improvement in its global entrepreneurship rankings and is the third-largest start-up economy in the world after the United States of America (USA) and United Kingdom (UK).[4] This study is also important in terms of its policy timing. India is currently
drafting a new science, technology and innovation policy (STIP) to replace the existing policy, which was created in 2013, while the start-up policy of India has completed five years and has attained a maturity conducive for a review. Hence, the Indian healthcare start-up sector has been used as the unit of analysis in this paper for understanding the healthcare innovation lifecycle (emergence- adoption-diffusion), and its interaction with the policy ecosystem with the aim to answer the following three research questions:

1. What is the existing healthcare start-up landscape and policy in India?
2. What are the existing gaps in the healthcare start-up lifecycle?
3. What policy measures can be recommended to address these gaps?

Based on the findings, the study creates a conceptual framework for policy analysis across the healthcare start-up lifecycle, which can be tested, modified and applied to other country contexts.

The paper is structured first to share the methodology used to answer the above research questions, which is followed by the results and discussion section. The results and discussion section provides a background and overview of the healthcare sector, the start-up policy and the ecosystem in India. This is followed by the findings emerging from each domain specific to each research question. After this, the implications of the findings are discussed, followed by the conclusions. Through these sections, the study explores the current healthcare start-up landscape in India in order to understand the progress, gaps and future policy implications for healthcare innovations in India. Based on the findings, a conceptual framework is created for policy analysis with potential for global applicability.

Methods

This paper is based on an analysis of open access data available in the public domain and did not require any ethical clearance. Documents published on healthcare start-ups, reviews and reports were analysed. The start-up India portal website (www.start-upindia.gov.in) was used to identify existing healthcare start-ups, their categories and stages, i.e., ideation, validation, early traction and scaling. Perspectives from experts [Key Informants (KI)], which were available open access online as part of the STIP consultative process,[5] were also analysed to obtain deeper insights. The consultations included 96 different domains across different policy makers and ecosystems, i.e. health; innovation and entrepreneurship; governance and system interconnectedness; strategic, disruptive and futuristic technology; access to knowledge and resources; financing, equity and inclusion; policy governance and programme linkages. A thematic analysis was done in each of these seven domains to identify core themes emerging across the start-up lifecycle with a focus on gaps and possible solutions. In all, the perspectives of 28 KIs, who are experts in the field of health, finance, start-ups, incubators and policy-making affiliated with academia, industry and government were analysed for this paper. Using inductive analysis, the emerging themes were then used to create a conceptual framework, which would be useful for researchers, innovators and policymakers to identify gaps and recommend or implement solutions.

Results and Discussion

Indian Healthcare sector

The Indian healthcare sector is one of the largest and fastest-growing sectors (CAGR 22.9%) in India both in terms of revenue and employment (fourth-largest) and is projected to reach $372 billion by 2022.[6] Economically, India belongs to an emerging market economy (world’s third-largest start-up economy), and an important investment and market destination globally especially for healthcare including pharmaceuticals, vaccines and medical devices. The Government of India (GoI) think tank, National Institute of Transforming India (NITI), along with other ministries and departments are involved in facilitating innovation through favourable policies and entrepreneurship programmes. This has leveraged India’s position in the ranking of start-up ecosystems, development of information, and increase in knowledge and technology-based enterprises.[7] Investments in health technology start-ups increased by 45% and the biotechnology industry comprises more than 2700 biotech start-ups and is estimated to reach 10,000 by 2024.6 By 2050, the population in India is expected to reach 1.7 billion people and elderly population is expected to grow to 19% (from 8% in 2015)[8] adding to the increasing burden of Non Communicable Diseases (NCDs). This demographic and epidemiological profile change will demand further evolution of the Indian healthcare sector.

To address this demand, India is leapfrogging the use of health technologies for telemedicine, low-cost diagnostics, e-pharmacies, home-based healthcare, vaccines, biosimilars, precision medicine and genomics. These health technology start-ups are using artificial intelligence (AI), machine learning (ML) and other modern technologies to improve access, affordability and quality of healthcare[9] The GoI has plans to further develop India into a global healthcare hub by leveraging its relatively lower-priced treatment options. Hence, policies encouraging these initiatives have been on the ministerial agenda of both the state and federal/union government towards facilitating health technology creation, adoption and diffusion. The key policy favouring the growth of new healthcare technologies in India is the start-up policy[10] which came into effect in January 2016.

Start-up policy

In order to build and sustain entrepreneurship and innovation at the start-up level a number of policy initiatives were taken starting with the ‘Make in India’ initiative in 2014. This initiative was aimed at encouraging foreign investment and increasing domestic manufacturing capacity. The two key steps initiated in this policy initiative were to increase the foreign direct investments (FDI) limits for most of the sectors and protection of intellectual property rights of entrepreneurs, innovators and creators. This was followed in 2015 with the ‘Standup India’ initiative to focus on increase bank funding to start-ups and promote entrepreneurship among women and marginalised sections of Indian society. This was followed closely by the ‘Digital India’ initiative with the aim to connect rural India by digital infrastructure. These above policy initiatives set the stage for the creation of the start-up policy which was officially launched on January 2016 by the Department for Industrial Policy and Promotion (DIPP), now known as Department for Promotion of Industry and Internal Trade (DPIIT), and located within the Ministry of Commerce and Industry.

The definition of a start-up

There is no universal definition of a start-up, and it varies across different countries. DPIIT defines a start-up using the parameters of location, time, annual turnover, innovation and scalability. Using these parameters, a start-up is currently defined as an entity registered or incorporated in India established for not more than 10 years, with annual turnover not exceeding INR 1 billion (approximately 13.5 million USD) in any preceding financial year, and working towards innovation, development or improvement of products or processes or services and is a scalable business model with a high potential of employment generation or wealth creation.[11] It excludes entities formed by splitting up, or reconstruction, of a business already in existence. To facilitate the process of registration of start-ups and to create a national data base of start-ups, the DPIIT has created a start-up India...
Current status of India’s healthcare start-ups: Evidence from start-up India portal

By March 2022, healthcare start-ups have emerged as the second-largest start-up sector registered in the Start-up India portal (over 5000 registered healthcare start-ups). Health and wellness (28%), medical devices (15%), pharmaceuticals (13%) and biotechnology (7%) categories currently contribute to over 60% of the healthcare start-ups in India. The start-up India portal classifies a healthcare start-up into four stages - ideation, validation, early traction and scaling. These stages can be considered as the equivalent of emergence (ideation and validation), adoption (early traction) and diffusion (scaling) of healthcare innovation lifecycle. Table 1 shows the category-wise distribution of healthcare start-ups and their distribution according to lifecycle stages in the start-up India portal. Medical devices have received the maximum impetus through this policy with 66% in the emerging phase followed closely by the biotechnology sector (64% in emerging phase). The high emergence of medical devices start-ups is a significant positive policy impact, since India is a major importer of medical devices. The growth in the biotechnology sector, apart from a positive impact of the current policy also benefited historically from the National Biotechnology Development Strategy initiated in 2007, which focused on research and development; regulations; technology transfer; and diffusion; intellectual property; and building human capital.[23] However, both these sectors have the lowest rate of diffusion (9%) as compared to the other sectors. This is indicative of the longer time period required by medical devices and biotechnology products to be adapted and diffused.

Table 1. Healthcare start-up categories and their stages

<table>
<thead>
<tr>
<th>Categories</th>
<th>Emergent (%)</th>
<th>Adopted (%)</th>
<th>Diffused (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health and Wellness</td>
<td>48</td>
<td>38</td>
<td>14</td>
</tr>
<tr>
<td>Medical devices</td>
<td>66</td>
<td>25</td>
<td>9</td>
</tr>
<tr>
<td>Pharmaceutical</td>
<td>59</td>
<td>28</td>
<td>13</td>
</tr>
<tr>
<td>Healthcare IT</td>
<td>50</td>
<td>38</td>
<td>12</td>
</tr>
<tr>
<td>Biotechnology</td>
<td>64</td>
<td>27</td>
<td>9</td>
</tr>
</tbody>
</table>

Evidence from the STIP consultation process

Thematic analysis of perspectives from the expert KIs involved in the STIP consultation process focused on understanding progress, gaps and possible solutions. The analysis revealed three dominant or core themes as gaps across the health innovation lifecycle and its ecosystem. These were awareness and access to information, mentoring and networking, and funding. Table 2 provides the key thematic areas identified as gaps, and their relative intensity and distribution across the lifecycle.

Table 2. Thematic gaps across the healthcare start-up lifecycle with their relative weights

<table>
<thead>
<tr>
<th>Healthcare start-up stages</th>
<th>Thematic gaps</th>
<th>Emergence</th>
<th>Adoption</th>
<th>Diffusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Awareness and Access to information</td>
<td>+++</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mentoring and Networking</td>
<td>+++</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Funding (Amount and Timeliness)</td>
<td>+++</td>
<td>++</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Awareness and access to information along with funding were identified as important gaps in the emerging stage. Funding along with mentoring-networking emerged as a key issue during the adoption stage, while mentoring-networking continued to be a gap in the diffusion stage. Based on the above thematic areas, a convergent stream framework (CSF) model (Figure 1) is proposed, to understand the role and linkages among the multi-thematic areas of gaps across the ecosystem.

lifecycle of healthcare innovations, which could be used to identify and time the solutions. This model can be applied, tested, modified by researchers, innovators and policymakers working in other countries and in different contexts to conceptualise the type, magnitude and location of gaps in the health innovation lifecycle in order to provide suitable solutions.

Figure 1: Convergent Stream Framework (CSF) model.
In this CSF model, healthcare innovations can be considered like a large stream flowing across changing time, contexts and ecosystems. The three stages of emergence, adoption and diffusion are different parts of the same stream and reflect the evolution of innovations. The multiple thematic gap areas are the multiple smaller streams, which converge with the flow of this large stream at different points. The nature of these streams (gaps), their size and point of convergences with the lifecycle stage would vary across different contextual realities and time. Figure 1 represents the application of this conceptual model based on the findings of the theoretical analysis of this study, which reflects the current Indian scenario.

In addition to the above core themes across the start-up lifecycle, there were some important insights for the start-up ecosystem and future priorities. Almost all the KIs mentioned that there were multiple sources and types of information regarding start-ups available at multiple places, which resulted in confusion among those interested in initiating a start-up. The link between academia and industry was also stated to be weak, and the roles of mentoring and networking was emphasised. Funding availability, especially in the early stage, was mentioned as a major drawback, which in turn affected the long-term motivation of the entrepreneur and innovator. The areas needing priority for further exploration by healthcare start-ups included primary healthcare, non-communicable diseases (NCDs), crowdsourcing of data, contact tracing, pharmacovigilance, knowledge-sharing platforms, data acquisition and analysis by frontline workers.

The analysis also revealed a gap in translation between knowledge economy and commercial economy as evident from the weak university-industry network and the gap in mentoring and networking. Entrepreneurship is infrequently considered as a career option in India, given the historical societal preferences of salaried jobs and careers. This social culture needs to be addressed by policy options like reducing barriers and facilitating entrepreneurship efforts, in order to encourage entrepreneurship as a career. Risk of failure has also been identified as a reason for reluctance in pursuing opportunities for initiating a start-up. This highlights the role of soft policy options facilitating early mentoring and networking in the start-up process to provide and sustain motivation, opportunity and skills. However, this study finds that even after five years of the start-up policy, this remains a gap which needs to be addressed. In India, necessity-driven proportion of total early-stage entrepreneurial activity (TEA) is significantly more than improvement-driven opportunity proportion.[24] Financing emerged as an important obstacle, especially in the critical early phase and is a major contributor to start-up exit with over 75% of entrepreneurship exiting the market in India due to lack of profitability or financial issues.

Conclusions
The movement towards developing and promoting start-ups began in September 2014, with a very early high level push towards ‘Make in India’. This resulted in the release of the Start-up India action plan on January 2016, and the creation of the first Start-up India Hub in April 2016. Within five years, healthcare has emerged as one of the dominant start-up sectors in this hub. Many GoI ministries (and departments) and the NITI are involved in polices and schemes involved in programmes and schemes for facilitating start-ups in India. However, the start-up India portal was created by the DPIIT under the Ministry of Commerce and Industry in April 2016. The definition of start-ups has been amended twice during this five-year period to increase its scope and bring it to its present definition. The ongoing COVID-19 pandemic has further opened a window of opportunity for healthcare start-ups to be prioritised in the policy-making agenda. This is also reflected in the current consultative process towards framing the new STIP, wherein healthcare has a significant role. In this context, the present study reviewed the current start-up landscape in India using health sector start-ups as a case study in order to understand the progress, gaps and
future implications of start-ups in India. A conceptual framework for understanding the nature of gaps and their linkages in the start-up lifecycle has been proposed. This study is limited to registered healthcare start-ups in the start-up portal and does not include other start-ups which are not registered in this portal. However, the findings of this study are similar with previous studies on start-ups in other sectors and other parts of the world.

Healthcare start-ups have already emerged as hotspots of activity due to the COVID-19 pandemic and their role in addressing this crisis and the ‘new normal’ is critical. The global innovation index report 2020[4] has identified the decline in venture capital across the world which has affected start-ups and their growth is at risk.[28] However, the health of financial institutes is still stable and there is a significant shift in the direction of venture capital towards healthcare.[28] Numerous healthcare start-ups have emerged during the COVID-19 pandemic addressing the preventive, diagnostic, curative and rehabilitative domains of healthcare.[29] In this context, the findings of this study becomes even more important for the post-pandemic start-up ecosystem and policy directions, and the convergent stream framework emerging from this study is conceived as a conceptualisation tool with potential for global applicability. During this pandemic, India is witnessing the emergence of ‘innovation commons’ from volunteers building digital platforms which can then be used to build innovations on top.[4]

In the healthcare sector, considering India’s poor doctor: population ratio, innovations such as digital health using such platforms have a huge potential to reach to the masses. However, innovation is not only about new technologies or processes but also about people and culture and as the literature on innovation for public health in low and low-middle income countries suggests, technical innovations are incomplete unless accompanied by associated institutional and social innovations.[30] Hence, the innovation ecosystem should attempt at making healthcare start-ups as a leveraging tool for translating interdisciplinary learning into multisectoral action for improving health. This would also be useful for health diplomacy and contribute towards building relationships at various levels and with different actors, which is particularly relevant in the context of the ongoing COVID-19 pandemic.

While the triple helix of university-industry-government relations,[31] will play a key role in the future of healthcare innovations, it is also important to involve the civil society and community based organisations from the beginning to understand the socio-culturalacceptability of new products or processes emerging from these innovations. While the new STIP policy is in the making, and the accumulation of past performance is counted, perhaps what counts most is the resourcefulness of these assets in relation to further developments.

The start-up movement in India started in 2016 and has made significant contributions to the economy and healthcare sector, but there are gaps and room for improvement. Policy measures are critical not only to tide over the crisis but also for long term sustainable solutions. The pandemic provides a major opportunity to facilitate innovation and entrepreneurship by addressing these critical gaps through better ecosystems. In this context, the role of Health Technology Assessment (HTA) for identifying responsible innovations (start-ups) in healthcare which contribute to efficient, equitable and quality healthcare systems is critical.[32,33]

Although the usefulness of an ecosystems approach is established, its leveraging to inform the practice of innovation for Universal Health Coverage (UHC) has been limited to date, especially in the developing countries. Future research should try to answer whether the new start-up policy initiatives emerging from this crisis addresses issues of UHC like affordability, accessibility and quality of healthcare; and whether the use of healthcare innovative technologies has decreased or increased the inequity in society. In addition, there is a need for empirical research to assess the effectiveness and efficiency of policies in reducing uncertainty and generating incentives and the social legitimacy and acceptability of healthcare innovations in the evolving context. It is important that policymakers analyse the social dynamics generated by innovation policies without assuming its benefits. In an increasingly globalised world with no country isolated, the pandemic provides a universal policy space to convert a crisis into an opportunity by working towards a coherent, responsive and inclusive innovative ecosystem for sustainable development goals.

References