Mutual Learning for
Mixed Health Systems

Towards Digital Transformation for Universal Health Coverage

Mutual Learning for Mixed Health Systems: https://innovation4uhc.com/

Core technical team

Priya Balasubramaniam Director of the Centre for Sustainable Health Innovations and Senior Public Health Scientist, PHFI
Health system analyst and co-convenor of the series of consultations

Tom Barker Senior Health and Nutrition Convenor at IDS
Strategies for engagement with policymakers and change agents

Gerald Bloom Professorial Fellow in the Health and Nutrition Cluster at IDS
Health system analyst and co-convenor of the series of consultations and leader of the report team

Lewis Husain Co-Leader of the Health and Nutrition Cluster at IDS
Evaluation methods and learning approach to the management of change

Evert Jan-Quak Researcher at IDS
Strategies for engagement in markets for the poor

Anabel Marin Leader of the Business, Markets and the State Cluster at IDS
Analyst of innovation systems

Erica Nelson Fellow in the Health and Nutrition Cluster of IDS
Community engagement for equity and participatory approaches

Case studies of regulatory reform

Kenya: Dr Radha S. Karnad Chief Medical Officer, Health X
India: Shambhavi Ravishankar Consultant, Ikigai Law

Leaders of national transformation labs

Argentina: Centre for Research on Transformations at the School of Economics and Business of the National University of San Martín
Bangladesh: Rubaiyath Sarwar Innovision Consulting
India: Priya Balasubramaniam Centre for Sustainable Health Innovations and PHFI
Zimbabwe: Mungai Lenneiye Udugu Institute

Contents

1 Introduction

The Covid-19 pandemic has re-emphasised the need to ensure equitable access to safe, effective and affordable health services. The very rapid shift to the use of smartphone apps and telephone consultations (telemedicine) has highlighted the potential impact of digital innovations on the capacity of health services to meet this need. It is time to take digital health seriously.

In 2021, The Lancet and the Financial Times published a report by a commission of experts entitled *Governing health futures 2030: growing up in a digital world*. It describes the many ways that digital technologies are affecting health and access to health services (Kickbusch *et al.* 2021). The report emphasises the changing inter-relationships between the health and digital technology sectors and makes the case for effective governance of digital health. It outlines measures that can be taken to influence the speed and direction of change, with the aims of building trust and ensuring that the needs of poor and vulnerable people are met. Its focus is on global trends and global responses. This report complements that document by focusing on actions that LMICs can take to ensure that digital innovations contribute to their strategies for improving health and access to health services

Visions of a transformed health sector

As digital health technologies are becoming more sophisticated and more widely available, there is discussion about their impact on existing health services and the consequences this will have for the users. A number of international organisations,[1] information technology companies,[2] management consultancies[3] and business organisations[4] have published optimistic visions of a health sector transformed by digital technology. These organisations envisage a future in which individuals measure health indicators with inexpensive diagnostic devices, input data through a smartphone or similar device, and access algorithms that help them manage their health, or select an expert to consult in person or online. Many commonly used drugs will be supplied through an e-prescription. Individuals will have electronic records that keep them informed and ensure

smooth communication between different medical specialists. Data from these records will facilitate the development of individually tailored treatments.

Others warn that there is a long history of technological innovations being promoted as 'silver bullet' solutions to intractable problems, but whose impact falls short of the rosy predictions. Technological innovations often fail to deliver for a number of reasons that include challenges in adapting them to different contexts, varying levels of social acceptance, and the influence of powerful stakeholders on how new technologies are translated into goods and services. A number of analysts emphasise potentially negative consequences of the spread of digital health. They fear that people who do not have internet access or cannot afford to pay for a private service may be excluded. Availability of digital health solutions could reduce the pressure on governments or insurance companies to ensure the availability of 'traditional' health-care options. Companies could use digital health services to promote a costly style of care that relies heavily on diagnostic devices and drug treatments. There are concerns about the privacy of patients and the possible use of data as a commercial asset or an instrument of political control.

These utopian and dystopian visions present different possible futures for the health sector. Both envision a transformation of many aspects of the way it is organised. The existence of these competing visions highlights the degree to which actions by governments and other stakeholders at national and international levels can influence the organisation and delivery of health services and their ability to meet the needs of an entire population, including poor and socially excluded people.

Genesis of this report

This report presents the outcome of a series of consultations organised by the Mutual Learning for Mixed Health Systems platform led by the Public Health Foundation of India (PHFI), the Institute of Development Studies (IDS) and Amref Health Africa. The aim was to get a clear picture of the contribution (if any) that the private sector has been making to the achievement of national efforts to increase access to equitable and effective health services and to identify promising innovations for governing a mixed health system. It involved more than 300 senior government officials, leaders of private companies, technology innovators and health system analysts working in Asia, Africa and Latin America.

An initial set of meetings in India, Vietnam and Rwanda explored innovative approaches for government engagement with the private sector aimed at accelerating progress towards universal health coverage. These meetings highlighted a growing interest in the potential role of digital innovation. PHFI and IDS then led additional consultations focusing on digital health: online meetings on lessons from the response to the Covid-19 crisis; panel discussions focusing on India's rapid development of digital health; and a high-level panel discussion with leaders in digital innovation and health system strengthening as part of a satellite session at an international conference in Bogotá in late 2022. These discussions identified the following issues:

- Most participating countries had mixed health systems in which private providers contributed to the response to the Covid-19 pandemic, but many lacked effective governance arrangements to ensure the provision of services that are accessible to all population groups.
- There was a recognition of the rapidity of development of digital health and that it was time to move past proof-of-concept projects towards the incorporation of innovations into strategies for health system

strengthening at scale, involving new types of collaboration between the public sector and companies with expertise in digital health.

- It became apparent that there is a big difference in the understanding and perspectives of stakeholders: technology innovators had little knowledge of the organisation and governance arrangements in health systems and health policymakers knew little about the digital health industry and the factors that influence the emergence and rapid introduction of innovations.
- There was little evidence of the involvement of citizen groups in discussions about digital transformation of health systems.

Many of the people consulted were based in countries with mixed health systems that struggled to provide universal access to safe, effective and affordable health services. There was a hope that digital technologies could contribute to an acceleration of progress towards this goal, by enabling people to monitor many health-related indicators and obtain expert advice on how to manage their problems – despite shortages of well-trained personnel, weaknesses in quality assurance, and resource-constrained public services. However, the people consulted were unsure about how to manage this process of change.

'There is a recognition of the rapidity of development of digital health and that it is time to move past proof-of-concept projects towards the incorporation of innovations into strategies for health system strengthening at scale.'

From visions of transformation to the management of change

Despite the many predictions of a digital transformation of the health sector, progress towards this goal has been slow. More than ten years ago, Christensen, Grossman and Hwang published an influential book that described how digital technologies have disrupted several economic sectors and predicted that they would have a similar impact on health (Christensen, Grossman and Hwang 2009). The authors argued that an important aspect of this kind of transformation is the establishment of what they called a 'value framework' that can ensure that social objectives are met, while also enabling companies to generate revenue. In most countries, the creation of an institutional framework to incorporate digital innovations into the health system is at an early stage. This is largely due to some distinct features of the health sector:

- Health care involves a mix of services including the measurement of health-related indicators, access to expert advice, easy availability of drug treatment; the capacity to provide these services at an affordable cost requires a number of technological and organisational innovations.
- The performance of the health sector is influenced by regulations that ensure that health services are safe and effective, and there have been many challenges in adapting them to the new circumstances.
- Health has high political visibility and governments tend to give higher priority to short-term risks and benefits than to the longer-term implications of their decisions.
- The development of new kinds of relationships between public health services and digital health companies has been affected by the limited experience of many governments in the governance of a mixed health system.

Until recently, the impact of digital health innovations has been modest, leading health policymakers to pay little attention to them. The failure of many proof-of-concept projects to result in major changes to health system performance has contributed to a sense of disillusionment. Several factors have increased the likelihood of incorporating digital health innovations at scale. First is the rapidly growing proportion of the population who own a smartphone or similar device and can access the internet at an affordable cost. Many people, especially the young, already seek health advice online. Second are technological innovations that make it easy to measure health indicators such as blood sugar, oxygen saturation and so forth. Thirdly, many countries have a thriving information technology start-up sector that is actively developing digital health services.

The response to the Covid-19 pandemic illustrated the capacity in many countries for digital health innovation. In the context of a health emergency, many governments removed regulatory constraints to digital health (temporarily or permanently) to enable the rapid establishment of digitally enabled health services and the creation of new kinds of partnership between the public and private sectors. India, Indonesia, the Philippines, and Rwanda, for example, experienced big increases in the coverage of telemedicine. It is now important that governments and other stakeholders strengthen their capacity to influence the development and performance of digital health services to ensure they fulfil their promise, while guarding against possible problems.

This document focuses on LMICs – a broad category that covers greatly differing economies with a variety of institutional arrangements. Historically, one factor that has tended to unite them was that they were mostly importers of cutting-edge technologies and their governments had a limited ability to influence the arrangements to regulate

these technologies. These distinctions are becoming blurred as an increasing number of countries have built a capacity for innovation and potential leadership in digital health. The challenges that countries in different positions in global value chains face are different. This will affect how they navigate the changes brought by digital health technologies. This report does not provide a blueprint for countries to follow. Rather, it presents a framework that national stakeholders can use as a basis for developing an appropriate strategy for managing digital health transformation.

'In most countries, the creation of an institutional framework to incorporate digital innovations into the health system is at an early stage... but the response to the Covid-19 pandemic illustrated the capacity in many countries for digital health innovation.'

Building a common understanding

The World Health Organization (WHO) *Global Strategy on Digital Health 2020–2025* recommends that digital technologies be viewed as 'an essential component and an enabler of sustainable health systems and universal health coverage' (WHO 2021: 15). It calls on countries to formulate and implement digital health strategies and establish

'Digital health transformation will entail changes to the roles and responsibilities of a variety of stakeholders. None has a full picture of the emerging digital health system.'

mechanisms to involve a wide range of stakeholders in decision-making. This report aims to help countries to achieve this objective. It focuses on the need to situate a digital health strategy in the context of governing a mixed health system and engaging with a large and rapidly changing information technology sector. It also emphasises the need to involve citizens in decision-making to ensure accountability and maintain trust in a context of rapid change. Its focus is on next steps in incorporating digital innovations into national strategies for health system strengthening and reform, while recognising the longer-term impact of decisions and the global dimension of digital health governance.

The discussion that follows takes as its starting point the broadly agreed health sector goal of providing equitable access to safe, effective and affordable services that people can trust. Digital health transformation will entail changes to the roles and responsibilities of a

variety of stakeholders. None has a full picture of the emerging digital health system. Health system managers have little understanding of the technology sector; technology innovators have little understanding of the structure and the institutional arrangements in the health sector; and citizens have only a limited understanding of both sectors.

The following sections have been structured to contribute to a common understanding between these stakeholders and to outline concrete ways forward. Section 2 introduces the digital health sector. The following three sections outline issues to be addressed in managing the process of change from the perspectives of the health sector, the technology innovation ecosystem and citizens, respectively. The report concludes with a discussion of the need for a learning approach to institutional change and a presentation of next steps that countries can take in managing digital health transformation.

2 The digital health sector

This section introduces the rapidly changing digital health sector. There is a limited amount of information in the public domain about its structure and the strategies of its key players. This means that it is impossible to predict how the industry will look even a few years from now. The following paragraphs describe the kinds of actors involved and outline some factors that may influence its direction of development.

There is no simple way to draw a boundary around the digital health sector, because it involves a variety of technologies relevant to health care. WHO classifies interventions on the basis of target user groups (WHO 2018),[5] while market analysts tend to categorise digital health in technological terms (Grand View Research 2022; Global Market Insights 2023).[6] In this report we focus on the technologies that are used increasingly in primary health care and that are relevant for LMICs.

The digital health industry is constituted of companies that develop and provide digital products and services. These companies span a spectrum from very large digital platforms to start-ups that supply specific solutions to health-care providers and other clients. They provide services that involve all aspects of the health system including delivery of health care, disease surveillance, logistics and system management, and direct support to people in managing their health (Oparin, Panibratov and Ermolaeva 2021). They work with a variety of clients and operate within a complex regulatory framework.

The global digital health market

The global digital health market has grown significantly and is projected to continue to grow. It was estimated to be worth more than US$210 billion in 2022 and is projected to increase at an annual rate of between 16 per cent and 28 per cent, reaching between US$780 billion and US$1.5 trillion by 2030 (Grand View Research 2022; Global Market Insights 2023). Currently the largest market is North America, but the fastest growing market between 2022 and 2030 is expected to be Asia (*ibid.*).

In 2021, the telemedicine segment of the global digital health market was estimated to be the largest with a market revenue

share of more than one-third. Digital health services (e.g. pre-installation and post-installation services covering project planning, staffing, implementation, training, and resource allocation and optimisation), compared to the provision of software and hardware technologies, dominates the market and accounts for nearly half the market revenue share (*ibid*.). However, the software segment is anticipated to grow rapidly owing to the fast adoption of software systems by patients, health-care facilities, providers, and insurance payers (*ibid*.).

The market players include large health technology and information technology companies, which offer numerous subscription plans, digital health platforms, and enhancing data security features. US companies currently account for a substantial share of the market, but Chinese and Indian companies are growing rapidly.

Health technology companies include many start-ups that pioneer new technologies and services. There is increasing evidence of the entry of local entrepreneurs to health markets in LMICs, often in partnership with larger international companies, international development agencies, and governments. Health-care technology start-ups in India, for example, raised a total of US$504 million between 2014 and 2018 –strengthened by government investment in digital infrastructure with the aim of enabling digital interoperability (Bode *et al*. 2021).[7]

Other market participants include internet and mobile phone operators who hope to play the role of holistic information and communications technology (ICT) and digital service partners for governments, health providers and health tech companies.[8] Leading pharmaceutical companies are exploring how digital transformation of health care can provide new ways to develop and distribute drugs.[9] Digital health also includes non-profit organisations and non-governmental organisations (NGOs) that pilot new services, support social enterprises and target specific groups of clients.

'The global digital health market has grown significantly and is projected to continue to grow… the fastest growing market between 2022 and 2030 is expected to be Asia.'

Changing power relations

The rise of digital health has led to the entry of new market players into the health sector. This is leading to concerns about how this could change power relations in the health sector (Ozalp *et al*. 2022; Ebeling 2021). There is a lot of speculation about the potential impact on efforts to ensure equitable access to effective and affordable health care.

One issue raised by several analysts is the potential role of large digital platforms. Successful platforms achieve rapid growth through the so-called 'network effect' which makes it difficult for the users to leave the platform, while using algorithm-driven data analysis to improve and expand their offering (OECD 2019). In the case of digital health this would mean a continuing refinement of treatment algorithms based on the analysis of data on treatment outcomes. These platforms could become powerful players in health care if current governance arrangements remain unchanged.

There are big debates about how these arrangements should be reformed (Ozalp *et al*. 2022). On the one hand, digital health companies need to accept that they are entering a highly regulated sector. On the other hand, too many

restrictions could slow innovation and make it difficult for companies to survive economically. One area of intense debate concerns the access, use and control of sensitive health data by commercial actors. Digital health companies need access to health data to develop new health products and services (Li, Nirei and Yamana 2019). Although these products and services could improve health care, legitimate questions remain regarding data protection and security. It has been estimated that approximately 30 per cent of the world's data volume is generated by the health-care industry and this is expected to grow (Thomason 2021). Harnessing these data could be of huge commercial value. The regulatory arrangements put in place regarding access and use of these data will strongly influence both the immediate wellbeing of patients and the longer-term direction of development of the health sector. This is leading to a call for investment in the development of health-related digital public goods (United Nations 2020).

Another issue is that large tech companies use their market power and financial means to make acquisitions to build a more integrated suite of services and to enter new markets (CB Insights 2021),[10] but also to buy up potential competitors (Prado and Bauer 2022; Song and Pan 2021).[11] Analysts have pointed out that this has the potential to diminish competition and reduce the quality of innovations (Schechter 2018; McLeod 2020). Regulators face difficult issues in ascertaining the degree of concentration of ownership of digital health companies that is desirable.

Several analysts emphasise the degree to which large technology companies invest effort and resources on engagement with external stakeholders with the aim of influencing the rules that shape the market (Jaworski, Kohli and Sahay 2000). The development of a valuable technology is not enough for a company to grow (Nenonen, Storbacka and Windahl 2019). Successful technology companies actively seek strategic partnerships and spend a lot of money to influence or engage with regulators, policymakers, and clients (Kaartemo and Nyström 2021). There is nothing new about this, but big technology companies have a great deal of resources and capabilities to co-create or shape institutional arrangements that govern the market. This raises concerns about unequal power between these companies and governments of LMICs and highlights the need for measures to build the capacity of these governments and for international agreements on rules of engagement. Policy briefings to the G20 have drawn attention to this matter and the 2023 G20 in India is considering the launch of an initiative to address this issue (Bloom *et al*. 2019).

'It has been estimated that approximately 30 per cent of the world's data volume is generated by the health-care industry and this is expected to grow. Harnessing these data could be of huge commercial value.'

Digital health as an ecosystem

The market is increasingly perceived to be made up of networks or ecosystems in which multiple stakeholders are active. Building a viable digital health ecosystem is considered more and more relevant to implementing digital health solutions and determining how the market will be shaped. Such a viable ecosystem would be one to which each stakeholder contributes by strengthening network effects, integrating and applying their own resources and capabilities to enrich digital health services. That is why this report emphasises the importance of viewing digital health through a systems lens. The current digital health ecosystem is fragmented and often built around specific and contextualised technical solutions that have been created and adapted over time through different processes and approaches (Hermes *et al*. 2020). A recent report by McKinsey emphasises the leadership roles that government and the private sector need to play in building a coherent digital health ecosystem (Bode *et al*. 2021). The report of the *Lancet/Financial* Times commission, referred to above, emphasises that the ecosystem should be 'driven by public purpose, not private profit' (Kickbusch *et al*. 2021).

Policymakers need to address a number of questions in managing digital transformation. How can low-income populations in urban and rural areas be reached, engaged with, and empowered by digital health services (Herselman *et al*. 2016). How can the ecosystem approach be used to achieve innovative solutions that are sensitive to local economic, social, cultural, and organisational factors (Khubone, Tlou and Mashamba-Thompson 2020)? How should large digital platforms contribute to these processes and how will they interact with other stakeholders to influence the shape of markets (Neumark and Prince 2021)? Who will be accountable for improving the availability, access, and delivery of digital health-care services? How will countries adapt their institutional arrangements to take these technologies into account? It can take many years to develop trust-based relationships. During this time effective stewardship, strong governance structures and long-term finance will be needed (Frost *et al*. 2018). The following sections present a framework to help stakeholders to begin to address these questions as they build a digital health ecosystem for public purpose.

'Building a viable digital health ecosystem is considered more and more relevant to implementing digital health solutions and determining how the market will be shaped.'

3 The pluralistic health system

The formulation and implementation of a digital health strategy, as advocated by WHO, is not simply a question of incorporating technological innovations into the delivery of medical care. It involves the creation of new kinds of partnership between organisations in the health and information technology sectors and new governance arrangements for health system integration. This section is about the mixed health systems within which this kind of strategy must be embedded.

One characteristic of the health sector is the population's expectation that the government will protect them against major health shocks and ensure that medical care is safe, effective and affordable. The way that governments have tried to meet this expectation has changed over time. During the second half of the twentieth century many LMICs created publicly financed and managed health systems. This approach reflected broader development strategies that relied heavily on state-owned enterprises to lead the construction of a modern economy (Bloom, Standing and Lloyd 2008). As markets have become increasingly important in these countries, pluralistic health systems have emerged in which both governments and markets play important roles (Bloom and Standing 2001; Mackintosh *et al.* 2016). The creation of institutions to govern health system performance has not kept up with these changes and problems have emerged with the cost and quality of services.

A wide variety of non-state actors are active in pluralistic health sectors. They include health service providers, whose size ranges from individual practices through medium-size organisations such as clinics or hospitals, to larger organisations which manage or oversee many facilities. Other entities produce and supply drugs, diagnostic equipment or other health-related services. Many private providers function like businesses, which respond strongly to financial incentives. This can lead to the provision of unnecessarily costly care and/or to a neglect of quality. Others, such as faith-based health facilities or NGOs, may define their mission as meeting social needs. So-called 'social impact' organisations explicitly aim to balance earning profits and achieving social goals (Vimarlund, Nikula and Nøhr 2021). In all these cases, facilities are influenced by both immediate financial pressures and a longer-term effort to build and maintain a good reputation. The institutional arrangements within which they are embedded can influence the balance

between these incentives, and thus their performance in meeting social needs.

In some countries, a large proportion of providers of health-related goods and services work outside the legal framework. In South Asia and Africa, for example, informal drug shops are an important source of advice and drugs, especially for people with lower incomes (Gautham *et al*. 2014; Awor, Miller and Peterson 2014). This reflects the broader reality that a substantial proportion of economic activity in these countries takes place in an informal sector of small businesses and the self-employed. Evidence indicates that easy access to antibiotic treatment of common infections has contributed to reductions in mortality, but studies have also found that informal providers recommend inappropriate treatments (Sudhinaraset *et al*. 2013; Gautham *et al*. 2014; Das *et al*. 2016). One common pattern is that poor and socially excluded groups tend to rely on informal providers. If countries are serious about reducing inequalities in access to care and accelerating progress towards universal health coverage, they need to find ways to improve the performance of these providers. Digital innovations may contribute by giving them access to treatment guidelines, facilitating referral and making it possible to monitor their performance.

Health systems also include organisations that interact with providers of health services, such as government or insurance schemes that organise social financing; intermediary organisations, such as local government health departments, large NGOs and academic institutions that support and monitor the performance of providers; government regulatory agencies responsible for enforcing adherence to laws and regulations; and civil society organisations such as professional bodies, business associations and citizen groups, which monitor the performance of providers and influence their reputation. They all influence health system performance. The emergence of digital health has led to the involvement

of new types of organisation, such as mobile phone companies, IT platforms, and small start-up companies in the health sector.

Institutional arrangements

Long experience has led to a consensus that unregulated markets for health services do not perform well in meeting a population's needs. Governments play an important role in providing public health services and in financing medical care to provide more equitable access and prevent impoverishment. They are also responsible for ensuring that health services are effective and that people are not exploited when they are sick and most vulnerable. The possibility of this occurring arises from the existence of information asymmetry – the power imbalance between experts and those who rely on their advice. Societies have responded by establishing institutions, such as self-regulating professions and government employment of health workers, to help people identify appropriate practitioners and to discourage exploitative behaviour by these experts (Arrow 2004; Bloom *et al*. 2008; Leonard *et al*. 2013). The rapid spread of digital technologies can have a contradictory impact on information asymmetry (WHO 2021; Bloom *et al*. 2017; Labrique *et al*. 2018; Ilin *et al*. 2022). On the one hand, it can empower people by providing direct access to information and advice. On the other hand, it can erode trust in health experts and expose people to exploitation online. This illustrates the need for new governance arrangements.

Over the years it has become clear that top-down regulatory arrangements have a limited capacity to influence the performance of a pluralistic health system, in which providers of health services are influenced by a combination of government regulations and individual

incentives. This has stimulated a search for alternatives to top-down enforcement of rules. In so-called 'decentred' or 'smart' regulation, governments, the private sector and the general public need to play active roles in governing the health sector to ensure that it addresses social priorities (Sheikh, Saligram and Prasad 2013; Bloom, Henson and Peters 2014; Gunningham and Grabosky 1998; Hunter *et al*. 2022). Strategies for influencing performance tend to combine administrative controls, market-oriented actions and measures to empower clients and citizens:

- The first involves the enactment and enforcement of regulations concerning the safety and effectiveness of health workers, facilities and health-related products, such as drugs and diagnostic devices.
- The second comprises actions by individuals or associations to establish and maintain a reputation for good quality. This could be a purely private arrangement such as a hospital chain or a franchising arrangement. Or, it could take the form of self-regulation through organised professions or business associations. These arrangements can provide protection against incompetent and exploitative behaviour, but also powerful stakeholders can use them to shape markets in their own interest.
- The third concerns initiatives that empower users of health services to make informed decisions by providing information on performance and educating consumers on how to use this information.

The government can also influence performance through its role as a purchaser of health services (including digital services) directly, or through a compulsory insurance scheme. The contracts it signs and the mechanisms for monitoring performance can provide strong signals to the providers of services. The effectiveness of these signals depends on the technical skills of the contract manager.

Effective governance requires a combination of approaches involving cooperation between government and other stakeholders to influence health system performance. One example is the use of community score cards that involve local stakeholder groups in assessing the performance of health facilities.[12] In a number of countries the drug regulatory agency works closely with pharmaceutical companies to establish standards and identify breaches of these standards. The same often applies to professional regulatory agencies. These forms of 'smart regulation' enable the creation of partnerships to establish and enforce standards of health system performance. It is important to establish mechanisms for consultation and decision-making that take the interests of the population, including poor and vulnerable people, into account, in order to counteract a tendency by the powerful to act in their own interest.

'In so-called "decentred" or "smart" regulation, governments, the private sector and the general public need to play active roles in governing the health sector to ensure that it addresses social priorities.'

Strengthening institutions for health system governance and digital health

In 2020, WHO published a report that called for strengthening governance of what it described as 'mixed' health systems (WHO 2020). It identified six behaviours critical to the governance of private sector health services:

- **Build understanding** – collect and analyse data to align priorities for action.
- **Foster relations** – work together to achieve shared objectives in a new way of doing business.
- **Enable stakeholders** – establish an institutional framework that empowers actors.
- **Align structures** – establish organisational structures to align with policy objectives.
- **Nurture trust** – build mutual trust among all actors as reliable participants.
- **Deliver strategy** – agree a sense of direction and articulation of roles and responsibilities.

This section outlines a strategy for strengthening governance of digital health that draws on these behaviours.

- **The first step is to build a shared understanding by documenting the key elements of the health sector to provide a basis for plans and strategies.** This should include documenting the roles of different types of health provider in meeting the needs of different categories of user of services, important aspects of the relationships between these providers, governance arrangements and perceived problems that digital innovations are intended to address.
- **The second step is to build a consensus between stakeholders on core objectives of digital innovations.**

This is especially important in the health sector, in which the expectation that service providers will behave in an ethical manner underpins the trust that people have in them. Any strategy for change will need to maintain this trust.

- **It is then important to reach agreement on short-term plans for incorporating digital innovations into the health system, at scale.** This could involve specific interventions to address gaps in the health sector, the creation of new types of service delivery partnership and/ or strengthening the governance arrangements. As part of this, it is important to identify the concerns of different stakeholders about possible undesirable outcomes; reach agreement on the roles and responsibilities of each stakeholder in implementing the agreed change; and put in place measures to ensure that all participants have the capacity to undertake their agreed role (Tsevelvaanchig *et al*. 2018). Finally, it is important to establish mechanisms to involve all stakeholders in monitoring the implementation of the agreed plans.

One challenge that government health services face is the need for new kinds of contract with the suppliers of services. Government procurement procedures rely on a clear specification of a service and well-defined procedures for assessing value for money. It is difficult to apply this approach in the context of a rapidly evolving technology. Governments will need to build a capacity for ongoing engagement with digital health service providers to leave open the possibility for innovation and change, while ensuring accountability for the use of public resources. This is likely to include a requirement that reports by service providers include appropriate analyses of the data they are collecting.

Another challenge is the need to remove regulatory constraints to digital health innovation. Annexe contains a report by HealthX, a Kenyan digital health innovator. It describes how the Kenya Medical Practitioner and Dentists Council

responded to the Covid-19 pandemic by developing a virtual medical services licence that enabled registered and licenced health facilities to offer virtual medical services. The number of registered providers increased rapidly and by late 2022 it had reached 50. This was an emergency response, whose main aim was to remove constraints to the provision of telemedicine. It represents a first stage in the adaptation of the regulatory system to digital health.

'One challenge that government health services face is the need for new kinds of contract with the suppliers of services... another is the need to remove regulatory constraints to digital health innovation.'

Managing system change and transformation

The immediate focus of a digital health strategy needs to be on relatively short-term measures to address gaps in existing health services. However, it is important to recognise the dynamic nature of the digital health sector.

In response to the Covid-19 pandemic, several countries substantially expanded the provision of telemedicine. One review of the spread of telemedicine in the advanced market economies has concluded that the technology and the organisational arrangements for incorporating it into primary health care is too immature to have had a big impact on the performance of the system (Jimenez *et al.* 2021). In order to have a greater impact, digital health will need to involve more use of point-of-care diagnostics, algorithms to tailor care to individual needs and electronic records to facilitate referral arrangements, among other things.

It is hard to predict the direction and speed of change in the sector as digital health technologies mature. How will technologies and the way they are bundled evolve? How will the organisational arrangements in the sector evolve and what kinds of companies will emerge? As digital health is used more widely, what kinds of regulation will the governments of advanced market economies put in place and how will this influence the direction of change of global markets? One important issue will be the likely impact of digital transformation on the capacity of countries to adapt their health sector to local needs and maintain an independent capacity to provide services (van Stam 2022).

Some analysts argue that the relative shallowness of the institutional arrangements in many LMICs will reduce the resistance to a rapid digital transformation of the health system once a tipping point is reached. This raises the possibility that some countries will be able to focus their efforts on establishing institutional arrangements more aligned with the new technologies (Mitchell and Kan 2019). This was the conclusion of a member of a panel of Indian experts on health system governance, who emphasised the absence of international best practice models for regulating digital health and suggested that India had the potential to be a leader. In the preparation of this report, we invited Ikigai Law, an Indian firm that specialises in technology and innovation, to provide some early learning about the process of regulatory reform (see Annexe). They identified the following priority areas for future regulatory action:

- **Ethical management** of health data to support research and innovation, while protecting the rights of patients.
- **Evaluation** of the safety and efficacy of emerging technologies such as artificial intelligence.
- **Quality control** of health-care professions and products supplied in the digital space. Countries need to monitor for problems that may emerge and begin to build a capacity to address them (Ziebland, Hyde and Powell 2021).

The implementation of change and the shaping of the digital health market will be influenced by the relative power of different stakeholders, but also by the need to secure widespread belief in the legitimacy of the rules and a willingness to adhere to them. Market-shaping is a political process with a wide range of possible outcomes (Fligstein 2002). Successful management of the incorporation of digital health will require the creation of a coalition that includes representatives of populations that are relatively weak and socially excluded, and the health services that address their needs. These stakeholders will, themselves, need to build their capacity to play effective roles as part of a decentred approach to health system governance. In the absence of this kind of competent leadership, there is a risk that the future development of the health sector will be largely influenced by the interests of powerful groups.

The management of change can be viewed as a process whereby institutions are established through trial and error. We can anticipate a period of continuing and accelerating change in many LMICs and it will become increasingly important for governments to build a capacity to manage adaptation to change. The direction that health system transformations take will be strongly influenced by the capacity of governments and of citizen groups to respond to social needs.

'Some analysts argue that the relative shallowness of the institutional arrangements in many LMICs will reduce the resistance to a rapid digital transformation of the health system once a tipping point is reached.'

4 Digital health innovation system

Digital health transformation involves innovations in both hardware and software. Many of these innovations are being developed by information technology companies. Governments face big challenges in finding ways to engage with these companies to increase access to equitable, effective and affordable health services, while overseeing a longer-term process of change. In this section we introduce the idea of a digital health innovation system to provide a framework for guiding this engagement. The innovation system perspective focuses on how governance arrangements can influence the kinds of innovation that emerge and the overall direction of health system development.

Digital health is a global industry, and developments in one country can have global significance. The governments of countries where major digital health companies are based have begun to negotiate the new rules to shape their own health systems. The decisions they make will strongly influence the direction of development of the global digital health sector. Governments of most middle- and low-income countries, which are adopters of the major digital health innovations, face the challenge of creating incentives and capabilities to adopt available innovations rapidly and effectively, while creating opportunities for domestic companies to enter the system and develop locally adapted products and services. They can also build the capacity to influence initiatives to establish regional or global norms and standards.

The innovation system perspective

The innovation system framework provides a tool for understanding and exploring ways to steer the development of a digitally enabled health sector. The emergence and implementation of digital health solutions is not happening randomly. The kind of innovations that emerge and are taken to scale is influenced by the incentives that innovators face. Innovation processes can be shaped, adapted and managed. It is possible to put in place a combination of financial incentives and governance arrangements to encourage the types of innovation consistent with development objectives, such as the provision of equitable access to health services. But this requires an understanding of the structure of the system and the functions it performs (Bergek *et al*. 2008).

- Its **structure** includes existing and emergent organisations, the way that markets operate, the institutions that influence the behaviour of organisations and the available knowledge.

- Its **functions** include knowledge development, resource mobilisation, market shaping, and capacity to influence the direction of change through policies, legitimisation, entrepreneurial experimentation and development of external economies.

Both elements are relevant for understanding the processes of adoption and innovation of digital technologies and of designing appropriate interventions.

It is useful to map the main structural components of a system. The innovators are very often firms, but public sector institutions can also play an important role. The leading firms can be categorised in terms of whether they are national or international, they are large or medium-size and their sector of origin. Questions concerning the structure of the relevant markets include: Are the main users of digital health services individuals, governments, NGOs or other firms? Are the users changing with the new technologies? What challenges do users face in managing contracts with providers of digital services? Which institutions, formal and informal, are promoting or blocking particular types of innovation? Weak institutions, lack of relevant knowledge and capabilities and failures in interactions, due to market concentration, can all affect adoption and innovation processes (Klein Woolthuis, Lankhuizen and Gilsing 2005).

It is also important to understand which functions are working well, which are not, and what measures can be taken to facilitate change. For instance, low levels of trust among potential customers can block market formation; lack of financial opportunities can block resource mobilisation and research and development (R&D); lack of entrepreneurial capabilities within organisations can block experimentation (Bergek *et al*. 2008). The inter-relationship between functions matters. For instance, the presence of entrepreneurial management without the necessary organisational elements in place can lead to innovation capabilities that are utopian, fragmented, and short-lived. On the other hand, the introduction of organisational routines to support innovation, without entrepreneurial roles, could quickly lead to non-dynamic and inflexible arrangements (Greenhalgh *et al*. 2017).

Knowledge development, entrepreneurial experimentation, and market formation need to be seen together to understand the factors influencing the emergence of an innovation that can have impact at scale. Mobilisation of investment finance is a crucial factor, particularly for adoption at scale. It is important to understand how key actors in different parts of the system (e.g. service providers, regulators and technology companies) make alliances, connect to each other, or remain disconnected and fragmented regarding issues such as investments, authorisations and provision of funds (Musiolik, Markard and Hekkert 2012). Through their market and non-market interactions they create policies, norms, standards, support programmes and views about the potential of the new technologies that are shaping innovation and their impact (Bergek *et al*. 2008). One especially challenging issue is the important role of finance by government, insurance schemes and philanthropies to ensure that services are affordable to the poor and socially excluded. The business model of providers of services to this population group and the contracting practices of funders or purchasers of services need to adapt to this reality (Cassiolato and Dias Soares 2015).

Legitimation is a key function, especially when analysing innovations based on new knowledge and new technologies and whose likely impacts are not well understood. This is especially important in the health sector, where it is essential to maintain the trust of users and providers of services. In such circumstances, social acceptance and compliance with relevant regulations and institutions becomes central. Without sufficient legitimacy, the new technology and its proponents will struggle to be considered appropriate and desirable by relevant actors, affecting their ability to mobilise resources, build a market and secure political support (Bergek *et al*. 2008). It takes time and effort to build legitimacy for a technological innovation.

Analysts of innovation in LMICs have added another function that is relevant when innovation and transformation processes begin with the importation of technologies and innovations. These countries need to monitor existing technologies and build specific types of technological and complementary capability to enable local actors to access, understand and handle the best imported technologies and eventually adapt and improve them to fit the local context. The systems in these countries need to take on this function, while at the same time creating incentives for domestic firms to learn and take advantage of the opportunities to create locally adapted products and businesses (Labrique *et al.* 2018).

In many LMICs, health providers face challenges with the lack (or limited coverage) of a reliable data and communication infrastructure, lack of interoperability between different devices in different departments and organisations, limited ICT resources (including for training staff), shortages of people with basic ICT knowledge and skills, maintenance problems due to a lack of sustainable funding, and issues with governance systems related to confidentiality, regulations and trust (Haque *et al.* 2019; Mugo and Nzuki 2014; Kiberu, Mars and Scott 2017; Gudi *et al.* 2021).

'Without sufficient legitimacy, the new technology and its proponents will struggle to be considered appropriate and desirable by relevant actors, affecting their ability to mobilise resources, build a market and secure political support.'

Managing transformation processes

Digital technologies do not just affect specific services and isolated components of a health system. Over time, they are likely to transform many aspects of the system's operation. Experience from the transformation of other sectors has shown that decisions made early in a transformation process can influence the future direction of change (Côté-Boileau *et al.* 2019). Public policy cannot leave this kind of transition to market forces alone. The kind of system that emerges and the degree to which it addresses social goals, such as equitable access to health care, will depend on early actions by government and other stakeholders (Schot and Steinmueller 2018). Government must play a central role in shaping the direction of system change. Analyses of system transformation focus particularly on issues of vision creation, power, value systems and forces resisting structural change.

The management of a change from a situation that is well understood to one that is largely unknown is very challenging (Köhler 2019). There is often a tension between forces and actors that push for stability and those that push for change. The interaction between these two tendencies and the way it is managed can influence system-level transformation (Fuenfschilling and Truffer 2014). One factor that influences the direction of change is the interaction between stakeholders with different interests and different relative power (Kivimaa and Kern 2016). It is important to understand the underlying politics and decision-making processes that can influence the governance of the innovation system and ensure that people at risk of being excluded from health services, because of income, ethnicity, geographical location and so forth, are included in decisions about innovation priorities. It is also important to include the providers of services most used by these groups.

Market structures can influence the direction and speed of digital transformation. One potential challenge could be the emergence of a small number of large companies with excessive power to shape the characteristics of the digital health innovation system in their favour. This kind of concentration could spur digital health transformation, but it could also reduce the capacity for future innovation. Experiences from other sectors can throw light on how this might happen and on measures to avoid it (Marin, Stubrin and van Zwanenberg 2023). A second potential problem could arise if companies that provide treatment advice have a financial incentive to promote a style of care that favours high levels of use of diagnostic tests and expensive pharmaceuticals. There may be a case for regulation to avoid ownership structures that internalise this kind of conflict of interest within companies.

The management of system-level changes can be conceived as involving four types of activity (Loorbach 2010):

- Strategic activities take place in a 'transition arena', where multiple stakeholders from civil society, business, public health, policy, and science identify potential transition pathways and **define shared visions**.
- Tactical activities are concrete strategies for agenda-building and supporting coalitions that involve commitments to invest and collaborate.
- Operational activities involve the translation of ideas into actions such as innovation experiments, demonstration projects, or implementation activities, combined with learning-by-doing.
- **Reflexive activities** are needed for further learning that should lead to new or adjusted visions.

Decisions about whom to include or exclude from the above activities will influence pathways and outcomes. There are many challenges in engaging with key stakeholders – for instance, to align a common ground for long-term visions with concrete short-term operational activities that need funding.

> **'There is often a tension between forces and actors that push for stability and those that push for change. The interaction between these two tendencies and the way it is managed can influence the system-level process of transformation.'**

Steps towards the formulation and implementation of a strategy for digital health innovation and transformation

This section outlines some initial steps in the incorporation of an innovation system approach into a strategy for digital health transformation.

- **Understand the emerging system(s)**
  The building blocks of the existing infrastructure, networks, institutions and actors in the system have to be mapped and analysed. They can then be examined in relation to existing challenges. For instance, are different building blocks blocking or stimulating participation and equal access, and is the existing infrastructure accessible and affordable for all?

- **Build consensus on the direction of change**
It is important to reach agreement between stakeholders on the objectives of digital transformation. It is also important to identify concerns that people have about potential undesirable impacts of digital health and the measures that can be taken to address these concerns.

- **Identify constraints to adoption and diffusion**
Major influences on adoption are capability building, legitimacy and the possibility of viable business models. Specialised capabilities are needed to identify appropriate innovations from abroad. Governments and technical agencies need to build these capabilities. The new technologies also need to be accepted by different types of users. It is important to ensure that digital health innovations take account of the values of inclusion, security, and adherence to regulations and standards.

  Establish an agreement to ensure interoperability between different initiatives to reduce duplication and enable the building of system capacity over time. Any agreement on this issue will need to be complemented by rules to preserve patient confidentiality and define appropriate uses of the data collected.

  When addressing issues of diffusion other functional aspects of the digital health innovation system need attention to ensure they are implemented (Greenhalgh *et al*. 2004). These include support for the functioning of new markets and their regulation to avoid market concentration and/or forms of ownership that could encourage costly kinds of medical care.

- **Incentivise business to invest in innovations for equity in health**
The rapid incorporation of digital innovations is likely to involve new

kinds of partnership between public and private organisations. Innovators need to build a network with market and non-market actors and aim for continuous improvement through frequent monitoring and feedback from the groups of stakeholders in health care.

- **Carefully consider power relations**
Measures are needed to prevent powerful stakeholders from influencing the direction of development in their own interest at the expense of the public good. A lack of consideration of power relations and conflicting interests within the health innovation system can lead to the failure to understand systematic and unfair differences in health outcomes.

  Studies of scaling up have pointed to practical issues that need to be addressed in order to provide access to social groups who have tended to be excluded from health services. There is a consensus that services provided on a commercial basis are unlikely to meet the needs of these people and that funds from government and/or philanthropies will be needed to ensure that the services are affordable.

  Organisations providing digital health services to this population will need to create a business model that takes into account this form of financing. This will require new kinds of partnership and new arrangements for funding or purchasing these services.

- **Create institutions with the capacity to inform the management of these changes**
This could be a department in an appropriate government ministry. It could be supplemented by a thinktank or university department that can keep in touch with international developments. These institutions need to understand the demand and supply sides very well. Who within the system is interested and has the capability and resources

to search for, fund and support innovative digital solutions? Which research institutions and firms can deliver innovative solutions? They also need to help make connections between the two sides, by facilitating multi-stakeholder meetings and experimentations, for example.

The identification of emerging niches with the potential to lead development in different directions is crucial (van Winkle *et al*. 2019). Support for this kind of development requires building an alliance to push the innovations developed in these niches, and to deal with power imbalances between innovators and the actors with power in the incumbent system that resist changes.

'A lack of consideration of power relations and conflicting interests within the health innovation system can lead to the failure to understand systematic and unfair differences in health outcomes.'

5 Citizen engagement for health equity

In this section we use the concepts of citizen engagement, accountability and health equity to explore some of the potential challenges and unintended consequences of digitalisation, and how powerful actors might be held to account by the populations they are meant to serve. In mixed health systems the question of who in the health sector is accountable for what and to whom can be difficult to disentangle. We focus on accountability mechanisms and structures that are already in place and that can be strengthened and adapted to the new challenges of digital transformation with the aim of mitigating health inequities. To address differences in health outcomes that are avoidable and unjust within digitalisation processes requires taking accountability seriously.

As the use of digital technologies in the health sector grows, we argue that meaningful forms of accountability will require investment in building digital citizenship capabilities. It will also require creating adaptive and inclusive governance mechanisms that can act as a check on potentially undesirable outcomes. Accountability for equity in digital health requires creating space for the needs and perspectives of vulnerable and marginalised groups in design, implementation, and evaluation processes. It demands a value framework that centres on the pursuit of equitable health outcomes for all, rather than on the improvement of health services for the few.

'Accountability for health equity in digital health requires creating space for the needs and perspectives of vulnerable and marginalised groups in design, implementation, and evaluation processes.'

Social accountability

To understand the current landscape of health system accountability practices, it is helpful to take stock of the situation prior to the Covid-19 pandemic. In 2018, in light of the 40th anniversary of the Alma Ata 'Health for All' declaration, governments and international health agencies expressed serious concern about the lack of progress towards achieving universal health coverage by 2030 (Rumbold *et al.* 2017). Equally, there were substantial critiques of the quality

and safety of government-provided health services for those populations unable to pay out of pocket (Stenberg *et al.* 2019). In parallel, the expansion of private medical care in LMIC settings was accompanied by increased demands for strengthened accountability mechanisms such as patient score cards, new legal channels for answerability and redress, media-led investigations, government intervention and forced market exits for those health service actors unable to deliver on commitments (WHO 2020). Social accountability efforts – meaning grass-roots and community-led initiatives to hold health actors to account – had in some cases led to joined-up transnational initiatives pushing for health system reforms (Brinkerhoff and Wetterberg 2016; Edward *et al.* 2015; Flores 2018). New terms such as the 'commercial determinants of health' captured the growing awareness of how social, economic, political, and environmental factors combined with the power of the private sector could negatively impact on health outcomes in the absence of effective governance and transparency (Kickbusch, Allen and Franz 2016).

From an accountability standpoint, digitalisation is a double-edged sword. On the one hand, it promises lower costs, increased system efficiencies, expanded access to services, improvements to health management information systems (HMIS), improved public health surveillance and an increased capacity to make strategic decisions in real time (Aerts and Bogdan-Martin 2021). Where there have been substantial barriers to accessing supportive and skilled health workers as a 'first point of contact', digitalisation can enable direct access to expert advice and continuous management of chronic health problems (Faujdar *et al.* 2020). On the other hand, it raises serious questions about the effects on quality of care, privacy of health data, potential abuses of health data and a deepening 'digital divide' that could negatively impact access to health information, services, and care for already marginalised and vulnerable populations (Ziebland, Hyde and Powell 2021).

It may be useful to consider the conclusions reached by the Making All Voices Count research programme (2013–2017) which started from the optimistic premise that new technologies could be applied to long-standing challenges of accountability and governance in the public sector in Africa, South East Asia, and the Middle East. This programme of work identified in multiple case studies that technological innovations did not improve accountability outcomes unless paired with supportive and enabling democratic structures, spaces of open and inclusive deliberation, increased citizen capabilities, and a critical consideration of the ways that new technologies might 'expand the possibilities for surveillance, repression and the manufacturing of consent' (Edwards, Brock and McGee 2018).

These findings chimed with a now established debate in international development. Sceptics of digitalisation of the public sector portrayed 'big data' global actors as a new form of exploitation and extraction of 'data value' (Couldry 2019). Others recognised the potential of these transformations for creating new relationships between citizens and governments premised on the transfer and flow of individual data, as well as the increased availability of data on public sector performance (Hintz, Dencik and Wahl-Jorgensen 2018). Prior to the Covid-19 pandemic, data was already considered the 'new oil' by critics of digitalisation in international development. In the field of global health concern mounted about the increased influence of health technology and telehealth actors on health outcomes in under-resourced settings (Sharon 2018; Tiffin, George and LeFevre 2019). For those examining these processes with a critical eye, it was clear that the digitalisation of health systems and services would be a political and social process, as much as a technical one.

Determinants of health technologies

This was the backdrop against which the Covid-19 pandemic shocked health systems on a global scale, putting accountability for health equity on temporary hold (Nelson *et al.* 2022; Loewenson *et al.* 2020). Governments and private sector actors benefited from the window of opportunity created by the pandemic to innovate, without some of the more cumbersome aspects of regulation and public scrutiny. The rapid increase in the use of digital technologies to achieve public health aims, including disease surveillance and remote/virtual forms of disease management, was not without substantial challenges to trust and accurate health information. The pandemic sparked an 'infodemic' – that is, what WHO described as an 'epidemic of misinformation' fanned by the lack of trust in government and public health actors and by purposeful planting of Covid-19 misinformation on social media (Tangcharoensathien *et al.* 2020). The introduction of Covid-19 'track and trace' apps raised further concerns about the ethics and risks of new types of government surveillance (Lucivero *et al.* 2020).

What then are the key issues at this stage in the recovery and reconfiguration of post-Covid-19 health systems, when the reality of the expanded digitalisation is beginning to sink in? A starting point is to consider which actors or institutions have 'answerability' when it comes to potentially negative health outcomes. One helpful way to frame these questions, borrowing from Kenworthy (2019), is to think about technology itself as an influencing factor in shaping health. As Kenworthy describes it, we can better envision the potential effects of new technologies on health by breaking its effects into three categories of influence:

- Technology as a **social determinant** of health;
- Technology as a **commercial determinant** of health;
- Technology as a **political determinant** of health.

'The digitalisation of health systems and services is a political and social process, as much as a technical one.'

What might these three categories mean in practice?

A social determinant of health refers to the non-medical factors that influence health outcomes. These range from income inequality, food insecurity, structural conflict, working life conditions, education, and the effects of stigma and discrimination as experienced by specific population groups according to gender, race, ethnicity, religion, and/or health conditions (WHO 2010). Health inequities, according to WHO, 'flow from patterns of social stratification – that is, from the systemically unequal distribution of power, prestige and resources among groups in society' (*ibid.*). As health systems become increasingly digitalised, the social dynamics and social realities created by, or mediated by, these new technologies will affect existing patterns of social stratification, directly or indirectly affecting health outcomes. This potential increase in health inequity in the face of the expanded application of new technologies in health systems is often referred to as the 'digital divide'. It focuses on issues of access to, and ability to interact with, new technologies to achieve desired health outcomes (Beaunoyer, Dupéré and Guitton 2020). Focusing on the digital divide alone, however, can create blind spots in terms of our understanding of

the wider influence of technology on social stratification, social dynamics, and subsequent health inequities.

Thinking about technology as a commercial determinant of health calls attention to the fact that technologies developed by the private sector and applied to mixed health systems may reshape health-care markets, influence data use and enable profiteering in ways that will also have material effects on health outcomes and health inequities (particularly if there is no concern given to the needs of vulnerable and marginalised populations). The evidence does not yet exist for the health effects of the tech sector writ large on national-level or global-level health metrics, but as the ability to collect data on individual health status becomes more sophisticated, it will become increasingly feasible to track how specific types of digital interventions or innovations contribute to positive or negative effects on individual and population-level health.

Finally, it bears thinking through the potential effects of technology as a political determinant of health. Innovations in the digital tech sector have the potential to enable new channels of public debate and the creation of feedback loop mechanisms that empower more robust forms of citizen-to-state and patient-to-provider accountability. At the same time, technologies have the capacity to create opportunities for increased government surveillance and control of populations. In light of these effects, we can posit that technology will have a significant influence on the shape of debates over health rights and health entitlements at national and at global level in this period of digital acceleration (Kenworthy 2019; Tagmatarchi Storeng and de Bengy Puyvallée 2021).

Developing accountability approaches based on citizen engagement

It will be enormously challenging to hold powerful tech actors and powerful health actors **jointly** to account for the material effects of these digital transformation processes. However, the work of citizen engagement for health equity does not start from scratch. There are already existing arrangements in a number of countries (Lodenstein *et al.* 2013; Martin Hilber *et al.* 2016; Cornwall 2011), on the back of which new structures and mechanisms to achieve greater accountability can be adapted. Accountability for health equity implies a direction of travel in terms of who is held to account, for what and with what objectives. It calls for identifying the means through which health duty-bearers (private or public) can be held to account when citizen/patient/population health needs are not sufficiently met or when adverse outcomes are generated by digitalisation processes. Citizen engagement in the recent past has included local, regional and national-level health committees that track and influence health service performance, health outcomes and resource allocation (Cornwall 2011). It has included citizen-led score cards which redefine health services quality and health sector performance criteria, then monitor and publicise the results (or lack of results) when demands for change are made (Yilla *et al.* 2014). Accountability for health equity can encompass the role played by the health professions (whether in terms of self-regulating performance or in acting to influence health policy change). It can also include participatory budgeting processes of public health services and other mechanisms through which citizen voice and feedback are channelled upwards to government, potentially shifting government decisions in favour of greater health equity (Allen *et al.* 2016).

Health systems are incredibly complex, which means simply identifying key stakeholders and decision-makers, as well as the levers to shift health inequities, can be a substantial hurdle. The relationships that determine which actors are held to account, for what and to what end are necessarily influenced by political and social dynamics. These dynamics are in constant flux. The challenge will be to adapt these arrangements while prioritising investments targeted at building the capabilities needed to hold health and technology sector actors jointly to account for their impact on health equity.

Given health systems' complexities, there is some comfort to be taken from looking at a longer trajectory of attempts at global and national levels to improve health system performance and address health inequities through strengthening citizen engagement.

In a reflection on the last 20 years of health-focused accountability research and practice, Nelson, Bloom and Shankland wrote that 'accountability processes that target systemic and structural drivers of inequity within health systems have the potential to shape a different future, as do those that involve citizens directly as agents of change' (Nelson, Bloom and Shankland 2018). With the incorporation of new technology actors into mixed health systems, it is not yet clear what new accountability mechanisms will be required so that these new actors are answerable to citizens and health service users. The legal frameworks and governance arrangements of the digitalisation of health systems at national and international levels, as discussed in Section 3, are in the process of development. However, even working out who these actors are both within and external to health systems and what kinds of relationship they hold with already established health system actors, would be a useful exercise. For example, are data processors health systems actors? What professional associations related to the digitalisation of health might be relevant

that have not yet been considered in 'traditional' health accountability initiatives? Should digital interfaces that mediate the relationship between health workers and patients be considered health actors and subsequently be held to account by citizens/patients for their role in influencing health outcomes and health inequities? What about the effects of artificial intelligence (AI) applied to health surveillance processes? Who would be held to account for undesirable impacts of these innovations?

One of the limitations of applying existing accountability approaches to digitalisation is the impossibility of anticipating how health data collected now might be combined and recombined in future, with potentially deleterious effects on health equity. On the point of health data alone, Saksena *et al.* (2021) suggest five actions to prioritise now with the goal of generating the potential for accountability in a digitalised health future. These are:

- Developing health technologies with a 'privacy by design' approach;
- Holding data processors themselves as legally liable;
- Keeping the collection of health data minimal and limited;
- Not assuming consent at 'patient entry' but giving repeated consent processes and options to opt out;
- Building citizen/patient/ population-level awareness of data privacy issues and risks.

It is this last point – building citizen capacity – that is key to strengthening accountability relationships and processes in increasingly digitalised health systems. Up to a point, much of this rapid change has occurred without, broadly speaking, public knowledge or direct engagement. From health rights activist groups to technical experts in health systems strengthening to anti-corruption advocates and good governance enthusiasts, the question of how to hold new technologies to account for the health effects they create is wide open. Commercial and public health objectives

are not, *de facto*, aligned (Kickbusch, Allen and Franz 2016). Rules of engagement are unclear, and regulation remains a source of tension between governments, private sector actors and citizen groups.

Citizen engagement for health equity is a means to centre power in these debates and relationships. It can create discomfort in that such an approach challenges the perspective that digitalisation of health systems is a purely technical exercise. It asks those involved in working towards common solutions to recognise that these debates do not occur on equal ground, and that consideration for the needs of those excluded from the rooms (real or metaphorical) where decisions are made and policies created, should be an absolute priority. Accountability for health equity in a digitally transformed (and transforming) context requires building on existing strengths. This means generating greater awareness and capacity to engage with digitalisation processes for already existing civil society and community-led accountability efforts. It demands independent research, in collaboration with those seeking the means to strengthen legal and governance frameworks at national and international level. It necessitates going beyond simple narratives of techno-optimism or techno-pessimism, and instead recognising the complex political, economic, and social agendas that are, and will be, bound up in this transformation process.

'The question of how to hold new technologies to account for the health effects they create is wide open… but citizen engagement for health equity is a means to centre power in these debates and relationships.'

6 A learning approach for the management of digital transformation

Previous sections have described the speed and complexity of the changes implied by the digital transformation of a health system. There are no best practice models for countries to copy with regard to the organisation and governance of a digitally enabled health system. That is why countries will need to include a learning approach in their digital health strategy (Kruk *et al*. 2018).

The need for a learning approach

A number of health system analysts describe the health sector as a **complex adaptive system** with a range of characteristics that make its behaviour unpredictable and its development non-linear. This complexity arises from the interaction of thousands of actors with their own patterns of behaviour and organisational routines that support the provision of multiple kinds of services (Paina and Peters 2012; Peters 2014; Xiao *et al*. 2013). The ways in which different actors in the health system – agencies and individuals – behave are dynamic, and their interactions can lead to outcomes that are hard to predict in advance. Introducing new interventions into a complex system inevitably creates both intended and unintended outcomes. Such self-organising complexity creates challenges for planners, regulators and managers to effectively steer their development (Plsek and Greenhalgh 2001; Greenhalgh *et al*. 2017). Dynamic, often experimental change management approaches are needed to help steer the development of the system in a desirable direction.

An increasing body of analysis exists that links health systems' ability to learn to the successful management of complex change. Such analyses point to the context-specific nature of change and hence learning and adaptation efforts – that apparently similar interventions in different places may well function differently for reasons that are not immediately obvious (Peters *et al*. 2009). Many low-income countries have under-resourced this aspect of health system management (Kruk *et al*. 2018). However, some countries have managed complex health sector reforms through experimentation and learning (Husain, Bloom and Xiao 2023) and others are building this capacity (Akhnif *et al*. 2018).

Building learning health systems

A recent report from the Alliance for Health Policy and Systems Research at WHO provides a useful statement of the function of learning, seen as 'a means for progress and empowerment for health systems […] by developing the inbuilt ability to generate and use the knowledge and skills they need to constantly improve and perform' (WHO *et al.* 2021). This can improve health system functioning; support adaptation and innovation; and support self-reliance.

This understanding of learning sees knowledge generation and use as action-oriented (Kruk *et al.* 2018), and requires that knowledge is applied to anticipate, prevent, or solve problems (WHO *et al.* 2021). The context-specific nature of change in health systems requires learning that asks *how* interventions or reforms work, alongside assessments of their effects. Learning is a continual process, relying on structures, capacities and approaches that must be purposively developed and fostered (Peters *et al.* 2009).

The WHO report emphasises different dimensions of learning including:

• the need to involve a wide range of actors such as service providers, researchers, analysts, and the public;
• the variety of approaches to learning such as the use of routine data, special implementation research studies, formal evaluations and a variety of consultations and so forth (WHO *et al.* 2021).

Tools for learning

Over the past ten years, at least since the Bellagio Call to Action on Global eHealth Evaluation (Bellagio eHealth Evaluation Group 2011), there has been consensus regarding the need for evaluation of digital health interventions and how they can be integrated into health systems. WHO produced guidelines in 2016 (WHO 2016), and other global health agencies have developed similar toolkits and frameworks (Labrique *et al.* 2018).

Simultaneously, there is a burgeoning literature assessing the effectiveness and uptake of interventions in specific country contexts. While routine monitoring and evaluation approaches, such as 'theory of change' approaches, remain important (WHO 2016), there is increasing evidence that sophisticated methods such as realist evaluation (Pawson 2013), and ones grounded in socio-technical approaches to understanding change are likely to be valuable (Greenhalgh 2018).

Increasing diversity in approaches to evaluating digital health interventions

Theory of change: Unpacking interventions to develop plausible theories about causality that provide a basis for tracking outcomes and for making claims about attribution.

Realist evaluation: Assessing how programmes function through evaluations that examine how different contexts and operating mechanisms affect outcomes.

The NASSS framework: A framework that examines technology adoption as a social, institutional and organisational process, with multiple possible outcomes, including Non-adoption (N), Abandonment (A), failure to Scale-up (S), to Spread (S), or to achieve Sustainability (S).

There is no one-size-fits-all approach for assessing digital health interventions – local context is critical – but there are a range of frameworks and tools to support this. These should be thought of as decision support tools that can be deployed as needed (Husain, Bloom and Xiao 2023). This will require that countries strengthen their capacities to perform these kinds of function. It also has implications for international agencies and donors, given that strengthening these capacities will require technical and financial resources.

'There is increasing evidence that sophisticated methods such as realist evaluation, and ones grounded in socio-technical approaches to understanding change are likely to be valuable.'
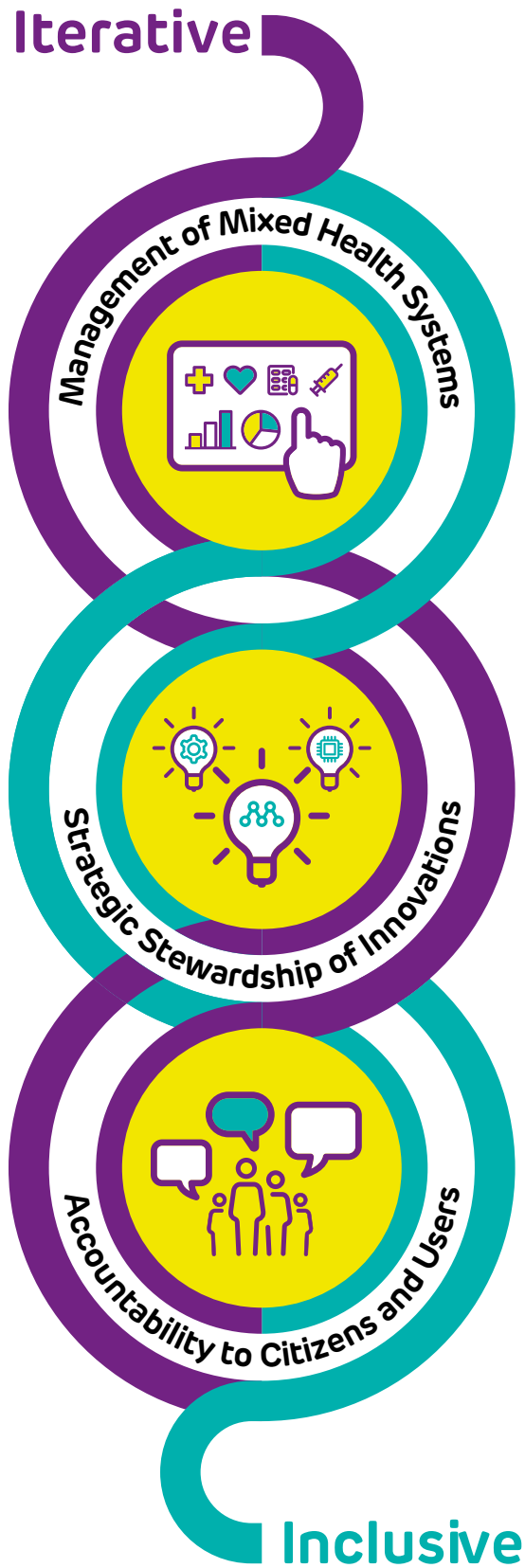
7 Conclusions: Implementing digital health transformation for universal health coverage

Equity-Led Approach to Digital Health Transformation

Iterative

Management of Mixed Health Systems

Strategic Stewardship of Innovations

Accountability to Citizens and Users

Inclusive

International consensus is growing on the contribution that digital innovations could make to national efforts to ensure equitable access to effective and affordable health services. The global digital health sector is large (worth US$210 billion) and is expected to grow rapidly. This growth has tended to be fragmented and most countries have not established clear mechanisms to steer digital health transformation. There is a shared vision of what a digitally enabled health system might look like and an agreement that countries need to formulate and implement strategies for digital health transformation. But there are no best practice models for countries to emulate or road maps to guide this transformation.

This section outlines an approach for supporting the implementation of digital health transformation that takes the complex and rapidly evolving nature of the digital health sector into account. It begins with a systems approach to the management of change and then outlines an inclusive and iterative approach for aligning the direction of change with policy objectives for increasing access to equitable, effective and affordable health services and making progress towards universal health coverage.

A systems approach

Sections 3, 4 and 5 of this report presented a systems approach that focuses on three aspects of the rapidly evolving digital health system.

- **Section 3**
  Discussed the need to establish institutional arrangements for influencing the performance of a mixed health system. This entails new kinds of engagement between public and private actors and the involvement of key stakeholders in agreeing to norms and standards and ensuring adherence to them. These stakeholders will need to build their capacity to participate effectively in these new institutions. It is important to create mechanisms that ensure that the perspectives of people with less economic and political power are taken into account.

- **Section 4**
  Discussed the need for strategic governance of the digital health innovation ecosystem. This will involve new kinds of partnership between technology and health and between public and private sectors. Government actions can influence the kinds of innovation that emerge and are incorporated widely. It is important to involve digital technology companies (large and small) and government agencies responsible

for business and technology policies in health sector discussions about digital transformation. Mechanisms are needed to avoid excessive concentration of market power and forms of ownership that could create incentives for a costly style of care.

- **Section 5**
  Argued that it is critical that investments are made to build the capacities of citizens and digital health service users to hold digital health transformation processes to account. It is equally important that all actors involved in digital health transformation are committed to improving health equity. Existing social, political and bureaucratic accountability mechanisms will need to be adapted to a changing digital health landscape, one that enables and encourages citizen and user participation in the creation of new governance arrangements.

An inclusive and iterative approach

Section 6

Discussed the challenge of managing change in complex systems, such as the digital health sector. It argued that all stakeholders should participate in building a full picture of a rapidly changing reality and in identifying the new roles and responsibilities of each stakeholder. It also advocated for the incorporation of learning into the management of change. This will require organisations with the capacity to undertake assessments of interventions and convene a variety of stakeholders including government, the private sector and representatives of users of digital health services.

We plan to organise **transformation labs (T-Labs)** to support this kind of process. We use this term to express the importance of experimentation and learning. The T-Lab approach draws on

the experiences of other sectors in which it has been important to build a consensus on socially desirable policies and actions despite big differences between stakeholders in terms of their knowledge and perspectives, their economic interest and their relative power.

T-Labs are spaces where diverse stakeholders from health and non-health sectors come together to build an understanding of the opportunities and potential problems associated with digital health innovations and to then shape and co-create activities that support digital transformation aligned with national policy priorities. They involve interrogation and experimentation that challenge established institutional models; recognise the need for innovation in governance; and foster unconventional partnerships that may eventually become the norm. The labs will generate evidence and stimulate new thought processes on innovative ways to incorporate new technologies into strategies for improving health service performance.

We envisage a multi-year process that involves established digital leaders, emerging entrepreneurs, the start-up community, health sector managers, health and technology policymakers and civil society organisations, among others, to identify priority actions for change, to agree on the roles and responsibilities of each stakeholder in the implementation of those actions and to establish mechanisms for adjusting implementation on the basis of experience and evidence. The learning generated will help to build the capacity of stakeholders to engage effectively in digital health transformation.

The success of T-Labs depends on several factors. It is important to reach agreement between stakeholders on the shared values that form the basis for any intervention because stakeholder ownership and trust are critical to forging joint solutions. It is necessary to build a common understanding of the context within which any intervention

is embedded. It is important to ensure that the perspectives of people with little economic, social or political power are represented. It is also important to involve local thinktanks and research organisations as important contributors to the management of change.

Organising T-labs requires skilled facilitation to ensure that all voices are heard and recognised. The process begins by building agreement on the goals of digital health transformation and a mutual understanding of the current context. This leads to a review of priority actions for improving access to health services and/or strengthening an aspect of digital health governance. Three examples that have already arisen during preliminary consultations illustrate the kinds of actions that could be selected: (i) strategies for scaling a successful intervention for improving access to basic health services, involving new kinds of partnership between different types of organisation and new approaches to public health funding; (ii) challenges to the implementation of an interoperability policy or another regulatory initiative; and (iii) ways to ensure that government support for technology innovators encourages them to take health development priorities into account. For each intervention to succeed, a variety of stakeholders will need to play an important role.

As interventions are implemented, small studies document what went well and why, as well as any undesirable outcomes. The methods and findings are reviewed at regular meetings to monitor progress and revise implementation strategies. This strengthens the capacity of all stakeholders to participate in a learning approach to digital health transformation. It may be necessary to arrange activities to build the capacity of stakeholders to engage effectively in this process. This particularly applies to groups that represent citizens as users of health services and/or technology platforms. Although the focus of the T-Labs is on implementing priority actions, this is

framed in a broader context so that they contribute to the management of the transformation process.

The digital health industry is global, so changes in market shaping or governance arrangements in one country are likely to affect other countries. National strategies need to be informed by developments elsewhere. That is why opportunities for mutual learning between countries are needed. Also, international initiatives to develop so-called 'digital public goods' may provide useful pro-equity resources, that countries should keep an eye on. Countries also need to build their capacity to participate in regional and global negotiations about the governance of digital health.

The Mutual Learning for Mixed Health Systems platform has brought together a team with the capacity to organise transformation labs for digital health transformation. The plans for the next phase of work include inception labs in several countries including Argentina, Bangladesh, Zimbabwe and India. The core technical team and the leaders of the country labs are listed on the title page of this report. The aims are to build national capacities to manage digital health transformation and create a mechanism for mutual learning between countries and for engaging in global debates.

Annexe

Regulatory
adaptation to
digital health in
Kenya and India

HealthX Africa: a Kenya-based primary health care service provider built on the vision of a doctor for every Kenyan

HealthX exists to ensure that every Kenyan has easy access to the most affordable medical services anywhere in the country and anytime, day or night. By doing so, the company seeks to put the power of health-care decision-making back in the hands of every citizen.

Health and demographic environment

Kenya has adopted universal health coverage (UHC) as a priority in its development agenda. The case for UHC is incontrovertible, with the right to health being a fundamental human right guaranteed in the Constitution of Kenya, and critical to the achievement of Kenya's Vision 2030. To achieve this ambitious goal, the Government of Kenya has spearheaded multiple important policy and administrative reforms and programmes aimed at improving access to health care.

Despite considerable investment and planning at both national and county level across the country, health infrastructure and resources lag behind the health needs of the population. The Kenya Master Health Facility List identifies 13,517 public and private health facilities in Kenya,[14] an insufficient number to serve the population of 50 million and growing. As of 2019, Kenya had 12,090 registered medical doctors, resulting in a ratio of 25 doctors per 100,000 population.[15] This means Kenya has some way to go to achieve the World Health Organization's recommendation of one doctor per 1,000 population. The distribution of that existing health workforce is inequitable, with 80 per cent of clinicians serving 20 per cent of the population,[16] primarily in urban settings. According to the Kenya Demographic Health Survey report 2022, only 25 per cent of all Kenyans have any health insurance (including National Health Insurance), meaning that the majority pay out of pocket for all health expenses. Deaths from non-communicable diseases (NCDs) are on the rise, at 39 per cent in 2021, up from 27 per cent in 2015, and projected to reach 55 per cent by 2030, according to the National Strategic Plan for the Prevention and Control of NCDs 2021/22–2025/26.

This is where the Government of Kenya's successful prioritisation of, and investment in, the ICT sector may

reap significant rewards for health. Kenya – which is known as Africa's 'Silicon Savannah' – is a regional leader in terms of broadband connectivity, ICT infrastructure, value-added services, and mobile money/banking.[17] Data from the Communications Authority until end of June 2021, show active mobile SIM cards subscriptions standing at 64.4 million, representing 132.2 per cent market penetration (many Kenyans have more than one SIM), with internet subscriptions reaching 46.7 million, of which 99 per cent are mobile data subscriptions. Millions of Kenyans use their phones multiple times daily to communicate, access financial services, work from home, shop online, study, and socialise. Health care is one of the final frontiers that has been less accessible through the use of mobile phones and digital technologies in Kenya.

Regulatory environment

The health-care system in Kenya had no formal provision for the delivery of health care through telemedicine until the onset of the Covid-19 pandemic in 2020. At that point, the Kenya Medical Practitioner and Dentists Council (KMPDC) moved swiftly to respond to the restrictions imposed by the pandemic and to ensure that patients were still able to get health care when they needed it. The KMPDC developed a 'Virtual Medical Services' licence and began issuing approvals for existing registered and licensed health facilities to offer virtual medical services. By February 2021, 20 health facilities had received approvals from the KMPDC to offer telemedicine services in the country, and this number has subsequently grown. Anecdotally, there may now be more than 50 registered telemedicine providers in the country. No other professional regulatory bodies have put in place regulations or licensing for telemedicine at the moment, meaning that all health-care cadres must go through the KMPDC to offer telemedicine, and abide by the KMPDC licensing regulations for telemedicine.

These include:

- Linkage to a physical, brick-and-mortar licensed and registered health facility, to enable data reporting into the Kenya Health Information System through a Master Health Facility List (MFL) Code;
- Oversight from a medical director responsible for clinical care delivery through telemedicine, and registered with the KMPDC;
- That all telemedicine practitioners shall meet the registration and licensing requirements under CAP 253 Laws of Kenya and attending rules;
- That all practitioners shall provide services within their scope of practice;
- That the facility will maintain a list of all licensed medical and dental practitioners providing virtual services on the telemedicine platform;
- That practitioners shall not use collected personal health information for research without ethical approval;
- That the virtual facility shall maintain a record of all services provided;
- That all the practitioners shall ensure compliance with the Ministry of Health policies on telemedicine (which do not currently exist), eHealth and any other related areas, to address data storage and systems standards, data privacy and security and interoperability of the system among others; and
- That provisions of the Data Protection Act shall be adhered to.

The Data Protection Act 2019 is overseen by the Office of the Data Protection Commissioner (ODPC), and all health facilities are now required to be registered with the ODPC.

Operations of HealthX Africa

Registered in April 2021, the first few months of HealthX were spent in obtaining regulatory approvals, including building a physical Level 2 Medical Clinic to be licensed by the KMPDC in order to obtain the Virtual Medical Services

licence. HealthX has prioritised quality, trust, patient-centredness and data security in the structuring of their office and the running of their services. These regular services include:

- Offering telemedicine services exclusively from an access-controlled Digital Operations Call Center (DOCC) linked to the HealthX medical clinic, with all clinical staff delivering telemedicine consultations from within the DOC only (no calls from home or other locations except virtual clinics).
- Full-time, salaried HealthX medical doctors, clinical psychologists, clinical nutritionists, and care coordinators who provide services exclusively for HealthX (unlike many telemedicine platforms in Kenya that allow any interested clinician to register and offer services via telemedicine when they want to – the 'Uber model').
- The recording of every clinical consultation – voice, video, or chat – as well as documentation of the same in the shared electronic medical record.
- Medical consultation services offered 24 hours a day, seven days a week with no appointment required, and a commitment to connect patients to a HealthX doctor within five minutes.

HealthX was the first telemedicine provider in Kenya to offer an affordable subscription model – a model rapidly taken up by competitors after it was launched. Current pricing of packages begins at Kes 495 (less than US$4) for one full month's access to the Care package. Through the affordable subscription packages, HealthX patients have unlimited access to a full-time team of HealthX doctors, nutritionists, wellness advisers, and mental health professionals.

HealthX uses a variety of digital solutions, with telemedicine being the initial priority to ensure that all the services are of high quality, are affordable and accessible, including a toll-free line to enable users with feature phones to have a consultation; an app that enables video, voice and chat consultations, push notifications and reminders, vital signs monitoring and so on; and a virtual clinic, which provides the app-like services on a tablet or screen, with Bluetooth-enabled diagnostic devices to provide more information to the clinician on the patient's condition and expand their diagnostic capabilities.

HealthX fills an important gap in African health systems that has long gone unaddressed – that patients do not access primary health care (preventive, promotive and curative) in a timely manner. HealthX does not seek to replace brick-and-mortar facilities or in-person consultations nor to disrupt an already disrupted and fragmented health system. Rather, it seeks to be a piece of the puzzle in strengthening the health system in Kenya, and being an option for accessing care for the millions of uninsured Kenyans who have a willingness to pay, an ability to pay a certain amount, an awareness of their rights as patients, and a knowledge of health-care quality, but who find themselves priced out of the existing private health-care system.

Ikigai Law: an early mover in creating a focused health tech law and public policy firm in India

Ikigai Law is a law and policy firm with a sharp focus on technology and innovation. The firm specialises in working with new and emerging technology businesses, helping them to navigate ambiguous and evolving legal frameworks.

Through its dedicated health tech practice, the firm assists clients at every stage of the life cycle of a health product. They have worked with companies that provide telemedicine, online sale of medicines, artificial intelligence and machine learning (AI/ML) powered medical devices, rural-facing tele-ICUs. The firm has worked with government entities like the (Indian) National Health Authority, the (Indian) Ministry of Health and Family Welfare, and the British High Commission in India. It has also worked with non-profit organisations like the Public Health Foundation of India, the Centre for Mental Health Law and Policy, and Parliamentarians with Innovators for India. The health tech practice was born of the realisation that there would be a need to study and navigate the legal and ethical issues emerging as a result of the Indian government's ambitious initiatives to drive digital health care and the innovations of India's entrepreneurial start-up community.

Sampling of health tech at Ikigai

The health tech practice works across three verticals: (i) policy – helping to create enabling laws through strategic advice and stakeholder engagement; (ii) product – enabling businesses to develop products and structure their business models to take into account regulatory risks; and (iii) general corporate and commercial – developing and negotiating contracts, advice on investment rounds, among other aspects.

Under its policy vertical, Ikigai led a delegation of Indian experts on a five-day study tour in the UK. This involved sessions with the National Health Service (NHS) UK, NHS AI Lab, the Medicines and Health products Regulatory Agency, discussing the regulation of software as a medical device (and more narrowly, AI as a medical device), as well as embedding ethics in the development of AI-enabled health products, building an innovation ecosystem, and approaches to inter-regulatory coordination.

The firm's product vertical advised a manufacturer and operator of remote ICUs. The operation of such units raises significant liability issues for the manufacturer and operators – for example, on account of system downtime, loss of network or power. The team assisted on contractual arrangements between the manufacturer, intensivists and hospitals, and advised on containing liability risks for the client. Likewise, the team advised a health tech company in designing their AI diagnostic tool that diagnoses and then recommends ayurvedic products. This involved study of medical devices regulations in India and the US.

Driving conversations on health tech

The health tech team at Ikigai write extensively on legal and policy issues affecting the health tech space. Illustratively, the team has written about the trajectory of medical devices regulation in India, the clinical evaluation process for medical devices under the Medical Devices Rules 2017, price control of medical devices, the need to clarify how software devices are evaluated, considerations for starting a telehealth platform, the opportunities presented by the Ayushman Bharat Digital Health Mission's Sandbox for the health tech industry, the various attempts to regulate e-pharmacies in India, and digital accessibility of telehealth platforms.

A 2020 webinar hosted by Ikigai examined telemedicine practice guidelines to help platforms understand the law and how to comply. The webinar featured the views of leading experts in telemedicine.

The future of digital health policy in India and need for research and learning partnerships

The Indian government is keen to use technology for social good, and with a vibrant start-up community, is working to solve issues plaguing health-care infrastructure and delivery in India. Between 2018 and 2022, the Indian government launched the Ayushman Bharat Digital Health Mission (ABDM – India's flagship mission to enhance digital health-care delivery), the National Tele-Mental Health Programme, guidelines for telemedicine and online sale of medicines, its own telemedicine platform (e-sanjeevani), and has used apps for managing the pandemic (Co-WIN and Aarogya Setu). These publicly funded and run initiatives will test India's health-care infrastructure and professionals, and also its laws. Ethical, legal and policy questions will increase, as technology is used more for health-care delivery, research and innovation, and public policy/legal interventions. For instance:

- Health research: What does ethical health data management look like for research and innovation? How can the government and organisations encourage health-care research while protecting patient rights and privacy?
- Health innovation evaluation: How will the government evaluate the safety and efficacy for human use, of emerging technologies in health care such as artificial intelligence and machine learning? Do governments have the capacity needed to look into the algorithms and resulting data for the evaluation? Is peer review of health technologies a solution?
- Health care online: What policies will help with the quality control of health-care professionals (e.g. therapists, doctors on a telemedicine application) and products (e.g. drugs which can be damaged or altered while being delivered) in the digital space?

The answers to these complex questions lie in the independently funded research involving key stakeholders like civil society, industry, legal and policy experts, public health experts, investors, and government.

Endnotes

¹ For example, see the World Health Organization's *Global Strategy on Digital Health 2020-2025*; the Inter-American Development Bank's report *The Golden Opportunity of Digital Health for Latin America and the Caribbean*; the Asian Development Bank's report *Transforming Health Systems through Good Digital Health Governance*; USAID's report *A Vision for Action in Digital Health 2020-2024: Accelerating the Journey to Self-Reliance Through Strategic Investments in Digital Technologies*; and the Tony Blair Institute for Global Change report *Reviving Global Health Systems: How Technology Can Improve the Quality and Quantity of Life* (all accessed February 2023).

² For example, see the recent purchase of One Medical by Amazon (**https://press. aboutamazon.com/news-releases/news-release-details/amazon-and-one-medical-sign-agreement-amazon-acquire-one-medical**), the expansion of Alibaba in digital health (**https://www.spglobal.com/marketintelligence/en/news-insights/latest-news-headlines/china-s-big-tech-to-continue-disruption-of-healthcare-sector-despite-crackdown-61610882**), IBM investments in blockchain solutions for digital health passes (**https://www.hhmglobal.com/knowledge-bank/news/ibm-watson-health-to-launch-blockchain-powered-digital-health-pass**) (all accessed October 2022).

³ For example, see the McKinsey & Company report *Unlocking digital healthcare in lower- and middle-income countries*; the Boston Consultation Company and FICCI report *Leapfrogging to a Digital Healthcare System - Re-imagining Healthcare for Every Indian*; the Ernst & Young report *Embracing digital: is COVID-19 the catalyst for lasting change?* (all accessed February 2023).

⁴ For example, see The Broadband Commission's report *Digital Health: A Call for Government Leadership and Cooperation between ICT and Health*; the GSME report *Digital Health: A health system strengthening tool for developing countries*; the IFPMA report *Biopharmaceutical Industry's Global Policy Principles on Digital Health* (all accessed October 2022).

⁵ The classification of digital health interventions published by WHO identifies more than 80 cases of digital technology use and groups them by primary target user-groups, which include client-oriented technologies (such as those that provide compliance reminders for appointments and treatment, and transmit health-event alerts), provider-oriented technologies (such as those that support the identification and registration of clients, clients' health records, and telemedicine), manager-oriented technologies (such as those that support the management of human resources, supply chains, notifications of public health events), and data services-oriented technologies (such as those that enable the collection, management, analytics, exchange of data) (WHO 2018).

⁶ The market players prefer to categorise their digital health in technological terms, such as tele-health care (telecare and telehealth), which provide support and assistance at a distance using ICT and the remote exchange of clinical data between a patient and their clinician (e.g. activity monitoring, remote medication management, video consultation); mHealth, such as smartphone applications relating to health and/or wellbeing and connected wearable devices (e.g. monitoring and diagnosis services); health analytics, such as software solutions and analytical capabilities needed to assimilate big data (some include here precision medicines and genomics); and digital

health systems, which provides digital health information storage and exchange of digitised patient medical records (e.g. e-prescribing systems). See, for example, the digital health market trend and outlook reports by Grand View Research (2022) *Digital Health Market Size, Share & Trends Report*; Global Market Insights (2023) *Digital Health Market* (both accessed February 2023).

[7] This is still low compared to the US where venture funding for digital health companies has increased constantly over the past decade, with a 72 per cent increase between 2018 and 2020, and a total venture funding of US$14.1 billion (de Silva and Zweig 2020).

[8] For example, see GSMA publications *Digital Health: A health system strengthening tool for developing countries* (2020) and *Scaling Digital Health in Developing Markets* (2017) (both accessed February 2023).

[9] For example, see the 2022 publication by The European Federation of Pharmaceutical Industries and Associations (EFPIA), International Federation of Pharmaceutical Manufactures and Associations (IFPMA), Japan Pharmaceutical Manufacturers Association (JPMA) *Biopharmaceutical Industry's Global Policy Principles on Digital Health* (accessed February 2023).

[10] See also Stacey, K.; Fontanella-Khan, J. and Palma, S. (2021) 'Big tech companies snap up smaller rivals at record pace', Financial Times, 19 September 2021, **https://www.ft.com/content/e2e34de1-c21b-4963-91e3-12dff5c69ba4** (accessed February 2023).

[11] For example, CB Insights (2021) mention that the five US big tech companies have collectively acquired more than 800 start-ups during the past decades: **https://www. cbinsights.com/research/tech-giants-billion-dollar-acquisitions-infographic/** (accessed February 2023).

[12] For more information, see the BMC collection on 'Lessons about intervening in accountability ecosystems: implementation of community scorecards in Bangladesh and Uganda', **https://www.biomedcentral.com/collections/accountability-ecosystems** (accessed March 2023).

[13] See **https://www.makingallvoicescount.org/**

[14] For further information, see: Ministry of Health (2023) Kenya Master Health Facility List, **http://kmhfl.health.go.ke/#/home**

[15] For further information, see: **https://www.statista.com/statistics/1238125/number-of-registered-medical-doctors-in-kenya/**

[16] For further information, see: Government of Kenya (2011) Kenya National e-Health Strategy 2011-2017, **http://publications.universalhealth2030.org/uploads/kenyanation_ehealth_strategy.pdf**

[17] For further information, see: **https://www.trade.gov/country-commercial-guides/kenya-information-communications-and-technology-ict**

References

Aerts, A. and Bogdan-Martin, D. (2021) 'Leveraging Data and AI to Deliver on the Promise of Digital Health', *International Journal of Medical Informatics* 150: 104456, **https://doi.org/10.1016/j.ijmedinf.2021.104456**

Akhnif, E. *et al.* (2018) 'Are Our "UHC Systems" Learning Systems? Piloting an Assessment Tool and Process in Six African Countries', *Health Research Policy and Systems* 16.1: 78, **https://doi.org/10.1186/s12961-018-0340-y**

Allen, P. *et al.* (2016) 'Public Contracts as Accountability Mechanisms: Assuring Quality in Public Health Care in England and Wales', *Public Management Review* 18.1: 20–39, **https://doi.org/10.1080/14719037.2014.957341**

Arrow, K.J. (2004) 'Uncertainty and the Welfare Economics of Medical Care. 1963', *Bulletin of the World Health Organization* 82.2: 141–49, **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2585909/**

Awor, P.; Miller, J. and Peterson, S. (2014) 'Systematic Literature Review of Integrated Community Case Management and the Private Sector in Africa: Relevant Experiences and Potential next Steps', *Journal of Global Health* 4.2): 020414, **https://doi.org/10.7189/jogh.04.020414**

Beaunoyer, E.; Dupéré, S. and Guitton, M.J. (2020) 'COVID-19 and Digital Inequalities: Reciprocal Impacts and Mitigation Strategies', *Computers in Human Behavior* 111: 106424, **https://doi.org/10.1016/j.chb.2020.106424**

Bellagio eHealth Evaluation Group (2011) 'Call to Action on Global EHealth Evaluation', Consensus Statement of the WHO Global EHealth Evaluation Meeting, Bellagio, **https://www.who.int/publications/m/item/call-to-action-on-global-ehealth-evaluation** (accessed February 2023).

Bergek, A.; Jacobsson, S.; Carlsson, B.; Lindmark, S. and Rickne, A. (2008) 'Analyzing the Functional Dynamics of Technological Innovation Systems: A Scheme of Analysis', *Research Policy* 37.3: 407–29, **https://doi.org/10.1016/j.respol.2007.12.003**

Bloom, G. and Standing, H. (2001) 'Pluralism and Marketisation in the Health Sector: Meeting Health Needs in Contexts of Social Change in Low and Middle-Income Countries', *IDS Working Paper Series* 136, 2001, **https://opendocs.ids.ac.uk/opendocs/handle/20.500.12413/3898**

Bloom, G., Henson, S. and Peters, D.H. (2014) 'Innovation in Regulation of Rapidly Changing Health Markets', *Globalization and Health* 10.1: 53, **https://doi.org/10.1186/1744-8603-10-53**

Bloom, G., Standing, H. and Lloyd, R. (2008) 'Markets, Information Asymmetry and Health Care: Towards New Social Contracts', *Social Science & Medicine (1982)* 66.10: 2076–87, **https://doi.org/10.1016/j.socscimed.2008.01.034**

Bloom, G.; Berdou, E.; Standing, H.; Guo, Z. and Labrique, A. (2017) 'ICTs and the Challenge of Health System Transition in Low and Middle-Income Countries', *Globalization and Health* 13.1: 56, **https://doi.org/10.1186/s12992-017-0276-y**

Bloom, G., Katsuma, Y.; Rao, K.D.; Makimoto, S. and Leung, G.M. (2019) 'Deliberate Next Steps toward a New Globalism for Universal Health Coverage (UHC)', Policy Brief Under T20 Japan Task Force 1: 2030 Agenda for Sustainable Development, 15 March 2019, **https://t20japan.org/policy-brief-deliberate-next-steps-toward-new-globalism-for-uhc/** (accessed March 2023).

Bode, M.; Goodrich, T.; Kimeu, M.; Okebukola, P. and Wilson, M. (2021) 'Unlocking Digital Healthcare in Lower- and Middle-Income Countries | McKinsey', New York: McKinsey & Company, **https://www.mckinsey.com/industries/healthcare/our-insights/unlocking-digital-healthcare-in-lower-and-middle-income-countries** (accessed February 2023).

Brinkerhoff, D.W. and Wetterberg, A. (2016) 'Gauging the Effects of Social Accountability on Services, Governance, and Citizen Empowerment', *Public Administration Review* 76.2 (2016): 274–86, **https://doi.org/10.1111/puar.12399**

Cassiolato, J.E. and Dias Soares, C. (2015) 'Innovation Systems, Development and Health: An Introduction', in *Health Innovation Systems, Equity and Development* (Rio de Janeiro: E-Papers, 2015).

CB Insights (2021) 'Visualizing Tech Giants' Billion-Dollar Acquisitions', Research Brief, New York: CB Insights, **https://www.cbinsights.com/research/tech-giants-billion-dollar-acquisitions-infographic/**

Christensen, C.; Grossman, J. and Hwang, J. (2009) *The Innovators' Solution: A Disruptive Solution to Health Care*, New York: McGraw-Hill

Cornwall, A. (2011) *The Participation Reader*, ZED Books, **https://www.zedbooks.net/shop/book/the-participation-reader/**

Côté-Boileau, É.; Denis, J-L.; Callery, B. and Sabean, M. (2019) 'The Unpredictable Journeys of Spreading, Sustaining and Scaling Healthcare Innovations: A Scoping Review', *Health Research Policy and Systems* 17.1: 84, **https://doi.org/10.1186/s12961-019-0482-6**

Couldry, N. (2019) The Costs of Connection: *How Data Is Colonizing Human Life and Appropriating It for Capitalism, Culture and Economic Life*, Stanford, California: Stanford University Press

Das, J.; Chowdhury, A.; Hussam, R. and Banerjee, A.V. (2016) 'The Impact of Training Informal Health Care Providers in India: A Randomized Controlled Trial', *Science (New York, N.Y.)* 354.6308 (7 October 2016): aaf7384, **https://doi.org/10.1126/science.aaf7384**

de Silva J. and Zweig M. **(2020) Market insights report: chasing a new equilibrium**. Rock Health, in: Kickbusch, I. *et al.* (2021) 'The Lancet and Financial Times Commission on Governing Health Futures 2030: Growing up in a Digital World', *The Lancet* 398.10312: 1727–76, **https://doi.org/10.1016/S0140-6736(21)01824-9**

Ebeling, M.F.E. (2021) 'Mining the Data Oceans, Profiting on the Margins', *Global Policy* 12.S6 (2021): 85–89, **https://doi.org/10.1111/1758-5899.12887**

Edward, A. *et al.* (2015), 'Enhancing Governance and Health System Accountability for People Centered Healthcare: An Exploratory Study of Community Scorecards in Afghanistan', *BMC Health Services Research* 15.1: 299, **https://doi.org/10.1186/s12913-015-0946-5**

Edwards, D.; Brock, K. and McGee, R. (2018) 'Transforming Governance: What Role for Technology?', Programme learning report, Making All Voices Count, Brighton: Institute of Development Studies, **https://www.makingallvoicescount.org/publication/transforming-governance-role-technology/** (accessed February 2023).

Faujdar, D.S.; Sahay, S.; Singh, T.; Kaur, M. and Kumar, R. (2020) 'Field Testing of a Digital Health Information System for Primary Health Care: A Quasi-Experimental Study from India', *International Journal of Medical Informatics* 141: 104235, **https://doi.org/10.1016/j.ijmedinf.2020.104235**

Fligstein, N. (2002) *The Architecture of Markets. An Economic Sociology of Twenty-First-Century Capitalist Societies*, New Jersey: Princeton University Press, **https://press.princeton.edu/books/paperback/9780691102542/the-architecture-of-markets**

Flores, W. (2018) 'How Can Evidence Bolster Citizen Action? Learning and Adapting for Accountable Public Health in Guatemala', Accountability Note no. 2 (Accountability Research Center, 2018), **https://accountabilityresearch.org/publication/how-can-evidence-bolster-citizen-action-learning-and-adapting-for-accountable-public-health-in-guatemala/** (accessed February 2023).

Frost, M.J.; Tran, J.B.; Khatun, F.; Friberg, I.K. and Rodríguez, D.C. (2018) 'What Does It Take to Be an Effective National Steward of Digital Health Integration for Health Systems Strengthening in LMICs?', *Global Health: Science and Practice*, 6.1: S18–28, **https://doi.org/10.9745/GHSP-D-18-00270**

Fuenfschilling, L. and Truffer, B. (2014) 'The Structuration of Socio-Technical Regimes— Conceptual Foundations from Institutional Theory', *Research Policy* 43.4: 772–91, **https://doi.org/10.1016/j.respol.2013.10.010**

Gautham, M. *et al.* (2014) 'Informal Rural Healthcare Providers in North and South India', *Health Policy and Planning* 29.1.1: i20-29, **https://doi.org/10.1093/heapol/czt050**

Global Market Insights (2023) '*Digital Health Market*', **https://www.gminsights.com/industry-analysis/digital-health-market** (accessed February 2023)

Grand View Research (2022) *Digital Health Market Size, Share & Trends Report*

Greenhalgh, T. (2018) 'How to Improve Success of Technology Projects in Health and Social Care', *Public Health Research & Practice* 28.3: 2831815, **https://doi. org/10.17061/phrp2831815**

Greenhalgh, T.; Robert, G.; Macfarlane, F.; Bate, P. and Kyriakidou, O. (2004) 'Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations', *The Milbank Quarterly* 82.4: 581–629, **https://doi.org/10.1111/j.0887-378X.2004.00325.x**

Greenhalgh, T. *et al.* (2017) 'Beyond Adoption: A New Framework for Theorizing and Evaluating Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies', *Journal of Medical Internet Research* 19.11: e367, **https://doi.org/10.2196/jmir.8775**

Gudi, N.; Lakiang, T.; Pattanshetty, S.; Sarbadhikari, S.N. and John, O. (2021) 'Challenges and Prospects in India's Digital Health Journey', *Indian Journal of Public Health* 65.2 (2021): 209–12, **https://doi.org/10.4103/ijph.IJPH_1446_20**

Gunningham, N. and Grabosky, P. (1998) *Smart Regulation: Designing Environmental Policy*, Oxford Socio-Legal Studies Series, Oxford: Clarendon Press

Haque, M.E.; Ahsan, M.A.; Rahman, F. and Islam, A. (2019) 'The Challenges of EHealth Implementation in Developing Countries: A Literature Review', *Journal of Dental and Medical Sciences* 18.5 (2019): 41–57, **https://www.iosrjournals.org/iosr-jdms/papers/Vol18-issue5/Series-12/H1805124157.pdf**

Hermes, S.; Riasanow, T.; Clemons, E.K.; Böhm, M. and Krcmar, H. (2020) 'The Digital Transformation of the Healthcare Industry: Exploring the Rise of Emerging Platform Ecosystems and Their Influence on the Role of Patients', *Business Research* 13.3: 1033–69, **https://doi.org/10.1007/s40685-020-00125-x**

Herselman, M. *et al.* (2016) 'A Digital Health Innovation Ecosystem for South Africa', in *2016 IST-Africa Week Conference*, 2016, 1–11, **https://doi.org/10.1109/ISTAFRICA.2016.7530615**

Hintz, A.; Dencik, L. and Wahl-Jorgensen, K. (2018) *Digital Citizenship in a Datafied Society*, Medford, MA: Polity Press, **https://www.wiley.com/en-gb/Digital+Citizenship+in+a+Datafied+Society-p-9781509527151**

Hunter, B.M.; Murray, S.F.; Marathe, S. and Chakravarthi, I. (2022) 'Decentred Regulation: The Case of Private Healthcare in India', *World Development* 155: 105889, **https://doi.org/10.1016/j.worlddev.2022.105889**

Husain, L.; Bloom, G. and Xiao, Y. (2023) 'Building Policy Capacity for Managing Rapid, Complex Change in China's Health System', *Policy and Society* 42.1: 28–48, **https://doi.org/10.1080/14494035.2021.1933336**

Ilin, I.; Iliashenko, V.M.; Dubgorn, A. and Esser, M. (2022) 'Critical Factors and Challenges of Healthcare Digital Transformation', in *Digital Transformation and the World Economy: Critical Factors and Sector-Focused Mathematical Models*, A. Rudskoi, A. Akaev and T. Devezas (eds) (2022) Studies on Entrepreneurship, Structural Change and Industrial Dynamics, Cham: Springer International Publishing, 205–20, **https://doi.org/10.1007/978-3-030-89832-8_11**

Jaworski, B.; Kohli, A.K. and Sahay, A. (2000) 'Market-Driven versus Driving Markets', *Journal of the Academy of Marketing Science* 28.1: 45–54, **https://doi.org/10.1177/0092070300281005**

Jimenez, G. *et al.* (2021) 'The Role of Health Technologies in Multicomponent Primary Care Interventions: Systematic Review', *Journal of Medical Internet Research* 23.1: e20195, **https://doi.org/10.2196/20195**

Kaartemo, V. and Nyström, A.-G. (2021) 'Emerging Technology as a Platform for Market Shaping and Innovation', *Journal of Business Research* 124: 458–68, **https://doi.org/10.1016/j.jbusres.2020.10.062**

Kenworthy, N.J. (2019) 'Crowdfunding and Global Health Disparities: An Exploratory Conceptual and Empirical Analysis', *Globalization and Health* 15.1: 71, **https://doi.org/10.1186/s12992-019-0519-1**

Khubone, T.; Tlou, B. and Mashamba-Thompson, T.P. (2020) 'Electronic Health Information Systems to Improve Disease Diagnosis and Management at Point-of-Care in Low and Middle Income Countries: A Narrative Review', *Diagnostics* 10.5: 327, **https://doi.org/10.3390/diagnostics10050327**

Kiberu, V.M.; Mars, M. and Scott, R.E. (2017) 'Barriers and Opportunities to Implementation of Sustainable E-Health Programmes in Uganda: A Literature Review', *African Journal of Primary Health Care & Family Medicine* 9.1: e1–10, **https://doi.org/10.4102/phcfm.v9i1.1277**

Kickbusch, I.; Allen, L. and Franz, C. (2016) 'The Commercial Determinants of Health', The *Lancet Global Health* 4.12 : e895–96, **https://doi.org/10.1016/S2214-109X(16)30217-0**

Kickbusch, I. *et al.* (2021) 'The Lancet and Financial Times Commission on Governing Health Futures 2030: Growing up in a Digital World', *The Lancet* 398.10312: 1727–76, **https://doi.org/10.1016/S0140-6736(21)01824-9**

Kivimaa, P. and Kern, F. (2016) 'Creative Destruction or Mere Niche Support? Innovation Policy Mixes for Sustainability Transitions', *Research Policy* 45.1: 205–17, **https://doi.org/10.1016/j.respol.2015.09.008**

Klein Woolthuis, R.; Lankhuizen, M. and Gilsing, V. (2005) 'A System Failure Framework for Innovation Policy Design', *Technovation* 25.6: 609–19, **https://doi.org/10.1016/j.technovation.2003.11.002**

Köhler, J. *et al.* (2019) 'An Agenda for Sustainability Transitions Research: State of the Art and Future Directions', *Environmental Innovation and Societal Transitions* 31: 1–32, **https://doi.org/10.1016/j.eist.2019.01.004**

Kruk, M.E. *et al.* (2018) 'High-Quality Health Systems in the Sustainable Development Goals Era: Time for a Revolution', *The Lancet Global Health* 6.11: e1196–1252, **https://doi.org/10.1016/S2214-109X(18)30386-3**

Labrique, A.; Vasudevan, L.; Weiss, W. and Wilson, K. (2018) 'Establishing Standards to Evaluate the Impact of Integrating Digital Health into Health Systems', *Global Health: Science and Practice* 6. Supplement 1: S5–17, **https://doi.org/10.9745/GHSP-D-18-00230**

Labrique, A.B.; Wadhwani, C.; Williams, K.A.; Lamptey, P.; Hesp, C.; Luk, R. and Aerts, A. (2018) 'Best Practices in Scaling Digital Health in Low and Middle Income Countries', *Globalization and Health* 14.1: 103, **https://doi.org/10.1186/s12992-018-0424-z**

Leonard, D.K.; Bloom, G.; Hanson, K.; O'Farrell, J. and Spicer, N. (2013) 'Institutional Solutions to the Asymmetric Information Problem in Health and Development Services for the Poor', *World Development* 48: 71–87, **https://doi.org/10.1016/j.worlddev.2013.04.003**

Li, W.C.Y.; Nirei, M. and Yamana, K. (2019) 'Value of Data: There's No Such Thing as a Free Lunch in the Digital Economy', Discussion Paper, Tokyo: Research Institute of Economy, Trade and Industry (RIETI), **https://www.rieti.go.jp/en/publications/summary/19030027.html**

Lodenstein, E.; Dieleman, M.; Gerretsen, B. and Ew Broerse, J. (2013) 'A Realist Synthesis of the Effect of Social Accountability Interventions on Health Service Providers' and Policymakers' Responsiveness', *Systematic Reviews* 2: 98, **https://doi.org/10.1186/2046-4053-2-98**

Loewenson, R. *et al.* (2020) 'Reclaiming Comprehensive Public Health', *BMJ Global Health* 5, no. 9: e003886, **https://doi.org/10.1136/bmjgh-2020-003886**

Loorbach, D. (2010) 'Transition Management for Sustainable Development: A Prescriptive, Complexity-Based Governance Framework', *Governance* 23.1: 161–83, **https://doi.org/10.1111/j.1468-0491.2009.01471.x**

Lucivero, F. *et al.* (2020) 'COVID-19 and Contact Tracing Apps: Ethical Challenges for a Social Experiment on a Global Scale', *Journal of Bioethical Inquiry* 17.4: 835–39, **https://doi.org/10.1007/s11673-020-10016-9**

Mackintosh, M. *et al.* (2016) 'What Is the Private Sector? Understanding Private Provision in the Health Systems of Low-Income and Middle-Income Countries', *Lancet* 388.10044: 596–605, **https://doi.org/10.1016/S0140-6736(16)00342-1**

Marin, A.; Stubrin, L. and van Zwanenberg, P. (2023) 'Technological Lock-in in Action: Appraisal and Policy Commitment in Argentina's Seed Sector', *Research Policy* 52.2: 104678, **https://doi.org/10.1016/j.respol.2022.104678**

Martin Hilber, A.*et al.* (2016) 'Strengthening Accountability for Improved Maternal and Newborn Health: A Mapping of Studies in Sub-Saharan Africa', *International Journal of Gynaecology and Obstetrics: The Official Organ of the International Federation of Gynaecology and Obstetrics* 135.3: 345–57, **https://doi.org/10.1016/j.ijgo.2016.09.008**

McLeod, J. (2020) 'Inside the kill zone: Big Tech makes life miserable for some startups, but others embrace its power', Financial Post: Innovation - FP Startups – Entrepreneur, **https://financialpost.com/technology/inside-the-kill-zone-big-tech-makes-life-misera-ble-for-some-startups-but-others-embrace-its-power** (accessed February 2023).

Mitchell, M. and Kan, L. (2019) 'Digital Technology and the Future of Health Systems', *Health Systems and Reform* 5.2: 113–20, **https://doi.org/10.1080/23288604.2019.1583040**

Mugo, D.M. and Nzuki, D. (2014) 'Determinants of Electronic Health in Developing Countries', *International Journal of Arts and Commerce* 3.30 (2014): 49–60, **https://www.researchgate.net/publication/272159190_Determinants_of_Electronic_Health_in_Developing_Countries**

Musiolik, J., Markard, J. and Hekkert, M. (2012) 'Networks and Network Resources in Technological Innovation Systems: Towards a Conceptual Framework for System Building', *Technological Forecasting and Social Change*, Contains Special Section: Actors, Strategies and Resources in Sustainability Transitions, 79.6: 1032–48, **https://doi.org/10.1016/j.techfore.2012.01.003**

Nelson, E., Bloom, G. and Shankland, A. (2018) 'Introduction: Accountability for Health Equity: Galvanising a Movement for Universal Health Coverage', *IDS Bulletin* 49.2, **https://doi.org/10.19088/1968-2018.131**

Nelson, E.; Waiswa, P.; Schattan Coelho, V. and Sarriot, E. (2022) 'Social Accountability and Health Systems' Change, beyond the Shock of COVID-19: Drawing on Histories of Technical and Activist Approaches to Rethink a Shared Code of Practice', *International Journal for Equity in Health* 21.1: 41, **https://doi.org/10.1186/s12939-022-01645-0**

Nenonen, S.; Storbacka, K. and Windahl, C. (2019) 'Capabilities for Market-Shaping: Triggering and Facilitating Increased Value Creation', *Journal of the Academy of Marketing Science* 47.4: 617–39, **https://doi.org/10.1007/s11747-019-00643-z**

Neumark, T. and Prince, R.J. (2021) 'Digital Health in East Africa: Innovation, Experimentation and the Market', *Global Policy* 12.S6: 65–74, **https://doi.org/10.1111/1758-5899.12990**

OECD (2019) *An Introduction to Online Platforms and Their Role in the Digital Transformation*, Paris: Organisation for Economic Co-operation and Development, **https://doi.org/10.1787/53e5f593-en** (accessed February 2023).

OECD (2014) *The Digital Economy, New Business Models and Key Features*, 16 September 2014, Paris: OECD, **https://doi.org/10.1787/9789264218789-7-en** (accessed February 2023)

Oparin, E.; Panibratov, A. and Ermolaeva, L. (2021) 'Digital Health Studies: Business and Management Theory Perspective', *Journal of East-West Business* 27.3): 234–58, **https://doi.org/10.1080/10669868.2021.1931622**

Ozalp, H.; Ozcan, P.; Dinckol, D.; Zachariadis, M. and Gawer, A. (2022) '"Digital Colonization" of Highly Regulated Industries: An Analysis of Big Tech Platforms' Entry into Health Care and Education', *California Management Review* 64.4: 78–107, **https://doi.org/10.1177/00081256221094307**

Paina, L. and Peters, D.H. (2012) 'Understanding Pathways for Scaling up Health Services through the Lens of Complex Adaptive Systems', *Health Policy and Planning* 27.5: 365–73, **https://doi.org/10.1093/heapol/czr054**

Pawson, R. (2013) *The Science of Evaluation: A Realist Manifesto*, SAGE Publications Ltd, **https://uk.sagepub.com/en-gb/eur/the-science-of-evaluation/book238842**

Peters, D.H. (2014) 'The Application of Systems Thinking in Health: Why Use Systems Thinking?', *Health Research Policy and Systems* 12.1: 51, **https://doi.org/10.1186/1478-4505-12-51**

Peters, D.H.; El-Saharty, S.; Siadat, B.; Janovsky, K. and Vujicic, M. (2009) I*mproving Health Service Delivery in Developing Countries*, Directions in Development – Human Development, Washington DC: The World Bank, **https://doi.org/10.1596/978-0-8213-7888-5**

Plsek, P.E. and Greenhalgh, T. (2001) 'The Challenge of Complexity in Health Care', *BMJ* 323.7313: 625–28, **https://doi.org/10.1136/bmj.323.7313.625**

Prado, T. S. and Bauer, J. M. (2022) 'Big Tech Platform Acquisitions of Start-Ups and Venture Capital Funding for Innovation', *Information Economics and Policy* 59: 100973, **https://doi.org/10.1016/j.infoecopol.2022.100973**

Rumbold, B. *et al*. (2017) 'Universal Health Coverage, Priority Setting, and the Human Right to Health', *The Lancet* 390.10095: 712–14, **https://doi.org/10.1016/S0140-6736(17)30931-5**

Saksena, N.; Matthan, R.; Bhan, A. and Balsari, S. (2021) 'Rebooting Consent in the Digital Age: A Governance Framework for Health Data Exchange', *BMJ Global Health* 6.Suppl 5: e005057, **https://doi.org/10.1136/bmjgh-2021-005057**

Schechter, A. (2018) 'Google and Facebook's "Kill Zone": "We've Taken the Focus off of Rewarding Genius and Innovation to Rewarding Capital and Scale"', University of Chicago, ProMarket Stigler Center for the Study of Economy and State, **https:// promarket.org/2018/05/25/google-facebooks-kill-zone-weve-taken-focus-off-reward- ing-genius-innovation-rewarding-capital-scale/** (accessed February 2023)

Schot, J. and Steinmueller, W.E. (2018) 'Three Frames for Innovation Policy: R&D, Systems of Innovation and Transformative Change', *Research Policy* 47.9: 1554–67, **https://doi.org/10.1016/j.respol.2018.08.011**

Sharon, T. (2018) 'When Digital Health Meets Digital Capitalism, How Many Common Goods Are at Stake?', *Big Data & Society* 5.2: 2053951718819032, **https://doi.org/10.1177/2053951718819032**

Sheikh, K.; Saligram, P. and Prasad, L.E. (2013) 'Mapping the Regulatory Architecture for Health Care Delivery in Mixed Health Systems in LMICs', Working Paper Series No. 26, Melbourne: Health Policy & Health Finance Knowledge Hub, University of Melbourne, **https://apsredes.org/wp-content/uploads/2013/07/REGULATORY-ARCHITETURE.pdf** (accessed February 2023)

Song, W. and Pan, Y. (2021) 'Tech Giants and New Entry Threats', Conference paper for CSWIM Workshop, 2021, **http://2021.cswimworkshop.org/wp-content/ uploads/2021/06/cswim2021_paper_81.pdf** (accessed February 2023).

Stenberg, K. *et al.* (2019) 'Guide Posts for Investment in Primary Health Care and Projected Resource Needs in 67 Low-Income and Middle-Income Countries: A Modelling Study', *The Lancet Global Health* 7.11: e1500–1510, **https://doi.org/10.1016/S2214-109X(19)30416-4**

Sudhinaraset, M.; Ingram, M.; Kinlaw Lofthouse, H. and Montagu, D. (2013) 'What Is the Role of Informal Healthcare Providers in Developing Countries? A Systematic Review', *PloS One* 8.2: e54978, **https://doi.org/10.1371/journal.pone.0054978**

Tagmatarchi Storeng, K. and de Bengy Puyvallée, A. (2021) 'The Smartphone Pandemic: How Big Tech and Public Health Authorities Partner in the Digital Response to COVID-19-19', *Global Public Health* 16.8–9: 1482–98, **https://doi.org/10.1080/17441692.2021.1882530**

Tangcharoensathien, V. *et al.* (2020) 'Framework for Managing the COVID-19 Infodemic: Methods and Results of an Online, Crowdsourced WHO Technical Consultation', *Journal of Medical Internet Research* 22.6 (26 June 2020): e19659, **https://doi. org/10.2196/19659**

Thomason, J. (2021) 'Big Tech, Big Data and the New World of Digital Health', *Global Health Journal*, Special Issue: Intelligent Medicine Leads the New Development of Human Health, 5.4 (1 December 2021): 165–68, **https://doi.org/10.1016/j.glohj.2021.11.003**

Tiffin, N.; George, A. and LeFevre, E.A. (2019) 'How to Use Relevant Data for Maximal Benefit with Minimal Risk: Digital Health Data Governance to Protect Vulnerable Populations in Low-Income and Middle-Income Countries', *BMJ Global Health* 4.2: e001395, **https://doi.org/10.1136/bmjgh-2019-001395**

Tsevelvaanchig, U.; Narula, I.S.; Gouda, H. and Hill, P.S. (2018) 'Regulating the For-Profit Private Healthcare Providers towards Universal Health Coverage: A Qualitative Study of Legal and Organizational Framework in Mongolia', *The International Journal of Health Planning and Management* 33.1: 185–201, **https://doi.org/10.1002/hpm.2417**

United Nations (2020) *Roadmap for Digital Cooperation*. New York: United Nations

van Stam, G. (2022) 'Conceptualization and Practices in Digital Health: Voices from Africa', *African Health Sciences* 22.1: 664–72, **https://doi.org/10.4314/ahs.v22i1.77**

van Winkle, B.; Solad, Y.; Vaswani, N. and Rosner, B.I. (2019) 'Navigating the Digital Health Ecosystem to Bridge the Gap from Innovation to Transformation: A NODE.Health Perspective on Digital Evidence', *Digital Biomarkers* 3.2: 83–91, **https://doi.org/10.1159/000500194**

Vimarlund, V.; Nikula, N. and Nøhr, C. (2021) 'Business Models and EHealth Social Innovations for Social Care Services: Serving the Two Sides of the Market', *Health Policy and Technology* 10.4: 100555, **https://doi.org/10.1016/j.hlpt.2021.100555**

WHO (2021) 'Global Strategy on Digital Health 2020-2025', Geneva: World Health Organization, **https://apps.who.int/iris/bitstream/handle/10665/344249/9789240020924-eng.pdf** (accessed February 2023)

WHO (2020) 'Engaging the Private Health Service Delivery Sector through Governance in Mixed Health Systems', Strategy Report of the WHO Advisory Group on the Governance of the Private Sector for Universal Health Coverage, Geneva: World Health Organization, **https://www.who.int/publications-detail-redirect/9789240018327** (accessed February 2023).

WHO (2018) *Classification of Digital Health Interventions v 1.0 - A Shared Language to Describe the Uses of Digital Technology for Health*. Geneva: World Health Organization, **https://apps.who.int/iris/bitstream/handle/10665/260480/WHO-RHR-18.06-eng.pdf** (accessed October 2022).

WHO (2016) *Monitoring and Evaluating Digital Health Interventions: A Practical Guide to Conducting Research and Assessment*, Geneva: World Health Organization, **https://apps.who.int/iris/handle/10665/252183** (accessed February 2023).

WHO (2010) 'A Conceptual Framework for Action on the Social Determinants of Health', Discussion Paper Series on Social Determinants of Health, No. 2, Geneva: World Health Organization, **https://apps.who.int/iris/handle/10665/44489** (retrieved in February 2023).

WHO; Sheikh, K.; Abimbola, S. and Alliance for Health Policy and Systems Research (2021) *Learning Health Systems: Pathways to Progress: Flagship Report of the Alliance for Health Policy and Systems Research*, Geneva: World Health Organization, **https://apps.who.int/iris/handle/10665/344891** (accessed February 2023).

Xiao, Y.; Zhao, K.; Bishai, D.M. and Peters, D.H. (2013) 'Essential Drugs Policy in Three Rural Counties in China: What Does a Complexity Lens Add?', *Social Science & Medicine* 93 (1 September 2013): 220–28, **https://doi.org/10.1016/j.socscimed.2012.09.034**

Yilla, M.; Nam, S.L.; Adeyemo, A. and Kargbo, S.A. (2014) 'Using Scorecards to Achieve Facility Improvements for Maternal and Newborn Health', *International Journal of Gynecology & Obstetrics* 127, no. 1: 108–12, **https://doi.org/10.1016/j.ijgo.2014.07.011**

Ziebland, S.; Hyde, E. and Powell, J. (2021) 'Power, Paradox and Pessimism: On the Unintended Consequences of Digital Health Technologies in Primary Care', *Social Science & Medicine* 289: 114419, **https://doi.org/10.1016/j.socscimed.2021.114419**

Photograph captions and credits

Front cover
Community health workers in Bihar, India, use the COMPREHENSIV digital health platform, developed by the Public Health Foundation of India's Hi Rapid Lab, on an Android mobile phone to screen several early-stage diseases.
Credit: PHFI Hi Rapid Lab, Hyderabad, 2021

Page 2
Community health workers in Bihar, India, use the COMPREHENSIV digital health platform, developed by the Public Health Foundation of India's Hi Rapid Lab, on an Android mobile phone to screen several early-stage diseases.
Credit: PHFI Hi Rapid Lab, Hyderabad, 2021

Page 7
Captured in 2020, this photograph depicted a field researcher from Universidad del Valle de Guatemala (UVG), who was using a mobile data collection tool for greater efficiency, during door-to-door interviews, for an antimicrobial resistance (AMR) research project in Quetzaltenango, Guatemala. Centers for Disease Control and Prevention (CDC) partners with Washington State University, and UVG, to strengthen epidemiological surveillance for AMR in Guatemala.
Credit: Nicholas S. Tenorio, Health Communication Specialist, CDC, 2020

Page 8
Community health workers in Bihar, India, use the COMPREHENSIV digital health platform, developed by the Public Health Foundation of India's Hi Rapid Lab, on an Android mobile phone to screen several early-stage diseases.
Credit: PHFI Hi Rapid Lab, Hyderabad, 2021

Page 13
A Pathfinder-trained frontline health worker working in Nairobi, Elizabeth conducts regular home visits to 40 households throughout her community—all with the help of a mobile phone. She's part of Pathfinder's initiative called "mHMtaani," or "mobile health for our communities".
Credit: Direct Relief, Nairobi, 2015

Page 20
Wislyne S. Yarh Sieh is a registered nurse and Officer in Charge (OIC) at Kpallah Community Clinic in Brewerville, Liberia. Wisylne worked as a healthcare worker during the Ebola outbreak in 2014-2015. The Ministry of Health did not have a centralized system to communicate vital information to healthcare workers across the country at the same time. UNICEF and USAID worked together to create a platform that utilized mobile phones to facilitate a two-way communications system between healthcare workers and the centralized ministry. Because of this new technology, healthcare workers across the country can receive text messages with important information about health emergencies. They are also able to use their phones to inform the Ministry of Health about the status of stocks in the clinic.
Credit: USAID, Liberia, 2020

Page 27
The WeMUNIZE programme in Nigeria is implemented by local technology start-up Black Swan Tech Ltd through USAID's Maternal and Child Survival Program led by Jhpiego. Faced with limited local record keeping and low levels of literacy and connectivity, the WeMUNIZE program uses a combination of digital record keeping and community engagement to increase early childhood immunizations.
Credit: KC Nwakalor for USAID/Digital Development Communications, Nigeria, 2019

Page 34
Young women look at their cell phones during a community meeting in Aurangabad, India. **Credit: Simone D. McCourtie/World Bank, 2009**

Page 37
Habiba Suleiman, 29, a district malaria surveillance officer, begins her work day at the health clinic where she receives SMS and GPS messages about new potential malaria cases and their locations. Thanks to this rapid and effective method of receiving information, Habiba can then go to patients' homes to test them and carry out any necessary treatment. USAID has helped provide Habiba with the tools she needs to combat malaria in Zanzibar, where the disease was once the number one reason behind child death. By equipping Habibia with a phone, tablet and motorcycle, USAID ensures that she can quickly get to patients and record data regarding their health and the state of their home. For Habiba, this work is critically important: "In life, health is important over everything."
Credit: USAID, Zanzibar, 2015

Page 38
Captured 2013 in Ethiopia, this image depicts the left hand of the photographer, U.S. Centers for Disease Control and Prevention's (CDC), Center for Global Health, Public Health Advisor, Samra Ashenafi, holding a Garmin GPS-60 device, while he was participating in a micro-planning session, focused on an Ethiopian vaccination campaign. These Global Positioning System (GPS) devices are needed, when including the geospatial coordinates of remote settlements, involved in the country's national immunization plans.
Credit: Samra Ashenafi, CDC, Ethiopia, 2013

Page 43
Star Arogya Digi Seva initiative is an assisted telemedicine programme being implemented by the Public Health Foundation of India and is supported by Star Health and Allied Insurance. The programme aims to improve quality and access to healthcare through bridge personnel trained in providing assisted tele-medicine solutions.
Credit: Public Health Foundation of India, Chennai, 2021

For more information please contact:

Dr Priya Balasubramaniam
Public Health Foundation of India
priya.balu@phfi.org
Centre for Sustainable Health Innovations, Singapore/India
priya@sustainablehealthinnovations.com

Dr Gerry Bloom
Institute of Development Studies, UK
g.bloom@ids.ac.uk

Mutual Learning for Mixed Health Systems