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NARRATIVE/SYSTEMATIC REVIEWS/META-ANALYSIS

The Role of Telehealth in Enabling Sustainable Innovation and Circular Economies in Health

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Abstract

Digital health interventions, including the use of telehealth augmented by artificial intelligence (AI), support an increasingly broad range of improvement goals for prevention and treatment. Limitations obstructing the many digital benefits of the targeted healthcare innovations from reaching their full potential include the lack of robust usability and user-centered design, nimble regulatory policy, and lack of adequate high-quality evidence and methodologies to evaluate the performance generalization and clinical robustness. We explore health innovation using different value systems and solutions proposed to overcome the fundamental limitations arising in the data value system. We propose a new telehealth paradigm and incorporate intervention designs, which combine clinical innovation with innovation in data resource development. Machine learning and AI have the potential to enable circular economies for digital and health innovation, in which sustainable solutions can be offered within a data-enabled collaborative and shared digital ecosystem. Alignment of industry standards, adjustments to regulatory policies, and the embrace of new governance models for telehealth-based innovation are essential for this new approach for health innovation scaling, clinical adoption, and social innovation.

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The world of healthcare was compelled in 2020 to adapt quickly when faced with a global pandemic crisis. Many countries adapted with telehealth and shifted to the widespread provision of healthcare utilizing telephone and video consults or remote patient management and triaging. These were important, as in-person patient visits became limited and medical offices were forced to close or maintain social distancing.[1,2]

Telehealth extends beyond the doctor–patient relationship, defined as the delivery and facilitation of health and health-related services. Examples include medical care, provider and patient education, health information services, and self-care via telecommunications and digital communication technologies.[3] Healthcare provision through telehealth includes telephone support, messaging, smartphone applications, internet-based approaches, and remote monitoring.[4] There is a distinction between the terms telehealth and telemedicine (TM), with TM considered a subset of telehealth, and strictly referring to the provision of clinical healthcare services using digital-based communication technologies. Aspects of data capture during remote TM care are significantly limited. The transition to telehealth is key for the adoption, scaling, clinical robustness, and sustainability of digital health interventions (DHIs). This transition is needed to generate evidence in support of safe use, integration of DHIs and tools into clinical practice and to support patient care and outcome improvements.

Digital health interventions support a broad range of first-order improvement results, including the discovery of new knowledge on disease and treatments using artificial intelligence (AI), real-world evidence (RWE) for health technology assessments and clinical trials, better informed clinical and policy decisions, patient engagement and continuity-of-care, expanding access to care, and transformation of healthcare.[5,6] Digital phenotyping is an emerging DHI

paradigm that relies on smartphones and wearables to support the continuity of care and improve scalability.[7–15]

Multiple reviews have examined the positive evidence for effectiveness, cost-effectiveness, patient perceptions, and effects of telehealth on mortality. However, several ongoing concerns remain.[16–18] An often-overlooked aspect when examining telehealth's role in digital innovation is the social value created by DHIs, which can be leveraged to deliver social innovation. Social innovation can be understood as long-lasting changes through scaling and adoption. The changes include the organization and functions of health systems, governance transformations, innovation in care models, and the re-organization of care processes, which might include institutional and system transformations.[19] Social innovation initiated by DHIs can impact social values such as creating a trusting and trusted health system.[20]

The integration of the DHIs mitigates the frequently small telehealth project results that are limited in time or region and often do not translate into sustainable changes in the organization and function of health systems.[21]

Social Value of Digital Health Interventions

Transformational changes can be achieved in population health through DHIs that are designed, developed, and scaled with social value and social innovation as endpoints. Approaching health innovation from the perspective of social value in addition to clinical and economic value can help industry and regulators map the true complexities involved in achieving the quadruple aim. Four interdependent goals consist of (1) enhancing patient experience and safety, (2) improving population health, (3) reducing costs and preventing loss of revenue, and (4) improving wellness and satisfaction of healthcare workers.[22] Restoring the balance in data ecosystems with DHI scaling and robust clinical practice integration, can help prevent data asymmetries,[23] and enable patient-centered collaboration models, leveraging cooperation and continuity between DHIs towards circular economies in health.[24–26]

A circular economy is based on three principles, driven by design: eliminate waste and pollution, keep products and materials in use, and regenerate natural systems. A circular economy aims to drive sustainability, equity, and digital inclusion,[27] translating to further transformation cycles and resilience. Accelerating the use of AI for knowledge discovery is needed[28–35] to encourage and foster cooperation and implement industry standards that translate knowledge discovery into readily available, high-quality service interventions.

Standards and practices in healthcare must be reevaluated to enable intelligent transformation cycles. By applying knowledge supported by evidence that fuels these transformation cycles,[36] the data value challenge must be addressed.[37,38]

Designing and delivering business and social value through health innovation technologies, such as AI, is a challenge.[39,40] The challenge of sustaining and scaling value manifests in the gaps between AI investments supporting telehealth and the variable and poor performance generated from clinical trials, clinical practice integration, and clinical robustness.[41–43] Inclusion and equity are critical for global-scale social innovation initiatives to succeed [44] Failure to deliver inclusive digital development for the benefit of patients, communities, providers, or innovators, undermines applications and sustainability of AI discovery.[45]

Often it is difficult to distinguish which of the value systems contributes more to the needs of patients, thus making scaling more complex. Consider for example an AI-backed referral device or application for patients with congestive heart failure, which besides offering support to the care continuum and patient pathway selection can also capture reliable and valuable continuity-of-care data. These data are required to transition clinical reasoning to clinical coherence, and precision medicine, and to support meaningful, scalable, and sustainable DHI.[46–48]

Medical Device Development Challenges

From a medical device development perspective, value demonstration and scaling are about proving robust performance in improving patient outcomes under real-world conditions. Typically, this requires costly randomized controlled trials or a new pragmatic clinical trials ecosystem capability, which is challenging as few have the knowledge or the experience to run large trials.[49] Evaluating telehealth clinical robustness often falls below accepted evidence thresholds for improvement due to the lack of proper expertise and investments. A strategy that might work to overcome this bottleneck is to approach innovation from the perspective of a clinical-economic evaluation,[40,50] which can facilitate the introduction of new devices into clinical practice by proving efficiency improvements at an embryonic phase of digital transformation.[39] This approach can simplify things if new innovations demonstrate social, economic, and business values before they impact clinical practice value.

Data Value Predicament in Health Innovation

Data value is a circular dependency between DHIs and social innovation, which aims to deliver inclusive data. Addressing this data value predicament in health innovation offers flexibility within innovation ecosystems, to help close the implementational gaps between design and delivery. Telehealth-driven innovation can deliver a better data ecosystem. However, current regulatory policy paradigms that focus on DHIs as standalone medical devices do not facilitate the proposed data-coupled approach to expand access to care and strengthen continuity and

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patient-centric models. Efforts to regulate AI prescriptively are both celebrated and vilified,[51] perceived as decelerating progress until we better understand the true impact of these technologies and prepare health systems to support innovative ideas. While standalone medical device regulation aims to distribute liability more evenly across the stakeholder spectrum and thus increase the regulatory impact on healthcare outcomes,[52,53] it often deflects attention from the core issues of the liability process, for example, for a telehealth device designed to triage patients, to an encounter with outpatient clinics, to hospitalization, and post-discharge digital care. The current paradigm fails to promote trust and the safe development and integration of DHIs.[54–56]

Device-centered regulatory policies neither address access-to-care efficiencies nor reverse the course of increased health disparities. Instead, they often lead to new digital inequities for vulnerable groups.[57,58,59] Digital health interventions delivered in the current policy when they exacerbate existing inequities, can lead policymakers to more regulatory control and a spiral of deceleration in the digital health economy and health innovation.

Real-world evidence,[33,39] is shaped into an engineered 'ground truth', artificially augmented and synthesized[60,61] to simulate temporal context and longitude[62] – conditions necessary to measure performance against desired patient outcomes. This approach is not sustainable, as it is both resource-intensive and fails the tests of explainability and reproducibility.[63] Trial designs based on RWE have the potential to increase scaling efficiency and reduce the cost of innovation.[64] Capturing and transferring value along the innovation supply chain with data sharing is key to delivering trust and performance.

Importance of Regulatory Sandboxes

Regulatory sandboxes (a published regulatory approach that allows testing of innovations under a regulator's oversight) enable accelerated learning about opportunities and risks that a particular innovation carries and develop the right regulatory environment. Regulatory sandboxes test innovative technologies, products, services, or approaches, which are not compliant with the existing legal and regulatory framework.[65] Policies such as regulatory sandboxes can help with controlled acceleration and scaling. Sandboxes require instruments that provide legal flexibility, for example, in the form of experimentation clauses (i.e. temporary rules allowing experiments to be conducted). Regulatory sandboxes may not, however, resolve the obstacles encountered in scaling innovations because of the poor design of data ecosystems and lack of appreciation of the complex elements involved in the innovation. Scaling AI will continue to be challenging until information sharing becomes a standard of care.

The Innovator's Predicament

There will likely be little improvement in the safety and quality of healthcare systems without resolving the data value predicament. New value margins can be created and shared equitably by effectively addressing the data value predicament – including equity and inclusion in data samples used for clinical and policy decisions and facilitating connected innovation.

Supporting the Workforce of the Future

Hospitals and health systems continue to face healthcare workforce and staffing shortages, with job vacancies of specialized nursing personnel increasing by as much as 30% between 2019 and 2022. Insufficient resources for training, poor work-life balance, utilization inefficiencies, and scope of practice limitations on healthcare providers contribute to shortages and provider burnout.[66]

Technology can profoundly influence work processes – mitigating, for example, the burdens associated with redundant paperwork or low clinical value tasks. This depends on integrating and streamlining voluminous regulations, and mitigating the increasingly apparent role ambiguity, in part due to siloed DHIs. Abundant evidence suggests that doctors waste over two-thirds of their time doing paperwork causing much frustration to patients and staff, waste, and non-added-value.[67,68]

The array of regulations that govern healthcare overwhelms people in the industry. Almost every aspect of the field is overseen by one regulatory body or another, and sometimes by several. Healthcare professionals feel that they spend more time complying with rules that direct their work than doing the work itself.[69,70] The growing shift of tasks done by various members of the healthcare team, and the relaxation of licensure and credentialing during the COVID-19 pandemic are causing much confusion and misalignment given ambiguous role clarity. This role clarity is a key facet of interprofessional collaboration, which is crucial for effective, safe, and reliable interprofessional team functioning and exceptional service.[71,72]

Technology has the potential to enhance throughput and reduce costs.[73] There will likely be improvements in skill/task alignment (working at the top of one's license). Teamwork will be prioritized, and data analytics and data-driven decision-making, and workflow optimizations will become increasingly the norm.[74,75] All this focus on labor arbitrage is built on the assumption that tasks can be easily sorted by licensure or training without sacrificing quality. This leads to an insidious equivalence being developed in which healthcare professionals are seen as potential substitutes for one another. Significant differences in training length and intensity are casually being washed away. Pandemic-inspired changes have greatly lessened these restrictions allowing more flexibility in which less trained people

are doing jobs of credentialled and highly trained providers. Time will tell if this innovation comes at the price of quality of patient care, industrial action, and burnout rates.[76]

Well-designed telehealth platforms can enable better team coupling and data-driven awareness and mutual accountability towards the group's task – better servicing of patients. Real-time data analytics and transparency can help improve clinical workflow and rebuild team trust and encourage truth-telling by healthcare team members.

Limitations of the Regulatory Policy Paradigm for Telehealth

There are several challenges to the present regulatory policy approach for telehealth, which broadly ignore the domains and intersections of, the sciences of human factors, implementation science, improvement science, safety and risk management sciences, and more. Regulatory policy paradigms for telehealth do not provide recommendations for action. For example, regulators are concerned that the growth of telehealth will lead healthcare providers to only offer telehealth, thus reducing the available supply of providers physically located in given geography; out-of-state telehealth providers will 'come in' and take low acuity and private-pay patients/patient dollars away from local providers, which could cause them to close, move, or care for fewer patients as a percentage of total patients. Furthermore, out of state telehealth providers will operate outside of the local regulatory policy paradigm, thereby weakening state and local regulatory influence and oversight. This is especially true for behavioral health and pharmacy care, but can generally lead to problematic telehealth policy paradigms in, for example, requirements that telehealth providers have a physical office location (or see patients in person x times over x time period). None of these factors have been adequately addressed, despite their impact on the regulatory policy paradigm, and thereby the political-economic market in which telehealth and DHIs exist.

Discussion

The DHI market is driven by the current device-centered regulatory paradigm rather than access to a functioning data-driven innovation ecosystem. While the pandemic accelerated the demand for digital innovation and the inadequate means and policies to scale DHIs to social value demonstrations, the transfer of value and sustainability in the current innovation ecosystems continues to be compromised. This raises legitimate questions about value.[77]

This calls for wide reform, nimble regulation, and sustained innovation to address the innovators and data value predicaments. A digital innovation acceleration superstructure that connects DHIs across the care continuum, comprising standards, aligned and enabling telehealth-based governance and regulatory policies that can (1) enable data resource innovation, (2) address the pressing governance and transparency issues inhibiting DHIs from expanding into the space of community-health and public health, (3) lend structure to real-world data for trusted evidence, (4) provide a new pathway to radically different structures in delivery models, (5) reduce healthcare worker's workload, (6) improve outreach, engagement, and prevention at scale, all while (7) collecting structured data.

Health innovation interventions can impact healthcare and public health systems but only if they positively impact outcomes that matter to patients.[78] Examples include patient-reported health-related quality of life, symptom severity, satisfaction with care, resource utilization, hospitalizations, readmissions, and survival. Resource utilization is a measure of how much of the available resources one is currently using. It can help healthcare payors and executives to plan how to utilize resources more effectively in order to ensure that the organization is being as productive as possible.[79] Efficient organizations enhance the service, quality, and flow for patients in their interactions with the healthcare system. There are limited data investigating the impacts of telehealth on these outcome measures.[78] There are many good studies investigating in-person care, for example, heart and lung failure diseases such as myocardial ischemia, asthma, and more.[80]

Digital health interventions are likely to succeed if they are developed directly and cooperatively in partnership with end-users – i.e. patients and front-line clinicians. The new telehealth paradigm for participatory, connected, and interactive innovation should address these needs. Telehealth can deliver the necessary data validation when coupled with the use of smart mobile devices, telehealth, or mHealth apps while enabling the integration of digital devices into a digital care continuum where they can be evaluated for clinical robustness with RWE.[81]

Telehealth should be considered a safe alternative to some traditional face-to-face medical procedures.[80] Given the trends in technological advances in the past decades, it is likely that healthcare reliance on telehealth will continue to grow. These findings can be utilized to guide policymakers and service evaluation.

Several key research questions remain unanswered. These include the need to evaluate the risks of different telehealth patient care interventions, utilize longitudinal and adaptive study designs, and with heterogenous, diverse, and large sample sizes to follow up with participants. There is growing evidence for comparing in-person care to telehealth with favorable results, evaluating telehealth results using in-person care as the comparator or pre-telehealth care as the gold standard.[40] Ongoing and future audits must monitor the veracity of these assumptions and make that part of all external accreditation.

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A longitudinal study design will allow researchers and health practitioners to ensure that the treatment options do not yield long-term unforeseen concerns. Finally, studies with an increased number of participants are encouraged for the results to be more generalizable. In the case of longitudinal studies of in-person care, the multi-factorial elements known to impact outcomes are known to suffer from a variety of biases.

Conclusions

Current evidence-generation systems of DHI require an overhaul. Embracing new value systems is important to reforming current regulatory shortcomings and fostering connected innovation acceleration. Further development of normative, legal, and regulatory frameworks is necessary to further systems medicine and translational precision medicine,[82] promote broad adoption of common standards across healthcare modalities (whether digital or in-person) and sustain systems change to promote health innovation.[83]

Solving these problems will require a focus on three key domains:

1. improving the integration of and access to high-quality data from traditional clinical trials, electronic health records, and personal devices and wearable sensors;
2. restructuring clinical research operations to support and incentivize the involvement of patients and front-line clinicians; and
3. articulating ethical constructs that enable responsible data sharing to support improved implementation (78)

Much needs to evolve regarding data ecosystems and the integration of RWE into existing clinical practice and gold standards of care. This is in contradistinction to regulating single devices at the atomized level. Despite the abundance of standards for the classification of clinical observations, there are not sufficient standards to evaluate the new telehealth paradigm. Appropriate standards must aim to support the integration of DHIs into a patient-centric continuum, to provide for connectivity and interaction among DHIs, and to enable the seamless transition of activity from one telehealth service to another. Creating incentives for integration and data sharing will be essential to achieve more timely and equitable improvement in health outcomes.

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