

Rationale for Establishing a Digital Health Research Center at Mayo Clinic

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The Mayo Clinic center for digital health (CDH) employs nearly 700 individuals, bringing solutions and expertise to enable Mayo Clinic's digital transformation. Leaders and their respective teams provide critical digital expertise in areas such as agile business methodology, artificial intelligence and machine learning, data and analytics strategy and governance, digital product and platform strategy and management, digital practice enablement, and user experience and customer support. Mayo Clinic established the predecessor to CDH (the Center for Connected Care) in 2012 to provide expertise, knowledge, and strategic direction for telehealth and virtual care services, bringing together efforts that had previously been spread throughout sites, divisions, and departments across the organization.¹ In 2019, CDH was established, bringing together the Center for Connected Care with other teams across the organization that were focused on data and analytics, artificial intelligence and machine learning, knowledge and content management, and digital user experience.

Mayo Clinic offers an entire suite of ready-to-use solutions that clinicians, care teams, patients, and consumers use today. These solutions span patient engagement and access, virtual care, care guidance, platforms, and analytics.¹ Patient engagement and access solutions include patient self-scheduling, digital check-in, secure access to personal medical records, secure messaging with care team members, and wayfinding. Virtual care solutions include home hospitals, remote patient monitoring, and virtual visits (video, phone, and e-consult). Care guidance solutions include knowledge delivery assets like AskMayoExpert and clinical calculators.

Platform solutions include public-facing websites and authenticated patient platforms such as the patient web and the Mayo Clinic mobile application. Analytics solutions include tools such as the COVID-19 response dashboards and tools to reduce bias. With partners across Mayo Clinic, CDH enables the programmatic, operational, infrastructure, and administrative support for these digital health products and services. In addition, it provides subject matter expertise and guidance on digital health-specific regulatory, legal or adherence, contracting, licensing, credentialing, revenue or billing, information technology, product (selection, deployment, and support), government relations, public affairs, training, education, and research needs.²

As Mayo Clinic established itself as a digital health care organization, there was a realization that research must remain central to this transformation effort. The core of this model is the ability to understand the value and outcomes of our digital health products and services in a meaningful, intentional, systematic, and perpetual way. This approach includes the development of leading indicators of performance, with insights from these indicators regularly integrated into the product or service lifecycle. Mayo Clinic Center for Digital Health Research and Outcomes Unit was established in April 2021, to support and encourage the clinical scientific investigation of digital health care and its delivery within Mayo Clinic practice. The unit's mission is to advance digital health care through meaningful study of the reliability, validity, efficacy, safety, effectiveness, quality, service, and clinical and economic value of digital health practice in the context of overall health care delivery.

In service of this mission, the unit aims to foster and support multidisciplinary teams in

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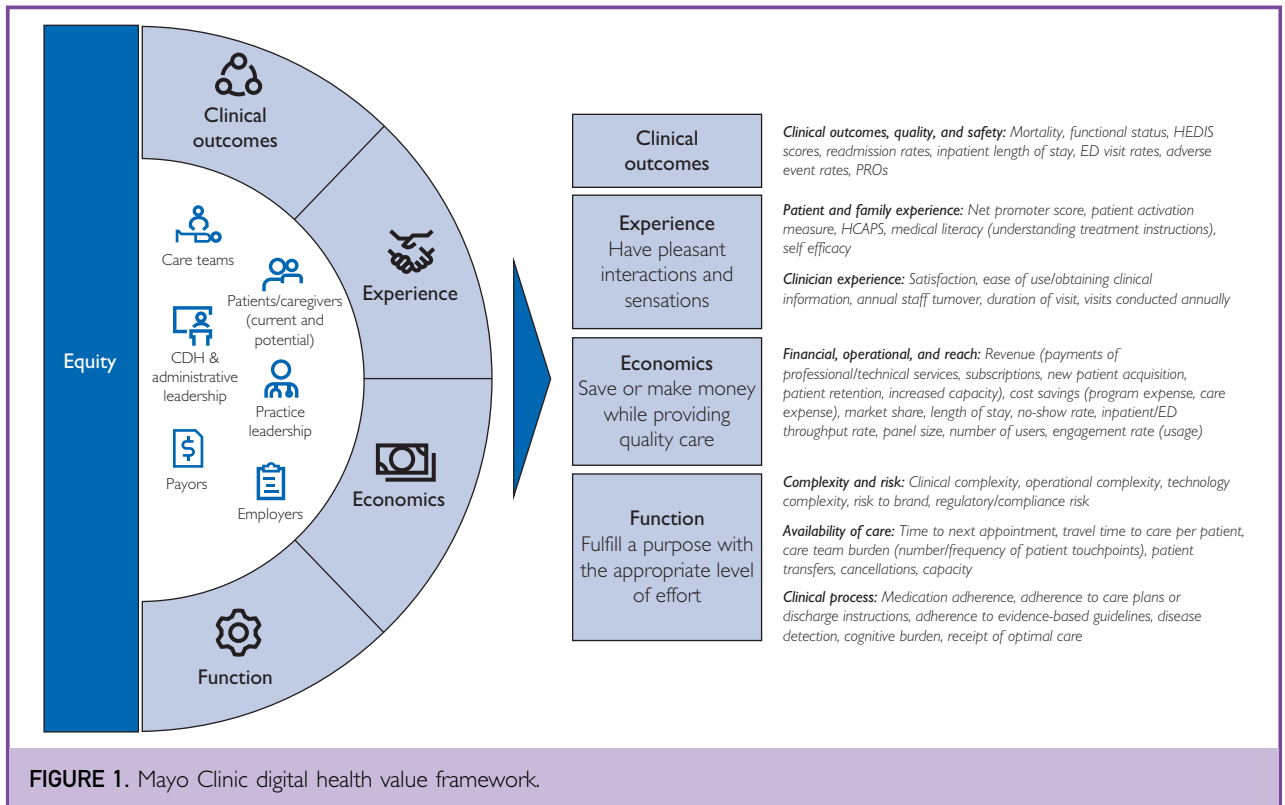
delivering the necessary insights for the application and advancement of digital health care. To this end, it aims to intentionally define, measure, and communicate how these digital health products have affected our patients, care teams, and practices. These aims are accomplished through operational, analytical, and medical subject matter expertise in digital health care delivery to define relevant digital health outcome measures, conduct value analysis, integrate value measurement into the digital product lifecycle, and provide study development and management support for integrated, coordinated, and prioritized digital health evaluation and research. The unit leverages a value framework to provide a holistic view of potential measures across a variety of outcomes of interest—health outcomes, experience, economics, and system or process function—grounded in equity and safety (Figure 1). This framework has been adapted from existing quality models,³ and progressively refined over time. The appropriate evaluative methods are chosen depending on the type, goals, objectives, and effect of the initiative, the available resources, and the research question being addressed. The approaches range from ongoing and routine measurement that is scalable and flexible, to highly structured evaluations that ask and answer specific questions in a way that generates generalizable knowledge. Example means of evaluation include randomized controlled trials, prepost studies, observational studies, quasi-experimental studies, cost-effectiveness or cost-benefit analysis, qualitative studies, health impact analysis, and dashboards or scorecards. With that, the unit has 3 primary focus areas to support efforts across that continuum:

- (1) Continuous product value and effect measurement that is focused on supporting our CDH product teams directly in continually defining and assessing the key performance indicators for their products and portfolios. This information is then used to enhance product capabilities and to drive ongoing investment decisions (ie, support ongoing investment planning to inform if Mayo Clinic should continue to invest in each product at current levels, increase levels, evolve the product value proposition, or narrow its investment).

The key areas under this domain are cost-effectiveness and cost-utility analysis, process evaluation, quasi-experimental analyses of outcomes, dashboards, and scorecards. A recent example is the contribution to quality and value frameworks for virtual care.³

- (2) Digital health research and insights that is focused on applying systematic methods to evaluate opportunities for enhanced clinical effect through digital means. These findings are also translated into tangible practice recommendations to help inform practice change on the basis of evidence. Foundational elements of structured, systematic evaluation include supporting qualitative, observational, and prepost studies and real-world prospective (randomized and pragmatic) trials both within CDH and from across the clinical practice. In addition, the unit helps to define and prioritize key topics for investigation, coordinate and facilitate the conduct of studies, communicate findings to facilitate practice insights, and translate discoveries into practice recommendations. A recent example is the video telemedicine diagnostic accuracy study.⁴
- (3) Scholarly advancement that funding that is focused on supporting academic pursuits in the digital health care space and helps to provide visibility into Mayo Clinic's work across the practice. Research personnel screen for external and internal grant funding, match funding with protocols, and offer digital health research awards. Moreover, the unit provides mentorship opportunities for clinicians, scientists, and allied health staffs to build digital domain expertise and to provide a means of organic collaboration to accelerate research. Opportunities are also provided for medical students and postgraduate medical trainees to engage in scholarly digital health research. A recent example is the contribution to professional medical education and virtual care.⁵

To accomplish these goals, the unit maintains a collaborative infrastructure that enhances institutional capacity to effectively perform studies involving digital health care



delivery. Skills development among interested collaborators and partners is advanced through individual investigator assistance and mentorship in protocol development, grant acquisition, study conduct, analysis, publication, and results dissemination. Resources include those to facilitate the design, development, implementation, conduct, analysis, publication, and dissemination of digital health-based research and research-related projects relevant to departments and centers across Mayo Clinic, Mayo Clinic health system, Mayo Clinic college of medicine and science, and partner and affiliate organizations. This model allows for effective administration and coordination of research through a centralized team, serving as a trusted resource for investigators across the Mayo Clinic organization. The unit partners associated closely with Mayo Clinic center for the science of health care delivery that provides robust access to expertise across numerous fields (applied clinical informatics, data science, dissemination and implementation science, economics, engineering, ergonomics, human

factors, experiential learning, health care policy, health services and outcomes research, health economic analysis, human-centered design, information technology, knowledge synthesis, population health, qualitative research, and social and behavioral science). Additional resources are available through active collaborations with Mayo Clinic center for clinical and translational science activities (CCaTS), one of the 50 medical research institutions funded through the National Institutes of Health Center for Translation Science Activities awards. Through MC CCaTS, collaborators have access to educational resources (certificate, masters, and PhD programs) and research resources (including a clinical research unit and core facilities, and consultative resources in biostatistics, epidemiology, and research design). Additional resources available either directly through the unit or through internal partnerships include study coordination and study personnel for the efficient management of patient screening, subject recruitment, regulatory adherence, fiscal oversight, data integrity, and data safety monitoring.

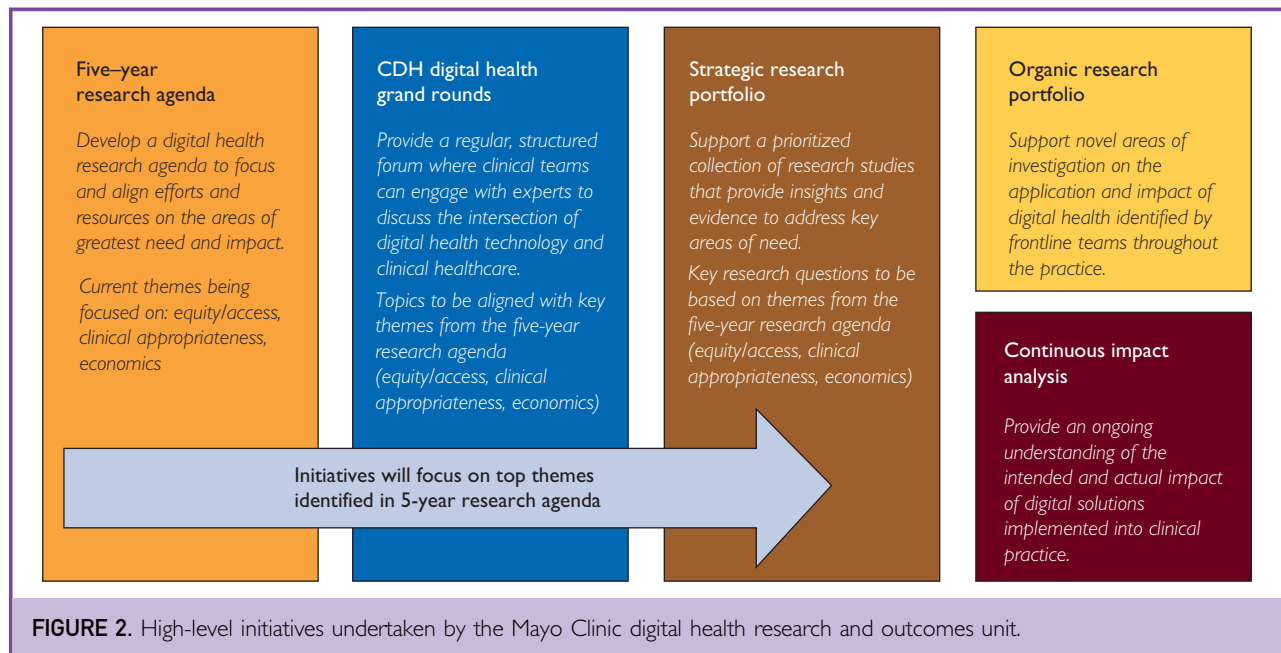


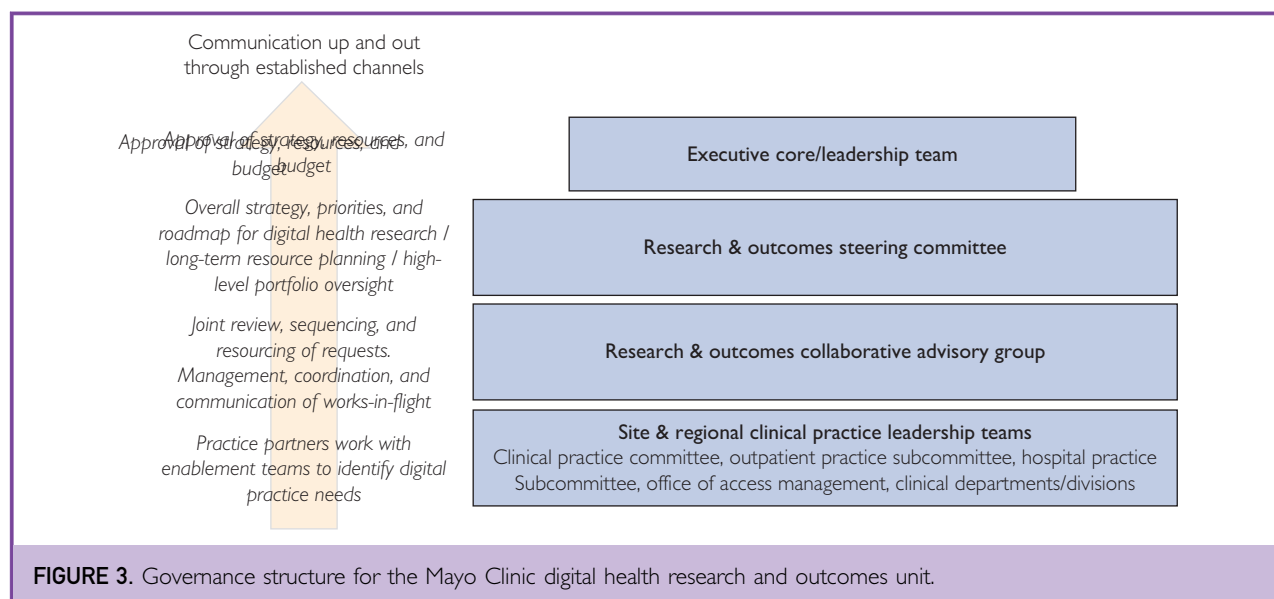
FIGURE 2. High-level initiatives undertaken by the Mayo Clinic digital health research and outcomes unit.

Proactive communication about the effect of digital health products is vital to inform future implementation and product development. Research discoveries are regularly shared through presentations at regional, national, and international digital health and clinical conferences, peer-reviewed research publications, and CME conferences, seminars, and proceedings. In the 24 months since the unit's inception, it has helped to initiate and conduct over 30 studies and contributed to over 70 manuscripts spanning topics such as clinical effectiveness, clinical access, and the effect of new care, staffing, and training models. To accelerate these efforts, the unit is establishing a digital health research agenda, a 5-year research agenda to focus and align research efforts.⁶ This approach helps to proactively identify critical areas for evaluation and ensures that evidence is available to inform key conversations and decisions. In addition, it targets resources devoted to digital health research to arenas with the greatest perceived effect and establishes a balanced research portfolio. The key themes identified through this process include clinical appropriateness, parity, equity or access, and economics. Modestly prioritized themes were related to licensing, legal and adherence, and patient engagement. The lesser prioritized themes were digital scalability, the

potential for fragmentation in the health care system, team dynamics, and potential issues of waste, fraud, and abuse. Figure 2 shows the relationship between different initiatives across the unit's focus areas.

The unit is directed and overseen by a highly qualified staff and is guided by a multidisciplinary steering team (Figure 3). The unit is led by a medical director, who oversees and directs the continued planning, development, and operations of the unit and engages physicians and other health care providers in the research process, assisting them in the development and selection of digital health-related study ideas and projects and serving as a mentor to investigators as appropriate. The unit's ongoing operations are coordinated and managed centrally by a director and a team within the unit that acts as liaisons, connecting collaborators with internal and partner resources. These resources provide assistance for study design, biostatistics, ethics, subject advocacy, volunteer recruitment resources, general research education and training, and study-specific conduct needs. They also ensure that all necessary administrative and financial processes are in place before conducting the study.

The steering team is comprised of a multidisciplinary team of physicians, career



scientists, and administrative leaders. This team is responsible for providing guidance on the governance and direction necessary for the development and maintenance of quality research and outcomes programs. They inform the overall direction for the development of program goals, objectives, and standards set by the unit's leadership team and ensure the delivery of such activities are coordinated and managed appropriately, effectively, and efficiently. To affect these goals, the steering team endorses the unit's comprehensive strategy and roadmap for the ongoing study and evaluation; provides guidance on roadmap activities across teams and stakeholders; provides guidance on the prioritization of incoming requests and new development (roadmap items); and endorses the recommended staging of projects proposed by the leadership team.

A literature review did not present other published examples of digital health research centers to allow for comparison. However, through personal communication, other similar centers are in various stages of development at Thomas Jefferson University, Emory University School of Medicine, University of Washington, Geisel School of Medicine, Dartmouth-Hitchcock Medical School, Stanford University, School of Medicine, University of Pittsburgh, Massachusetts General Hospital and Harvard University.

CONCLUSION

More research in digital health is needed to answer critical questions during the next several years that could help satisfy patients, providers, payers, and politicians, and lay the foundation for permanent telemedicine policy.⁷ The formulation of centers for digital health research at academic institutions of health care with personnel and resources to advance digital health care through meaningful study of reliability, validity, efficacy, safety, effectiveness, quality, service, and clinical and economic outcomes may be one solution.

POTENTIAL COMPETING INTERESTS

Given their role as Editorial Board Member, Dr. Bart Demaerschalk, had no involvement in the peer-review of this article and has no access to information regarding its peer-review. None of the other authors have conflicts of interest to disclose.

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