

Charter

Summer 2024

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Overview

Connected Health is an approach to health maintenance, healthcare, and health management in which digitally-enabled products, services, and/or interventions are designed around the needs of those who are healthy to those who require care. It includes the sharing and exchange of health-related data so that all people can maintain their health or receive care in the most proactive and efficient manner possible.

Connected Health requires all necessary stakeholders to be able to 'connect' through 1) devices and technologies outside the walls of the clinic, 2) data and information exchange networks, 3) digital communication, engagement, and collaboration platforms, and 4) pathways to action and intervention, as suits the users'/patients' needs and preferences.

Connected Health offers the potential to maintain health where it exists and transform the sick care system into a healthcare system, improving health outcomes and health equity while reducing the burden of disease and healthcare costs.

Vision

To improve the overall health of all individuals through digitally-enabled products, services, and interventions that collectively connect health.

Mission

To address fragmentation in connected health across the healthcare ecosystem by convening a broad and inclusive range of stakeholders necessary to move from sick care to whole health. The Connected Health collaborative community (CHcc) will bring together all stakeholders to reimagine a system based on trustworthy data, information, and interventions. Together, this collaborative community will use interdisciplinary expertise, research, and case studies to develop and demonstrate best practices and advance harmonized approaches to speed the ethical, effective, equitable, and safe use of connected health to improve lives - for everyone.

Goal and Strategy

The goal of the CHcc is to convene the many stakeholders necessary to establish and implement a shared vision of connected health that is equally accessible and effective for everyone. As with all collaborative communities, the goals and efforts may evolve over time as we learn more and see more opportunities for impact.



This will require focused and persistent pursuit of:

- Optimizing the human-centered use of digital health innovation across contexts of use and wherever it can do the most good for all people, in particular, medically underserved and populations with health disparities
- Establishing global best practices for successfully developing and deploying connected health products, services, and interventions
- Supporting the advancement of the appropriate infrastructure, regulatory science, reimbursement pathways, incentives, and commercial practices to foster success in the real world and at scale
- Fostering a diverse and inclusive community of experts in pursuit of our vision and mission

CHcc will help move health promotion and care into the home which is strategically aligned with the values of US Food and Drug Administration's Health Care at Home Initiative and Home as a Healthcare Hub program. CHcc will also align with and augment other government programs including, but not limited to the Veteran's Health Administration's Home Based Primary Care and Whole Health programs; the Center for Medicare and Medicaid Services Acute Hospital Care at Home program, Hospital Without Walls initiative, and Chronic Care Management resources; and the US Department of Housing and Urban Development's Older Adult Home Modification Program (OAHMP).

Mechanisms for sustained engagement of and impact on the community will include an annual strategic review of success to date and opportunities for improvement going forward.

Membership

The CHcc is open to all organizations who share our vision and are actively working to achieve it. All member organizations within CHcc will serve as equals, and the collaborative will always look to include at least two patient advocacy organizations. Member organizations will constitute a diverse range of companies and institutions from across industry sectors, patient groups, government agencies, and academia representing all of the stakeholders necessary for successful workstream execution and subsequent implementation. CHcc will encourage varied representation from clinicians, clinical scientists, engineers, data scientists, and developers within those companies and institutions. Patients and community groups will also be diverse and inclusive. Finally, CHcc will pursue broad engagement from a variety of government agencies and offices including, but not limited to, the US Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), the



Veterans' Health Administration (VHA), the Office for the National Coordinator for Health IT (ONC), the Office for Civil Rights (OCR), the National Institute of Standards and Technology (NIST), the National Institutes for Health (NIH), Health Resources and Services Administration (HRSA), the Indian Health Service (IHS), and the US Department of Housing and Urban Development (HUD).

To maintain their membership, organizations must adhere to the <u>Digital Medicine</u> <u>Society (DiMe) core values</u> and actively participate in:

- At least one project working group in the active CHcc portfolio
- Selecting and/or serving on the 12-seat CHcc Steering Committee. A Steering Committee member serves for an annual cycle, and will meet via video conference quarterly.
- The dissemination and implementation of all best practices and harmonized approaches for connected health developed by the collaborative

Governance

All decisions made by the collaborative community are supported democratically through a simple majority verbal or email vote of participating members, with dispute adjudication exercised before the full community. No member may vote by proxy. In case of a tie, the Steering Committee may cast an additional vote to support pursuing initiatives that improve the overall health of all individuals through connected health approaches, and modalities.

The 12-member Steering Committee will be responsible for guiding the overall direction of the community and providing oversight and accountability for impact against our goals listed above.

The charter may be amended from time to time upon the request of participating members subject to written approval by vote of the membership.

DiMe serves as the Convener for CHcc and the Consumer Technology Association (CTA) serves as the Hosting Partner. DiMe as Convener is responsible for:

- Providing general oversight of CHcc
- Administrative and operational support
- Securing funding and providing financial oversight



- Recruiting and engaging an open, diverse, and inclusive collaborative community
- Implementing mechanisms for sustained engagement of the community
- Securing the impact of CHcc activities against the community mission and goals
- Ensuring compliance of CHcc activities with DiMe's charitable mission

CHcc will be co-chaired by a leadership representative from DiMe and CTA.

Project working groups

CHcc activities will be conducted by a rolling series of project working groups of relevant subsets of the community. They will focus on developing and disseminating action-oriented deliverables as well as developing, implementing, and evaluating demonstration projects, where appropriate. Project working groups will be multi-stakeholder and will be characterized by:

- Ensuring all perspectives are incorporated, including representatives from regulatory agencies, payers, and the patient community alongside industry and academic experts
- Practicing evidence-based approaches that incorporate regulatory science, where indicated
- Championing equity and justice through the goals and impact of all project working group activities and deliverables
- Developing and deploying strategies and resources for dissemination and implementation

The output of all project working groups will be publicly available and open for public comment. Products may include, but are not limited to:

- Frameworks, processes, and blueprints to support standardization and implementation
- Impact case studies, practical use cases and implementation projects to model harmonized best practices
- Return on investment, forecasting and other models to incentivize innovation and adoption



- Frameworks and pathways for potential digital health business models to foster success at scale
- Educational resources to drive adoption at scale and for the benefit of all people
- Peer review publications to expand the necessary scientific foundation for the field
- Template contracts, agreements, and specific pre-competitive pilots to foster collaboration
- Recommendations and feedback to regulators, policy-makers, and payers through the public comment process
- Methods, results, and evaluations of demonstration projects

Working groups may address topics that include, but are not limited to:

- Developing reference data architectures and technical implementation guides to support the connection of all stakeholders and digital solutions
- Establishing best practices that advance care at home
- Identifying payment models and optimizing pathways to payer coverage for connected health activities and pathways
- Advancing approaches to aging at home
- Leveraging food as medicine as part of connected health
- Supporting caregiver support, health, and wellness
- Commercializing preventative health as a viable care pathway

Measuring success

Impact will be assessed at both the collaborative community and working group level through fit-for-purpose frameworks that evaluate:

- Process and participation measures
 - Ex: Regular benchmarking of the diversity, inclusion, and equitable engagement of members
- Output measures



• Ex: The on-time delivery of high-quality, action-oriented products and solutions; the launch of pre-competitive pilots

Outcome measures

Ex: The inclusion of outputs into regulatory practice and/or guidance;
the establishment of fit-for-purpose reimbursement pathways and
commercial incentives for Connected Health; the implementation of new
health and care pathways within the Connected Health paradigm

About the Digital Medicine Society

<u>DiMe</u> is a global non-profit and the professional home for all members of the digital medicine community. We are committed to advancing the ethical, effective, equitable, and safe use of digital technologies to redefine healthcare and improve lives. Together, we tackle the toughest digital medicine challenges, develop clinical-quality resources on a tech timeline, and deliver these actionable resources to the field via open-source channels and educational programs.

For more information about DiMe and to view our work, please visit our website.

