Home as a Health Care Hub

Executive Summary of Research Process and Findings

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Executive Summary

The Home as a Health Care Hub initiative aspires to reimagine device use in the home environment as an integral part of the health care system, with the goal of achieving better health outcomes for all people in the U.S. Its vision is that all people can optimize their health through medical technologies where they live. Fostering innovation in health and wellness solutions at home is especially important in light of today's many health care challenges including an aging patient population, an epidemic of chronic disease, a growing shortage of health care providers, a contraction of care facilities, and rising costs of care. This initiative adopts a holistic perspective, encouraging the consideration of wellness and medical needs of people across the entire lifespan from prenatal to end-of-life care.

A key component of this initiative is the creation of an Idea Lab for developers to visualize how their medical devices fit into the lifestyles and homes of people as well as integrate well with other health technologies. These medical devices could serve purposes of prevention, diagnosis, treatment, rehabilitation, and monitoring. In addition to focusing on the integration of health technology, the work also identifies critical features of the home itself that could promote wellness, manage disease, support healing and recovery, and maintain health. It also identifies important barriers for which users can begin imagining possible solutions.

Diabetes was chosen as a test case because it is associated with a very large burden of morbidity, mortality, and cost. According to the Centers for Disease Control and Prevention (CDC), diabetes costs the U.S. health system more than $300 billion annually, representing a 35 percent increase over the past decade, which is disproportionately borne by underserved communities. In addition, its effects cross many medical disciplines, its care includes a wide variety of medical devices, and it is a condition where improvements in its management in the home environment can have a significant impact on ultimate outcomes. Diabetes impacts people of all ages and disproportionally affects medically underserved, low-income and rural populations in the U.S. Therefore, this study addresses a diverse population, and it is anchored within the context of affordable housing, a scenario with challenging design constraints.

The discovery phase of this initiative commenced with a comprehensive literature review across four domains: clinical, technology, housing design, and affordable housing. Input was received from subject matter experts and representatives of patient organizations, professional societies, medical device and consumer technology developers, and regulators. The U.S. Food and Drug Administration (FDA) convened a public meeting and opened a docket for public comments. This literature review was assimilated into an overview of the current state of established and emerging diabetes health technologies used at home, home design considerations needed for the inclusion of these technologies in the home, and home design conditions beyond home-use of health technologies. This overview was validated and enhanced based on input from three constituencies individuals with diabetes and their care partners with health access constraints, medical device and consumer technology developers (including those with experience

developing wearables and home use devices), and health care providers with experience providing care to individuals living with diabetes. The team also obtained insights from visiting two affordable housing sites. Insights from the discovery phase were synthesized into core health needs, a spectrum of user needs, technology considerations, home design conditions, and key takeaways. From this discovery phase, a basic Design Concept Package was developed with eight experience principles and twelve preset design concepts to set the stage for an Idea Lab.

Discovery Phase Insights

Aspects of Managing Diabetes[1]

Managing diabetes requires active involvement from individuals as well as their care partners, health care team, and others in their support network. Aspects of managing diabetes can be conceptualized in five categories, outlined in the table below.

Table 1: Aspects of managing diabetes

Healthy Lifestyle Maintenance	*Care Coordination*	*Education & Social Support*	*Clinical Assessment*	*Prevention of Complications*
• Physical activity • Healthy weight • Sleep hygiene • Nutrition and healthy eating • Mental health • Smoking cessation • Alcohol moderation • Stress reduction • Social support accommodation • Activities of daily living (ADLs)	• Routine provider team visits & telehealth • Regular nursing care • Home aide / family care partners • Community health worker • Referrals to specialists and therapists	• Patient education • Health coaching • Peer group support • Family • Community programs	• Glucose levels monitoring • Blood pressure monitoring • Cholesterol levels management • Pedal pulses measurement • Medication management (including insulin) • Weight and fitness trending • Lab testing	• Retinal screening and management • Foot / wound care • Kidney disease screening and management • Neuropathy screening and management • Fall prevention • Infection prevention • Medication management • Achieving and maintaining healthy weight, fitness, and nutrition

People Living with Diabetes Have a Range of Different Needs[2]

Numerous aspects of how people living with diabetes function were considered to inform an analysis of the impact of the built environment on health and wellness. These aspects included those related to people's physical, cognitive, sensory, and (digital- and health-specific) literacy functioning, along with a heterogenous set of corresponding needs, including level of independence and need for care support.

[1] *Developed from core health needs and spectrum of user needs literature review [1] (see References), input from the three constituencies described above, and visioning workshops with clinical experts.*

[2] *Developed from core health needs and spectrum of user needs literature review [1] (see References), visioning workshops with clinical experts, and input from steering committee*

Technology Considerations[3]

Digital health technologies (DHTs) used at home for diabetes include Mobile Apps (e.g., weight loss apps that store weight data and track trends over time, nutrition-tracking apps to help monitor food intake); DHTs that are wearable (e.g., fitness sensors that monitor heart rate, continuous glucose monitors); other sensor-based DHTs that are portable but not wearable (e.g., smart mats that measure health data such as body temperature, foot ulcers and weight, smart speakers for reminders and alerts); and home-embedded technologies (e.g., smart thermostats with automatic settings to optimize energy use and comfort, refrigerator light sensors that provide food-related routine information). Challenges for health technologies used at home include those related to hardware and software requirements, user interface design, interoperability, data privacy, risk for patient harm, personalization, and the quantity and quality of data needed for advanced analytics including machine learning. Moreover, rural areas and low-income communities are particularly impacted by issues such as affordability constraints, user adoption among groups experiencing socio-economic disadvantages, physical space, internet dependency and connectivity.

Housing Design Conditions[4]

Housing design considerations are a key mediator between health needs (clinical assessment, healthy lifestyle and self-management, complication prevention, provider visits and care coordination, and education / support) and technology opportunities (ranging from apps, to wearables, smart objects and home embedded technologies). Nine housing design considerations were identified as umbrella categories for innovators to consider while designing for homes that can support use of medical devices and be a hub for health care.

[3] *Developed from technology considerations literature review [2]* (see References)

[4] *Developed from home environment and affordable housing literature review [3] (see References)*

Figure 2. Summary of health needs, housing design considerations and technology

The evidence shows that housing design plays a crucial role in determining how well individuals with diabetes adapt to and manage their condition at home.

Discovery Phase Conclusions

There is a growing body of evidence around both the effective use of medical devices at home and elements of the built environment that promote diabetes prevention and care. However, there is very little evidence at the intersection of these two fields, which is an opportunity for research and innovation. Additionally, the dependencies between health needs, technology needs, and home environment needs have not been investigated or published in literature.

The following are key takeaways from field research and workshops that included individuals with diabetes, care partners, providers and device developers:

1. **Accessibility and affordability** are significant challenges.
2. **Mobility** is a primary concern for individuals with diabetes.
3. **Data privacy and security** are concerns for all stakeholders.
4. **Connecting to providers** is a key priority for individuals with diabetes and providers.
5. **Awareness of existing technologies**, let alone emerging technologies, is lacking for individuals with diabetes, care partners, and providers. Where technologies are in use, training, support, and maintenance are a concern.
6. **Current devices** are generally not designed to capture standardized data (**interoperability**), not well connected (**data transmission and sharing**), and are not easy to use (**usability**). This makes integration into the home both a challenge and a design opportunity for patients as well as providers who use medical data to inform patient care decisions.

7. Diabetes care takes a **high emotional toll** on both individuals with diabetes and care partners.
8. **Baseline conditions** (e.g., reliable power and internet access, space for medical devices) are not a given and cannot be taken for granted.
9. **Living conditions** were a key concern for providers but were not top of mind for individuals with diabetes, care partners or device developers. Device developers shared not thinking about home environments comprehensively during their design process.

Design Concept Package

Experience Principles

Based on the exploration conducted in the discovery phase, principles were developed as an anchor for understanding what experiences the ideal home as a health care hub would support. The experience principles will also serve as a guidepost for innovators to experiment with different health technologies and environmental conditions to address the current constraints of affordable housing conditions in relation to future state aspirations.

These principles emerged as important for the Ideal Home as a Health Care Hub:

1
Protect personal privacy and dignity both digitally and physically, establishing clear boundaries of where, how and with whom information is shared and care is provided in the home

2
Prioritize accessibility and affordability, ensuring the availability of cost-effective solutions for low-income individuals and those living in under-resourced and rural areas

3
Accommodate a wide spectrum of care needs, including those related to wellness, disease prevention and reversal, complex co-morbidities, and advanced disease states

4
Minimize disruptions in care continuity, reducing the potential for device failures and malfunctions that can result in disruption of care

5
Integrate technologies seamlessly into the home, enabling the use of intuitive, unobtrusive platforms.

6
Empower individuals to effectively manage their care needs, increasing agency, and reducing care burden to help patients to live healthier longer

7
Provide a comprehensive understanding of an individual's health, including lifestyle factors, to enable a holistic approach

8
Enable a personalized approach, offering a range of options that meet individual preferences, lifestyles, and care needs

Preset Design Concepts

To design medical devices that work seamlessly within the home, one first seeks to understand the constraints of the home itself. Based on insights from the discovery phase, 3 housing typologies (manufactured homes, multi-family housing, and single-unit homes), 5 key spaces (living rooms, bedrooms, kitchen, bathroom and entrance) and multiple zones within those spaces were identified. Twelve preset design concepts were created based on different combinations of housing typologies and spaces. The preset design concepts illustrate a range of living conditions in which device developers can visualize opportunities and test different ideas.

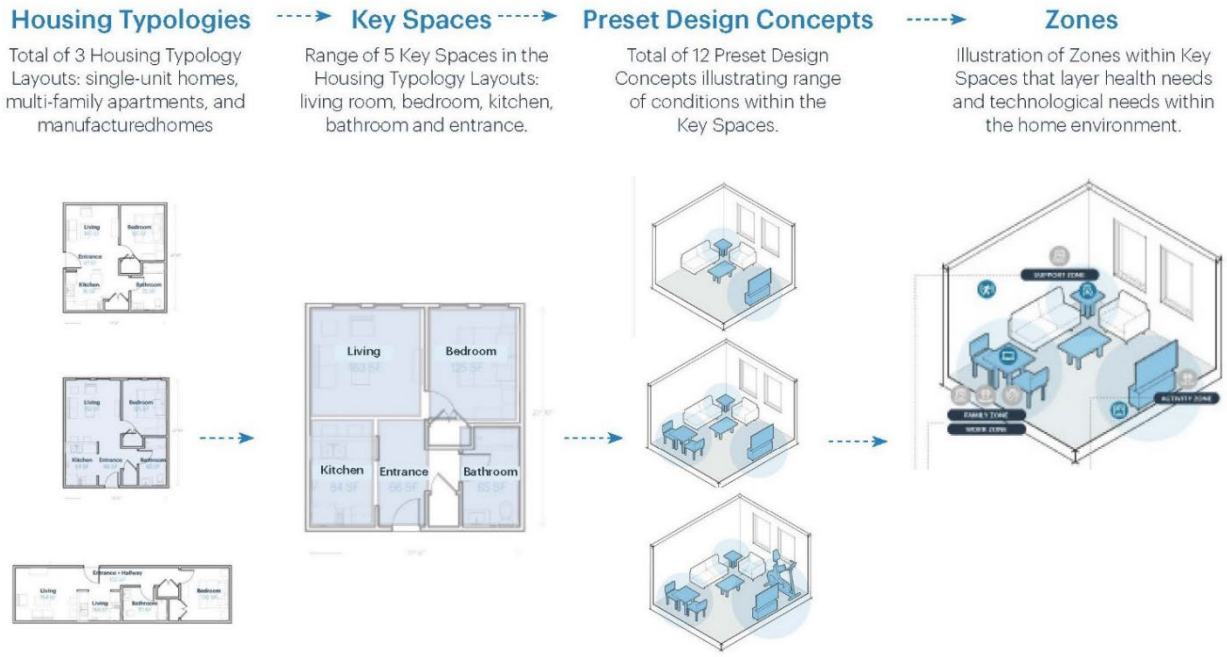

Figure 3. development of preset design concepts

Home as a Health Care Hub Idea Lab

Building on research from the discovery phase, the Home as a Health Care Hub Idea Lab was created to catalyze meaningful innovation that can enable people to optimize their health and wellness where they live. While the Idea Lab focuses on diabetes as a test case, this initiative is intended to catalyze solutions supporting prevention, wellness, and management of a variety of chronic diseases and other medical conditions.

The Home as a Health Care Hub Idea Lab includes:

- **Fictional personas** representative of a range of persons living with diabetes in affordable housing. *The personas incorporate a variety of information related to medical device use, caregiver support, daily activities, and more. Each persona reflects different situations that collectively cover the range of medical device use (e.g., home hemodialysis, wound vacuum, glucometer, continuous glucose monitor, blood pressure monitor, etc.) observed with and expressed by real people living with diabetes during the discovery phase.*

- **Lilypad™**, which is a virtual reality (VR) experience of homes reflecting the range of affordable home models (e.g., single family home, mobile home, apartment) observed with real people living with diabetes during the discovery phase. *The Lilypad allows users to virtually explore the homes and visualize first-hand how the personas manage daily living with diabetes. Using information from the personas, users can act out daily tasks in the VR space. This is intended to help innovators visualize opportunities for improved and novel solutions. Users can also download the VR files and bring their own innovations into the space for usability and other evaluations.*

- **Considerations for Innovators** based on research from the discovery phase. *This is intended to support meaningful medical device innovations that all people can access to optimize their health at home.*

- **Research and Insights** from the discovery phase will be added to the Home as a Health Care Hub Idea Lab over time.

Conclusion

There is an untapped potential to bring innovation in medical technology and home environments together to better support wellness and health care needs of all Americans. The research to date shows a significant gap in literature focusing on the integration of knowledge and practice of these fields. Bringing medical, digital, and physical infrastructure together in an integrated systems solution, with the human at its center, can help optimize the home to promote, support, and maintain health. The Home as a Healthcare Hub Idea Lab is a launch point for medical device developers, patients and care partners, providers, regulators, and the housing design community to explore this opportunity.

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