## Approach to Human-Centered, Evidence-Driven Adaptive Design (AHEAD) for Health Care Interventions: a Proposed Framework



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Human-centered design (HCD), an empathy-driven approach to innovation that focuses on user needs, offers promise for the rapid design of health care interventions that are acceptable to patients, clinicians, and other stakeholders. Reviews of HCD in healthcare, however, note a need for greater rigor, suggesting an opportunity for integration of elements from traditional research and HCD. A strategy that combines HCD principles with evidence-grounded health services research (HSR) methods has the potential to strengthen the innovation process and outcomes. In this paper, we review the strengths and limitations of HCD and HSR methods for intervention design, and propose a novel Approach to Human-centered, Evidence-driven Adaptive Design (AHEAD) framework. AHEAD offers a practical guide for the design of creative, evidence-based, pragmatic solutions to modern healthcare challenges.

*KEY WORDS:* health services research; human-centered design; implementation science; intervention design.

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H uman-centered design (HCD) offers a novel approach for developing solutions to "wicked problems" in healthcare that involve complex interactions between population health demands, rapidly advancing technology, financial pressures, and workforce strain.<sup>1</sup> By definition, wicked problems, such as childhood obesity, physician burnout, and access disparities, lack one-off solutions.<sup>2</sup> Due to their complexity and interdependence, working to solve single aspects of these problems often affects other components,<sup>2, 3</sup> and attempts to address multidimensional issues in public health and healthcare using traditional research methods lead to gaps between research and practice.<sup>2, 4</sup> A framework integrating HCD principles and practices with evidence-grounded research methods has potential to generate interventions acceptable to stakeholders that positively influence outcomes of interest.<sup>4, 5</sup>

### WHAT IS HUMAN-CENTERED DESIGN?

Human-centered design is an empathy-driven problem-solving approach with inspiration, ideation, and implementation stages.<sup>6</sup> HCD examines human desirability (what the user really needs) and uses those insights to develop technologically and economically feasible solutions.<sup>6</sup> The design process values "failing fast and often," prioritizes outside-the-box thinking over prescribed processes to generate unique solutions, and has been increasingly used in fields like marketing and product design.<sup>6, 7</sup> While HCD can rapidly produce pragmatic interventions, this approach typically does not integrate frameworks and rigorous methods central to evidence-based health services research. As such, adoption of HCD principles by health services researchers has been relatively slow.<sup>4</sup>

Two recent systematic reviews examine the emergence of HCD methods in healthcare. Both Altman 2018 (n = 24 studies) and Bazzano 2017 (n = 21 studies) noted the feasibility of using HCD in multiple healthcare domains and across diverse patient populations and conditions to produce solutions that may not be considered in traditional research settings. Both reviews found that most instances of HCD use in healthcare contexts were technology related. Importantly, the reviews noted discrepancies in quality and methodological rigor among the studies and found that few studies evaluated the solutions derived using HCD. The valuate care delivery in multidisciplinaryse limitations in HCD methods present barriers to wider healthcare acceptance and adoption.

## HEALTH SERVICES RESEARCH METHODS FOR INTERVENTION DESIGN: STRENGTHS AND LIMITATIONS

When used appropriately, health services research (HSR) methods produce effective, evidence-based interventions.

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Developed in response to complexities in modern healthcare settings, HSR utilizes qualitative and quantitative methods to improve and evaluate care delivery in multidisciplinary healthcare fields and considers psychosocial factors, access, cost, quality, and health outcomes<sup>8, 9</sup> to test interventions. Recognized ways to deal with complexity and human uncertainty in HSR include consideration of concepts like causal inference,<sup>10, 11</sup> treatment effect heterogeneity,<sup>12, 13</sup> and regression to the mean.<sup>14</sup> Theoretical frameworks, particularly those from implementation science,<sup>15–17</sup> guide delivery and evaluation of interventions. HSR approaches incorporate rigorous testing and re-testing to lend credibility and proof of prior causality when designing new interventions; validated records of past failures and successes can inform predictive models and provide insights when considering solutions.

Employing HSR methods, however, does not ensure successful implementation and evaluation.<sup>4, 18–20</sup> Implementation science has documented countless cases of failure to scale evidence-based interventions, and users often adapt interventions to suit their environment or needs, potentially affecting the fidelity of intervention delivery.<sup>21, 22</sup> When brainstorming and designing interventions prioritizing spread or scale, traditional methods can prevent consideration of unique or creative solutions.<sup>4, 23</sup> For example, focusing on "average patients" disadvantages patients who represent vulnerable minorities,<sup>24, 25</sup> and designing for common healthcare scenarios overlooks insights from unusual or exceptional cases.<sup>7, 26</sup>

### HUMAN-CENTERED DESIGN: STRENGTHS AND LIMITATIONS

HCD addresses many gaps evident in HSR. Because the HCD process begins by exploring user desires and motivations, interventions developed using HCD may be more desirable and feasible to implement and sustain. HCD emphasizes the user's (e.g., patient, provider, or caregiver) needs throughout the design process. By meeting users in spaces they live, work, or play; learning about their experiences; valuing their insights throughout the design process; and drawing inspiration from analogous fields, HCD exposes teams to unique possibilities and creative solutions.<sup>27-30</sup> HCD nearly always involves interdisciplinary teams that harness expertise from diverse fields to provide a range of perspectives.<sup>27–30</sup> Additionally, HCD typically uses rapid prototyping, testing, and iteration-a practical alternative to time- and resource-intensive steps required by traditional research.<sup>6</sup> Public health research methods like Intervention Mapping and Community-Based Participatory Research (CBPR) also engage users and patients in interven-tion design processes.<sup>29, 31, 32</sup> The distinction between these research methods and HCD lies in the nature of community involvement; CBPR values long-term, collaborative relationships between research teams and communities, while HCD focuses less on design team-community integration and more on gathering insights and involving stakeholders at strategic points to produce usable and desirable products or interventions.<sup>29</sup>

Applying HCD to healthcare settings presents challenges. Structures and ethical requirements within traditional academic settings such as institutional review boards (IRBs), legal contracting, and protection of confidentiality place necessary constraints on human-centered design teams, forcing compromises on a flexible and rapidly iterative process.<sup>5, 33</sup> Funding agencies may be skeptical of HCD's unconventional methods, although organizations like USAID and the Bill & Melinda Gates Foundation are beginning to support projects grounded in HCD.<sup>34</sup> Finally, a lack of widespread understanding and variation from traditional research processes makes publication of HCD intervention work in peer-reviewed journals difficult, limiting the dissemination and long-term evaluation of such designs. Table 1 outlines the similarities and differences between traditional research and human-centered design.

### AHEAD FOR HEALTH CARE: A PROPOSED FRAMEWORK

A framework combining principles of empathy-driven HCD with evidence-grounded HSR methods has the potential to generate pragmatic, high-impact healthcare interventions.<sup>4, 5</sup> Fig. 1 presents an Approach to Human-centered, Evidence-driven Adaptive Design (AHEAD) for healthcare. This framework was initially developed for the *Stanford Presence 5* project, which demanded a combination of HSR and HCD methods.<sup>35</sup> Table 2 illustrates how the AHEAD framework was used in study activities for this project. Each component of AHEAD is described below. After defining a problem and assembling an interdisciplinary team, information gathering activities draw on evidence and inspiration to generate a knowledge base for synthesis. Guiding principles inform the

Table 1 Comparison of Intervention Design Steps Using Traditional HSR vs. HCD Methods

Traditional HSR	Human-centered design	
Define the research question Review existing evidence (e.g., examine available health system quality and cost data, conduct patient/clinician surveys or inter- views)	Seek inspiration through observations, interviews, researcl (e.g., observe workflows where the intervention will take place, interview patients and other caregivers in their homes, review published evidence, observe analogous settings)	
Design an intervention guided by established theory (e.g., considering the relationship between context or behavior and outcomes, or process and outcomes)	Ideate by cycling between brainstorming, prototyping, and testing (e.g., discuss possible solutions within the team, develop physical prototypes, solicit feedback from end-users)	
Test the effectiveness of the intervention (e.g., randomized controlled trial)	Implement and evaluate in an iterative fashion (execution, evaluation, evolution)	

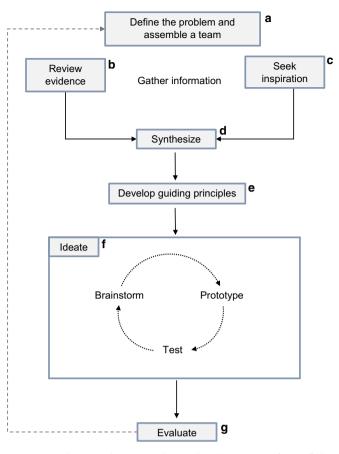


Figure 1 Approach to Human-centered, Evidence-driven Adaptive Design (AHEAD). After defining a problem and assembling an interdisciplinary team (a), information gathering activities draw on evidence (b) and inspiration (c) to generate a preliminary knowledge base for synthesis (d). In the design phase, teams establish guiding principles (e) and ideate (f), which involves rapid iterations through brainstorming, prototyping, and testing cycles to develop an intervention that is subjected to rigorous evaluation (g).

design phase, which involves rapid iterations through brainstorming, prototyping, and testing cycles to develop an intervention that is subjected to rigorous evaluation.

# Step 1: Define the Problem and Assemble a Team

What Problem is the Team Interested in Solving? Who Can Help Solve it? In step 1 of AHEAD, elements from HCD and HSR are integrated to define the problem. These two processes approach problem identification from opposite ends of the inquiry spectrum. Health services researchers form defined research questions and hypotheses at the project's outset and remain neutral and objective when working with subjects. In HCD, designers search for problems through need-finding activities. The design process often begins with in-depth exploration into user needs to identify a problem requiring a design solution. This approach leads to insights about overlooked problems but lacks the theoretical grounding and systematic approach of traditional research methods.<sup>5</sup> In public health and healthcare settings, the process of need-finding might involve qualitative interviews with patients and physicians, which generate valuable themes and typically require IRB approval.<sup>5</sup>

Both HCD and HSR approaches have well-established methods for need-finding, but this process is given greater emphasis in HCD (which may explain one observation that interventions developed with design thinking have greater satisfaction, usability, and effectiveness than traditional interventions).<sup>30</sup> Incorporating diverse perspectives is essential during problem identification-and assembling an interdisciplinary team is an integral part of AHEAD. Many reviews of HCD in health emphasize the importance of assembling a diverse team within and outside of academia and including stakeholders touching multiple problem aspects.<sup>27-30, 36</sup> Purposeful assembly of interdisciplinary teams can prevent deviation toward familiar designs.<sup>27, 36, 37</sup> HSR also values interdisciplinary teams, but team member expertise often stays within medical and academic fields. When using AHEAD, teams should include the expansive range of voices more typically found in HCD. For example, one project examining childhood asthma management included not only physicians and public health researchers on their team, but social workers and design scholars as well.<sup>38</sup> Although each team member may have different roles and expertise, there should be one AHEAD team often works together instead of team members working separately on their expertise-specific components.

AHEAD framework domains	Stanford Presence 5 Project	Primary method	Outcomes
Define the problem and assemble the team (a)	- Problem: Time constraints, technology, and the administrative demands of modern medicine often impede the human connection that is central to clinical care	HCD HSR	- Clarification of needs (e.g., need for simple, scalable, evidence-based intervention); cohesive re- search team with diverse perspectives to inform intervention development
	<ul> <li>Team: Clinicians, health services researchers with implementation science expertise, communication science researchers, anthropologist, linguist, and medical educators</li> <li>Team Process: Engage in team-building exercises to</li> </ul>	HCD HSR	
Review evidence (b) and seek inspiration (c)	highlight individual skills, expertise, and perspective - Review Evidence: Secondary research through a systematic review of interpersonal interventions in health care ( $n = 73$ )	HSR	Formative research that generated a preliminary list of 31 evidence-based practices (questions or actions) that enhance physician presence with patients
	- Gather Evidence/Seek Inspiration: Interviews and observations of diverse primary care encounters (27 observations across 3 clinics)	HCD HSR	
	<ul> <li>Seek Inspiration: Interviews with professionals in non-medical fields to provide analogous perspectives</li> </ul>	HCD	
Synthesize (d) - Synthesize evidence and information ga during Inspiration phase to identify a refur practices that enhance physician presence - Delphi panel of 14 national experts to p evidence according to patient experience,	- Synthesize evidence and information gathered during Inspiration phase to identify a refined list of	HCD HSR	A list of 8 practices, reviewed and validated by experts to clearly enhance physician presence with patients
	<ul> <li>Delphi panel of 14 national experts to prioritize evidence according to patient experience, provider experience, and implementation feasibility</li> </ul>	HSR	Paritie
Develop guiding principles (e) and ideate (f)	- Brainstorm: Journey mapping and framework development to scope design principles and opportunities (e.g., daily clinic flow from patient/ provider lens)	HCD	A novel and scalable intervention, grounded in evidence, to help clinicians cut through the challenges of contemporary clinical care and forge meaningful connections with their patients
	- Brainstorm: Co-creation sessions with 10 physicians to develop initial prototypes	HCD	connections with their patients
	<ul> <li>Prototype: User feedback sessions with diverse providers inside and outside of clinic to test the feasibility and acceptability of preliminary intervention designs</li> </ul>	HCD HSR	
	- Test: Live prototyping in varied clinics to assess implementation and maintenance metrics	HCD	
Evaluate (g)	- Multi-site pilot of the intervention to determine its effect on patient and clinician experience	HSR	Evidence about effectiveness and implementation of intervention

Table 2 Case Example AHEAD Framework: The Stanford Presence 5 Project

After assembling an interdisciplinary team, establishing a supportive, cohesive dynamic is essential.<sup>39</sup> HCD emphasizes team building as equally as team assembly,<sup>7</sup> while HSR often prioritizes assembly over cohesion. The field of team science identifies several characteristics of effective teams and strategies to strengthen team dynamics that can be applied within AHEAD.<sup>40</sup> Broadly, interdisciplinary teams share a strong vision and goal; create communication channels for defining roles, assigning responsibilities, and resolving conflict; establish trust; and promote fun through team-building exercises and celebrations of success. Activities to strengthen team dynamics include highlighting individual strengths, checking in during group meetings, and setting the expectation that every team member can and should contribute.<sup>40</sup>

### Step 2: Gather Information through Evidence and Inspiration

What is the Experience of Users Dealing with this Problem? What Strategies Have Been Tested in the Past? After defining the problem and assembling a cohesive interdisciplinary team, the researchers begin information gathering to identify themes for potential solutions. In this phase, AHEAD incorporates methods from both HCD and HSR. Traditional research typically involves systematic or exhaustive reviews of the medical literature to examine previous evidence.<sup>41</sup> In contrast, HCD inspiration activities use direct observation and immersion in the field to expose the design team to typical and unusual user experiences.<sup>5, 7, 27, 29, 30, 36</sup> Teams can also observe and interview individuals outside healthcare who have "analogous experiences" (i.e., similar or relatable challenges) to describe or inspire solutions with implications in healthcare.<sup>27, 36, 42</sup> AHEAD recommends reviewing existing research and evidence while also seeking inspiration from users (with special consideration for patients), extreme cases, and analogous fields to highlight themes or topics that may be overlooked in traditional evidence bases.

#### Step 3: Synthesize

What Common Themes Emerged from Information Gathering? What Values Will Guide the Team throughout the Rest of the Design Process? Formative information gathering from evidence review and inspiration generates a comprehensive understanding of the problem and preliminary ideas about intervention structure and content. Next, in the synthesis phase, the team identifies emerging themes and insights arising from both methods or that showed up disproportionately in one over the other. This process should include critical review of gathered evidence to evaluate past successes and failures, consider how real users might react to potential interventions, and flag themes meriting further exploration.

After gathering evidence and inspiration from a wide range of perspectives, the team should solicit feedback from outside individuals on their synthesis and any conclusions drawn. HCD acknowledges the value of outside perspectives to avoid information silos and "groupthink" within teams.<sup>27, 43</sup> HSR methods often use structured approaches for synthesis such as Delphi panels, a validated method for quantifying expert opinion through multiple rounds of independent ratings. Typically, researchers conduct Delphi panels to generate consensus around clinical guidelines or quality indicators,<sup>44, 45</sup> but they can also be applied to the design of innovative healthcare delivery interventions.<sup>35</sup> When seeking opinions, teams should include diverse voices (e.g., gender, race-ethnicity, and expertise) and gather both quantitative (e.g., rankings of feasibility) and qualitative feedback.

## Step 4: Intervention Design: Guiding Principles and Ideation

# How Can the Team Rapidly Iterate to Design a Meaningful Intervention?

*Guiding Principles* After synthesizing findings and before entering the HCD-driven ideation phase, the team establishes guiding principles and defines the scope of the problem space for their intervention. Agreement on principles like the degree of evidence-backing, inclusiveness and sensitivity to diversity, and budgetary constraints helps ground and focus the team before ideation. HCD strategies for creating guiding principles include writing a team mission statement or brainstorming values that the intervention should reflect (e.g., easily adopted, minimal training, appropriate for diverse settings). Teams can also use more traditional frameworks to ensure that the intervention content aligns with an evidence-based or theoretical model. These HCD- and HSR-inspired activities also strengthen the collaborative dynamic established during team assembly.

*Ideation* After establishing guiding principles, the research team goes through several rounds of ideation—rapid cycles of brainstorming, prototyping, and testing. In HSR contexts, researchers sequentially design and test a pilot before refining the intervention and studying it in a formal trial. In HCD, the ideation phase is characterized by flexibility and speed. The team aims for quantity rather than quality of ideas and creates sacrificial prototypes for learning purposes. This emphasis on creative output has proved successful in the business world; IDEO, a global design company, found that that when teams

iterate on five or more ideas, they are 50% more likely to successfully launch a product or solution.<sup>46</sup>

*Brainstorm* During early prototype brainstorming, all ideas are welcome, and team members should suspend disbelief to extend creative boundaries. Brainstorming with multiple team members helps incorporate diverse perspectives and generate ideas rooted in different disciplines. Specific guidelines for brainstorming published by HCD leaders include sketching, movement between ideas posted around a room, and creation of and interaction with rough physical prototypes to boost creativity and generation of a large quantity of ideas (100 ideas in an hour-long brainstorming, preliminary ideas can be organized to combine ideas or elements of ideas in logical ways. This is best done visually (e.g., physically rearranging ideas on index cards) to reveal connections between ideas or concepts.<sup>7</sup>

*Prototype* The team then progresses to prototyping. Rapid prototyping refers to the cycle of quickly creating ideas out of cheap and disposable materials, soliciting feedback from potential or analogous users in a convenient setting, and incorporating that feedback to refine ideas and create new prototypes.<sup>7</sup> Complementary activities include storyboarding (drawing the journey of the intended user interacting with the prototype).<sup>47–49</sup> and role-playing (acting out the intended users' interactions with the prototype).<sup>50</sup> Prototype design sessions with users and stakeholders, including physicians, patients, family members, and health system leaders, can yield insights beyond those considered by the design team.<sup>36</sup>

*Test* After development, prototypes are tested with end-users. Unlike HSR, testing during ideation does not incorporate control groups or formal evaluation measures. This process is a low-cost and efficient way to gain insights about early prototypes. When applying these methods to healthcare settings, however, ethical considerations limit contact with patients and caregivers, and safety concerns often prohibit the use of rough prototypes in clinics. In some circumstances, it may be possible to test rapid prototypes with patient representatives or clinicians outside of clinical settings while staying compliant with IRB requirements.<sup>51-53</sup> For example, after conducting patient needs assessment interviews, a group from the University of Chicago used testers demographically similar to patients at their target clinics to design a waiting room app for contraceptive counseling.<sup>51</sup> This use of "analogous testers" proved successful; real patients using the app reported higher knowledge of contraceptive effectiveness and a greater interest in long-acting reversible contraceptive options.<sup>51</sup> Another team ran participatory design sessions with a Patient and Family Advisory Committee (PFAC), comprised of leaders from various patient support groups the design team worked with in the need-finding phase, to design a dashboard displaying trends in prostate cancer care.<sup>52</sup>

After field testing, the research-design team can further develop the prototype to prepare for formal implementation and evaluation or take lessons learned and reenter the earlier stages of the ideation process.

#### Step 5: Evaluate

Does the Intervention Promote Positive Outcomes? Once design activities are complete and the intervention is implemented, a rigorous evaluation should be conducted to examine the intervention's effectiveness, as well as potential adverse consequences. A hybrid design<sup>54</sup> that incorporates qualitative and quantitative methods can evaluate effectiveness across key outcomes (e.g., health outcomes, patient/provider experience, utilization, and costs) and generate important information about implementation (e.g., feasibility and fidelity, implementation costs, sustainability).<sup>55</sup> Rigorous evaluation methods, including randomization when appropriate, increase the study's credibility with health system leaders and policymakers and the likelihood that findings will be incorporated into future reviews and clinical guidelines, thereby leading to more widespread and lasting impact. Importantly, findings should also prompt reflection about and improvement of the intervention design.

#### DISCUSSION

This paper proposes a framework for integrating HCD and traditional HSR methods in the development of healthcare delivery interventions. Drawing on the strengths of both methods can counterbalance their individual limitations and facilitate the design of innovative, acceptable, and sustainable solutions in healthcare settings. Interventions derived using AHEAD have the potential to offer practical solutions to providers and healthcare managers due to the framework's reliance on existing evidence and focus on stakeholder acceptability throughout the entire design process.

AHEAD builds on previous studies that examined opportunities to harness HCD for specific healthcare intervention design purposes. One study proposed "best practices" for using HCD to improve user experience with at-home health devices for patient users.<sup>28</sup> These practices highlight aspects of design thinking that are valuable in designing for patients, such as the assembly of diverse, multidisciplinary design teams; centering design around empathy for users; developing deep understandings of tasks and setting; user involvement throughout the design process; and iteration through flexible prototype development.

Human-centered design has also been used in CBPR to design innovative solutions in collaboration with vulnerable populations.<sup>32</sup> HCD focuses on understanding and designing for the user, while CBPR approaches intervention design through equal partnership between community members and researchers to define problems and identify solutions to improve

health and reduce disparities.<sup>29, 56</sup> HCD methods echoed in CBPR include co-creation, user engagement throughout design stages, and multiple rounds of iteration.<sup>29</sup> One study used an approach that combined HCD and CBPR methods to address violence and other adversities that influence the health of Latinx youth. Engaging youth in design activities promoted dialogue between opposing individuals and groups and revealed opportunities for health promotion and change.<sup>57</sup>

Others have proposed combining HCD with implementation science to identify promising strategies for intervention design. For example, Dopp et al. conducted a conceptualization exercise in which a multidisciplinary panel of experts identified implementation science and human-centered design strategies that are similar or complementary and described how drawing on these disciplines might improve use of evidence-based practices.<sup>58</sup> Two other examples are the SHIFT-Evidence framework (which focuses on three principles: "act scientifically and pragmatically"; "embrace complexity"; and "engage and empower")<sup>59</sup> and the Veterans Affairs' Quality Enhancement Research Initiative,<sup>60</sup> which focuses on addressing the "knowing-doing" gap, needfinding for problem definition, ongoing stakeholder engagement, and robust evaluation. These frameworks were designed with the goal of facilitating implementation of evidence-based practices. The AHEAD framework offers a unique contribution by drawing on principles of HCD that examine analogous fields and adjacent experiences when there is a clearly defined problem but limited evidence about potential solutions.

Innovating within the scientific method can be lengthy, inflexible, and resource-intensive, and proposed solutions often fail to address the users' real needs. Development of the electronic health record (EHR) provides a stark example of consequences when users are excluded throughout the design process. Excluding providers from designing a system they use daily has had monumental consequences, with an association between physician EHR use and increased stress, burnout, and job dissatisfaction.<sup>61, 62</sup> By including users from the outset, human-centered healthcare approaches can avoid similar disconnects. For example, one research team in Argentina used HCD techniques to redesign the alert system for drug-drug interactions in the EHR. After implementation, the new system resulted in fewer errors and unnecessary alerts and improved workload optimization and user satisfaction.<sup>63, 64</sup>

#### LIMITATIONS

This paper proposes a framework for integrating HCD and HSR to drive healthcare innovation. Our review of existing literature was scoping but not systematic in its approach, and may not have captured all existing HSR and HCD frameworks. Future research is needed to validate this framework and determine whether solutions derived achieve the desired and predicted effectiveness, implementation, and dissemination outcomes. Time and resource constraints may limit use of this framework, as well as gathering financial and institutional support needed to assemble interdisciplinary teams.<sup>40</sup> Additionally, not all teams have access to collaborators with HCD expertise and contracting with outside design firms can be expensive.<sup>36</sup> However, there are a growing number of academic institutions with design schools and many opportunities to gain exposure to design methodology and skills.<sup>65</sup>

#### CONCLUSION

Complex factors influencing population health and healthcare drive demand for innovative intervention design frameworks. An opportunity exists to integrate creative approaches from HCD with rigorous methods from HSR; the resulting AHEAD framework can guide the design of healthcare delivery interventions. Future efforts should examine whether interventions derived from this integrated framework generate effective solutions for "wicked" healthcare challenges.

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#### Compliance with Ethical Standards:

**Disclaimer:** The views expressed herein are those of the authors and do not necessarily reflect the views of the Gordon and Betty Moore Foundation, or the Stanford University School of Medicine.

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