

Establishing a Research Agenda on Mobile Health Technologies and Later-Life Pain Using an Evidence-Based Consensus Workshop Approach

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Running title: A research agenda on mHealth and later-life pain

Abstract: The rapid growth of mHealth devices holds substantial potential for improving care and care outcomes in all patient populations, including older adults with pain. However, existing research reflects a substantial gap in knowledge about how to design, evaluate, and disseminate devices to optimally address the many challenges associated with managing pain in older persons. Given these knowledge gaps, we sought to develop a set of practice-based research priorities to facilitate innovation in this field. We employed the Cornell Research-to-Practice Consensus Workshop Model, an evidence-based approach to generating research priorities. Sixty participants attended the conference, where stakeholder groups included older adults with pain and their caregivers, behavioral and social scientists, healthcare providers, pain experts, and specialists in mHealth and health policy. Participants generated 13 recommendations classified into two categories: 1) Implications for designing research on mHealth among older adults, e.g., conduct research on ways to enhance accessibility of mHealth tools among diverse groups of older adults with pain, expand research on mHealth sensing applications; and 2) Implementation of mHealth technology into practice and associated regulatory issues, e.g., promote research on ways to initiate/sustain patient behavior change, expand research on mHealth cyber-security and privacy issues.

Perspective: This report highlights a set of research priorities in the area of mHealth and later-life pain derived from the joint perspectives of researchers and key stakeholder groups. Addressing these priorities could help to improve the quality of care delivered to older adults with pain.

Keywords: Pain, Aging, Mobile Health, Research Recommendations

INTRODUCTION

The health of aging populations in developed countries has not kept pace with improvements in life expectancy.⁹ Many older adults spend their final years coping with and managing multiple chronic conditions, many of which have pain as a primary symptom.^{17,29} Later-life pain is associated with substantial disability and suffering.^{17,29} Given the rapid increase in the number of aging adults living with chronic conditions and pain, rising healthcare costs, and shortage of caregivers to help care for affected individuals, experts have asked whether emerging technologies, in particular mobile health (mHealth) devices, can help to address these important and related challenges.^{13,18,31} While there are many challenges associated with managing pain across the life span, a focus on pain, aging and technology is appropriate because of its high population health impact in later-life and because age is an established risk factor for underassessing and under-treating pain.^{8,11,20}

The World Health Organization defines mHealth as the “practice of medical and public health through the use of mobile devices.”³³ mHealth tools include applications (apps) stored on devices such as smartphones, tablets, and wearables. Sensors on smartphones and wearables (e.g., Fitbit, Apple Watch) include GPS, accelerometer, compass, gyroscope, microphone, and camera capabilities and can automatically monitor outcomes relevant to the pain experience, including movement and sleep patterns. In addition, adoption of sensor-laden smartphones and wearables has grown rapidly. By 2020, almost 87% of North Americans and 82% of Europeans will use mobile phones;²⁸ many will employ the devices to track health indicators.

Although research has demonstrated the feasibility of using mHealth devices to enhance medication adherence,¹⁵ support behavior change,³ promote exercise,²¹ and support self-management¹² among older adults, mHealth has had limited reach and impact in pain care.^{5,7,27,32} Existing research reflects a substantial gap in knowledge about how to design, evaluate, and disseminate devices to address the many challenges associated with managing pain in older persons.

This research indicates limited to no involvement of healthcare providers, no end-user involvement in design and application development, limited device uptake in clinical settings, multiple barriers to routine device use at the patient and provider level, and scant evidence that mHealth devices improve outcomes.^{5,7,27,32} Nevertheless, other research demonstrates that older adults with chronic pain and their healthcare providers are interested in trying mHealth devices to reduce pain and improve outcomes.^{16,24}

Given these limitations in the knowledge base, we sought to develop a set of practice-based research priorities to facilitate innovation in this field. We employed the Cornell Research-to-Practice Consensus Workshop Model,³⁰ an evidence-based approach to generating research priorities.^{19,25,26} This model harnesses the collective wisdom of conference participants by engaging them in a process of generating research priorities that honors scientific expertise, practice wisdom, and experiential knowledge. The goal of the model is to generate a research agenda that fits more closely with the needs of key stakeholder groups, e.g., patients and providers.²⁵

METHODS

The Cornell model has been published³⁰ and methods are available online;⁶ we therefore summarize briefly the method's steps below. The Weill Cornell Institutional Review Board approved the study and all participants provided informed consent.

Non-Technical Background Report

The project team first developed a background report that summarized major issues in the area of mHealth and later-life pain care including recommendations for future research. The investigative team searched MEDLINE for English-language articles published from January 1 2000 through March 1st 2017 using a variety of search terms to identify relevant articles. The report, sent to invitees before the conference, aimed to provide participants with a common knowledge foundation and stimulate informed discussions regarding existing knowledge gaps. In preparation

for the conference, invitees were encouraged to read the report paying attention to three questions: (1) Do you agree with the knowledge gaps listed in the report?; (2) Do you disagree with any of the researchers' priorities for new knowledge?; and (3) Based on your own experience, what are the most important areas where knowledge is limited?

Conference Participants

We employed purposive sampling, a non-random sampling technique used to identify and select individuals or groups of individuals with particular knowledge of or experience with a given condition. Investigators used their respective networks to identify prospective participants with a goal of assembling a diverse sample with respect to age, gender, and race/ethnicity. Prospective participants (N=72) were contacted by email or telephone, invited to participate, and asked to recommend additional individuals to invite. Project team members invited individuals iteratively until reaching approximately 70 participants, suggested by the method's originators⁶ as an optimal number for an effective conference process.

Eligibility guidelines for the 6 stakeholder groups were: 1) Older patients had to have chronic non-cancer pain (pain on most days over the previous 3 months), while caregivers were spouses/significant others of invited patients; 2) Behavioral and social scientists were selected based on their expertise with aging issues; 3) Healthcare providers had to be involved in direct service provision, with familiarity in providing care to older adults; 4) Pain experts had to have expertise in pain care delivery or researching pain; 5) Technology experts had to have expertise in developing, evaluating and/or marketing mHealth products; while 6) Health policy experts had expertise in developing and/or implementing health policy.

Of the 72 invitees, 60 (83%) attended the conference on April 7, 2017. Participants were not compensated for their time. Most participants (Table 1) were female (n=42, 70%) and white (n=44, 73%). Healthcare providers included nurses (n=2), social workers (n=2), physicians (n=3) and

pharmacists (n=4). Disciplines represented in the behavioral and social science group included sociology (n=4), psychology (n=5), and health communication (n=3). Pain experts included practitioners (n=3), as well as investigators (n=8) focused on translational pain research. Finally, professionals working in policy roles provided expertise regarding funding and implementation (n=3). Technology stakeholders included startup company leaders (n=3), staff members (n=2) and researchers (n=5) working on various mHealth devices.

Panel of Expert Discussants

Before the conference we identified one discussant from four of the six stakeholder groups (technology, pain, social/behavioral science, healthcare providers), who agreed to share their perspectives on the report with attendees at the start of the conference. We did not ask a member from all six groups to speak because of time concerns. These presentations aimed to promote the equal value of scientists', practitioners' and other stakeholder groups' views and to model respectful and productive dialogue.

Consensus Conference

Following the presentations, attendees met in 9 small groups composed of 7-8 participants each for 60 minutes to generate recommendations, guided by a facilitator who was familiar with the Cornell model. Each group contained at least one member of each stakeholder category, with the exception of the health policy group as there were too few health policy experts to be represented at each table (Table 1). Each group was asked to generate approximately 10 recommendations. All groups reported their recommendations to the larger group, which allowed for further clarification and discussion. The groups collectively generated 95 recommendations. There were many duplicate recommendations, which were commented on by presenters who described their group's recommendations. A notetaker simultaneously recorded the discussion of the recommendations, including notes about duplication. Immediately following the presentation (and prior to the

afternoon session), the investigators and notetaker summarized the 95 recommendations into 24 general themes, merging the many duplicate recommendations.

In the afternoon session, the entire group reviewed and discussed the 24 recommendations, then voted on them. Participants were allotted 10 votes and instructed to vote on the recommendations they considered to be the most important priorities for future research. Five participants did not vote (having to leave the conference before the voting took place), while four cast fewer than 10 votes.

Follow-up Roundtable Meeting

Following the conference, the investigators (CR, EW, KP, CEL) met as a group twice to discuss how to combine recommendations into categories. The group determined that further merging was possible and developed a list of 14 recommendations (e.g., making the tools accessible for diverse racial, ethnic, socioeconomic, age, and patient groups was combined into one recommendation (thereby reducing 5 recommendations into 1); while security and privacy concern issues were combined into another recommendation.) The project team created a document with the 14 recommendations and a summary of the group discussions, which was then sent to participants several weeks after the conference, along with an invitation to participate in a two-hour, follow-up meeting. At the meeting, participants clarified the wording and meaning of several recommendations and consolidated two recommendations felt to be similar. All members of the follow-up roundtable meeting agreed to making these changes.

Analysis

Descriptive statistics were performed to characterize the sample. Votes were tallied for the recommendations generated at the conference and summed for the merged recommendations. The stickers used for voting had been consecutively numbered and color-coded by stakeholder group, making it possible to aggregate votes by group.

RESULTS

The Cornell method generated 13 recommendations (Table 2). Two categories of recommendations emerged: 1) Implications for designing research on mHealth among older adults; and 2) Implementation of mHealth technology into practice and associated regulatory issues. Table 2 presents recommendations by category, organized by strength of endorsement (i.e., total number of votes), from the most strongly (n =135) to least strongly (n = 11) endorsed.

Implications for Designing Research on mHealth among Older Adults

Of the 543 total votes cast, 435 votes (80%) endorsed the eight recommendations outlined below.

Conduct research on ways to enhance accessibility of mHealth tools among diverse groups of older adults with pain (135 votes, 24.9%). Specific suggestions in this category included designing mHealth tools to be as affordable as possible to achieve the greatest possible reach across income groups. Participants across all stakeholder groups endorsed the design of mHealth platforms that would be usable across diverse older age groups with pain, including the oldest old, different levels of educational attainment, and across different cultural groups. The participants defined usability across diverse groups as mHealth tools that could meet the needs for information, understanding, and taking action among older adults with pain, regardless of background.

Promote research/commercial partnerships and other initiatives that expedite bringing mHealth innovations into practice (67 votes, 12.3%). Many participants voiced the importance of having multiple disciplines (e.g., medicine, clinical practice, information science, psychology, sociology) represented in the co-development of effective mHealth tools for pain management. Participants thought that establishment of multidisciplinary partnerships, including specialists in commercial development, had substantial potential to address device development and implementation barriers more quickly.

Conduct research on the impacts of mHealth on physical and mental well-being (56 votes, 10.3%).

Participants voiced concerns about the psychological and social impacts of mHealth, including potentially negative effects on users' mental health and level of social interaction. A key concern was that mHealth adoption by older patients with pain and their providers could increase users' social isolation; or that unevenness of implementation and adoption might increase social exclusion and promote health disparities. Possible solutions included developing mHealth tools that improve access to social support. Conducting research that compares mHealth support with health support from in-person interactions with providers constitutes one approach to addressing this recommendation. Another possible solution proposed was to develop mHealth tools that connect older patients with pain to one another. In addition, participants recommended that researchers explore how mHealth use might impact users' level of physical activity, quality of life, and psychological well-being, as well as perception of pain, i.e., could it cause users to focus too much on their pain? These endorsements were particularly common among patient and caregiver participants; nearly 50% of their votes endorsed a need for research on human-media interaction.

Expand research on mHealth sensing applications (43 votes, 7.9%). One of the innovative ways that mHealth applications can capture an individual's pain experience is to implement features that collect data passively, e.g., using tools that capture movement and gait. These technologies could supplement the more time-intensive process of self-report. Stakeholders suggested that sensing could provide insights into how certain situations and events might trigger pain episodes. Such data could be fed back to patients to help them avoid or mitigate future episodes. Healthcare providers would also be able to use these data to supplement information collected during office visits.

Promote integration of users into basic research issues regarding mHealth and later-life pain (43 votes, 7.9%). Participants endorsed integrating the input of older patients with pain into basic research on mHealth. The strength of interdisciplinary teams is their capacity for innovation and their ability to

facilitate movement of ideas across research areas. Participants recommended that research teams include not only healthcare providers, mHealth technologists, and designers/developers, but also older patients with pain.

Conduct research on ways to personalize and tailor mHealth tools for individual users with pain (37 votes, 6.8%). Participants recognized that personalizing mHealth tools to accommodate individual preferences and characteristics and by tailoring devices for use by older individuals with different types of pain, living situations, and physical abilities could increase their uptake and impact. The tools might also provide services such as automatic appointment scheduling with a healthcare provider when needed to manage pain. More generally, tools tailored to individual context might also be able to connect older pain patients more effectively to local resources.

Expand research on ways mHealth data can inform intervention development and on ways to expand mHealth tool reach in clinical and non-clinical settings (28 votes, 5.2%). Participants suggested that data collected via mHealth tools would be useful for developing new interventions. Broad use of mHealth, combined with data on individual patient characteristics, has the potential to provide detailed data on individuals' pain experience over time, including triggers for pain episodes and the effectiveness of various treatments. Researchers and developers could explore these data for new ideas about how to treat more people, and how existing treatments might be improved. Although the focus of mHealth tends to be on individual users who live in the community, participants recognized that mHealth tools might also be useful for managing pain among older adults living in congregate settings such as assisted living and nursing homes.

Develop a core set of mHealth data and outcome assessments (26 votes, 4.8%). Participants endorsed enhancing the value of research to establish a core set of outcomes and indicators for pain and related outcomes collected using mHealth devices. Use of a consistent set of outcomes would facilitate more rapid sharing of data. Moreover, if patients saw these outcomes as a high priority, the

effectiveness of pain care could increase. Participants recognized a need for standard analysis procedures that would maximize the usefulness of the data for both patients and providers.

Implementation of mHealth into Practice and Associated Regulatory Issues

Participants cast 108 votes for the recommendations grouped in this category (20% of all votes cast).

Promote research on ways to initiate/sustain patient behavior change using mHealth tools (35 votes, 6.4%).

Participants recommended multiple areas of research regarding initiating and sustaining patient behavior change facilitated through use of mHealth to include: 1) taking pain medications as prescribed; 2) tracking pain levels and prompting appropriate pharmacologic and/or non-pharmacologic interventions and corresponding use; 3) pairing medication or pain management with tools to help co-manage depression and other conditions that might lead to non-adherence; 4) engaging caregivers in pain management, particularly for those patients with cognitive deficits; and 5) developing tools to help caregivers of older adults' with pain support behavioral change.

Conduct research on health system, workforce and patient education issues regarding mHealth use (26 votes, 4.8%). Participants endorsed research efforts focused on how best to inform older adults about the use of mHealth tools. They recognized that the use of mHealth tools would depend on healthcare providers having access to adequate education about these tools. Participants further recommended that researchers study the readiness of different healthcare systems to incorporate mHealth tools into practice, as well as their capacity to use data generated by the devices.

Expand research on mHealth cyber-security and privacy issues (20 votes, 3.7%). Although the number of votes for this recommendation was small, older adults with pain who attended the follow-up meeting emphasized how important privacy and security issues would be for earning their trust. Participants raised a variety of issues, including the secure sharing and management of data generated by mHealth tools, the rights of patients to provide informed consent for research or

commercial use of the data, long-term privacy of data (particularly when merged with other health data) and how commercial entities might access mHealth data for profit.

Expand research on sustainability of mHealth use at the patient, provider, and health system levels (16 votes, 2.9%). Participants were aware that many commercial mHealth tools are used over short (rather than long) periods of time.^{4,10} Eighty-one percent of these votes came from the researcher stakeholder group; there were no endorsements from the patient/caregiver group. Endorsees recommended research on how to sustain long-term tool use. An interesting sub-theme was rapid technological change, and how to update and replace outdated tools as new tools/systems emerged.

Promote research on ways mHealth tools can improve patient-provider (and provider-provider) communication (11 votes, 20%). More than half of the endorsements for this recommendation came from the healthcare providers and patient/caregiver stakeholders. Although not frequently endorsed, participants who voted for this recommendation suggested that mHealth tools promote or increase patient-provider interaction, rather than replace it. They also endorsed the potential for mHealth tools to increase information sharing among provider teams and provider-caregiver dyads, thereby enhancing and improving care to promote a more patient-centered approach.

DISCUSSION

The rapid growth of mHealth devices holds substantial potential for improving care and care outcomes in all patient populations, including older adults with pain. Efforts to address whether mHealth tools can improve pain outcomes in older adults are warranted.^{8,11,20} However, the reach of mHealth devices in pain care has been, to date, quite limited. To increase understanding of how utilization of mHealth can become more effective and widespread, we employed an evidence-based consensus conference model that deliberately engages researchers and other stakeholder groups as equal partners. Conference participants proposed 13 recommendations that represent promising

starting points for translational research efforts in this area. The first set relate to research design and targets of research, while the second set relate to research practice and regulation.

The first set of recommendations can be characterized by the need for “inclusion,” “tailoring device use to older adults,” and a focus on “real world validity,” while assuring that as mHealth research and commercial development advances, the psychological and social needs of people with pain in later life are taken into account. An important insight from this conference was that several patients and providers raised concerns that adoption of mHealth might isolate older patients from their providers and lead to *less* personalized care.

The second set of recommendations followed a similar track in that implementation into practice should take into account the situational needs of older adults for managing chronic illness, providing information that is accessible to older adults of varying education and experience, and the fit of these tools into local medical systems that serve older adults. That is, mHealth should be implemented in a way that adds value to care that is already being delivered, rather than displace pre-existing relationships.

Several of the recommendations from this conference have been raised in other publications and reports. The concerns about patient rights to informed consent, confidentiality, and privacy echo consumer research on the use of mHealth devices,² as well as published reviews and strategic plans for mHealth development.^{1,14,23} In addition, assuring accessibility for diverse users and integrating mHealth into existing health care delivery systems were also key recommendations of a recent draft mHealth development strategy by the National Science and Technology Council.²³

Addressing the research priorities described herein could have dividends at multiple levels. For healthcare providers faced with the task of caring for older adults with chronic pain, developing tools that improve both the monitoring and management of pain could improve the quality of care they deliver. At the patient level, generating a set of mHealth tools that promote access to quality

pain care could improve users' self-efficacy for managing pain and associated outcomes. Addressing the priorities described above could also have dividends at the system level, to include helping insurers determine which mHealth tools to reimburse for use in clinical settings.

The major strength of this project is its use of an evidence-based approach³⁰ to generate consensus research recommendations derived from the joint perspectives of researchers and key stakeholder groups. Direct involvement of patients with pain and their caregivers in generating the recommendations constitutes an important value-added aspect of the process. Furthermore, the recommendations are sufficiently general to have relevance to research on mHealth that focuses on other chronic conditions in later life. Despite these strengths, several limitations warrant consideration. The recommendations emerged from a relatively small participant sample and thus are limited by their experience, expertise and concerns. Participants were primarily female and White; future discussions of these recommendations would benefit from more diverse inclusion. We would also like to see this process repeated in other countries, with varied constituencies, and compare the findings. In addition, we did not test the reading level of the background report before distributing it to conference invitees. This could have resulted in non-professionals (patients and caregivers) having less understanding of research priorities judged to be important by the research community. Finally, providing a preset agenda of research recommendations (generated by researchers) may have created a bias in the consensus process. We compared the researcher recommendations discussed during the conference with the final set of conference recommendations and found an overlap of approximately 60%. Stated another way, 40% of the final recommendations were completely new supporting the consensus conference model as a way of generating ideas above and beyond what researchers perceive are important to investigate.

In conclusion, this report highlights research priorities in the area of mHealth and later-life pain that, if addressed, could help to improve the quality of care delivered to this growing

population of patients.²² The recommendations reflect a maturing and expanding of mHealth as a discipline and reflect the desire for greater inclusivity, depth, pathway to commercialization and adoption, and individualization of solutions.²³ The priorities give clear guidance on the need for greater research on sensing technology, and on the broader social and mental health context in which pain is experienced. These findings could help to establish an ambitious research agenda and should prove valuable to diverse stakeholders, including technologists, researchers, healthcare providers, funders, and policy makers interested in improving the care of adults with later-life pain.

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