Personal Connected Health Alliance

Personal Connected Health: The State of the Evidence and a Call to Action

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BY: John Sharp, MSSA
Sarah Cunard Chaney, MPH, MSc
Janna Guinen
Patricia Mechael, PhD, MHS

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Personal Connected Health Alliance

With a mission to help people make health and wellness an effortless part of daily life, the Personal Connected Health Alliance is a nonprofit organization formed by HIMSS that convenes the global personal connected health community, to accelerate the technical, business, policy and social initiatives necessary to advance the personal connected health field.

Introduction

Personal connected health represents an evolution towards increased personal engagement and connectivity to achieve health and wellness. This is facilitated by a broad range of technologies, including mobile and remote patient monitoring devices, telehealth and wearable technologies. Newer technologies include smart pills that can remind people to take their medications; implantable, and even ingestible, sensors.

A central tenet of personal connected health is that the individual has a natural interest in his or her own health, and given the right personal connected health tools, can engage in healthy behaviors. Other key features of personal connected health comprise:

- personal empowerment through health information
- prevention over treatment
- the use of technology to facilitate access to supportive healthcare resources
- the ability to seamlessly share health information
- better health as the primary goal of any program

The personal connected health market is growing, with some noting a greater than 30% annual growth rate through 2022,[1] but adoption and evidence lag behind. Physicians are not recommending apps and devices due to concerns about cost, usability and evidence of effectiveness.[2] Many new innovations in the field promise results for a defined population that shares a health condition or treatment, but fail to illuminate the impact of an individual's unique physiology, environment, genetics, and behavior, along with the presence or risk of co-morbidities. In addition, "[many] digital health products that demonstrate impressive results in clinical trials often fail to do so in real-world settings."[3] To achieve the goals of personal connected health, we must not only look to innovation, but also to the evidence that demonstrates the value of such tools.

As part of the Personal Connected Health Alliance's (PCHAlliance) efforts to define personal connected health, evidence was identified as a key driver for shaping the field. This publication aims to set an initial baseline for the current body of evidence in personal connected health in key sub-domains, namely behavior change and self-care, remote patient monitoring, remote counseling and mental health, as well as more broadly through key condition-specific studies. The publication incorporates a formal review of randomized controlled trials; a broad discussion of the role of evidence in adoption of personal connected health; and a discussion of evidence challenges and proposed areas for further research and collaboration.

Evidence Review

To understand the state of the *evidence* in personal connected health, a systematic review of published literature relating to personal connected health was conducted in April 2017, in order to demonstrate the frequency of themes and available evidence on health outcomes measurements. We used four internet-based search engines to search for the following terms: fitness tracker, remote patient monitoring, patient generated health data, smart clothing, mobile application, personal connected health, telemedicine, mHealth, evidence, and health. We restricted all searches to publications from January 1, 2013 until April 8, 2017, and in English language only. We also searched in PubMed using Medical Subject Headings (MeSH) from the National Library of Medicine corresponding to the above search terms.

The publication title and abstract were reviewed for each of the resulting 1,467 citations, for relevance. After removing duplicate citations and published results, reviewing title and abstract and conducting a deeper review of the remaining articles, a total of 53 controlled studies and trials were selected for analysis. The final studies selected are related to mobile technologies, remote patient monitoring, web-based counseling and other personal connected health technologies. The studies were categorized by functional theme relating to the technology intervention.

The findings, evidence and trends in each of the identified themes are summarized below. *Tables depicting methods and review results are included in the Appendices, together with references cited and the annotated bibliography pertaining to this evidence review.*

Behavior Change/Self-Care

The use of technology to promote behavior change or to help individuals care for personal health conditions is the largest of the themes identified, comprising 35 publications and representing 34 studies and trials [10–44]. A predominant theme related to behavior change/self-care is near-universal use of automated technology that does not require constant maintenance and interaction with healthcare providers or educators, unlike the home-health remote patient monitoring analysis discussed below. Automated technologies include text message reminders, alerts and automated education platforms aimed at encouraging individual healthy behaviors and lifestyle changes.

However, not all in this group are fully automated systems. Seven of the studies rely entirely or partially on a live coach, trainer or health educator [10, 20, 31, 32, 36, 39, 41]. Some of these studies compare delivery of therapy via phone or video to the same therapy normally delivered in person in order to validate this mode of service. For example, providing patients with counseling on diabetes care and behavior change was seen to be equally effective in person as utilizing telehealth devices, validating the use of this approach for people with diabetes [31]. Other programs aim to augment automated text messaging with phone-delivered sessions with a live coach. For example, a successful program to promote weight loss in young adults in Australia [10] combined live dietician contacts, an app, educational modules and text messages to promote healthy eating, exercise and weight loss behaviors.

The majority of studies utilized fully automated web-based programs, text message delivery systems or smartphone apps. All of the studies in this section target personal choice and promote personal health decision-making. Smoking cessation [16, 34], diabetes control [31, 37, 39], weight loss [10, 11, 17, 24, 26, 27, 40], medication or appointment reminders [21, 25], mental health, sleep or cognitive training [13, 19, 22, 33, 43], pain management [35, 36, 38, 42], control of high blood pressure [12], prenatal health [18, 23, 30, 32], sun exposure [14/15 both analyzing the same mobile app], asthma management [29] and injury recovery [44] are the topics employing fully or predominately automated delivery of messages and content.

Evidence of effectiveness is mixed in this group of studies. Web-based cognitive or pain management platforms is a key sub-theme in this area. These may be fully automated educational systems or platforms that mimic counseling based on cognitive behavioral therapy [13, 29, 35, 36, 38, 42], or may contain partial support from a live therapist [39, 41]. As one example, significant improvements were observed in pain scores for adults with chronic pain who participated in a web-based pain management program [35]. The program uses patient-reported data and algorithms to guide users through exercises and decisions tailored to the individual, much as a live therapist or counselor would do.

Two studies included in this review attempted to tease out the individual behaviors contained within the use of a self-care or health promotion app that may promote successful behavior change. Kim et al. [26] examined the specific activities of a popular weight management app.

Through examination of user data and separate surveys of those same users, they found that food-logging was associated with improved self-efficacy that resulted in more successful weight loss outcomes. In a simple study design using three versions of automated text messages, Shaw et al. [40] found a small but significant difference in successful weight maintenance in the group that received prevention messages. These kinds of studies can help us understand the behaviors and messages that accompany smartphone and app use in making daily health-related decisions.

Some seemingly simple studies demonstrate that just because the technology is available does not mean it will be useful or have any effect on personal health choices. The sun-protection educational app examined by Buller et al. [14, 15] presented alerts, suggestions, educational content and UV level updates through a smartphone app. Although not set up to measure ultimate health outcomes of skin cancer or sunburn, the studies found no self-reported improvement in sun-protection activities by people who downloaded the app.

Another smartphone app was tested as an alternative to a paper notebook used by pregnant women as a diary for record keeping and symptom monitoring in between prenatal checkups [30]. There did not seem to be any evidence that the paper diary was effective or ineffective in the first place and it was unclear which behaviors the diary was meant to encourage or promote. There was no measured difference in pregnancy outcomes between the paper diary and the app dairy groups. Similarly, an automated text message system in Guatemala was designed to remind new parents to bring their babies for upcoming vaccination appointments [21]. The baseline rate of child vaccination was already very high in the area and there was no improvement or difference between the text message group and the paper reminder group in rates of child vaccination.

Remote Patient Monitoring

The nine remote patient monitoring studies identified all utilize technology that enables healthcare providers to capture and receive quantitative data about their patients away from the clinic or hospital [1–9].

Three of these studies intended to show that rehabilitation or recovery from illness managed by remote monitoring achieved the same level of care and health outcomes that patients would receive in traditional in-clinic or face-to-face care [4, 6, 9]. For example, the results showing no significant difference in mortality and re-hospitalization rates between remotely monitored patients and those receiving care in the facility for chronic kidney disease reported by Ishani et al. [4] were seen as evidence that this type of intervention could be used effectively and safely for this population. These studies are important and demonstrate how remote patient monitoring can be used to reduce the burden of in-clinic visits for some patients and facilities.

Most studies here employed either implantable devices such as cardiac defibrillators [2] or peripheral instruments connected to devices in the home that could transmit physiological data to the healthcare provider, including blood pressure, weight, blood glucose or other indicators [1, 3, 4, 5, 7, 8, 9]. The patient may or may not be expected to utilize the data gathered for their own self-care or to adopt healthy lifestyle changes in relation to their condition. In Alibini et al. [3] patients with hypertension in Italy were sent home with a blood pressure monitor that could send regular information to the healthcare provider, but also linked to a web-based education platform for the patient to use, and received text message alerts and reminders aimed at improving self-management of high blood pressure lifestyle factors. The 303 patients followed-up after the study had significantly reduced office-measured blood pressure compared to control patients who only attended regular appointments with their physician. A similar study in Korea did not see significant effects on blood pressure of patient self-monitoring with in-person or telephone counseling [5]. Another study with heart failure patients using remote patient monitoring combined with personal responsibility did not see reduction in re-hospitalization rates, despite a comprehensive telemonitoring, remote data monitoring and educational coaching package [7].

The evidence shows mixed results for the effectiveness of remote patient monitoring programs, but the mixed modalities and combinations of personal responsibility, health education or passive monitoring by health personnel make generalizations about these devices difficult. Future studies that employ one monitoring device and simple interventions targeting a specific self-management behavior may help clarify this area. The large comprehensive care programs have an important place for aiding in rehabilitation of patients after hospitalization but are not able to differentiate the role and importance of each personal health device or the role that personal involvement plays in that environment.

Remote Counseling and Mental Health

The 12 publications identified related to remote counseling and mental health all involve technology to enhance or deliver therapy for depression or other mental health issues [45-65]. This group stood out as a separate theme because of the absence of any quantitative remote patient monitoring and the heavy reliance on trained professionals to deliver the mental health therapies. This can be considered qualitative remote patient monitoring.

The technologies used in these studies are not sophisticated — telephone or internet-based video are the only use of technology in 10 of the 12 studies. Improved mental health outcomes were demonstrated in all of the studies addressing depression and PTSD through telemedicine [45, 46, 48, 50/51/52, 53, 54, 55]. These successful results are probably due to the proven success of the cognitive behavioral therapy (CBT) delivered by a trained professional and less to the specific use of technology, although the use of phone and internet video for these services increases access.

One of the two studies in this group that incorporate web-based components is the only study in this review that specifically looks at social support networks online [49]. Crisp et al. compared depressed adults in Australia using a web-based training program for depression with a group using the web-based program combined with on-line support groups. The combination intervention group showed improvements in self-esteem and quality of life scores.

Evidence in this area shows promise, as there are indications of both improved outcomes and access.

Condition-Specific Use Cases in Personal Connected Health

Separate from the formal evidence review, a review of common use cases was conducted which showed that the use of personal connected health devices spans a broad range of health and wellness situations. These less formal and rigorous studies also indicate varying degrees of success, in relation to chronic illness, sleep, employee wellness, maternal and infant health; and cover a variety of uses of apps and devices. *For this review of use cases, references are cited in footnotes.*

Fitness trackers were initially developed to promote wellness through encouraging a more active lifestyle and quantifying oneself through data. Employee wellness programs have almost universally adopted some type of fitness tracker to improve the health of their employees. A survey of CEOs conducted by Fitbit showed that 47% thought there was a reduction in healthcare costs due to an employee wellness program and 44% thought that it reduced sick day use.[4] Other studies have developed cost-effectiveness models for wellness programs to try to demonstrate the cost/benefit ratio of preventing cardiovascular events.[5] Offering fitness trackers within an employee wellness program can increase the number of steps and time spent walking,[6] but demonstrating prevention of disease and reduction of healthcare costs is more of a challenge. Another study demonstrated healthcare cost reduction and lower modifiable risk factors for chronic disease in those with higher activity levels through the use of self-reported activity from a tracker.[7]

Tracking diet presents its own challenges, as it requires manual entry of the data into an app. In addition, some apps are integrating fitness with diet tracking. To simplify data entry, many diet apps now have the ability to scan bar codes and use reference databases for food items. One systematic review found "modest evidence that app-based interventions to improve diet, physical activity and sedentary [behaviors] can be effective. Multi-component interventions appear to be more effective than stand-alone app interventions; however, this remains to be confirmed in controlled trials."[8]

Sleep monitoring has become popular and is available through many fitness trackers as well as other devices, making it broadly available directly to the consumer rather than being limited to sleep labs. There are now some validation studies of sleep trackers.[9] These point to strengths and limitations in sleep estimates produced by personal health monitoring devices, requiring further study.[10]

Condition-Specific Use Cases in Personal Connected Health (continued)

Sleep monitoring through new devices and wearables is used as a wellness tool as well as for monitoring a chronic condition (sleep apnea). Most of the research around sleep devices has been focused on monitoring rather than improving sleep (e.g., Scalable Passive Sleep Monitoring Using Mobile Phones: Opportunities and Obstacles[11]). One study from the Netherlands did show an impact on insomnia using a phone app.[12] However, one must consider behavioral constructs behind the development of sleep apps. A review of these concluded that, "While the overall behavior construct scores were low, an opportunity exists to develop or modify existing apps to support sustainable sleep hygiene practices."[13]

Moving from primary prevention (wellness emphasis) to secondary prevention (reduce the impact of a disease which has already occurred), apps and devices have some similar applications but with a different emphasis. An important paper, "Digital medicine's march on chronic disease," makes the point that:

> Digital medicine offers the possibility of continuous monitoring, behavior modification, and personalized interventions at low cost, potentially easing the burden of chronic disease in cost-constrained health systems.[14]

The most well-studied programs are those in diabetes prevention (DPP). Diabetes prevention programs with in-person coaching groups have demonstrated effectiveness and now digital health programs with human coaching are demonstrating risk reduction. In one study, data was collected from a wireless scale, medical records and electronic surveys. Results showed significant weight loss, improved glucose control and lower total cholesterol at 12 months.[15] A related study estimated the return on investment for digital behavioral counseling for prediabetes and cardiovascular disease to be break even at three years.[16]

Monitoring cardiac conditions with apps and wearables has also gained an evidence base. A case report describes a man who presented to the emergency department with atrial fibrillation (AF), which led the emergency room staff to check his pulse rate readings from his activity tracker throughout that day, showing a significant increase mid-day when symptoms began. The authors conclude that activity tracking can be used in medical decision making.[17] A study of a device which attaches to a mobile phone to be used as a mobile ECG has been validated and tested in monitoring patients after cardiac surgery. It was shown to be "a non-invasive, inexpensive, convenient and feasible way to monitor for AF recurrence in post-cardiac surgery patients."[18] A study of remote monitoring in hypertension using a wireless blood pressure cuff and a protocol for calling the patient and adjusting medication demonstrated a 30-point drop in five weeks.[19] A study of telemonitoring patients with congestive heart failure (CHF), who transmitted body weight, ECG/heart rate, and blood pressure on a daily basis to the monitoring center, demonstrated a significant reduction both in the overall costs and in the number of days of hospitalization over two years.[20] In addition to cardiac monitoring, remote cardiac rehab is also seeing results. In a small study from the Veterans Administration, 50% of patients improved functional capacity through a "smartphone application that reminded participants to complete daily exercises, as well as blood pressure and medication logs."[21]

Pain is another example of a chronic condition being addressed by apps and devices. For example, a transcutaneous electrical nerve stimulation device was shown effective in reducing low back pain resulting in "reduced pain interference with walking ability and sleep, and greater pain relief."[22] Virtual reality has also been demonstrated as an effective treatment for pain.[23]

Maternal and Child Health apps and devices are also showing some promise. For instance, Text4Baby, a texting program for pregnant women which has been used internationally, has shown initial results that "exposure to the text messages was associated with changes in specific beliefs targeted by the messages."[24] Infant monitoring is another area of innovation with only preliminary evidence or lack of evidence leading to cautions about its use.[25] However, a meta-analysis of studies of mobile interventions with children did find effectiveness in some cases.[26]

Behavioral health has seen some stronger results. A literature review of the evidence found that apps addressed a broad range of issues using self-help (with tailoring or personalization), gaming and cognitive-behavioral therapy (CBT). These addressed problems such as depression, anxiety, eating disorders and borderline personality disorder. One of the studies reviewed indicated that "self-monitoring of mood can boost overall emotional self-awareness."[27] The article provides specific recommendations to improve the effectiveness of these mental health apps. Alcohol and substance abuse are also being addressed through personal connected health. A systematic review found that "the majority of studies provided support for the efficacy of mHealth in reducing substance use."[28]

Many other conditions are seeing a growing base of evidence, such as asthma, pulmonary disease[29] and cancer.[30] Symptom monitoring in autoimmune diseases[31] and celiac disease[32] are also being addressed.

Condition-Specific Use Cases in Personal Connected Health (continued)

Evidence Gaps and Considerations

Developing an evidence base for personal connected health is in its infancy. Although many technologies, disease states and wellness interventions are being evaluated, many studies have small sample sizes, are industry sponsored or are from a single institution. Clinical improvement, prevention and adherence are examined but the appropriate and optimal research methodological approaches, as distinct from drug trials, are still evolving. Validation of devices and apps is essential to produce reliable and replicable results.[33] A 2016 evaluation of telehealth evidence by the Agency for Healthcare Research and Quality (AHRQ) noted that some telehealth interventions identified by experts as currently relevant had no research evidence, or inadequate evidence.

Even though this review was limited to only the last four years of published studies, the rapid pace of technology development makes investigations published in 2013 and 2014 — which were reporting on trials and data collection from one or two years before that — outdated.

The lack of rigor in connected health research has often been criticized. According to authors of the *Asthma Mobile Health Study,* “using mobile health applications to conduct observational clinical studies requires rigorous validation.” Authors stated the “platform enabled prospective collection of longitudinal, multidimensional data,” but was limited by “selection bias, low retention rates, reporting bias, and data security.”[34] Another study, on building an evidence base for mHealth programs internationally, evaluated programs based on health focus, strategies, study design and evaluation assessment. Among the study’s limitations were consistency, capacity in designing and implementing randomized control trials, and accuracy of reported data.[35]

Designing randomized control trials is a challenge in connected health. This is largely due to the combination of technology, actors, and incentives. Questions often arise, such as:

- *What is the mechanism of effect in personal connected health — does monitoring itself produce change or only monitoring plus incentives plus coaching?*
- *What can we learn from psychology and behavioral economics?*
- *Does behavior change require ‘patient activation’ or a motivation to change?*
- *Can results be generalized from one app or device to another?*

In response to a study on wearable technology, which showed negative results, several comments addressed the issues, not only for that study but for research in personal connected health in general:

> Clinical trials can contribute knowledge about both efficacy and mechanisms of action. Efficacy concerns whether the intervention is “better” than a control, such as standard of care; mechanisms concern how the intervention produces desired outcomes — its hypothesized causal pathways. For pharmacotherapies, after years of bench research, a new drug’s action pathways are typically understood well enough that a clinical trial can both test efficacy and generate evidence about causal mechanisms.[36]

Commenters also noted that the failure of the study participant to use the device as prescribed, or the fact that the device was current at the time of the study but now is outdated, can influence applicability of the results. They also noted the necessity of defining a hypothesis that includes the causal pathway (such as active self-monitoring versus passive). The causal relationship related to technology use also has the potential to be confounded by the use of reminders and rewards as part of the study design. Others noted the importance of engagement with the intervention, the appropriate time to introduce the technology, and user experience design. Also, device accuracy needs to be validated and the subjects should be questioned about whether they are using other consumer-grade personal connected health technology. Cost-effectiveness studies in personal connected health are less common but are a challenge in any area of medicine.[37] Targeted recruitment has also been recommended as opposed to recruiting more broadly which can weaken results.[38] In addition, lifestyle intervention studies are difficult to blind and avoid bias.

Call to Action: Filling Gaps & Growing the Evidence

Most of the studies identified in the structured evidence review fall under one of two categories: 1) investigating how technologies can replace, enhance or supplement traditional healthcare provider-patient interactions or 2) investigating how technologies can create new opportunities for users to act independently in making healthy lifestyle choices. While the majority of the evidence-based investigations outlined in this review fall under the first category, fully exploring the potential of personal connected health will require many studies in the latter. Studies that strive to understand the underlying psychology of motivation and behavior change in lifestyle choices will remain relevant.[39]

Condition-Specific Use Cases in Personal Connected Health (continued)

Larger, multisite clinical trials are needed to move out of pilot phase and demonstrate scalability of connected health interventions. The growing number of review articles and meta-analysis publications is encouraging. A catalog of studies would be a helpful first step and a collaborative around connected health evidence has begun.[40]

Collaborative efforts, which utilize validated technology and engage patients in their use, will develop real-world evidence to move beyond the hype that may accompany consumer devices. Empowered patients may benefit from specific interventions like virtual coaching, which may be adopted as standard practice in the future.

The goal of personal connected health is to promote healthy behavior in each individual. To support this, research and evidence must evolve to a stage where a person becomes his or her own case and control through longitudinal data collection from a variety of sources, including personal connected devices and electronic and personal health records. Research in the field must thus be focused on developing an applicability to an ‘n of 1.’ Further, timely methods must be developed to keep pace with technological change and scaled trials are necessary, as they are what inform standards of care and practice.

In light of gaps uncovered in the aforementioned formal evidence review and review of use cases, we recommend the following areas of focus for future research and investment in personal connected health:

1. Increase the size of studies in personal connected health to enhance the body of meaningful evidence, working collaboratively if necessary.
2. Develop and disseminate consensus-based guidelines for research methodology in personal connected health, working with experts from across the field.
3. As part of developing consensus-based guidelines for research methodology, consider ways to accelerate research without compromising the quality of results.
4. Endeavor to validate apps and devices in comparative studies.
5. Fund studies exploring new ways for individuals to act independently to improve their health using personal connected health technologies.
6. Publish and promote a Research Priority Agenda via the Personal Connected Health Alliance and its members.

Conclusion

The potential of personal connected health is clear. It is emerging from individuals' natural interest in good health and the compelling nature of personal technology. As is often the case, investment and innovation in personal connected health is currently outpacing the evidence to support its most beneficial uses. There is a growing body of evidence in this field, but more work is needed, in particular in the areas of research methodologies and large-scale trials alongside a transition towards studies with an 'n of 1.' This will be made possible through the effective use of data exhaust from personal connected health devices in combination with other sources of personal health data. Collaboration between consumers, clinicians, industry, researchers, and regulatory bodies will also be necessary to develop real-world evidence validating personal connected health tools. Personal connected health will ultimately succeed in reaching its potential when timely evidence to support adoption begins to keep pace with innovation.

Authors:

- **John Sharp, MSSA,** Senior Manager, Thought Leadership
  Personal Connected Health Alliance
- **Sarah Cunard Chaney, MPH, MSc,** Research Analyst
  Personal Connected Health Alliance
- **Janna Guinen,** Senior Program Advisor
  Personal Connected Health Alliance
- **Patricia Mechael, PhD, MHS,** Executive Vice President
  Personal Connected Health Alliance

Footnotes

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The full Appendix can be found on the PCHAlliance website at:

www.pchalliance.org/sites/pchalliance/files/PCHA_Evidence_Paper_Appendix_FINAL.pdf

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