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### Annals of Clinical and Experimental Hypertension

#### **Research Article**

# Telehealth Technologies –Are They Useful or Simply Risky and Costly for Patients with Hypertension?

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#### Abstract

Hypertension is a prevalent condition, affecting 31% (67 million) of American adults; it is not under control for more than 50%. The disease contributed to or caused the deaths of 348,000 Americans in 2008, and like other chronic diseases, requires ongoing management and self-care. Self-management, however, is complex and patients require ongoing support. Several recent telehealth offerings provide a means with which to foster the knowledge and skills necessary for those with hypertension and diabetes to engage in successful self-management.

This manuscript considers the applicability, efficacy, and cost effectiveness of telehealth for individual patients and populations with high blood pressure (HBP). Risks associated with telehealth delivery and interventions are also highlighted. For the purposes of this paper, telehealth is broadly defined as telecommunication technologies, which include but are not limited to mobile phones, computers, the Internet, supporting software, and emergent offerings. Telehealth is a broad term, encompassing telemedicine, mobile health that is used for physician-patient interactions, diagnostics, care delivery, education, information sharing, monitoring, and reminders.

Telemedicine may have considerable utility for people diagnosed with HBP, but there are also considerable risks. Telehealth technology is rapidly evolving even in the absence of fully proven cost effectiveness and efficacy. For patients with poor access or social barriers that constrain access, telemedicine can be a particularly effective tool. Considering cost of in-patient and emergency department care for patients with hypertension, telehealth is a highly attractive alternative, but there are risks to consider.

Incorporating telehealth, which is increasingly characterized by mobile health, can increase both the capacity of healthcare providers and the reach of patient support, clinical management, and self-care. Telehealth studies need improvement; long-term outcome data on cardiovascular events need to be obtained. Additional risk analyses and economic studies are needed to prospectively evaluate the safety and cost savings for HBP self-management.

#### **INTRODUCTION**

Hypertension, commonly referred to as high blood pressure (HBP), is a prevalent condition, affecting 31% (67 million) of American adults, and it is not under control for more than half of these patients [1,2]. HBP contributed to or caused the deaths of 348,000 Americans in 2008 and like other chronic diseases; it requires ongoing management and self-care [3]. The Director of the Centers for Disease Control and Prevention (CDC), Tom Frieden, recently declared better blood pressure control as a national priority, raising the importance of tools that can help achieve it. Clinical guidelines state that systolic blood pressure level should be the major factor for detection, evaluation and treatment of hypertension [4]. Accordingly, a number of HBP self-care instruments are available, and evidence-based medicine is increasingly stressing the importance of patient self-care [5,6].

HBP is a common comorbidity among the nearly 26 million patients diagnosed with diabetes in the US and is also a major cardiovascular risk factor for those with prediabetes [7-9]. The Institute for Clinical Systems Improvement (ICSI) diabetes guidelines note that aggressive blood pressure control is just as important as glycemic control for management of the disease [7]. Individuals with hypertension and diabetes, for example, typically receive medical and medication management to control multiple factors: blood pressure, A1C, and weight. Two or more blood pressure lowering agents are often required to meet blood pressure goals. Blood pressure, weight, and blood glucose levels are to at least some extent amenable to behavior modification, which can be effected by education-related behavior change and self-management. Self-management, however, is complex and patients require ongoing support. Several recent telehealth

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offerings provide a means with which to foster the knowledge and skills necessary for those with hypertension and diabetes to engage in successful self-management.

Effective and efficient ways to improve clinical and economic outcomes for those with HBP and related chronic diseases are of considerable interest to key stakeholders (employers, health plans, physicians, and policy makers). Direct medical expense costs of HBP in the US are notable at \$47.5 billion; productivity losses add another \$3.5 billion [8]. Hence, affordable approaches to care delivery are being sought.

HBP care management and support are increasingly becoming available via telehealth. One indicator is the number of manuscripts published in the peer-reviewed literature. Telephonic, home-telehealth, and remote blood pressure monitoring devices as well as mobile applications (apps) for HBP have proven promising in recent studies [10-12].

Telehealth is both an individualizable tool for care management as well as a population-based approach that is believed to have the potential to optimize resources and increase access to self-management education and support [13,14]. The literature on telehealth includes several studies showing the approach to be efficacious, cost effective, and scalable; it also can increase access to care for individuals with chronic illnesses in underserved areas [15,16].

Conversely, various risks are associated with remote delivery of healthcare, which has been subject to limited oversight and regulation. Interestingly, it was only in October 2013 that the US Food and Drug Administration (FDA) released final guidance for mobile medical apps, outlining a tailored approach to these software programs that run on mobile communication devices and can perform the same functions as traditional medical devices [17].

This manuscript considers the applicability, efficacy, and cost effectiveness of telehealth for individual patients and populations with HBP. It also highlights risks associated with telehealth delivery and self-management interventions.

#### **MATERIALS AND METHODS**

For the purposes of this paper, telehealth is broadly defined

as telecommunication technologies, which include but are not limited to, mobile phones, computer, web, supporting software, and emergent offerings. Telehealth is a broad term, encompassing telemedicine, mobile health (m-health) that is used for physicianpatient interactions, diagnostics, care delivery, education, information sharing, monitoring, and reminders (see Table 1) for definitions.

Information was gleaned from published literature, Association and government websites, and policy experts working in the field in the US and abroad. A search of PubMed in Nov 2013 using the search terms "telehealth" and "hypetension" found 253 papers. A search using terms "mobile health" and "hypertension, yielded 50 papers, while "apps" and "hypertension" yielded five. A preliminary scan of the literature indicated that telephonic, home-telehealth, and remote blood pressure monitoring devices as well as mobile apps for HBP have proven promising [10-12].

#### **RESULTS AND DISCUSSION**

#### **Telehealth background**

Today, telehealth is transforming health care by moving diagnostics, education, and patient monitoring out of physicians' offices and into patients' home and other nontraditional care settings. Telephonic, general packet radio service (GPRS) or satellite connectivity, computer interface and m-health (provided via mobile medical apps) facilitate remote diagnostics, care delivery, and monitoring. For example, medical apps allow smartphones to become electrocardiography (ECG) machines to diagnose abnormal heart rhythms. Telehealth apps now also serve as mobile ultrasound devices, or interconnected glucose meters for people with insulin-dependent diabetes. Additionally, connectivity helps patients better manage their own health by enabling access to useful information (and reminders) that is at the patients' fingertips whenever and wherever they wish to find it.

As technology has improved in the last 10 years, so has the ability to deliver remote patient education and support. Accordingly, the demand for participation in telehealth programs and the development of new services has also increased. There is evidence supporting the increased demand for telehealth, especially in regard to chronic disease management and

#### Table 1:

Telehealth/telemedicine	According to the U.S. Department of Health and Human Services (HHS), telemedicine is the use of electronic information and telecommunication technology to "support long-distance clinical health care, patient and professional health-related education, public health and health administration" <sup>[a]</sup> Devices used to facilitate telemedicine can include smartphones, two-
	way video, and other wireless communications.
m-health	This term refers to "mobile health" or "mobile health care." It is the use of mobile and wireless devices to improve health outcomes, health care services, and health research. <sup>[6]</sup> It also encompasses mobile computing, medical sensor, and communications technologies for health care. <sup>[c]</sup> This can be used for monitoring services and transmitting real-time clinical or stored and forwarded data to assist providers in monitoring and establishing treatment plans for people with chronic illnesses such as hypertension.
Remote monitoring/remote monitoring devices	Remote monitoring, which both hypertension patients and caregivers may utilize, is sometimes referred to as homecare telehealth. Smartphone technology, Internet connectivity, and wireless monitoring devices can facilitate daily monitoring for patients with hypertension. Collected data may be stored and/or sent to an educator or physician.

<sup>a</sup> Health Resources and Services Administration. Telehealth. HRSA. http://www.hrsa.gov/ruralhealth/about/telehealth. Published November 20, 2012. Accessed November 9, 2013.

<sup>b</sup>Health Resources and Services Administration. mHealth. HRSA. http://www.hrsa.gov/healthit/mhealth.html. Accessed November 9, 2013. <sup>c</sup>Istepanian RSH, Jovanov RE, Zhang YT. Introduction to the special section on M-Health: beyond seamless mobility and global wireless health-care connectivity. *IEEE Trans Inf Technol Biomed.* 2004;8(4):405-14.

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education. Several groups drive the demand. According to Becker's Hospital Review of a recent report by InMedica, there are currently four main drivers of telehealth demand [18]. These are:

- 1. Federal-driven demand. In the U.S., readmission penalties introduced by the Centers for Medicare and Medicaid Services (CMS) are driving providers to adopt telehealth as a means of reducing readmission penalties. Worldwide, healthcare providers are looking to reduce healthcare expenditure through telehealth programs.
- 2. Provider-driven demand. Healthcare providers want to use telehealth to maintain ties with patients and improve quality of care.
- 3. Payor-driven demand. Insurance providers are also using telehealth to increase competitiveness and reduce inpatient pay-outs.
- 4. Patient-driven demand. For now, patient-driven demand is mostly limited to rural areas where there is poor availability of clinics and physicians. However, patients in metropolitan areas are expected to increasingly seek professional devices to remotely track their health, according to the report [18].

Additionally, the American Telemedicine Association recently reported that organizational and individual memberships have reached a new peak with 132 private companies, 134 healthcare institutions, and over 7,000 professionals [19]. This represents a jump of 10% in organizations and over 25% in individual members.

"The growth in ATA's membership reflects the growing use of telemedicine in the delivery of healthcare throughout the world," according to Ed Brown, ATA's president and Chief Executive Officer of the Ontario Telehealth Network [19]. Two examples support this view. The American Association of Diabetes Educators sought and received funding for studies in telehealth efficacy for providing education via telehealth to patients with diabetes and co-morbid conditions. Funding sources were sought and easily secured; the research was sponsored by a large national telecommunications company and a pharmacy management company. In the second example, a company that produces educational videos sponsored an "Innovative Use of Media and Technology Award," further indicating demand for services that fall under the telehealth umbrella.

Medicare as well as some commercial insurers are beginning to pay for telehealth services for a variety of chronic illnesses [20,21]. As coverage expands, both the demand for and supply of telehealth opportunities are anticipated to grow. In addition, patients recognize the benefits (time saved, increased access to quality care, and connectivity) of telehealth.

# Risks Associated with Telehealth/Risk Management – the Legal Viewpoint

In contrast to the provision of traditional face-to-face health care services, telemedicine presents a range of scenarios, each with his own inherent risks, which do not necessarily fit neatly into the legal framework established for face-to-face services. As such, risk identification and mitigation in the telehealth space are important factors to consider.

It has been recognized that technology enables health care organizations to deliver new ways of providing health care, which can blur the boundaries of health care settings and also the traditional roles of health care professionals [22,23]. It is this "blurring" of settings and professional roles which may give rise to new risks and questions surrounding the increase of liabilities for physicians who adopt and implement telehealth.

While the following scenarios are not exhaustive, telehealth legal risks can arise in relation to privacy and security requirements, jurisdictional boundaries, and informed consent. It has been recognized that legal or ethical guidance for health practitioners to safely navigate these circumstances is lacking. Given the actual or perceived level of risks associated with telehealth, this lack of guidance for physicians and other participants in telehealth is a concern, particularly when considering the adoption and uptake of telehealth services. Further, the FDA's recently published approach to the regulation of mobile medical applications lends support to the continuing ambiguous legal circumstances physicians engaging in telehealth may find themselves in [17].

Telehealth has functioned with little oversight or regulation until very recently. In fall 2013, the FDA increased its oversight but stated that it "intends to exercise enforcement discretion (meaning it will not enforce requirements under the Federal Drug & Cosmetic Act) for the majority of mobile apps as they pose minimal risk to consumers" [17]. Regulatory oversight will focus on those mobile medical apps that are likely to present a risk to patients if they do not work as intended. While the FDA has taken steps to clarify the regulatory framework applying to mobile health applications (i.e., by stipulating which medical applications they will focus their attention on), a gap may still exist in relation to the multitude of applications that do not fall within those criteria.

#### Applicability and Efficacy of Telehealth to HBP

The literature suggests the usefulness of telehealth for patients with HBP. The care delivery method boosts adherence to HBP treatment according a Brazilian study of 502 patients with the condition who attended web conferences over a period of six months [24]. Eakin et al. (2010) found regular, ongoing telephone contact helps to motivate patients to increase physical activity and improve their diets [23]. Studies show that successful outcomes may be achieved by combining telehealth with usual care or incorporating multiple telehealth approaches [25]. Bove et al. (2013) randomized 241 urban, underserved patients with systolic BP≥140 mm Hg to a telemedicine intervention or usual care, concluding that the intervention may be a useful tool for managing hypertension, particularly among nondiabetic subjects [26]. Carter et al. reported success with home-based use of wireless scales, blood pressure cuffs, and glucometers for patients with diabetes and co-morbid conditions [27]. A sixmonth telehealth randomized control group (RCT) study that focused on heart disease in Iowa reported improved A1c and systolic blood pressure (SBP) among those with HBP. In this study Wakefield also found that "although older patients may

not be accustomed to using technology, it doesn't mean they aren't willing to learn" [11]. Expanding on the typical telehealth communication capabilities, some hospitals aim to enhance safety and better manage clinical data via wireless sensor networks for care monitoring systems [28].

#### **Economic Analyses of Telehealth**

Over time, economic analyses of telehealth have yielded inconsistent findings and conflicting evidence. Systematic reviews conducted prior to 2009 on the cost effectiveness of telehealth interventions in general tend to demonstrate its cost effectiveness. But in 2002, Whitten et al. concluded that there is no good evidence that telemedicine is or is not a cost-effective means for delivering healthcare in general. Ekeland examined 80 systematic reviews on the effectiveness of telemedicine, of which 21 concluded that telemedicine is effective and that home monitoring of diabetes is among the interventions that are effective in reducing health services use; however, 41 concluded that evidence is limited and inconsistent [29]. Currell's Cochrane Review on diabetes-related care reported evidence on the feasibility and satisfaction with various forms of telemedicine for those who self-monitor at home or have video consultations but showed lack of evidence of improved health outcomes or costs [22]. One problem with many studies is that benefits may be undervalued because little research exists about additional benefits, such as travel-time costs avoided by patients in rural areas.

#### **Population-Based Strategies for Telehealth**

Several population health management programs (also known as disease management programs) utilize telephonic contact; both clinical and economic improvements have been reported from the intervention [30]. In 2009, Fjeldsoe et al. assessed SMS for delivering behavior change interventions, finding positive behavior change outcomes in 13 out of 14 studies, four of which, reported on targeted health behaviors and 10 on clinical care (e.g., disease management) [31]. These authors concluded that SMS-delivered interventions have positive short-term behavioral outcomes but noted the need for improvement in the quality of related studies.

Population health is integral to chronic disease management, which is of particular importance to low-income and minority communities. The usefulness of telephonic outreach by care managers to people with hypertension and other chronic illnesses has been demonstrated [32,33]. Moreover, the market for apps on mobile devices is growing rapidly—over 40,000 are available and being used in the US. Clinical management apps that facilitate chronic care management enable patients and providers to work to control blood pressure by helping patients monitor and record their blood pressure and access their electronic health records [33]. Because these attributes may be especially useful to members of underserved low-income and minority communities, identification of best practices for program implementation and engagement will be helpful.

#### **Policy Perspective - Issues/Benefits**

Public and private payers are increasingly interested in investing in cost-effective programs. These payers are currently

exploring policies that support the use of telehealth (including mobile applications) for chronic disease management. However, for policy to be effective, there will need to be more research on best practices and ways for payers (such as the government) to mitigate risk. In addition, Medicaid policy makers specifically struggle to ensure access for patients in rural areas, and telehealth offers potential opportunities to improve access. If more widely available at a lower cost, both self-management and telehealth/ m-health will help with the concurrent issue of resource distribution. As a matter of policy, payers are not interested in cutting programming but rather making spending more efficient. Policy makers struggle to establish policies focused on prevention so that more cost-effective disease management, specifically selfcare and less reliance on institutionalized care, is increasingly appealing.

#### State-Level Initiatives in the US

Many states are beginning to define telehealth, look at possible reimbursement models, and create pilot programs to show the return on investment as well as the health outcomes to the patient. As of October 2012, 13 states required private insurers to pay for medically necessary telehealth services that would otherwise be covered when provided face-to-face. These states are Maryland, California, Colorado, Georgia, Hawaii, Kentucky, Louisiana, Maine, New Hampshire, Oklahoma, Oregon, Texas, and Virginia [21].

An example of payer interest can be found in the state of Maine, where a number of barriers to access to care have been noted. The Telephonic Diabetes Education & Support program (TDES<sup>®</sup>), sponsored by Medical Care Development, Inc., has partnered with organizations such as Aetna Health, Blue Cross and Blue Shield (BCBS) of Maine, and the Maine Municipal Employees Health Trust to address this need [34]. The goal of TDES<sup>©</sup> is to help persons with diabetes, cardiovascular disease, hypertension, and/or high cholesterol overcome barriers to access by using telephone-based intervention to help increase the number of patients being involved with their own selfmanagement and improve health outcomes [35]. Since the implementation of the pilot program in 2004, participants have seen overall clinical improvements in A1c, blood pressure, total cholesterol, and LDL as well as improvements in HEDIS measures. The 2008 ROI showed a cost-savings of \$1,300 per participant, per year as well as a significantly higher medication adherence and use of preventative care, which can be associated with the higher quality of care. The success of this program has led to the second offering (TDES<sup>2</sup>) where participants who have completed the first phase receive advanced training in self-management.

#### **Telehealth Beyond the US Borders**

Telehealth is being implemented and accepted by practitioners and patients worldwide [35-38]. There is substantial potential for telehealth as a tool to improve reach and to reduce geographic disparities in developing nations. In India, for example, the market is significantly greater for traditional forms of telehealth for hypertension management vs. open-source self-management apps (which are limited to Android users with data packages). India's objectives and implementation strategy are very much parallel with telehealth in the US; however, it

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faces many additional implementation and financing setbacks, some unique to the context with other challenges generalizable. India's telehealth has largely been spearheaded by government initiatives or large, private, super-specialty hospitals that foster partnerships with rural hospital units, with the exception of a few non-governmental organization (NGO)-run programs [37-41]. As a result, most telehealth programs in India are narrow in terms of scope, although they still improve access to specialty care that otherwise would have been unattainable.

Globally, the burden of HBP has been growing rapidly, particularly in populations in developing nations. In India, its prevalence is rising at much faster rates in some states than in others. In Tamil Nadu, a study published in 2012 estimated that rural population prevalence of HBP is 21.4%, with 75% of those hypertensive individuals unaware of their status [41]. The Madras Diabetes Research Foundation (MDRF) founded a satellite-connected rural telemedicine facility via a rural, mobile diabetes care center [42]. The aims of the project, Sai Rural Diabetes Specialties Centre, include "to implement prevention of diabetes at three levels...to screen for diabetes... [and] to screen for diabetic complications" [42]. Obviously, there is considerable overlap with HBP and self-management.

In addition to the limited literature on evidence of telehealth in developing nations, uptake is low and limited in scale, as telehealth has many additional challenges in India and globally. Implementation challenges in developing nations include resource constraints, administrative capacity, donor interest, logistics and transportation, and technological setbacks, which all can prove to be significant barriers to scale.

## The Future of Telehealth for Hypertension Control and Self-Management

Making better blood pressure control a national priority raises the importance of tools that can help achieve it. The potential for ongoing growth of telehealth for HBP is high; nearly 60% of adults in the U.S. use laptops and smartphones to connect to the Internet by wireless means, and one in four smartphone owners eschew desktops or laptop computers for accessing the Internet [43]. At the same time, the published literature indicates that telehealth is acceptable to HBP patients because of its convenience and the way it increases access to care at low cost to the end user. Studies of telehealth programs show at least short-term clinical improvements. For blood pressure outcomes, such findings may be explained in part because home blood pressure readings may be more reliable than those obtained in a physician's office because of the "white coat syndrome" in which a patient's blood pressure is elevated in clinical settings, but not in other settings.

The majority of the studies we reviewed found evidence of effectiveness (clinical and patient satisfaction) of interventions delivered electronically; only a limited number found evidence of improved behavioral outcomes and cost effectiveness. Readers are cautioned to evaluate telehelath studies critically because few long-term studies have been conducted and some published studies a have flawed methodologies or lack objectivity. A large proportion of economic evaluations on telehealth and chronic conditions have tended to be inconclusive, and many studies showing positive results are not robust [44]. Mobile phone apps facilitate simple and fast communication about key health information between patients and care providers, reduce barriers, and augment care management. These apps now need to prove that they can help achieve optimal clinical and better economic outcomes for people with HBP and other chronic diseases.

At the state level, telehealth in general is gaining traction as studies relating to HBP show positive results for care management and clinical outcomes. A handful of economic evaluations suggest that telehealth interventions can save money, which is of prime importance to payers who are interested in advancing cost-effective care management programs that align with evidence-based medicine. Policy makers encourage adoption of affordable, safe, high-quality care that is provided in the right setting at the right time. The challenge will be making the case for reimbursement for telehealth and mobile applications for disease management. More research to demonstrate cost effectiveness and best practices for policy makers will be essential.

The use of mobile technologies for health-related computations and communication is a rapidly expanding area of research and practice, particularly with younger and "connected" patients. While underrepresented in the peer-reviewed literature, m-health communication tools can also be used to deliver preventive and educational services.

#### **CONCLUSIONS**

Telemedicine may have considerable utility for people diagnosed with HBP but there are also considerable risks. The telehealth technology is rapidly evolving even in the absence of fully proven cost effectiveness and efficacy. For patients with poor access or social barriers that constrain their access, telemedicine can be a particularly effective tool. Considering cost of in-patient and emergency department care for patients with HBP, telehealth is a highly attractive alternative, but there are also risks to consider.

Incorporating telehealth, which is increasingly characterized by m-health, is another item in the tool kit that has the potential to increase both the capacity of healthcare providers and the reach of patient support, clinical management, and self-care. However, long-term outcome data on cardiovascular events need to be obtained and future telehealth studies need to be improved so that they are valid, reliable, and generalizable. Additional risk analyses and economic studies are needed to prospectively evaluate the safety and cost savings for HBP self-management.

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