Chapter

Evaluating the Clinical and Cost Effectiveness of Musculoskeletal Digital Health Solutions

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Abstract

This chapter will introduce the clinician to the quickly expanding field of musculoskeletal-focused digital apps (MDA), with an eye towards helping the clinician select and recommend MDAs for optimal patient care. MDAs are increasingly being used for physical therapy and rehabilitation, telehealth, pain management, behavioral health, and remote patient monitoring. The COVID-19 pandemic has vastly accelerated the adoption of telehealth and digital health apps by patients and clinicians, and the digital health field will only continue to expand as developers increasingly harness artificial intelligence (AI) and machine learning (ML) capabilities, coupled with precision medicine capabilities that integrate personal health data tracking and genomics insights. Here we begin with an overview of several types of MDA, before discussing the epidemiology of musculoskeletal conditions and injuries, clinical considerations in selecting a digital health solution, payor reimbursement for digital apps, and regulatory oversight of digital health apps.

Keywords: digital health, telemedicine, physical therapy, musculoskeletal, artificial intelligence

1. Introduction

Digital health is a rapidly growing field. As of early 2019, there were over 318,000 mobile health applications in different app stores--and that number itself doubled since 2015 as consumers increasingly used mobile apps to manage their health [1]. Popular mobile health apps include AI-powered health symptom checkers, clinical records management apps, remote patient monitoring tools, patient self-monitoring tools, rehabilitation programs, and apps for medical condition education and management. In fact, healthcare applications constitute the most popular smartphone activity. Currently, 90% of physicians use smartphone applications for medical records, communication with their teams and for clinical content like UptoDate [2]. Over 75% of the largest health systems now offer mobile applications focused on patient engagement [3]. The global mobile health market is growing and is expected to reach $111 billion by 2025 with fitness constituting $50B in the US health market. The current COVID-19 Pandemic will accelerate the adoption and will further increase the adoption and growth [4].

An American Medical Association survey found that physicians' use of technology to provide televisits or virtual visits doubled from 2016 to February 2020, with nearly 30% of doctors adopting digital health technology [5]. And since the start of

Application	Category	Physical and Mental Exercises	Relaxation Practices	Learning Modules	Effective for Low Back Pain	No Hardware Required	Online Mentors	In-Person Mentors	Best for Large Businesses
Kaia Health	Multimodal Pain Therapy	Yes	Yes	Yes	Yes	Yes	Yes	No	N/A
Wellness Coaches	Onsite Personalized Therapy	Yes	Yes	Yes	N/A	Yes	No	Yes	N/A
HBD International	Solutions To Reduce Client (Company) Injuries	Yes (Employee Morale Boost)	N/A	Yes	N/A	N/A	Yes	N/A	Yes
Movement RX	Mind-Body Connection Improvement	Yes	Yes	Yes	N/A	Yes	Yes	N/A	Yes
PHZIO Media	Early Prevention and Intervention (Thru PT)	N/A	N/A	N/A	N/A	N/A	Yes	N/A	Yes
Airrosti	Prevention, Recovery, and Education	N/A	N/A	Yes	N/A	Yes	Yes	N/A	Yes
SimpleTherapy	Personalized Pain Recovery	Yes	N/A	No	N/A	No	Yes	N/A	N/A
Hinge Health	Sensor-Guided Exercise Therapy	Yes	N/A	Yes	N/A	No	Yes	N/A	Yes

Table 1.
Digital Health Apps for Managing Musculoskeletal Pain and Functional Limitations [9].

the COVID-19 pandemic, physician use of telemedicine has increased exponentially as digital technologies have become increasingly adopted by both physicians and consumers. Physical therapist and physiotherapist adoption of musculoskeletal-focused digital apps (MDA) has likewise expanded exponentially [6]. Consumer adoption of telehealth increased from 11% of care visits in 2019 to 46% in May 2020, as providers scaled the offerings and are seeing 50 to 175 times the number of patients via telehealth compared to before. In 2019, the annual revenue of US telehealth vendors was $3 Billion with a big focus on the virtual urgent care segment. With new Centers for Medicare and Medicaid Services (CMS) policies being implemented during the crisis to expand the use of virtual care, up to $250 Billion of current US healthcare spend could potentially be virtualized [7]. Primary care and behavioral health have led in the number of virtual visits. The services/clinical models that have the greatest potential for virtual care include on demand virtual urgent care, office visits, home health services and home medication administration services [8].

In particular, the number of mobile medical apps for musculoskeletal conditions and injury management is increasing exponentially as organizational health and wellness initiatives increasingly focus on pain management and holistic care. **Table 1** provides an overview of features present in several MDAs on the market as of August 2020. The general purpose of these different musculoskeletal apps is to provide therapy on a large sale for patients with musculoskeletal disorders. The MDAs surveyed in this table have physical or mental exercise programs, and some have behavioral interventions such as mindfulness practice. Most apps also have learning modules to teach organizations and individuals how to stay safe and protect themselves from further issues.

The MDAs surveyed differ in their targeted goals and their approach to achieving their goals. For example, Kaia Health concentrates on using multiple approaches to minimize pain, whereas Movement RX focuses on strengthening the mind-body connection to reduce pain. Wellness Coaches places emphasis on a very personalized and face to face therapy program. And while many apps do not have physical hardware, SimpleTherapy and Hinge Health use sensors that can be placed over joints to track progress and pain.

Moreover, most of the surveyed MDAs can be effectively used to improve population health, injury prevention and rehabilitation in large organizations and companies. The MDAs focus on individual health and progress, while also addressing how to prevent organizational ergonomic issues and manage musculoskeletal injury recovery.

2. Epidemiology of Musculoskeletal Conditions and Injuries

Musculoskeletal conditions continue to increase in incidence and prevalence, especially as the geriatric population grows, and organizations continue to have unremedied ergonomics issues. Musculoskeletal disorders are highly prevalent, yet frequently mismanaged and costly. Musculoskeletal injuries are also a top cost driver for employers, as no other chronic health condition causes more lost workdays and more healthcare spend than musculoskeletal injuries [10]. Musculoskeletal lower back injury is the leading cause of disability both globally and in the U.S., and the number one reason for missing work [11]. In the U.S. alone, musculoskeletal lower back injuries result in more than 260 million lost workdays each year as well as significant healthcare and disability insurance costs [12]. 1 in 2 adults in the U.S. were diagnosed with musculoskeletal conditions in 2012. Despite the high prevalence of musculoskeletal conditions, 80% of patients do not receive evidence-based care [13]. As detailed below, musculoskeletal pain continues to be frequently

mismanaged with opioid analgesics, and unnecessary surgery is frequently performed when physical therapy and rehabilitation would be more appropriate. Medical costs for imaging, diagnosis and treatment of musculoskeletal injuries and conditions continue to rise [14].

Musculoskeletal joint pain has significant impact on patient function and future health. Joint pain reduces physical activity, increases opioid use, impacts productivity, and leads to obesity [15]. Obesity in turn increases the risk for diabetes, heart disease, depression, and cancer [16].

Yet Musculoskeletal pain is frequently mismanaged with opioid analgesics. Even as warnings of an opioid crisis in the US have increased provider and patient awareness of the dangers of opioid analgesics, opioids remain a commonly prescribed treatment for lower back musculoskeletal pain. The dangers of opioid analgesics are well known and include dependence, dangerous side effects including respiratory depression, fatality from drug overdose, and high incidence of concomitant illicit drug use [17]. Moreover, when used to treat new diagnoses of lower back pain, opioid analgesics result in longer recovery times, increased serious adverse events, and greater healthcare utilization (emergency room visits and hospitalizations) compared to non-opioid analgesics [18].

Likewise, patients frequently receive inappropriate surgery for musculoskeletal conditions. Studies have shown that approximately 66% of surgeries are avoidable [19]. Inappropriate surgery for musculoskeletal conditions comes with significant recovery times, lengthening the treatment period, increasing cost of care, and yielding poorer pain and functional outcomes relative to conservative management and physical therapy [20].

Musculoskeletal issues will continue to rise, especially as the geriatric population grows, ergonomic work situations are not well controlled in factories and warehouses, and medical costs for imaging, diagnosis and treatment continue to rise. Studies predict that by 2030, there will be a 500% increase in total knee replacements [21], and a 200% increase in total hip replacements in 45- to 64-year-olds [22]. Likewise, studies project a 28% increase in spine surgeries by 2024 [23].

3. Critically Assessing Musculoskeletal Digital Apps

With increasing adoption of telehealth and digital solutions comes increasing demands on clinicians to recommend and use MDAs appropriately, while avoiding dangers and pitfalls. Here, we detail methods to assess the clinical effectiveness, the functionality, and the reliability of digital health solutions.

The landscape of digital health solutions on the Internet and app stores has been likened to the Wild West, given the inability of regulators to keep up with the explosive growth of medical apps. A significant pitfall to avoid is apps that falsely claim to diagnose, prevent, or treat a disease or medical condition. Such claims require FDA review and approval prior to marketing, and digital apps have been pulled off the market for making false claims. For example, in 2011, an app developer claimed that the app could use the blue light emitted from a mobile device to cure acne. The Federal Trade Commission (FTC) intervened to prohibit marketing of the app, and the app was removed from app stores for failure to obtain regulatory approval [24]. For digital health apps that do not make diagnostic, prevention, or treatment claims, however, regulatory approval is not required. Absent fraud, such apps will not be removed from the digital marketplace. It is thus important for clinicians to be able to assess the utility of digital health solutions.

Two well-known entities that evaluate Internet resources are the Health on the Net Foundation (HON) and the Agency for Healthcare Research and Quality

(AHRQ). HON published a HON Code of Conduct (HONcode) in 1996 that includes 8 principles for certifying information on health and medical websites. The 8 principles include Authority, Complementarity, Confidentiality, Attribution, Justifiability, Transparency, Financial Disclosure, and Advertising [25]. AHRQ proposed similar criteria, including credibility, content, disclosure, links, design, interactivity, and caveats [26]. Hanrahan et al. recommend applying similar criteria to the evaluation of digital health apps [27].

In assessing the clinical effectiveness of an intervention, the clinician will want to consider the types of study designs used to generate evidence of effectiveness [28]. Traditionally, randomized controlled trials are considered the gold standard in evidence assessment [29], followed by observational studies such as cohort, cross-sectional, and case-control studies, and ending with descriptive studies such as surveillance, surveys, and case reports [30]. However, a nuanced that takes into account the size of the study and the rigor of the study design, recognizes that large, well-designed observational studies can yield among the highest-quality clinical evidence. Moreover, observational studies offer evidence of clinical effectiveness under real-world conditions, in contrast with randomized trials, which may have restrictive inclusion and exclusion criteria and lack generalizability beyond the highly controlled experimental study settings [31]. A commonly used system of assessing the quality of evidence generated by medical studies is The Cochrane Collaboration's GRADE approach [32].

MDAs vary widely with regard to functionality. By being aware of the different functions offered by different MDAs, the clinician can tailor recommendations to patients with different musculoskeletal monitoring or rehabilitation needs. As detailed in **Table 1**, some apps are more focused on pain management, while others are focused on restoring and improving physical function. Some apps include hardware, such as EKG and heart rate sensors and sensors over joints to track movement. Other apps focus on behavioral interventions to address pain and help patients stay on track with physical therapy plans to address musculoskeletal injuries.

Evidence based exercise-therapy is another function offered by a number of digital vendors. From gathering detailed information on movement and activity and leveraging artificial Intelligence, digital apps can deliver personalized advice and exercise programs that adapt according to the progress made by the individual. Some apps focus on preventing the development of conditions and maintaining musculoskeletal health, including access to a comprehensive library of preventative exercise programs, including Pilates, yoga, stretching and strengthening options. TrackActive is a digital application that specializes in rehabilitation of musculoskeletal conditions and acts as virtual physio enabling people to assess and self-manage injuries and common conditions from home [33]. Based on the member profile, this application tracks members activities using different surveillance techniques and provides personalized recommendations. Telehealth apps that facilitate virtual second opinions for different musculoskeletal conditions are also increasingly being utilized [34].

Many digital apps now focus on musculoskeletal injury prevention in occupational settings. Musculoskeletal injuries are the largest single category of workplace injury and account for 28% of all occupational injuries [35]. Occupational health focused digital apps thus aim to reduce muscle, joint, tendon, ligament and nerve injuries/illnesses across the workforce to improve availability and productivity [36].

With 40% of all mobile apps related to healthcare, verifying accuracy of clinical content and validating apps for intended clinical uses is critical. While assessing the clinical benefit of MDA functions, it is important to review the available evidence. For example, one randomized controlled trial (n=215) concluded that an MDA that included behavioral interventions such as medication reminders, daily

surveys of symptoms and potential adverse effects, fared no better than usual care in reducing pain scores [37].

Mobile health apps for monitoring postoperative pain are another promising frontier for MDAs. Such digital apps can provide real time monitoring and symptom management and can help improve self-management skills with post-operative pain. To alleviate pain, digital apps can provide appropriate distraction, relaxation, and guided imagery techniques. However, a critical review of digital apps focused on self-management of pain showed very limited involvement of healthcare specialists and limited evidence based self-learning content. Lalloo et al. found that of 10 mobile applications meeting inclusion criteria, none provided social support, goal setting criteria, or had scientific evaluation or end users in their development [38]. Only 50% of the apps included a provider specialist in the development. There is accordingly a need to build comprehensive pain self-management, evidence based, personalized, AI-driven mobile applications.

When assessing an MDA's functionality, the clinician will want to assess the MDA's ability to not only improve subjective pain scores, but also to improve objectively quantifiable measures of disability function. The MDAs with highest likelihood of yielding clinical benefit are those whose efficacy on objective measures have been established in peer-reviewed studies [39]. For example, two smaller randomized controlled trials demonstrated efficacy of MDAs with respect to improving both knee and back pain and disability function [40, 41]. These beneficial impacts on both chronic musculoskeletal pain and disability function were subsequently confirmed in a large 10,000 participant longitudinal cohort [42].

Moreover, some MDAs offer population health surveillance features that can be useful to health officers in organizations tracking the health of their workforce. While such features can be very useful in workforce injury surveillance and prevention, it is important to be aware of privacy issues when deploying such solutions in an organizational or work setting. In particular, the ability to leverage Artificial Intelligence (AI) focused digital health apps for population health surveillance have garnered critical attention during the COVID19 pandemic. Tools that track disease activity in real time include contact tracing applications that identify and track individuals who might have come in contact with an infected person. User consent is essential for the adoption and sustained growth of such digital health applications [43, 44].

Finally, in evaluating the utility of digital health apps, clinicians should also recognize app performance issues such as functionality, stability/reliability, and stage of development, which affect the usability of the app and the benefit to patients. The proliferation of digital health applications has led app developers to focus on functionality, stability, security, privacy, usability, reliability, and data accuracy. In evaluating performance of mobile apps, it is advisable to utilize a framework that evaluates each dimension of the application. We recommend a framework consisting of rating domains and criteria for each domain. The domains are (1) Usability, which includes functionality, visualization, ease of install and use, multi-language support and ability to customize; (2) Content (Technical), which includes performance, stability, interoperability, portability, bandwidth and application size; (3) Content (Health), which includes quality, presentation and validation of the information, literacy level, measurement and interpretation of the information and potential for harm; (4) Security/privacy/compliance, which includes data authentication, protection, tokenization, authentication and pro-active breach signaling; and (5) Transparency, which includes member consent, cost of the app and accuracy of the description in the app stores [45].

4. Employer and Payor Reimbursement

The COVID-19 pandemic fueled rapid healthcare provider adoption of telehealth, as social distancing measures were implemented and government and commercial payors relaxed regulations and reimbursement requirements [46]. The transformation of care delivery in turn enabled consumers and providers to connect via virtual healthcare visits and associated modalities. The widespread adoption of telehealth has led both employers and payers to accelerate and look for innovative ways to reimburse for different digital health apps. For example, the recent $37 Billion merger of telehealth leader Teladoc and digital chronic disease management company Livingo has set the precedent for rapid change in adoption of digital applications with payers and employers ready for embracing them as part of mainstream providers [47]. In the fragmented U.S. market, potential barriers remain in terms of who will pay, but payers are starting to cover digital apps.

The Decision Resources Group found that across healthcare executives in integrated health networks (IDNs), Medicaid managed care organizations (MCOs), and pharmacy benefits managers (PBMs), 25% said their organization provides coverage for digital therapeutics, and an additional 45% expressed interest in providing coverage. In a 2019 survey, the National Business Group on Health found that 25% of large self-funded employers are considering creating orthopedic centers of excellence by 2021 [48]. Moreover, 45% of orthopedic COE contracts are structured as bundled payments. Given the potential for clinical benefit and cost savings, employers and health insurance payors are increasingly reimbursing use of digital health apps.

5. FDA Regulation of Digital Health Apps

Products intended to diagnose, prevent, or treat disease must be approved by the FDA prior to marketing. FDA regulation of medical devices balances two competing goals: [1] promoting innovation and improvement in medical devices; and [2] ensuring that medical devices are safe and effective [49]. Accordingly, FDA classifies medical devices according to potential risk. Class I devices are low risk and subject to general controls, and examples include bandages and sunglasses. Class II devices are intermediate risk and are often approved subject to the abbreviated 510(k) pathway, if the devices are able to rely on the prior approval of a similar device. Examples include pregnancy test kits, hearing aids, and powered wheelchairs. Class III devices require a premarket approval application (PMA) and are subject to full FDA review of safety and efficacy. Only 10% of medical devices fall in this category, and examples include implantable pacemakers, and high-frequency ventilators.

FDA has historically struggled to fit medical software and apps into the traditional medical device classification. In recent years, however, FDA has issued more detailed guidance informing app developers when digital health products will need to undergo regulatory review, and the requirements for regulatory approval [50]. FDA takes a risk-based approach to medical software and app regulation, focusing on devices that could pose a risk to a patient's safety if the device were not to function as intended. For example, software functions that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors—such as motion tracking sensors or EKG functionality—will be subject to regulation as a medical device [51]. Apps that perform patient-specific analysis and provide patient-specific diagnosis, or treatment recommendations, such as

image-processing software and radiation therapy treatment planning software, will also be subject to close regulatory scrutiny. On the other hand, FDA intends to exercise its discretion not to enforce regulations for lower risk apps that automate simple tasks for health care providers or help patients self-manage their disease without providing specific treatment suggestions. For example, FDA will not enforce its regulations on software functions that provide physicians easy access to the latest treatment guidelines, or software that coaches patients on the basics of conditions such as obesity or arthritis and provide strategies for weight reduction. Indeed, most digital health apps are not reviewed and cleared by FDA. In November 2013, only 100 of over 10,000 medical apps available on the marketplace were cleared by FDA [52].

To evaluate the clinical effectiveness and safety of software as a medical device, FDA will assess the following questions: [1] Is there a valid clinical association between the software output and the targeted clinical condition?; [2] Does the software correctly process input data to generate accurate, reliable, and precise output data?; and [3] Does use of the software's accurate, reliable, and precise output data achieve the intended purpose in the target population in the context of clinical care? [53]

Because medical-grade digital health solutions intended to diagnose, treat, or prevent a medical condition are subject to FDA scrutiny, the stamp of FDA approval is an important designation on which clinicians and organizations can rely in deciding whether to recommend or adopt digital health solutions. Conversely, lower risk consumer facing apps that do not make treatment recommendations are not subject to FDA enforcement. Thus, clinicians can use these principles, considering patient preferences, in recommending digital health apps to their patients.

6. Conclusion

Consumer driven health care is here to stay, and the digital health landscape is rapidly evolving to become increasingly consumer facing [54]. Payors are increasingly reimbursing for digital health solutions, especially medical apps that have proven effectiveness and that have obtained FDA approval. However, the functionality and clinical effectiveness of musculoskeletal digital health solutions varies widely. It is thus essential for healthcare providers to assess the available evidence supporting effectiveness claims in digital apps. By understanding the MDA landscape, healthcare providers can leverage digital health tools to provide optimal clinical care to individual patients, and to help manage and prevent musculoskeletal injuries on an organizational scale.

DOI: http://dx.doi.org/10.5772/intechopen.94841

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