Mobile Prescription Therapy: A Case Study

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ABSTRACT

This chapter introduces a novel category of therapy that is born from the confluence of clinical, behavioral and data science innovation, and the ubiquitous access to and acceptance of mobile and Internet technology. Mobile prescription therapy (MPT) is a solution that holistically engages patients in the self-management of their disease in collaboration with their healthcare provider. MPT decentralizes, and in novel ways democratizes, the delivery of healthcare by empowering patients and providers through the use of wireless mobile devices, clinical and data science, and the Internet. At its heart, MPT represents the convergence of mobile technology, clinical and behavioral science, and validated clinical outcomes, to create a new-to-the-world healthcare solution that supports patients in their daily self-care, and provides their healthcare provider with additional data for decision-making.

This chapter will first address the healthcare and economic challenges specifically associated with the management of type 2 diabetes and the rationale behind the need for mobile prescription therapy. It then presents the MPT solution components, primary features and value-enabling characteristics, and then summarizes the clinical and economic value propositions achieved. The chapter concludes with a glimpse into the future, and illuminates the "vectors of value expansion" that MPT can unlock to achieve better health and better care in a cost-effective and scalable manner for all chronic diseases.

CHRONIC DISEASE: WHY MPT?

Chronic disease management is a challenge, not only for the person with the disease, but also for the healthcare providers who are developing and guiding the treatment plan, the healthcare system, support and caregiver members, and payers who provide the infrastructure for the care delivery.

In 2012, spending on chronic diseases in the United States represented 75 percent of the $2-plus trillion devoted to healthcare, and such diseases were responsible for

seven out of 10 deaths annually.[1] As recently as 2009, more than 86 million Americans had not had any healthcare insurance coverage during the previous two years;[2] millions more lack full healthcare coverage today.[3] The pharmaceutical industry laments the current state of medication adherence, which for many drugs, quickly drops to below 30 percent in a matter of two to three refill periods for a given drug. And disease management, the "high-attention" call-center based services, are tapping into every avenue to determine how to raise engagement rates from levels that currently sit below 15 percent.

Unfortunately, our traditional healthcare infrastructure, workforce numbers and tactics have not grown rapidly enough to accommodate the rapid rise in our chronic disease patient population. One can argue that chronic disease management, which has a large self-management component, should not be managed with traditional approaches. In fact, during the last decade, standardized approaches to chronic disease management using tools such as the Chronic Care Model[4] have been rapidly evolving, and along with that, an increasing attention to and measurement for the patient's role have evolved as well.

That being said, there remain real barriers to managing chronic diseases that must be taken into consideration:

- **Chronic disease management is incredibly burdensome for patients.** Management of many chronic diseases requires patients to monitor and track significant amounts of multi-variate data (e.g., medications, physical/psychological symptoms, metabolic measurement, activity and nutrition, etc.) asynchronously throughout any given day, and to recall the correct (and often complex) treatment pathways.

- **Patients have limited support outside of the clinical setting.** Our healthcare system and most throughout the world were designed to support acute care; they don't effectively support the needs of chronic disease management. Patients forget much of their physicians' instructions within hours or days of leaving the clinic. In a dynamic world, patients need fingertip-access to relevant and timely education outside of their healthcare provider's office.

- **Healthcare providers don't get the data they need.** As a result of the undue burden on patients, healthcare providers often have limited, incomplete, and/or inaccurate information to use as a basis for treatment modifications.

- **Office visits are too short and too infrequent.** Typically, primary care physicians or general practitioners have 10-15 minutes or less during a patient office visit to review charts, examine patients, analyze data and develop a treatment plan. Typical patients may only see their physicians two or three times a year.

- **Primary care physicians aren't always aware of the latest evidence-based guidelines.** As the gatekeepers to our healthcare system, primary care doctors see and treat the overwhelming majority of patients. In the current clinical paradigm, it is unrealistic to expect primary care physicians to know and treat to the latest evidence-based guidelines for all chronic diseases.

While the role of patient self-management in chronic disease outcomes has been clearly established during the last decade, the inclusion of this activity in quality reporting has not occurred thus far. This omission is due primarily to the lack of well-defined and tested measures, the inherent challenges of self-reported data, and the

technological ability to capture this data. Remote monitoring devices (e.g., blood pressure cuffs, weight scales and even blood glucose meters) have provided initial movement into this area, yet these devices have heretofore served primarily as data transfer devices to display patient data in an electronic medical record (EMR) for review and analysis by the providers. Currently lacking with the remote monitoring, however, is insight or knowledge that can be gleaned through patient self-reported data.

At the same time, we know that simply transmitting raw data from patients to physicians does not generate a positive return on investment (ROI) in the form of health or economic outcomes.[5] To date, the health and economic outcomes of effective management of chronic diseases have traditionally been driven and measured from the perspective of the healthcare system providers, as this was where the data was available for collection, aggregation, and reporting. Initially, claims and administrative information provided the bulk of the data for reporting, and this informed the initial development of national metrics such as Healthcare Effectiveness and Data Information Set (HEDIS) and the National Committee for Quality Assurance (NCQA) quality measures. With the introduction of EMRs, electronic laboratory reporting and e-prescribing, the focus of these measures became more specific. For example, the diabetes care metric for glucose control has evolved from the percentage of the population having the hemoglobin HbA1c test done within a given time frame, to the percentage of the population having an HbA1c value greater or less than 9 percent.[6] However, as is well known today, healthcare providers are generally slow to adopt the use of EMRs for a variety of reasons, and among those were the cost and need to change their practice and workflow models. In 2009, the Health Information Technology for Economic and Clinical Health Act[7] (HITECH Act) incentivized electronic record adoption and promoted meaningful use of the records to impact quality of care. The Meaningful Use Rules outline a staged approach to the implementation of interoperable records and increasing specificity of quality metrics and involvement of patient-centric care at each stage. As more providers adopt the electronic records and work to integrate quality reporting into their workflows, the expectation is that their ability to achieve national care metrics will be increasingly facilitated.

What is needed now is to transform patient data into meaningful and medically relevant information for patients – at the right place, at the right time, in the right format, and with the right context. Mobile technologies help provide this missing fabric required to enable the transformation of data into actionable information and knowledge.

In 2012, cellular penetration in the U.S. crossed 100 percent of the population for the first time in U.S. history, topping 322M subscribers,[8] an interesting statistic when compared with the 256M passenger vehicles registered in the United States.[9] Monthly SMS volume has grown from a mere 5.8 billion messages in 2005 to over 2 trillion in 2012[10]. There is an opportunity to leverage the cellular platform as a means of providing actionable healthcare information access to those who do not have access to traditional means of care. The United States has an unprecedented opportunity to leverage a lower-cost platform to connect patients and providers, to facilitate actionable care at the right time, in a manner that fits into the day-to-day lives of patients and the clinical workflow of providers. There is an opportunity to address the issues in a smart, novel and efficient manner.

The cell phone represents a technology platform that is available to the patient on a 24/7 basis with the capability of providing real-time messaging (alerts, reminders, feedback), geo-location services and other features, as well as being an ideal data-capture device. These technology capabilities have stimulated the development of over one million health-related software applications for all the mobile phone operating systems (e.g., iPhone, Android, etc.). The applications range from health and wellness products to applications that are being specifically used to manage diseases. Some of the applications, depending on their actual and intended uses, will fall under the classification of "mobile medical application" and as such, will require review by the Food and Drug Administration (FDA).[11]

MPT: SOLUTION COMPONENTS

To overcome the challenges previously discussed, an MPT solution must exhibit several key characteristics:

- **Automation**: MPT must provide 24/7, real-time and longitudinal coaching for patients and decision support for healthcare providers to allow increased scalability and access to healthcare in the face of scarce provider resources.
- **Personalization:** The MPT must coach and provide feedback to patients based on the patient's personal profile and unique data inputs. That is, it must take into account their metabolic parameters, co-morbidity parameters and personal profile attributes in order to drive engagement that is tailored to them.
- **Contextualization:** Coaching must be relevant to an event that has just happened, is happening or that will likely happen. Therefore, the MPT must understand both temporal as well as situational context in order to increase the relevancy to and therefore engagement by the patient.
- **Patient-Level HCP Decision Support:** While healthcare providers today have access – through a plethora of media – to evidence-based guidelines, often times the guidelines may not apply to the patient in question. Therefore, the MPT should aspire to leverage evidence-based population guidelines that are tailored to the specifics of each patient's behavioral readiness, medical profile and personal data

In order to satisfy these characteristics, the MPT should be comprised of at least three critical components, which are illustrated below in Figure 15-1.

1. **Virtual Patient Coach**: Software available on multiple operating systems and devices, that provides real-time, contextually-relevant, personalized, clinical and behavioral coaching for the management of a patient's chronic disease. This software is driven by both evidence-based guidelines and the healthcare providers' instructions and settings that are deemed appropriate for a patient (and hence, the prescribed nature of the solution).
2. **Automated Expert Analytics System**™: An intelligent, cloud-based, longitudinal algorithm engine that observes multi-variate patient behaviors over time and provides additional coaching to patients and suitably timed alerts to care givers as necessary. This expert system is driven by a series of key patient indicators (KPIs) and evidence-based rules that suggest either reinforcing or corrective actions that can be taken in response to an observed pattern. It pro-

vides longitudinal observation and feedback in many domains, including the management of medications, symptoms, metabolic data and lifestyle data to then power the Virtual Patient Coach and Clinical Decision Support.

3. **Clinical Decision Support**: A decision-making support tool for healthcare providers to help them optimize their patients' therapies, care plans and outcomes based on observations and patterns (e.g., with respect to testing behavior, medication administration, etc.). This decision support can also include an automated "smart" assessment that relies on evidence-based rules to identify gaps and facilitate recommendations for therapy plan adjustments to the healthcare provider so that they are not left to manage large amounts of data and manually perform the pattern recognition function in the limited time they have with patients.
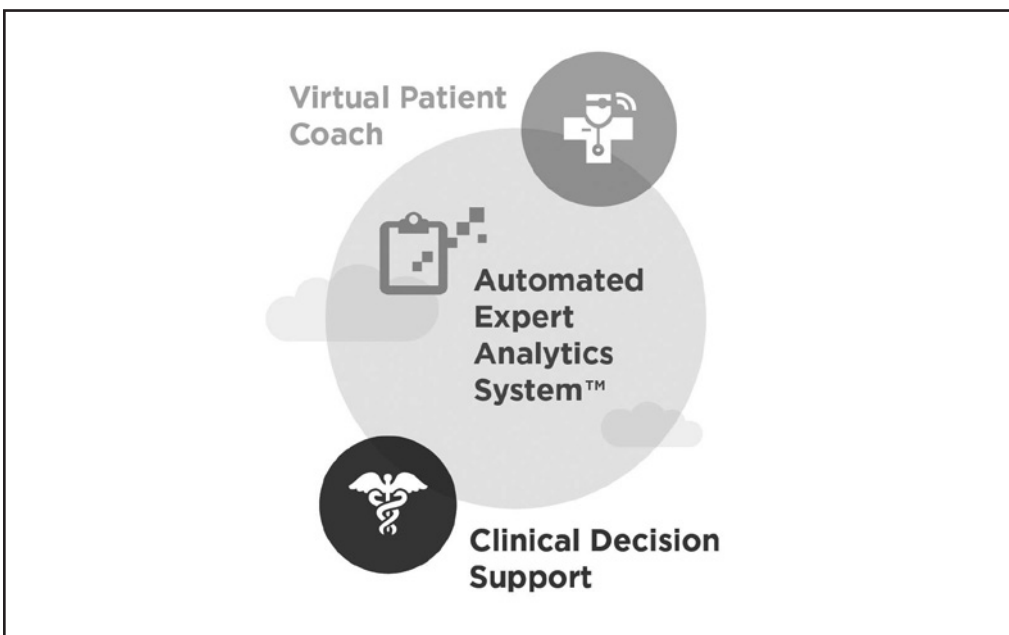

Figure 15-1: MPT Solution Components.

"APP" VS MPT

A common question is, "What is the difference between a mobile application (app) and an MPT?" Of the million-plus mobile applications across the various "app stores" such as iTunes and Google Play,[12] only a few can be categorized as MPT. Dr. Francis Collins, Director at NIH states "...we are also very concerned that as this technology comes forward so quickly, we need to be sure we're collecting the right evidence to show that these mHealth applications actually improve outcomes."[13] To demonstrate applicability for healthcare, the first condition an MPT must satisfy is to generate statistically valid results for health and economic outcomes. In addition, it must satisfy two additional conditions. First, MPT must meet the rules and regulations governing patient safety and repeatable, scalable and predictable quality systems (i.e., good manufacturing process). Second, in order to fit into clinical workflow and align with

the treatment plan, MPT should be prescribed and controlled by a licensed healthcare provider. In studies, over two-thirds of patients indicated a preference to get their mobile health solution from their doctor.[14] Figure 15-2 below summarizes these characteristics and hurdles that must be overcome for a solution to be considered an MPT.
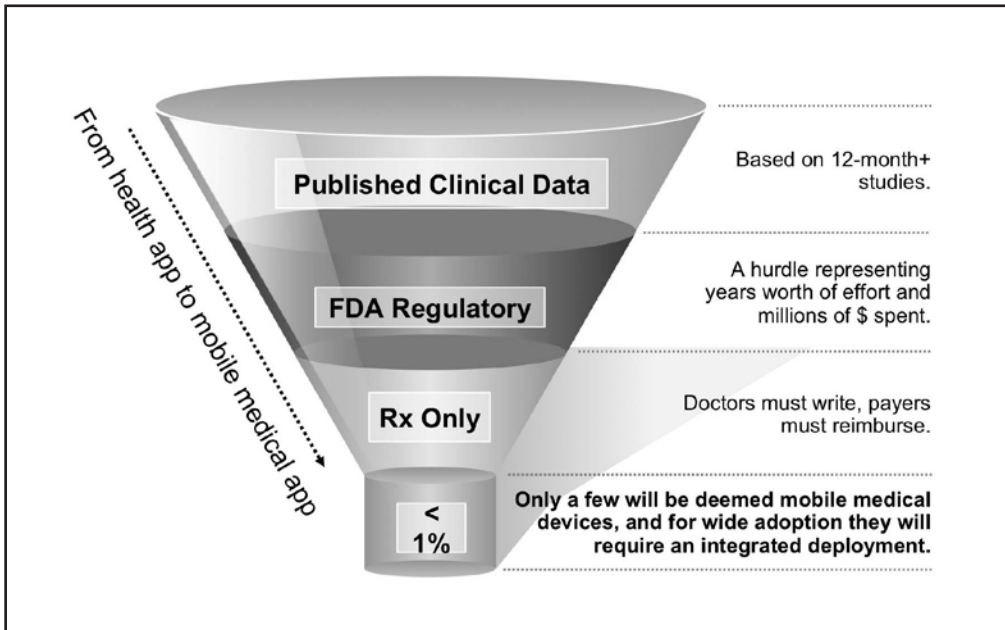

Figure 15-2: Hurdles to Classify a Product as MPT

MPT: VALUE PROPOSITION

The MPT value proposition for all healthcare stakeholders is multifaceted and must include the following benefits:

- Improved Health Outcomes: This is usually demonstrated as a statistically significant improvement in a key metabolic parameter (e.g., HbA1c for diabetes, cholesterol levels for hyperlipidemia, blood pressure for hypertension, etc.).
- Improved Economic Outcomes and ROI: Cost savings should accrue due to multiple factors that can include reductions in acute care costs (e.g., hospitalizations, emergency room visits, etc.), reduction in long-term care costs through improved health outcomes (e.g., reduced HbA1c), and the ensuing productivity uplifts that can be achieved (e.g., reduced absenteeism, increased presenteeism). The collective cost savings must create a positive ROI and be achieved rapidly (e.g. in a 6-12 month time frame).

MPT products must be systematically evaluated to demonstrate the value derived from their use. Even though this category of therapy is relatively new, the following data from clinical studies and costs savings modelling of a diabetes MPT provides evidence that MPT impacts outcomes.

Improved Health Outcomes

The Mobile Diabetes Intervention Study (MDIS), a year-long, cluster-randomized, clinical trial (RCT) utilizing a diabetes MPT was conducted with 163 type 2 diabetes patients and their primary care physicians.[15] The primary outcome was the change in glycated hemoglobin levels (HbA1c) over a one year treatment period. Patients in the intervention arm of the RCT received a diabetes MPT solution, and patients in the control group received standard care with their healthcare provider.

Using the diabetes MPT, patients entered diabetes self-care data (e.g., blood glucose values, carbohydrate intake, medications and other details) on a mobile phone and securely received automated, real-time educational, behavioral and motivational messages, with a further option to access their records and other helpful information via a web-based portal. The automated expert analytics system reviewed patient data and was able to supplement automated messages with additional advice and encouragement, with patients receiving an "action plan" every two and a half to three months.

The MDIS study results indicated the mean declines in HbA1c (the gold-standard measure for diabetes control) were 1.9 percent in intervention group and 0.7 percent in the control group (usual care alone), a difference of nearly 1.2 percent (P<.001). See Figure 15-3.
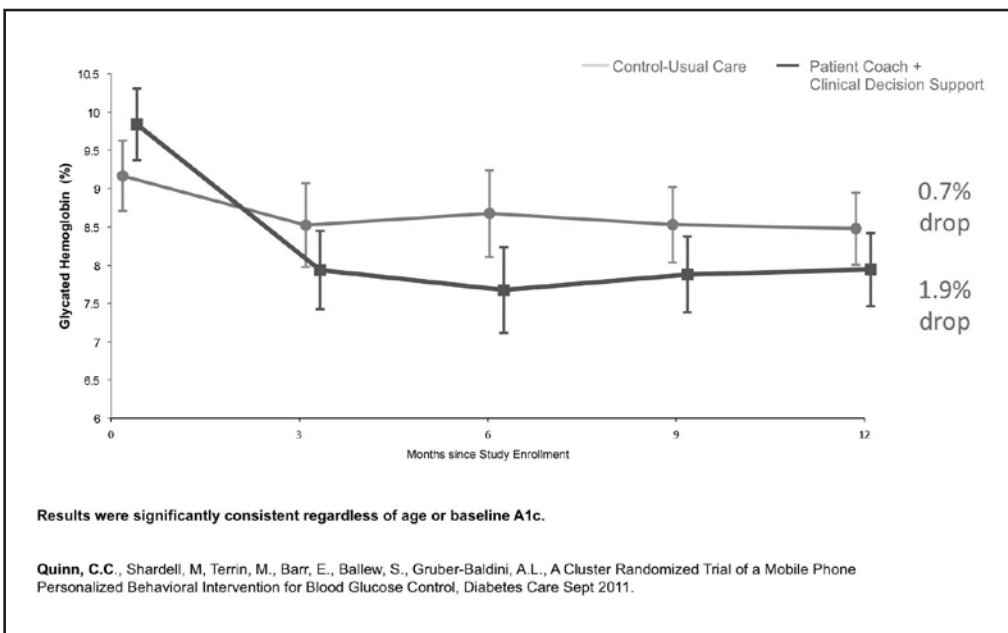

Figure 15-3: Mean Decline in HbA1c, Control vs. MPT Patients16

This diabetes MPT solution demonstrated meaningful health outcomes and prompted the following comment by Charlene C. Quinn, R.N., Ph.D., University of Maryland School of Medicine, lead investigator of the study: "The results indicate that doctors and patients can engage more effectively using mobile health tools like the WellDoc system to enhance patients' diabetes care and their blood glucose."

These health outcomes also led Richard Bergenstal, M.D., executive director of the International Diabetes Center at Park Nicollet and past president of the American Diabetes Association (ADA) to comment: "Finally, we have a good example of utilizing technology in the form of mobile diabetes coaching to help both patient and provider make the most effective lifestyle and management decisions."

IMPROVED ECONOMIC OUTCOMES AND ROI

To demonstrate the ROI of a MPT, a cost savings model was developed using data from the MDIS study. The model was developed in conjunction with Milliman, an actuarial firm, to estimate the direct and indirect savings associated with MPT. The estimated cost savings as seen in Figure 15-4 is based on improvement in A1C values over 12 months. Also, the cost savings are based on expected mitigation of complications associated with type 2 diabetes when patients improve and control A1C values. The estimated costs savings per user per month (PUPM) are as seen in Figure 15-4.

Source	Description	Low PUPM Savings A1C>7%	High PUPM Savings Top 50% with A1C>7%
2012 Milliman Modeling of Market Scan, NHANES, & UKPDS – Direct Costs	7 UKPDS Complications Coded as Primary Diagnosis	$150	$250
ADA, NHIS, NHANES, INGENIX, MEPS, NIS, NAMCS, NHHCS – Direct Costs	Other Complications*	$90	$140
ADA, NHIS, NHANES, INGENIX, MEPS, NIS, NAMCS, NHHCS – Indirect Costs	Absenteeism, Productivity, & Unemployment	$150	$240
	TOTAL RANGE	$390	$630

*Other Complications includes codes beyond the 7 UKPDS complications and also those coded as secondary or tertiary complications (e.g. an diabetes infection captured as a regular infection)

Figure 15-4. Estimated cost savings associated with using MPT.

Additional benefits of MPT on healthcare utilization were demonstrated in another one-year study with an urban, Medicaid population.[17] Patients using the diabetes MPT reduced their ER visits by 58 percent from the prior year and reduced hospitalization admissions by 100 percent. Additionally, they found the instant coaching feedback helpful and all agreed that the system improved their glucose testing behavior.

CONCLUSION

This chapter introduced the notion of MPT as a scalable, effective means of addressing many significant healthcare challenges for patients, providers and the system. In order to qualify as an MPT, a solution should be automated, personalized, contextually-relevant and be able to provide patient-level decision support to healthcare providers. Additionally, to qualify as being a MPT (vs. an "app") the solution should have published outcomes, adhere to applicable regulations governing patient safety and good manufacturing process, and must fit into clinical workflow to facilitate adoption by patients and providers alike. The chapter provided clinical and economic evidence of a diabetes-related MPT to illuminate the tangible health and economic benefits that can accrue from an MPT solution.

Looking to the future, multiple "vectors of value expansion" are possible for MPT. These include, but are not limited to, the following:

- Disease Continuum: Regardless of the disease, every patient who suffers from one or many chronic diseases must manage medications, metabolic measurement of some kind, lifestyle and symptoms. The rules and content will change. The platform will remain the same.
- Chronic Care Continuum: Whilst today much of the healthcare system is focused on acute care for chronic disease, MPT will allow movement further upstream in the chronic care continuum, to include patients who are pre-disposed to a disease (e.g., due to family history, heredity of the disease, etc.) or even further upstream for prevention.
- Data Continuum: In many ways, the value of the data collected from MPT will quite likely outweigh the value of the MPT itself! This data – which is both real-time and longitudinal, and can be generated by a patient or an MPT system – can be mined and modelled in referential and inferential ways, that include the realm of predictive and adaptive modelling, as well as intelligent pattern recognition that gives new insights into things never before seen as it relates to drug therapies, disease parameters and patient behaviors.
- Technology Continuum: The ever-growing realm of sensor data – such as that with activity and fitness, biometric sensors – that quietly capture important parameters for patients will dramatically help improve seamless engagement with multiple MPTs by patients. These solutions will be further accessible via multiple mobile Internet devices (MIDs), to ensure an enhanced seamless experience for the patient interacting with MPT through the device that is most convenient and available at any point in time.
- Personal Continuum: As the data collected expands to include the realms of "mind, body, soul" – that is, psychosocial, metabolic and socio-cultural data – so will the value unlocked expand to provide more tailored, contextually relevant and culturally-adaptive feedback to patients.

MPT is at the dawn of a new outcomes-oriented era in healthcare delivery, where the innovation potential is boundless.

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