

Enabling seamless integration of Care Providers into ACO payment model

Accountable real-time patient TeleCare management

Executive Summary

The last decade has seen a radical transformation in healthcare landscape. There have been a tremendous tectonic shifts in the provider compensation models, the emergence of technology and it's increasing adoption by care and wellness providers [1,2,3]. However, there are still a number of fundamental pieces that are missing to enable this tectonic shift to yield the tsunami of change in personalized patient care that was envisioned and promised [4]. In this proposal we provide one of the key element, associated with enabling patient, care providers and payors to work seamlessly by streamlining the operation and delivery model of personalized patient care for chronic patients. In addition, we believe that this ripple towards "horizontal" standardization of telecare will produce the butterfly effect to yield a tsunami of change in personalized care.

Market Opportunity

A significant market chasm exists between medical devices used for clinical care and those used by individuals for wellness. Medical devices, controlled by vertically integrated entities, want to restrict the mass proliferation of these devices to ensure high profitability. On the other hand, though wellness devices have had significant adoption they lack sustained adoption by mainstream patients due to lack of the integration of these devices into the personalized accountable care regimes of patients. Removing this barrier to integration by extending existing standards provides a unique opportunity for the creation of a new class of "accountable" care telecare devices that could drastically change the landscape of care delivery, both, in the costs of clinical care device and the proliferation in their variety.

Objectives

This proposal details the extensions needed to enable a new class of care devices that will enable a large number of care providers to seamlessly engage in a peer-to-peer manner to deliver care to a chronic care patient. It will also enable these device vendor and care providers to participate in the pay for performance shared risk and savings compensation model.

Milestones to Success

The key milestones for success are three-fold. The first is the demonstration of per-to-peer requisition, authentication and authorization of a care provider to access information from a patient's telecare device, while adhering to HIPAA requirements. The second milestone is the seamless inclusion of one or more care providers in the delivery of care. The third is the demonstration of the ability to track and validate shared saving compensation for all participants based on the improvement in the overall care outcome of the patient.

About TrustedCare & ARM

US TrustedCare Inc., is an Austin based digital health company engaged in the care management of chronic and at risk patients. TrustedCare is focused on improving the Transition of Care post an acute care episode through technologies that enable Home Care Agencies, Service Provides, Hospital and Individuals and their family members effectively and efficiently communicate and collaborate. TrustedCare participates in shared risk/saving agreements with provider and payors and is involved in enabling care networks to achieve significant outcomes improvements for patient under care.

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Contact Info

US TrustedCare, 11525 Stonehollow Dr., Ste #170 Dr., Austin, TX 78758, email:info@trustedcare.us.com

The Market Opportunity

The last decade has seen significant transformations in the landscape of healthcare in the US. The first being the shift from pay for care services to pay for care outcome, where in payments are based on effective wellness of the patient and any cost savings achieved are kept by the involved care providers. This has led to the formation of accountable care organizations (ACO) that include health and wellness providers engaged in the coordinated care of a patient. The second aspect has been the technology impact on the care delivery process, where-in patient care plans delivered by each provider are tracked, and yield improved efficiency in care. The third and final aspect is the proliferation of wellness devices and services that enable individuals to engage in preventive care. This has also resulted in payors providing incentives to individuals and providers to engage in such care.

The changing healthcare compensation landscape

The shift in payment model has resulted in an increasing number of ACO networks, with about 120 ACOs covering 5 million lives in 2011 to around 400 ACOs in 2015 covering approximately 30 million lives. In addition, it is expected that by 2020, 72 million lives will be covered by around 700 ACOs. Furthermore, this trend, where-in providers are incentivized to provide high quality outcome based care enabling them to participate in the shared saving is expected to also become the norm in coming years in both the private insurance and Medicaid market. This has led to significant motivation by these provider organizations and their payors to adopt wellness and real-time care management solutions to enable just-in-time care intervention, as well as, leveraging wellness care providers to improve the overall health status of their patients [1,4,5].

Healthcare automation trends and challenges

Over the last decade there has been a tremendous increase in healthcare automation on two fronts which have significantly improved the efficiency and the quality of healthcare. The first is the increased adoption of Electronic Health records (EHR) systems and the second is the increased use of Telecare medical devices. EHRs have significantly helped in improving the operational efficiency of healthcare providers, growth in Telecare medical devices have enabled providers to monitor the health of patients in real-time.

However, a key challenge to the extensive adoption of EHRs has been the lack of interoperability and the proprietary nature of these systems that have resulted in a significant impediment for provider collaboration. Furthermore, telecare medical devices too have faced challenges associated with integration and transportability of data. In the case of medical devices, the situation is further compounded by the fact that the vendors who profit significantly by building a proprietary vertical solution lack the motivation in opening access to their system to care providers. Though, various standards organizations have made significant impact towards interoperability of data between systems, the lack of motivation of medical device and EHR vendors to implement these standards has resulted in a limited adoption of telecare devices. This has resulted further reluctance by providers to adopting medical telecare resulting in significant impact to patient's adherence to care plans. [6,7,8].

Increased adoption of wellness and preventive care

Outcome based compensation has resulted in a shift to providers focusing on patient's wellness and preventive care. Furthermore, incentives and payment subsidies by payors has resulted in a high rate of adoption of telecare devices and wellness services [9]. Though these devices are based on standards, the lack of authorized, authenticated and trackable information that can be seamlessly correlated to a patient's care plan, does not provide sufficient value to care providers. This in turn has resulted in these devices not being used by patients for a period of more than six months resulting in the inability to quantify actuarial impact for payors and providers involved in shared risk or saving engagement [10,11,12].

Enabling a new class of Accountable Care devices

This endeavor enables a new class of telecare devices called Accountable Care Telecare devices. By extending the HEART WG standards to enable peer-to-peer authorization and authentication, as well as, by enabling a means to track and audit patient vitals in real-time a new level of care delivery is achieved that can significantly impact patient wellness outcomes and patient compliance. An example scenario is a chronic cardiac patient whose physician recommends he/she join a wellness provider like Weightwatchers for a cardiac recovery regime. Upon approval from the doctor the patient authorizes one of the care regimes recommended by Weightwatchers, based on the telecare device that the patient has. Weightwatchers then downloads a personalized walking regime to follow per hour a day and remotely monitors his/her vitals during that time. At the end of each day the data is audited and the verified results are sent to the payor and provider. After a period of 60 days of personalized day-to-day training the patient's vitals improve and the provider/ payor authorize compensation for the patient and Weightwatchers. In another scenario these vitals are simultaneously shared with the patient's endocrinologist and nutritionist.

The primary goal of this endeavor improves patient engagement in their care and drastically improve the portability of patient specific data to relevant care providers who are incentivized to improve patient care

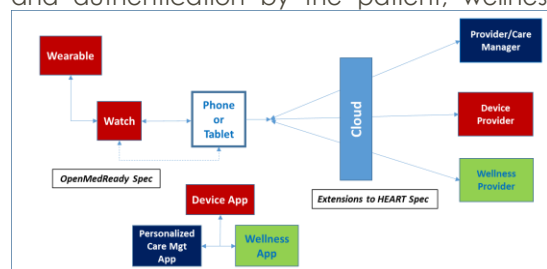
in a secure and authorized manner. Extending telecare wellness devices to enable accountable collaborative care provides a new lower cost point solution compared to telecare medical devices, thus enabling a whole range of standards based future devices in the market.

Overview of the Solution

In this section we will provide an overview of a new class of telecare devices called Accountable Care devices that have the capability of seamlessly engaging one or more service providers with a patient to enable accountable care. The figure below illustrates the components involved in the creation of an Accountable Telecare device specification. They are the mobile gateway, telecare device like a watch or a wearable, which could be sensors attached to the body or measurement devices. In addition are Care Management providers that engage with the Provider and Payer as well as Wellness providers who have developed an App for the patient.

The Extensions to the HEART Spec

In this endeavor we will leverage existing standards on Encryption (Symmetric, Asymmetric), FIDO, Auth2.0; OpenID and UMA spec to create new resources and User Manager Access profiles to enable authorization and authentication by the patient, wellness provider and the clinical provider. This will also enable



application level encryption of data from wearable or watch to phone or tablet to enable patient to bring their own smartphone device (BYOD), and prevent man in the middle attack from malicious application trying to sniff or manipulate data on the smartphone/tablet. The UMA spec will be extended to allow service providers to enable selection of specific resource access. In addition, we will need the ability for the recorded information to be digitally signed for verification by both patient and wellness

provider. As additional extensions are required we will engage with the HEART WG to explore avenues of standardization.

Mobile and TeleCare Devices Standards

Correlate to the extensions to the HEART spec need to be developed between the Smartphone Gateway and telecare devices. ARM will ensure that either existing standards are extended or new standards like OpenMedReady proposed by ARM. The OpenMedReady standard combines the following relevant features: 1. Patient data; 2. Patient identity association with data; 3. Patient Consent for sharing data with care provider needed for Accountable Telecare devices. ARM will employ a Trusted Execution Environment (TEE) on the smartphone which can protect patient data confidentiality and integrity. TEE will also be leveraged for certification and digital signature by the patient, Telecare device vendor, the wellness provider App and the Care Management App.

The solution prosed here is aimed at leveraging open standards to deliver accountability in a standards based manner. Currently, such care level accountability is only delivered by vertical medical telecare devices vendors who have charged significant premiums and restricted the enablement of a variety of telecare devices. Through this endeavor we aim to develop key building blocks that enable the proliferation of standards based telecare devices.

Milestones and Measures for Success

In this section we will outline the milestones for this project along with a list of measures to evaluate the project's success.

Key Milestones

There are three major milestones for this project: 1) First is the development of the capability of peer-to-peer requisition, authentication and authorization of a care provider to access information from a patient's telecare device. 2) The second milestone is the ability of a patient to seamlessly add one or more wellness or clinical providers to be able to access real-time data from the telecare device. 3) The third and final milestone is the capability of digitally validating the tracking and audited information from these service activities by the patient as well as providers to enable participation in shared saving compensations.

Key Measures of Success

Associated with the milestones discussed above we will be tracking a set of measures of success. For the first milestone the measures for success are the time taken for a patient or provider to engage in a Care collaboration relationship. This measure will track the ease as well as the duration of a time it took for the activation of a care service. In addition, we will track the number of patients that signed up for these services in a given period. The measure of success for the second milestone is the number of patients for which a healthcare provider, e.g., rehab provider, or a wellness provider e.g., an exercise coach, gather

real-time information via a personalized care program for the patient that the care provider provided. We will also measure how accurately and consistently they were able to monitor and track over the duration of the care regime. In addition, another parameter is how many additional providers could successfully engage in the care regime of the patient. For the third and final milestone we will evaluate how many patients and care providers collaborated successfully in the full duration of the care regime and received compensation. We will also measure how many care transmissions occurred, as an indicator of portability and patient adherence. Through these measure we will demonstrate the increased collaboration of patients with providers, the effectiveness of such engagements-both the time to get engaged and the duration, and show if there was significant improvement in patient adherence that resulted in significant improvement in health outcome and savings.

Milestones	Measures
Peer-to-Peer connectivity	(i) Time to engage; (ii) # of patient engaged
Real-time Data Access	(i) # of patient real-time data (ii) # of data points collected per regime (iii) number of care providers engaged
Care Auditing and Compensation	(i) Number of patient completed Care regime (ii) Number of transmission (iii) Improved outcome & compensation

Development Plan and Timeline

The development plan has three phases. Phase 1 focuses on implementing peer-to-peer communication between a care provider and a telecare device both of whom have infrastructures that support the HEART Spec. We have allocated three months for this effort. Phase 2 focuses on two parallel efforts. The first is the demonstration to engage two or more care providers in a peer-to-peer transaction (requisition, authorization, authentication) and the second is the validation of the audit and tracking of the care services delivered using the Accountable Telecare device. We have allocated 4 months for this effort. Phase 3 will have two concurrent sub-phase focused on scalability 3a and 3b. Phase 3a will focus on two sub-tasks associated with scale enablement. The first sub-task is to enable provider support for wellness service providers that are not using the HEART spec. We will work with the FIHR workgroup on this effort. The second sub-task in Phase 3a is providing plugin modules for Telecare devices that have yet to support the HEART Spec via TrustedCare's Mobile App. The second sub-phases, Phase 3b is focused on scale deployment validation and comprises two sub-tasks. The first is the number of patients managed by a care provider and the second is the number of service providers enabled. The goal of Phase 3 is to stress test this implementation. We believe this effort will take 6 months. We have allocated 13 months in total for this project. Below is a pictorial representation of the plan and time-line.

Table 1: Developmental Phases

	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12	Month 13
Phase 1	Single P2P Validation												
Phase 2				Multi P2P Validation									
				Audit/Track Single P2P		Audit/Track Multi P2P							
Phase 3a								Service Provider Extns		TeleCare Device Extns			
Phase 3b								Patient Scalability		Vendor Scalability		Device Scalability	

Overall Financial Impact

As outlined in the earlier sections there are three phases to the overall project. The initial phase is the development of the framework for the exchange of information from an Accountable Care device being used by the patient and his associated care providers. The second is the interface between the patient mobile gateway and the telecare devices and finally is the scalability of this framework across multiple service providers and telecare devices. Furthermore, the key aspects are the feature of authentication and authorization and the ability to Track and Audit the care services delivered by the care providers.

Activity	Sub-task	Provider	Device
Dsg & Dev	Personnel	\$ 150,000	\$ 100,000
	Dev Env	\$ 5,000	\$ 8,000
Scalability	Personnel	\$ 80,000	\$ 50,000
	Dev Env	\$ 8,000	\$ 8,000
	Interop Event	\$ 15,000	\$ 20,000
Miss	Certs & Mrkt	\$ 10,000	\$ 6,000
Sub-total		\$ 268,000	\$ 192,000
Total			\$ 460,000

Overall Cost

The overall cost of this project is estimated at \$450K. the overall breakdown of the costs are shown in the table below. These cost will be jointly shared by ARM, who will engage with device vendors and TrustedCare who will bear the cost of the Service Provider side development. The scalability validation efforts will also be jointly shared by TrustedCare and ARM. This is illustrated in the table on the left. The funds received as part of this proposal will be solely applied towards the efforts of the extension of the HEART spec.

Potential Revenue

As discussed, this new class of Accountable Care Telecare devices would enable providers, payors, and patients to engage in a new level of care collaboration as well as track overall cost and health improvements of chronic care patients. This capability, would enable health and wellness providers to

actively participate in additional shared savings compensation plans as well as enabling medical device vendors to also partner in the shared savings model. Our Initial estimates indicate that these providers would earn an additional 10-15 percent earnings per patient per year, which would be about \$1000-\$1500 per patient per year. The telecare devices vendors could garner about 10 percent of these saving premiums, which would be about an additional \$100-\$150 per device per year per patient, beyond the base price of device. Assuming that the life of the device is 2-years that would provide additional \$200-\$300 income to device manufactures.

Potential Challenges and Mitigation Plans

The potential challenges associated with this project are in two realms. The first of these is the Care Provider realm and the second is the Telecare device realm. In each of these realms there are both technical and EHR adoption challenges. In the case of the Care Provider realm the Accountable Care Telecare Protocol will be developed leveraging the HEART protocol for engagement between care providers and patients. Some EHRs being deployed by providers may not have HEART protocol. As a mitigation for this case we will work towards providing a broker translation module for an EHR to enable this. The second issue is that some of the care providers, in particular wellness providers may not have an HER system. In this case we will provide them with an applet to their Care Tools that would adhere to the HEART protocol that they could use to access the required information.

The similar correlate exits for Telecare device vendors. Some of these vendors may not be supporting HEART protocol on their devices or via their Apps in their Mobile gateway. In this case we will provide an add-on module to their Mobile App based on HEART Spec for demonstrating the Accountable Telecare Protocol. An added benefit of these mitigation plans is that, working with the HEART group these modules would serve as a reference for enabling accelerated adoption of the HEART Spec.

One of the key challenges of this endeavor is security and validation of HIPAA rights of the patient. We will adhere to secure design standards professed by HEART WG and ensure our implementation is compliant to HIPAA. As an additional step we will engage organizations HITRUST and PatientPrivacyRights to validate the data security design of our implementation.

Participants and Roles

There are two parties involved in this endeavor. The primary being TrustedCare, who is an ACO Care Management provider, engaged in providing Post-Acute and Population Care for chronic and high risk patients. TrustedCare has been developing real-time Care platform/analytics tools and is engaged with health and wellness providers as well as payors in a risk/saving sharing relationship. TrustedCare is collaborating with ARM to develop key capabilities in components and systems used in the development of telecare devices towards enabling this new class of Accountable Care devices. TrustedCare's, relationship with payor and health/wellness providers along with ARM's relationship with manufacturers of telecare device vendors provides a unique relationship to enable this solution as well as test and deploy this in the new healthcare paradigm. TrustedCare and ARM focus on enabling these capabilities as standards in the industry would be a key catalyst to enable the transformative changes that were envisioned under the new healthcare paradigm.

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