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Mobile Monitoring-Enabled Telehealth for Patients with Complex Chronic Illnesses

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Abstract. Telehealth has the potential to improve management of poorly controlled chronic diseases relative to clinic-based care alone. Mobile monitoring-enabled technologies could enhance telehealth for chronic illness care. Implementation in practice settings would rely on automated integration of data into the electronic health record (EHR). We describe the integration and visualization of data from four remote monitoring devices into the EHR that is coupled with the evaluation of an evidence-based nurse and pharmacist-led telehealth care model for patients with uncontrolled diabetes and hypertension. Using this new pragmatic infrastructure, clinicians use the EHR to prescribe for patients a suite of devices. Alerts are placed upon the data that notify a clinician when values go above or below set thresholds. These data are visualized in the clinical record and clinicians use the EHR as a tool for efficiently delivering and documenting patient telehealth encounters.

Keywords. Telehealth, diabetes, hypertension, digital health

1. Introduction

For patients with complex chronic illnesses such as uncontrolled diabetes and hypertension, clinic-based care may provide insufficient patient-provider contact and self-management support, resulting in persistently poor control [1]. Telehealth has the potential to improve management of poorly controlled chronic diseases relative to clinic-based care alone because it facilitates patient-provider contact and medication management, and better supports self-management. Mobile monitoring technologies could enhance telehealth for complex chronic illnesses by generating multiple streams of health data to facilitate patient self-management, and potentially by integrating mobile monitoring data to into a telehealth care model [2].

These technologies include carried, wearable, and in-home devices (e.g., blood glucose and blood pressure monitors, electronic scales, accelerometers) that permit frequent capture and transmission of physiologic and behavioral data from patients between clinic visits. Such health data may guide critical insights for patients, potentially translating to better self-management. Alternatively, integrating mobile monitoring data into an evidence-based telehealth intervention could improve chronic disease

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management outside the clinic setting. As over 81% of the US population owns a smartphone [3], the ability to gather mobile monitoring data from broad, generalizable populations is growing. Importantly, smartphones are increasingly used by individuals from low income and rural backgrounds, with over 71% owning a smartphone. Since low-income racial/ethnic minority patients are more likely than low-income whites to own smartphones [3], mobile monitoring-enabled telehealth interventions could reduce disparities in chronic disease outcomes.

Many health systems have not yet implemented telehealth interventions combining mobile monitoring, self-management support, and medication management in routine clinical practice for patients with uncontrolled chronic disease. Implementation in practice settings would rely on automated integration of data into the electronic health record (EHR). Such integration is now possible using both Apple Inc. and Android platforms, and in the USA with the major EHR vendors, including Epic and Cerner. We describe the integration and visualization of data from four remote monitoring devices into the EHR. This integration is coupled with the evaluation of an evidence-based nurse and pharmacist-led telehealth care model for patients with uncontrolled diabetes and hypertension. Clinicians use the EHR to prescribe for patients a suite of devices. Alerts are placed upon the data that notify a clinician when values go above or below set thresholds. These data are visualized and clinicians use the EHR as a tool for efficiently delivering and documenting patient telehealth encounters.

2. Methods

2.1. The EXTEND Trial

Expanding Technology-Enabled Nurse-delivered Chronic Disease Care (EXTEND) is an active comparator randomized trial (N=220) of two 24-month interventions: 1) mobile monitoring as a self-management tool (EXTEND); and 2) a 12-month nurse and pharmacist-delivered telehealth intervention incorporating mobile monitoring, self-management support, and medication management followed by a 12-month self-management period (EXTEND Plus). Patients receive mobile monitoring devices that tether to a smartphone to facilitate chronic disease self-management, including a glucose meter and test strips, a blood pressure cuff, a home scale, and a wrist-worn accelerometer.

Patients randomized to EXTEND Plus receive intervention components (mobile monitoring, self-management support, and medication management) administered by registered nurses (RNs). RNs work in conjunction with a PharmD clinician affiliated with their clinic for medication management. RNs deliver EXTEND Plus via scheduled telephone encounters every two to four weeks for 12 months. During encounters, RNs review data that patients transmit from the devices into the EHR. An encounter note is written and forwarded to the PharmD for medication management. With institutional review board approval, patients are recruited from five primary care and endocrinology clinics in Durham, NC, USA. These clinics provide care for diverse patient populations with diabetes, of whom >54% Black/African American and 14% are Latinx. Patient recruitment began in April 2022 following the information technology (IT) build.

2.2. Engaging Health System IT, Community Consultation Studio, and Device Selection

We began the IT build in May 2021 by engaging with our health system as they advanced opportunities for telehealth care. DUHS contracted with a 3rd party company, known as Validic, that integrates data from hundreds of clinical and consumer health devices. Streaming and REST APIs then deliver standardized data directly into the EHR. Over the course of a year, we built the data model, selected which devices to integrate, designed the ability to prescribe the devices with the EHR similar to a medication, designed SmartSets and SmartPhrases to clinician documentation, and designed and refined visualization of data from the devices.

We engaged a group of Black residents with diabetes in North Carolina, USA to help guide us in refining our approach. This focus group was recruited through a pool of community members via electronic flyers. The purpose was to discuss the EXTEND telehealth intervention for diabetes self-care and how to support them if they were to use multiple monitoring devices for diabetes management. Results from the community consultation studio were used to adapt our study materials, device selection, and patient outreach strategies.

Device selection was approached through a health equity lens, which prioritized devices that met necessary technical specifications while remaining functional for our study population. We selected from Validic's list of API enabled servers. This limited the devices to select from but allowed for ease of integration and data standardization. We used feedback from the community consultation studio to help guide the selection.

3. Results

3.1. Community Consultation Studio and Device Selection

The community consultation studio took place in October 2021. Participants (n=9) were aged 56-79 (7 female, 2 male). Participants gave feedback on how to frame the study to recruit patients, tailor intervention content, and engage them over time in the trial. Based upon feedback this also helped us in the selection of devices. We selected devices that work on iOS and Android, had the least number of apps to reduce complexity for participants to manage and our team to support, were consumer friendly, and easily accessible to racially, ethnically, and socioeconomically diverse populations. We selected a glucometer from OneTouch and three devices from Withings that included a Bluetooth enabled scale, blood pressure monitor, and activity tracker.

3.2. The Data Model

We completed the IT build in April 2022 with continued refinements. The IT build integrates patient-generated data from the four devices into Duke University Health System's (DUHS) data lake and Epic-based EHR. Providers enter orders for patient monitoring through Epic. Mirth interface engine transforms an HL7 message from Epic and then calls a Validic API to create the Validic user account based on a Duke-generated de-identified unique patient identifier. The patient then connects their Withings account through a unique tokenized URL to their newly established Validic account within the Validic portal. Below are the steps data undergoes to be transformed into visual graphs and trends clinicians see in Epic.

Step 1: Withings devices push data to the Withings app, which stores the data in the Withings cloud. Once in the cloud, data flows to the Validic API platform hosted by AWS (Amazon Web Services) to pull patient data from the Withings cloud and Accu-Chek cloud without going through an app (e.g., Apple Health). *Step 2:* Validic' s system normalizes the recorded data from different devices into a standardized data model which is made available to Duke as a streaming API. *Step 3:* Patient information is de-identified once in Validic. Validic randomly generates a UID that is associated with a tokenized URL, then links it to the patient's anonymous patient ID. *Step 4:* Duke consumes data from the Validic API in .json format which is then loaded to an internal data lake as FHIR observations. A process runs simultaneously to call an Epic API for recording of device data as a flowsheet so that it also exists in the patient's chart and their MyChart. *Step 5:* Once data is loaded to the Duke data lake, it is made available to a Tableau dashboard that is viewable from within Epic. The real-time data collected by patients during a day (step counts, blood pressure, weight, and blood sugar) require frequent syncing and analysis. Patient readings are processed through an open-source interface engine (Mirth) and transformed into FHIR (Fast Healthcare Interoperability Resource) observation records within the Duke data lake. *Step 7:* Clinical staff view the patient's data through an interactive Tableau dashboard within Epic. They also have the option to create a .pdf file or screen shot from the Tableau graphs and copy into the patient's chart.

3.3. Designing the Patient Encounter in the EHR

EXTEND Plus telehealth encounters are templated through SmartSets and SmartPhrases to facilitate intervention delivery and documentation. SmartSets enable prescribing of the four remote monitoring devices with set data fields to be entered, enables the data model, and then associates patients with the EXTEND Pool ID. This allows for a pool of nurses to monitor incoming data based on set thresholds. The SmartPhrases are templated notes for documentation during the telehealth encounters. The nurse selects from a drop down of content that populates EHR encounter note with pre-set topics and device information. The nurse is able to easily remove information that was not discussed.

3.4. Prescribing Devices and Data Visualizations

Remote monitoring devices are prescribed within the EHR. The clinician opens the associated SmartSet and clicks on devices to order. The order is placed the day before so the MyChart patient portal will create the link overnight. The order is linked with a Pool ID that is associated with the EXTEND care model. A duration for monitoring is selected, frequency of measurement, thresholds for alerts are created, and limits for in-basket alert notifications to clinicians are set. These in-basket notifications go to a pool in which EXTEND nurses and staff monitor the pool. The patient participant goes into the patient portal to click a hyperlink that gives authorization to pull data in through Validic.

Device data are presented as visualizations (i.e., graphs and trends) within Epic using Tableau that power the telehealth-based encounters. The original visualizations were developed with limited clinician input and provided limited clinical utility in understanding how blood glucose data fluctuates throughout the day in relation to eating. With clinician input, our team worked with the DUHS visualization team to reconfigure the display. The data are now color coded (red to green) to indicate high and low values and are averaged by time segments relating to meal times over 24 hours. The EXTEND

Plus study nurse copies visualizations as appropriate into the encounter note. This note is forwarded to a pharmacist for use in medication management.

4. Discussion

The COVID-19 pandemic was a catalyst for telehealth use and innovation. In 2020, investments in infrastructure to support telehealth care delivery were invested in across the US and by countries around the world. This enabled remote care delivery while abiding by social distancing measure for patients with a variety of conditions and chronic illness. With the advent of accessible remote monitoring tools that connect to a smartphone, patients can now track health data in their daily environments. When coupled with telehealth infrastructure, these data can be transmitted into the patient's clinical record to be used in care delivery. This may be particularly beneficial for patients with complex chronic illnesses such as diabetes and hypertension where clinic-based care alone may be insufficient.

EXTEND Plus represents a pragmatic approach to using data from four remote monitoring devices in a team-based telehealth care model for diverse patients with complex chronic care needs. Patients self-monitor and collect data in their everyday environments that informs care and medication management decisions. This approach can be replicated for other chronic conditions and care delivery models.

5. Conclusions

Telehealth has the potential to improve management of poorly controlled chronic diseases relative to clinic-based care alone because it facilitates patient-provider contact and medication management, and better supports self-management. Mobile monitoring technologies could enhance telehealth for complex chronic illnesses. Infrastructure to support telehealth care is increasingly possible. We describe a pragmatic approach to integrating mobile monitoring-enabled telehealth for patients uncontrolled diabetes and hypertension into existing clinical infrastructure.

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