TELEMONITORING IN TEXAS

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EXECUTIVE SUMMARY

Texas Legislature has passed several bills since 1997 to establish home telemonitoring as a reimbursable health service under Texas Medicaid. Reports from the Health and Human Services Commission suggest that the Texas Medicaid pilot program providing home telemonitoring services to eligible patients has seen a rise in clients over the years. With the scheduled sunset of the pilot program in September 2019, Texas will have to deliberate on whether to continue the pilot program, establish a permanent program, change policies on reimbursement, or discontinue reimbursing home telemonitoring for Medicaid patients in Texas. This report provides results from the following three studies to better inform this important decision:

- A literature review on the effectiveness of telemonitoring programs
- A case study of one telemonitoring company in Texas currently operating in the McAllen, Dallas, San Antonio, and Houston regions that provides:
 - A population-level descriptive analysis of the processes for telemonitoring for 2,527 patients using the company data from January 2016 to October 2018; and
 - A qualitative study on the integration of the home telemonitoring system into physicians' workflow based on stakeholder interviews

In sum, our literature review suggests that home telemonitoring will likely improve health outcomes, particularly for diabetes patients when implemented well. Our case study of a telemonitoring company in Texas provides further insight into understanding the key elements of the telemonitoring processes and how it may integrate with primary care to be effective.

A total of 2,527 patients started to get monitored daily for blood pressure (BP), blood glucose (BG), or both from January 2016 to June 2018. This analysis followed these patients from January 2016 to October 2018. The average age of the patients was 72 (SD \pm 12), with 66% being female, and most (77%) speaking Spanish. Most lived in an urban area (86%) with 77% in the McAllen area, 11% in the Dallas area, 9% in the San Antonio, and 3% in the Houston area. Patients lived in a zip code close to the primary provider and typically worked with one primary provider during the study period. However, 64 patients did have more than one physician during the study period. There were no major differences in patient demographics between those being monitored for BP or BG except the area of residence. Patients being monitored for BP (90% vs. 86%). These patients were being monitored by 76 different physicians, 54 in the McAllen area, 12 in the Dallas area, 5 in the San Antonio area, and 5 in the Houston area. On average, a physician monitors 21 (SD \pm 24) patients in a given month, with a total of 34 (SD \pm 41) unique patients, on average, for the whole study period.

In our sample, on average, patients were authorized for daily monitoring for 292 days $(SD \pm 234)$. Patients discontinue monitoring for many reasons including physician determination of no more medical need (e.g., stable after discharge from the hospital) and patients deciding

not to continue. Only 33% of patients have been monitored for longer than one year. Of the authorized days, on average, 48% (SD \pm 27) of these days required the company's non-clinical staff to follow up with a phone call to troubleshoot (e.g., battery issues, transmission issues) or remind patients to take the reading, with these efforts, 76% (SD \pm 39) of the days actually have a reading that is monitored. The findings were similar for both BP and BG readings, but BP monitoring required more follow up (46% vs. 41%). These calls are referred to as *adherence alerts*, and the goal is to maintain daily monitoring.

The home telemonitoring system, on average, automatically flagged 44% (SD \pm 26) of all monitored days for all patients being monitored for blood pressure, and 10% (SD \pm 15), for all patients being monitored for blood glucose, as having a reading that is out of acceptable range set by the physician. These *automatic clinical alerts* require a clinician, typically a trained nurse, to follow up with the patient through a phone call to assess the real clinical situation. The company has a service for augmenting these automatic alerts with additional clinical information by having a nurse call the patient. The protocol specifies how to classify these automatic alerts into three groups – red, yellow, and green alerts – requiring different actions that the nurse should take including calling 911 in case of an emergency. Green means no clinical attention needed but follow up with the clinical contact over email whereas red or yellow require clinical intervention and follow up should occur both over phone and email to the clinical contact. 85% (SD \pm 15) of the BP clinical alerts and 80% (SD \pm 21) of the BG clinical alerts were classified as being green (i.e., no clinical intervention needed).

Through the interviews conducted with 11 clinicians and observation of care processes at five clinics who adopted this home telemonitoring services (2 in Dallas-Fort Worth and 3 in McAllen), we identified potential areas for improvement related to the integration of telemonitoring technologies into clinician's workflow. In particular, a systems engineering framework was used to investigate the impact of home telemonitoring on five main components: people (health care providers, staff, and patients), tasks, tools and technologies, environment, and organizational conditions. Our findings suggest that the home telemonitoring technology is generally accepted and is well-integrated into clinicians' workflow, especially by younger clinicians. However, health providers and staff can benefit from systemic exposure to telemonitoring technologies. While the program initially suffered from patient dissatisfaction and attrition related to frequent follow-up calls, evidence suggests that this problem has been resolved as the program matured. According to our anecdotal evidence, while patients generally find the service helpful, patients' expectation to have the clinicians available continuously may not be realistic.

Our preliminary findings suggest that there is large variability between the clinics in roles involved with telemonitoring, specific tasks and review processes. While such variability is expected, clinics may benefit from specific guidelines and standardized best practices to avoid issues such as unbalanced workload, process inefficiencies, and unnecessary interruptions to workflow. An essential consideration for the integration of new technologies is investigating the impact on the utility of existing technology and tools. Our findings suggest that clinicians perceive the integration of home telemonitoring with Electronic Health Records to associate with significant efficiency gains. Other important enablers include reliable internet connectivity,

improved portability (e.g., for home visits), as well as integration with other telehealth modalities such as real-time visits. Other organizational variables such as differing perceptions of the technology between physicians and their staff, additional processes imposed such as medical transcription, and the impact on paper-oriented clinics should be investigated further to avoid process lapses and for seamless integration with primary care. Even with these challenges, we learned that physicians do consider continuous monitoring program for diabetic and high blood pressure patients to be beneficial for patients and providers and broadly stated the technology enjoys high acceptance.

We are in the process of obtaining and evaluating health outcomes and cost data for telemonitoring as well as additional stakeholder feedback to be included in the next updated release of this report to better inform telemonitoring policies.

In 2018, Medicare started allowing for billing of home telemonitoring with the CPT 99091 code. The new policy allows for billing of the provisioning of the equipment to deploy the equipment and \$59/month for physicians to monitor the vital signs. In 2019, Medicare published three new CPT codes, CPT 99453, 99454, and 99457, for billing of home telemonitoring services in detail. CPT 99453 can be used for set-up of equipment and patient education, CPT 99454 is used for device supply with daily recording or programmed alert transmission, and CPT 99457 is used for 20 minutes or more of healthcare professional time in a calendar month requiring interactive communication with the patient. More work is warranted to investigate how well these reimbursement policies will support effective telemonitoring of Medicare patients.

The requirement of physicians to get reimbursed only for interactive communication with the patients is of concern given that, on average, 46% (SD ± 27) of the BP authorized days and 41% (SD ± 26) of the BG authorized days in our study required adherence calls to help them troubleshoot to transmit the reading or remind patients. These non-clinical calls with the patients constitute the largest time interacting with them at the company. Even with these calls, on average patients missed 2.4 of 10 days transmitting a reading. In fact, of the 7.6 days, about 3.4 needed a phone call by a non-clinician to obtain the reading. In addition, nurses classified most automatic clinical alerts, 85% (SD ± 15) for BP and 80% (SD ± 21) for BG, as requiring no clinical intervention. Thus, for a cost-effective telemonitoring program, it will be important to provide for non-physician clinical expertise to interact with the patients to differentiate between automatic alerts that need physician intervention and those that do not as well as non-clinical time to troubleshoot and maintain daily monitoring. The clinical outcomes and cost savings of the home telehealth monitoring system needs further investigation. Although the Medicaid population is different from the Medicare population, and the exact requirements for an effective system will be different, we suspect that the nature of the system (e.g., needing non-clinical calls to patients for obtaining daily readings and trained nurses following up on automatic alerts to determine the real clinical nature of the alert) will still be the same.

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1. INTRODUCTION

Diabetes and cardiovascular diseases are two leading causes of death in the United States. Nearly 10% of Americans have diabetes (Benjamin et al., 2017) and 33% of US adults have cardiovascular disease (American Diabetes Association, 2018). Texans consistently have diabetes at higher rates than the national median; currently, 10.9% are diagnosed with the condition (Centers for Disease Control and Prevention, 2018). Both of these life-long conditions require regular follow-up with a clinical team and self-management home care strategies to control day-to-day disease progression and reduce the risk of long-term complications. Technology has begun to address the challenge of disease management and facilitate communication between patients and their providers. The last decade has seen an increase in usage of electronic information and telecommunication technologies to support and promote long-distance clinical health care, patient and professional health-related education, public health and health administration; a regimen defined as Telehealth (Health Resources and Services Administration, 2019).

Telehealth is becoming prevalent throughout the care continuum and utilizes several modalities to fulfill remote care. One such form of providing clinical services to patients through the use of electronic communication and software is known as telemedicine. Telemedicine has a long history in acute care. Calling or faxing specialists from out-of-state to review charts and discuss diagnoses has been upgraded with video calls and robotic, remote surgery. Care provided remotely in the post-acute care setting aims to predict patient outcomes after some trauma or recovery period. In community clinics, such as community resource centers or federally-qualified health centers, video conferencing with clinical specialists and health educators is facilitated by the community or social workers in remote or underserved areas. Telemedicine encompasses patient-to-doctor, doctor-to-doctor, and doctor-to-specialist communications to enhance patient care across the various places where healthcare is provided and uses a variety of synchronous and asynchronous technologies to facilitate care.

The Texas Medicaid & Healthcare Partnership (TMHP)¹ defines home telemonitoring as follows in the Telecommunication Services Handbook (Texas Medicaid & Healthcare Partnership (TMHP), 2019):

Home telemonitoring is a health service that requires scheduled remote monitoring of data related to a client's health, and transmission of the data from the client's home to a licensed home health agency or a hospital. The data transmission must comply with standards set by HIPAA.

Currently, Texas Medicaid has a pilot program that provides home telemonitoring reimbursement to providers treating clients who have hypertension or diabetes as well as other

¹ TMHP is the claims administrator for Texas Medicaid under contract with the Texas Health and Human Services Commission.

eligible conditions. It offers reimbursement for equipment installation and set-up, daily monitoring of a client's clinical data transmissions, and a weekly review of a client's clinical data by a physician. Utilization of Texas Medicaid telemedicine, telehealth, and home telemonitoring services has grown each year consistently. The number of clients utilizing these services increased 31 percent from fiscal years 2014 to 2015 and 30 percent from fiscal years 2016 to 2017. The number of providers offering these services also increased 64 percent from fiscal years 2014 to 2015, and 31 percent from fiscal years 2016 to 2017 (Health and Human Services Commission, 2016; Health and Human Services Commission, 2018). In the 2014-15 and 2016-17 bienniums, Texas Health and Human Services Commission (HHSC) noted an increase in client utilization and provider expenditures for telemedicine, telehealth, and home telemonitoring services (Health and Human Services Commission, 2016). Procedure code data, client primary diagnoses, and survey results from the Texas Council of Community Centers also indicates telemedicine and telehealth services are frequently utilized to aid in the delivery of behavioral health services. HHSC intends to continue monitoring this trend and to explore the efficacy of telemedicine and telehealth services to promote health care access and early intervention for Medicaid clients with behavioral health diagnoses and conditions. To inform future strategies, it is critical to understand how current home telemonitoring programs have impacted Texans with diabetes and hypertension and the factors associated with the effectiveness of home telemonitoring services.

This report aims to investigate the impact of home telemonitoring in Texas by conducting a case study of a Texas home telemonitoring company. We conduct 1) a retrospective database study of the company data on the patients and physicians, 2) a retrospective database study of the outcomes of patients using the services from a claims database², and 3) a stakeholder interview study on the integration of the provider's home telemonitoring system into physicians' workflow.

2. BACKGROUND

2.1 LITERATURE

There has been growing research on how home telemonitoring systems can support patient management and promote health. Understanding the use of technology for home-based patient care is a multidisciplinary effort. Researchers from many fields including public health, medical sciences, and engineering have studied the use, effectiveness, cost, and capabilities of home-based health technologies and new tools for this purpose are still evolving.

Several reviews have been conducted to identify the effect of home telemonitoring on glycemic control. The results of these studies have not been conclusive in the goal of understanding if home telemonitoring is beneficial to patients with diabetes. Two studies found

² The outcome study results are planned for release in the updated version of this report

little (Montori et al., 2004) or no positive effect (Farmer, Gibson, Tarassenko, & Neil, 2005) on glucose control when using glucometers with feedback to the care provider. Teleconsultations by voice or video call also show no difference in outcomes for people with diabetes (Verhoeven, Tanja-Dijkstra, Nijland, Eysenbach, & Van Gemert-Pijnen, 2010). Results of the studies were conflicting or inconsistent in three reviews (Baron, McBain, & Newman, 2012; Greenwood, Young, & Quinn, 2014; Jaana & Pare, 2007). However, a more recent study indicated that telemonitoring was the second most effective telemedicine strategy after teleconsultation in reducing HbA1c levels in diabetic patients (Lee, Chan, Chua, & Chaiyakunapruk, 2017).

Many individual studies do show positive results. Two groups found that web-based tools have led to improved outcomes (Angeles, Howard, & Dolovich, 2011; Dalton, 2008). Phone support and interventions were also effective in improving glycemic control in two studies (Liang et al., 2011; Polisena et al., 2009). Angeles et al. (2011) indicate multimodal delivery of web-based diabetes support (e.g., computer and mobile phone) could be better than using one technology alone. Indeed, home telemonitoring systems which incorporated more than one technology had better diabetic outcomes in three studies (Ali, Shah, & Tandon, 2011; El-Gayar, Timsina, Nawar, & Eid, 2013; Marcolino, Maia, Alkmim, Boersma, & Ribeiro, 2013). It is worth noting that patient outcomes in home telemonitoring systems may be impacted more by the configuration of the technology components and policy decisions implemented than home telemonitoring itself (Hammett, Sasangohar, & Lawley, 2018).

Another critical element of the existing research in home telemonitoring has been to focus on how these systems can be leveraged to improve health outcomes in vulnerable populations while simultaneously exploring barriers to care (Alvarado et al., 2017; Stowell et al., 2018). Stowell et al. (2018) found that 64.29% of the randomized control trials reported at least mild improvement in health outcomes. In studies of type 2 diabetic patients using remote health technologies, low-income populations have low rates of technology literacy which create significant barriers to adopting the new systems. These studies reported large dropout rates when the barriers reported impeded patient engagement (Alvarado et al., 2017).

Additionally, it is essential to understand the perspective of clinical professionals on home telemonitoring. Koopman et al. (2014) explore stakeholder perspectives about home telemonitoring, which are vital for the successful implementation of these systems. They suggest that there has been a general enthusiasm for extending home telemonitoring to primary care practices. However, they also point to careful consideration of information flow for successful implementation. Thus, careful consideration of how the home telemonitoring processes impact traditional healthcare processes is also crucial. Understanding the impact of the integration of home telemonitoring technologies on the clinicians' workflow is an important step to investigate challenges to adoption and sustained participation in home telemonitoring programs. The implementation of new health information technologies, such as telemedicine, may result in changes to the health providers' clinical, managerial, and administrative practices. These changes, if not well addressed, can lead to dissatisfaction, disruption to workflow, increased workload, reduced time efficiency and quality of care and may negatively affect patient safety (Jarvis-Selinger, Chan, Payne, Plohman, & Ho, 2008; Zheng, Haftel, Hirschl, O'Reilly, & Hanauer, 2010). A lack of understanding of such an important aspect of the system

design has been attributed to low or no adoption of the home telemonitoring technology by the clinicians (Brooks, Turvey, & Augusterfer, 2013). In addition, poor integration of new technologies may have a significant impact on: (1) patient outcomes (i.e. quality of care, patient satisfaction, and adequate monitoring of health condition) and (2) employee and organizational outcomes (i.e. financial performance, cultural change, and decision support) (Bowles, Dykes, & Demiris, 2015).

2.2 THE MEDICAID PILOT PROGRAM

Texas Legislature has passed several bills since 1997 to establish home telemonitoring as a reimbursable health service under Texas Medicaid. Current, Texas Medicaid provides home telemonitoring services to eligible patients in the state, specified in the Texas Government Code Section 531.02164(c). Essentially, telemonitoring is available for patients with diabetes and hypertension. In 2015, the sunset date of the bill establishing these services was moved from September 1, 2015, to September 1, 2019 (Health and Human Services Commission, 2016). Thus, a determination must be made on whether these services will continue beyond the current sunset date on September 1, 2019.

Reports from the HHSC demonstrate that use of home telemonitoring services are increasing among Texas healthcare providers and their clients. In 2016, HHSC published a report (Health and Human Services Commission, 2016) that provides data on utilization and expenditures from the 2014-2015 period of home telemonitoring reimbursements. According to this report, the number of clients who received home telemonitoring services in 2015 was almost eight times more compared to 2014 (1,328 clients compared to 173). The majority of providers are located in Metropolitan Statistical Areas (MSAs; McAllen-Edinburg-Mission, Dallas-Fort Worth-Arlington, and Brownsville-Harlingen). In addition, average Medicaid expenditures per provider increased from \$2,223.99 in 2014, to \$17,388.32 in 2015.

The HHSC updated their report in 2018 (Health and Human Services Commission, 2018) and provided data on utilization and expenditures from the 2016-2017 period. According to this report, the number of clients receiving home telemonitoring services more than doubled from 2016 to 2017; there were 2,685 enrolled patients in 2016 and 5,961 in 2017. The majority of providers remain in South Texas, and Medicaid expenditures dramatically increased over the prior biennium report. In 2016, this expenditure was \$34,334 on average and increased to \$55,276 in 2017.

3. CASE STUDY: COORDINATION CENTRIC

Coordination Centric (CnC) is a home telemonitoring company that started operating in mid-2015 in different regions of Texas including McAllen, Dallas, San Antonio, and Houston regions. CnC defines telemonitoring as "A health service that requires near real-time clinical

follow up to automated inbound data upon receipt of information outside of physician determined parameters." Thus, they believe after the initial proper clinical intervention; additional follow up may be necessary, i.e. reassess, troubleshoot, notify emergency personnel, coach patient, etc. The additional logistics involved with this service will require significant non-clinical patient contact for a variety of reasons including adherence.

Following this model, CnC provides hardware, software, and services (e.g., deployment, monitoring assistance and equipment management) to physicians and providers who want to prescribe telemonitoring services to their eligible patients. We have obtained two sources of data to conduct a case study of CnC for this report. First, CnC company data was obtained to conduct a descriptive statistical analysis of how a telemonitoring company processes work and to understand potential areas for improvement. Second, we conducted interviews with clinics using the CnC technology for telemonitoring to understand how the services are integrated with primary care. The first section below provides background information on the telemonitoring process at CnC and the methods used. The second and third sections provide the results of two studies respectively.

3.1 **TELEMONITORING AT COORDINATION CENTRIC**

3.1.1 TELEMONITORING PROCESS OVERVIEW

CnC uses multiple United States Food and Drug Administration (FDA) Class II devices to monitor blood sugar, blood pressure, weight, and pulse oximetry. The device(s) chosen for the patient generally depend upon patient conditions and physician preference. In this report, we focus on blood pressure and blood sugar which are the two most commonly monitored clinical parameters.

Figure 1 depicts the general processes and responsibilities of different entities involved in telemonitoring at CnC. It begins with the physician prescribing telemonitoring services to qualified patients for needed vital signs such as blood pressure, pulse, or blood sugar. Once pre-certification for payments has been processed, and deployment of the equipment to patients is complete, daily monitoring starts. Patients are expected to use the equipment to complete the daily self-assessments. The data will then be sent and monitored by CnC for anomalies. Physicians receive a report containing one week of individual patients' data via email and follow up with the patient if necessary. Once monitoring has been set up and is running correctly, there is also follow up billing for the monitoring activity and equipment maintenance. Both precertification and billing may be done by a third-party biller.

During the monitoring phase, two events may warrant further actions. First is when readings are not received either due to equipment or communication failure or patients did not take the readings (e.g., patients are hospitalized, or were busy that day). Second, when a reading for the day is out of acceptable range and may need clinical attention. A standardized system of procedures to handle both of these events is crucial to monitor patients accurately.

Hence, the CnC system handles these events by generating two types of alerts that may result in CnC staff calling patients: adherence alerts and clinical alerts respectively. Both of these alerts are described more in detail in the next section.

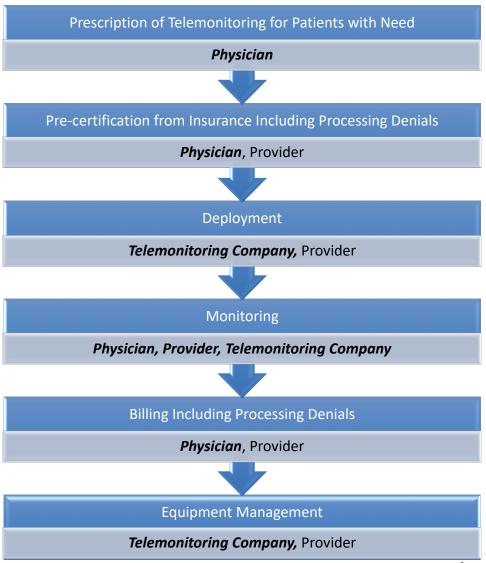


Figure 1. General Processes and Responsibilities for Telemonitoring³

³ In the figure, physicians can be MDs or nurse practitioners, or physician assistants working under the supervision of MDs and providers may be either Hospitals or Home Health Agencies under the Medicaid pilot program. Bolded entities indicate the general process used at CnC.

3.1.2 METHODS USED TO GENERATE SUMMARY STATISTICS

We conduct a longitudinal analysis by grouping new patients who start monitoring each month and follow them over time. For analysis, we define an episode as a contiguous block of authorized days for monitoring. Typically, Medicaid preauthorizes 60 days of service at a time. We combine all the contiguous authorization blocks that are approved to form one episode. If patients stop monitoring then return for monitoring with a gap of more than four days, it is defined as a separate episode.

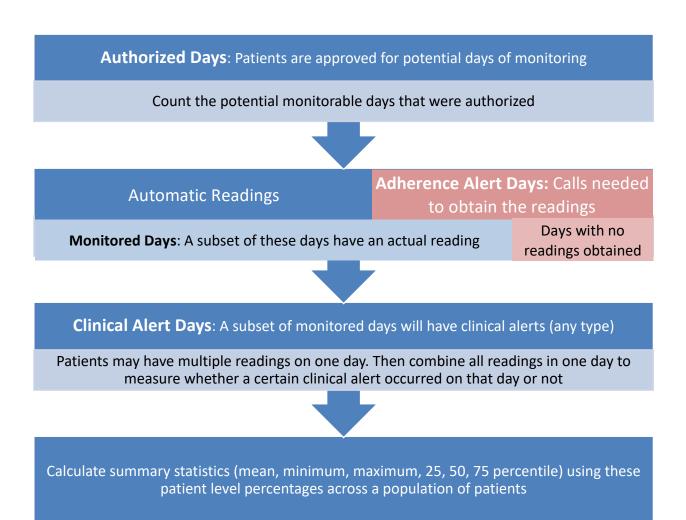
There were several steps needed to report summary descriptive statistics about the different types of adherence and clinical alerts in this population. We review these steps in Figure 2 before reporting the results. First, patient-level authorized days are calculated based on preapproved days for monitoring. To account for lag in deployment and collection of equipment in the front and end of the episodes, we calculate the *number of authorized days* as the sum of all days from the first reading to last reading in all episodes for the patient during the study period.

Second, on the authorized days patients are expected to take readings daily which is sent automatically to the server. The problem is that readings are not obtained at the server on all authorized days because there are days when there are issues with the equipment (e.g., battery issues, transmission issues) or the patient forgets. *Adherence alerts* are generated on these days with missed readings. For example, a timer may be set at 10 am according to the patients' schedule and preference for self-assessment. If a reading is not received by that time, an alert is created and must be cleared (generally within the hour) by a non-clinical team member confirming no reading was received. This adherence call to the patient is an attempt to receive the reading. This may result in trouble-shooting, retraining, or coaching the patients like to have someone check in regularly with different preferences for the frequency of check-in. These are coded into the automatic adherence alert system at CnC when trained technical staff properly deploy the equipment and educate the patient on its use. We define the *Adherence Alert Rate* as the percent of authorized days that require an adherence call in an attempt to obtain a reading.

 $A dherence \ A lert \ Rate \ (\%) = \frac{Total \ \# \ of \ Days \ with \ an \ A dherence \ A lert \ to \ Obtain \ the \ Reading}{Total \ \# \ of \ Authorized \ Days}$

 $Adherence Rate (\%) = \frac{Total \# of Monitored Days}{Total \# of Authorized Days}$

Not all adherence calls are successful in obtaining the readings. Thus, the *number of monitored days* are a subset of the authorized days that a patient has at least one reading, either with or without an adherence call. The *Adherence Rate* is defined as the percent of monitored days of authorized days. On days with multiple readings, we count them as one monitored day. The monitored days can be split into two categories based on how the reading was obtained: (1) readings that were obtained automatically with no issues, (2) readings that



were obtained after an adherence alert was generated (i.e., an adherence call to troubleshoot and/or coach patients is required).

Figure 2. Understanding summary statistics on adherence and clinical alerts for a population

Third, clinical alert days are a subset of the monitored days, regardless of how the reading was obtained, that generated a particular type of clinical alert. For example, any clinical alert days are the total number of days that any clinical alert occurred for a patient and a high systolic pressure alert days are the total number of monitored days with high systolic pressure. Sometimes, patients have more than one reading on a given day (i.e., the patient either intentionally or accidentally took multiple readings on one day). In these cases, we combined all clinical alerts from all readings on one day to determine if a particular alert type occurred on that day (e.g., did this patient have a high systolic pressure alert from any of the readings on that day). Thus, for each type of clinical alert, we calculate the percent of monitored days that generate the given clinical alert (e.g., high systolic pressure, or any alert) per patient.

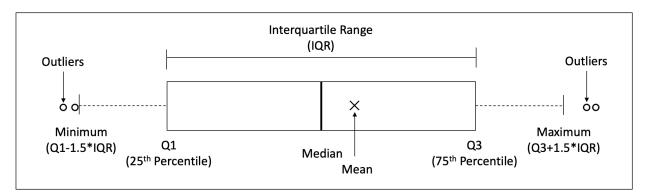
 $Clinical Alert Rate_{T} (\%) = \frac{Total \# of Days with Clinical Alert Type T}{Total \# of Monitored Days}$

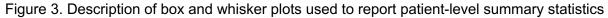
Where,

Type T_{BP} = {Any BP, High or Low Systolic Pressure, High or Low Diastolic Pressure, Three Consecutive High Systolic or Diastolic Days, and High or Low Pulse } Type T_{BP Clinical Severity} = {Red, Yellow, Green} Type T_{BG} = {Any BG, High or Low BG, Three Consecutive High BG} Type T_{BG Clinical Severity} = {Red, Yellow, Green}

Clinical alerts are generated by readings that are beyond the physician set parameters. When readings are outside acceptable ranges, a clinical alert is automatically generated and follow up phone calls are made by nurses at CnC to screen, classify, and dispatch the data. The nurses tag each reading that is out of range as red, yellow, or green after the call based on the CnC protocol. Green means no intervention is required and email is sent to multiple contacts. Yellow means clinical intervention is required and email is sent with a phone call to the clinical contract on file. Finally, Red means clinical intervention is required, and email is sent with a phone call to multiple providers. In rare cases of an emergency, the nurse may contact 911.

Finally, for each patient level measure, we report summary statistics, such as mean, minimum, maximum, 25, 50, 75 percentile using the patient level percentage among all patients in the population. These statistics are depicted on a box-whisker plot as shown in Figure 3. In the text, we most often report the mean (\pm SD) for the population. However, for measures that have many outliers, we will report the median instead.





In addition to the patient level measures, where appropriate, we also report these measures at the day level. For example, adherence rate could be reported at the patient level indicating summary statistics of individual patient rates for a population as discussed above. Also, the adherence rate could be calculated by taking all monitored days for a given population overall authorized days for the same population. It is important to note that when the unit of analysis shifts from patient to days, the results may be different.

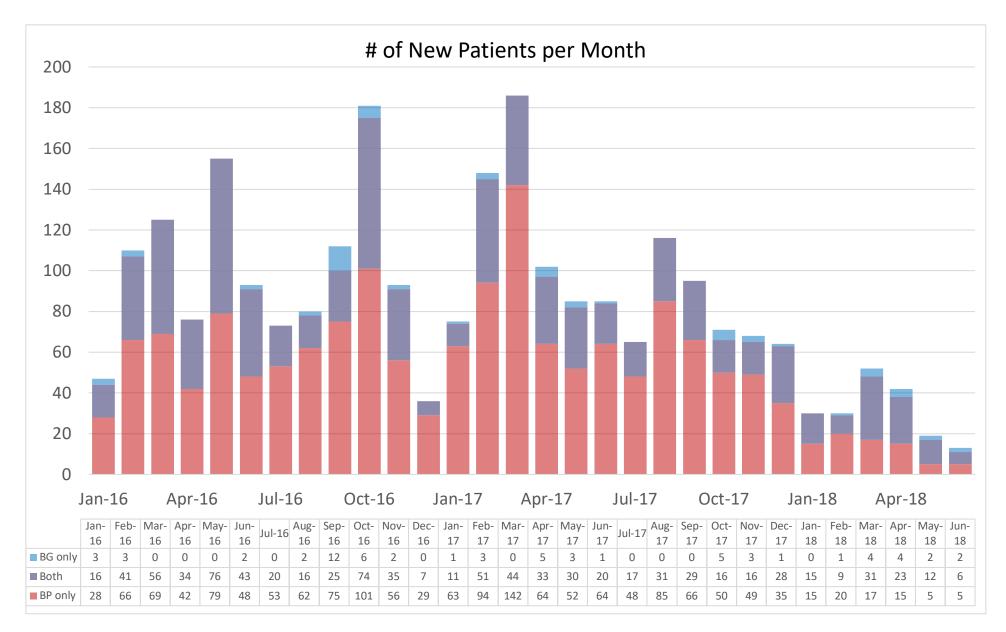


Figure 4. New patients approved to be monitored each month by CnC

Table 1. Patient characteristics of those who started to be monitored between January 2016 to June 2018.Note patients who are monitored for both BP & BG are included in both samples

	BP				BG		Overall		
	Total N	Mean (STD) or %		Total N	Mean (STD) or %		Total N	Mean (STD) or %	
Age	2462	72.3 (11.9)		930	70.7 (11.5)		2527	72.3	(12.0)
Female	2462	65.7%		930	67.0%		2527	65.7%	
Language									
Spanish	2462	76.5%		930	77.2%		2527	76.7%	
Residence Area									
McAllen	1878	76	6.3%	756	81.3%		1940	76.8%	
Dallas	276	11	.2%	99	10.6%		276	10.9%	
San Antonio	234	9	.5%	53	5.7%		237	9.4%	
Houston	74	3	.0%	22	2.4%		74	2.9%	
Urban-Rural Classification									
Urban	2104	85	5.5%	841	90.4%		2166	85.7%	
Suburban/Rural	358	14	.5%	89	9.6%		361	14.3%	
Distance from zip code of reside	ency to zip co	ode of prima	ry provider (m	iles)					
Urban	2094	10.0	(14.7)	839	8.8	(11.6)	2156	9.9	(14.6)
Suburban/Rural	358	19.3	(30.2)	89	21.8	(21.5)	361	19.4	(30.1)
# of episodes									
1	1868	75	5.9%	698	75.1%		1901	75.2%	
2	437	17	.7%	162	17.4%		463	18.3%	
3	118	4.8%		56	6.0%		122	4.8%	
4+	39	1.	.6%	14	1.5%		41	1.6%	
# of providers									
1	2395	97.3%		898	96.6%		2453	97.1%	
2 or 3	57	2.3%		30	3.2%		64	2.5%	
Unknown	10	0.4%		2	0.2%		10	0.4%	
# of authorized days	2462	291.2	(233.1)	930	285.2	(241.0)	2527	292.1	(233.8)
# of adherence alert days	2402	132.9	(139.1)	879	115.3	(128.4)	2475	137.0	(140.4)
Adherence alert rate	2402	46.2%	(26.6%)	879	40.7%	(25.8%)	2475	47.7%	(26.8%)
# of monitored days	2462	221.4	(193.0)	930	204.4	(192.6)	2527	223.4	(194.3)
Adherence rate	2462	75.0%	(21.0%)	930	70.1%	(23.4%)	2527	76.1%	(38.5%)

3.2 HOME TELEMONITORING DATA DESCRIPTIVE ANALYSIS

In this section, we report findings from a descriptive analysis of the CnC company data to understand the patients and physicians who have been receiving and giving services and highlight the crucial processes in telemonitoring. The results will suggest key components of telemonitoring services to be effective and potential areas for improvement. Most analysis in this section cover data from January 2016 to October 2018. We started with 2016 data when many of the company processes became more stable.

Figure 4 depicts how many new patients started their first episode of monitoring each month, from January 2016 to June 2018 and follow all patients to October 2018. That means patients have different length of follow up time ranging from 4 months to 34 months depending on when they started. The patients who had less than two weeks of authorized days were excluded.

In total, there were 865 unique patients monitored for both blood pressure and blood glucose, 1,597 unique patients monitored for only blood pressure, and 65 unique patients monitored for only blood glucose (See Figure 5). Patient characteristics for each sample are described in Table 1. The BP, BG, and Overall samples are the total number of unique patients for each group and are overlapped. That is those who were monitored for both blood pressure and blood glucose will appear in both BP and BG samples. Given that the monitoring processes and equipment used differs by what vital sign is being monitored, in the remainder of this section, we present separate results for telemonitoring of blood pressure (N=2,462) and blood glucose (N=930).

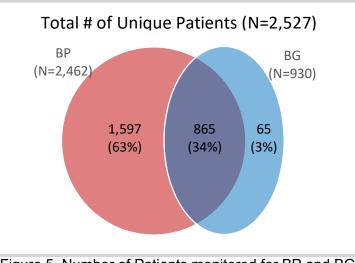


Figure 5. Number of Patients monitored for BP and BG

We used the 2013 RUCC urban-rural classification systems by the USDA Economic Research Services (Economic Research Service, 2013). RUCC classifies the degree of urbanization for each county along a continuum of nine codes based on the population size of

metro areas within metropolitan counties, and by the degree of urbanization and adjacency to a metro area for nonmetropolitan counties. Each patient was assigned the RUCC code from their county of residence. RUCC codes 1 and two were defined as urban, 3 to 7 as suburban, and 8 or 9 as rural and their definitions are below. Due to small sample size for rural areas, we had to combine suburban and rural in the analysis.

- Urban: counties in metro areas of 250,000 or more
- Suburban: counties in metro areas of fewer than 250,000 population, or urban population of 2,500 or more, either adjacent or not adjacent to a metro area
- Rural: completely rural or less than 2,500 urban population, either adjacent or not adjacent to a metro area

3.2.1 TELEMONITORING OF BLOOD PRESSURE (BP)

Patients on the telemonitoring program for BP

Table 1 depicts the summary of patient characteristics for those who were monitored for BP. There were a total of 2,462 patients who started monitoring during the study period with a mean age of 72 (SD \pm 12). 66% were female with more than 77% speaking Spanish. Race and ethnicity were not separately tracked. 76% lived near McAllen, 11% near Dallas, 10% near San Antonio, and 3% near Houston. 85% lived in urban and 15% in suburban or rural areas. The average distance from the center of the zip code of residence to the center of the zip code of the primary provider was 10.0 miles (SD \pm 14.7) for urban residents and 19.3 miles (SD \pm 30.2) for suburban or rural residents. Most patients only have one episode, continuously monitored days, but 594 patients had more than one episode coming back after a break in monitoring. Of these, 57 patients change primary care physicians between episodes together as the total number of approved days. On average patients had 291 (SD \pm 233) authorized days, and 221 (SD \pm 193) monitored days.

Adherence alerts and calls

Total number of authorized days for BP monitoring varied widely ranging from 14 days to 1,004 days (Figure 6). On average, patients had an adherence alert rate of 46% (SD \pm 27) requiring an *adherence call* to obtain the reading (Figure 7). Even with these alerts, on average patients a 75% (SD \pm 21) adherence rate, percentage of the authorized days with an actual BP reading (Figure 7). This means that on average patients missed at least 2.5 days of self-assessment for every ten days. Moreover, of the 7.5 days that there was a reading, close to half needed an adherence call to troubleshoot or remind the patient in order to obtain the reading. This suggests that adherence calls may be essential to have proper daily monitored data flowing to physicians.

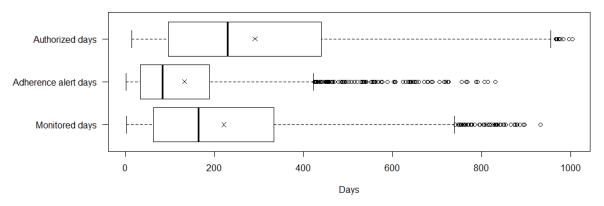


Figure 6. Patient Level Authorized, Adherence Alert, and Monitored Days for BP

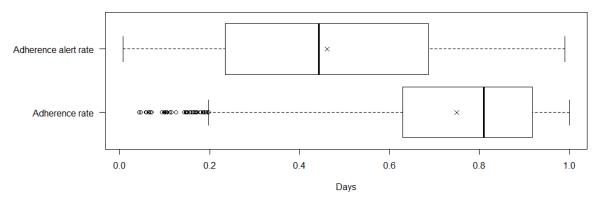


Figure 7. Patient Level Key Adherence Measures for BP

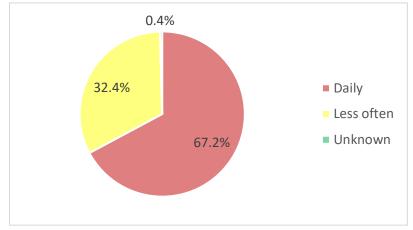


Figure 8. The percentage of adherence alert recurrence duration for BP

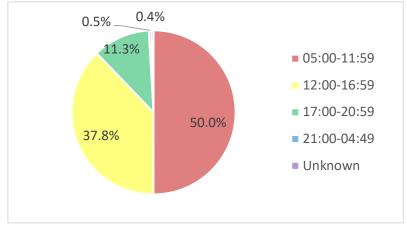


Figure 9. The percentage of adherence alert timer setting for BP

As discussed above, an adherence call is made by a non-clinician CnC staff at patient designated times if readings are missing based on the adherence alerts. Figure 8 describes the recurrence period of the alerts that are set up for the patients in our sample. Of those who have explicitly set a recurrence adherence alert, on average 67% of patients are set up daily with 32% being less frequent (e.g., only Monday, Wednesday, and Friday). We found in the interviews that CnC had some trial and error period in the beginning when some patients did not want to be called too often. Figure 9 describes the timer settings for adherence alerts. On average, 50% of patients prefer morning for the daily self-assessment with 38% setting in the afternoon, and 11% setting in the evening. The average time from alert to call was 40 minutes.

Clinical alerts and calls

The main purpose of telemonitoring is to track daily vital signs for patients with chronic conditions in order to prevent major health issues before they occur. Effectively monitoring the vital signs and taking action when needed is the most important part of telemonitoring. Monitoring the daily readings from patients can be a lot of work and easy to lose track for a busy clinic. Thus, at CnC, there are multiple components of the telemonitoring system to ensure that the daily readings are properly monitored and timely action is taken by the appropriate components.

We recap how BP clinical alerts work before reporting the results. First, the cloud server software is set up to generate clinical alerts when the reading is out of range. The acceptable range of the readings is set by the physician when the service is prescribed to the patient and may be changed over time. Second, when these clinical alerts are generated for out of range readings. These clinical alerts are based on the upper and lower bounds of blood pressure and pulse. The maximum pressure in the large arteries during one heartbeat is called systolic pressure and minimum between two heartbeats is called diastolic pressure. There is a normal specified upper and lower bound for both systolic and diastolic pressure, and pulse. CnC has a total of eight clinical alerts, six clinical alerts for systolic and diastolic pressure and two clinical alerts for a pulse. Any reading taken from the patient outside the acceptable range sends an

alert as either high for upper bound and low for lower bound. For example, if the blood pressure reading is lower than the lower bound for diastolic pressure, it will send out an alert as low diastolic pressure. An additional alert may also be generated when systolic and/or diastolic BP exceeds the upper limit for three consecutive days. This ensures that clinicians are aware that the abnormal reading is not an isolated event, but rather one that is following a previous abnormal reading. In addition to the BP alerts, clinical alerts are also generated for pulse rate when it exceeds the upper limit and drops below the lower limit. These are also classified as high and low alert types.

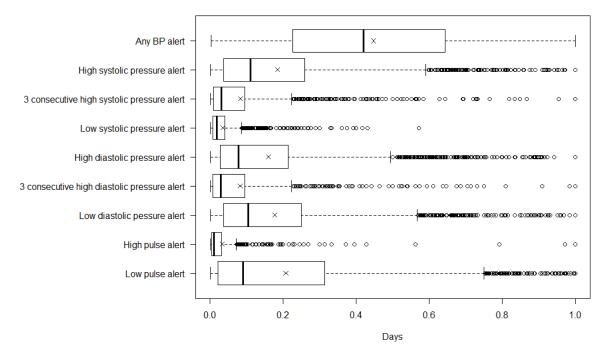


Figure 10. BP Clinical Alerts: The percentage of readings for each type of clinical alert

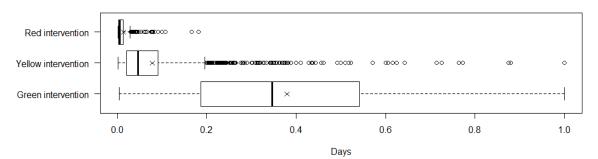


Figure 11. BP Clinical Severity Classified by Follow up Calls by Trained Nurses

When there is a clinical alert, nurses at CnC follow up with the call to the patient to determine the clinical severity of the reading. The CnC nurses classify each abnormal reading as red, yellow, or green based on a protocol and will augment the out-of-range reading with additional clinical information obtained through the call to support physician action as needed. The protocol specifies how to classify these automatic alerts into three groups requiring different

actions that the nurse should take including calling 911 in case of an emergency. Green means no clinical attention needed but follow up with the clinical contact over email whereas red or yellow require clinical intervention and follow up should occur both over phone and email to the clinical contact. Finally, the physicians who receive the weekly readings will monitor the readings and the supplemental information from the nurses to take any preventive action needed.

Of all the BP readings per patient, on average, the clinical alert rate for any type of BP alert was 44% (SD \pm 26) (Figure 10). The most frequent BP alert type was a low pulse with a mean of 20% (SD \pm 25), followed by high systolic pressure alert with a mean of 18% (SD \pm 20). Of all the BP readings per patient, the mean green, yellow, and red alert was 38% (SD \pm 23), 8% (SD \pm 9), and 1% (SD \pm 2), respectively (Figure 11). When these rates are converted to a percentage of clinical alerts, on average, 85% (SD \pm 15) were classified as green alerts that required no immediate clinical intervention.

3.2.2 TELEMONITORING OF BLOOD GLUCOSE (BG)

Patients on the telemonitoring program for BG

Table 1 also depicts the summary of patient characteristics for those who were monitored for BG. There were a total of 930 patients who started monitoring during the study period with a mean age of 71 (SD \pm 12). 67% were female with more than 77% speaking Spanish. Race and ethnicity were not separately tracked. 81% lived near McAllen, 11% near Dallas, 6% near San Antonio, and 2% near Houston. 90% lived in urban and 10% in suburban or rural areas. The average distance from the center of the zip code of residence to the center of the zip code of the primary provider was 8.8 miles (SD \pm 11.6) for urban residents and 21.8 miles (SD \pm 21.5) for suburban or rural residents. Most patients only have one episode, continuously monitored days, but 232 patients had more than one episode coming back after a break in monitoring. Of these, 30 patients change primary care physicians between episodes, having more than one doctor monitoring them over the full study period. We analyze all episodes together as the total number of approved days. On average patients had 285 (SD \pm 241) authorized days, and 204 (SD \pm 193) monitored days.

Adherence alerts and calls

A total number of authorized days for BG monitoring varied widely ranging from 14 days to 1,004 days (Figure 12). On average, patients had an adherence alert rate of 41% (SD \pm 26) requiring an *adherence call* to obtain the reading (Figure 13). With these alerts, on average, patients had a 70% (SD \pm 23) adherence rate, percentage of the authorized days with an actual BG reading. This means that on average patients missed at least three days of self-assessment for every ten days. Moreover, of the seven days with a reading, 2.5 days needed an adherence call to troubleshoot or remind the patient in order to obtain the reading.

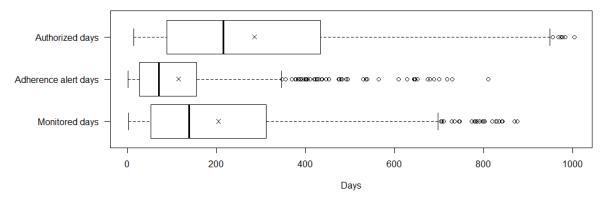


Figure 12. Patient Level Authorized, Adherence Alert, and Monitored Days for BG

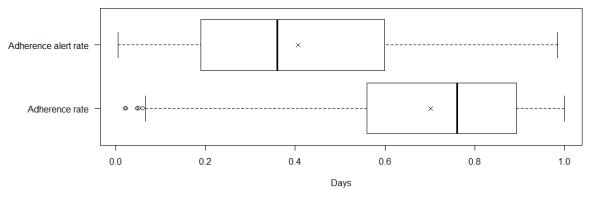


Figure 13. Patient Level Key Adherence Measures for BG

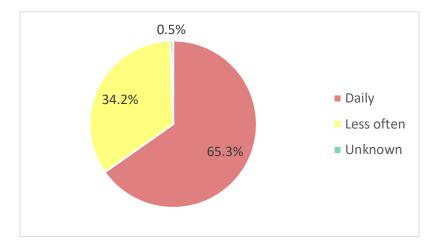


Figure 14. The percentage of adherence alert recurrence duration for BG

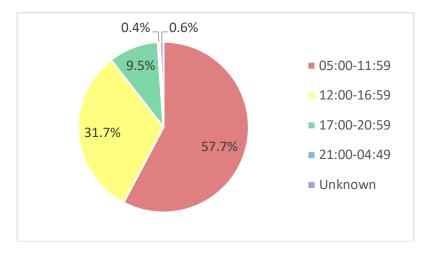


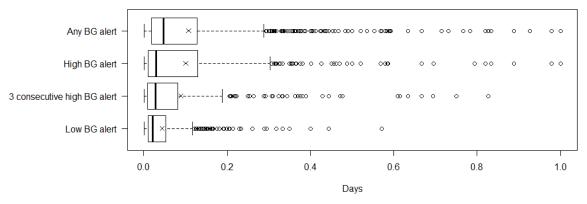
Figure 15. The percentage of adherence alert timer setting for BG

Figure 14 describes the recurrence period of the alerts that are set up for the patients in our sample. Of those who have explicitly set a recurrence adherence alert, on average 65% of patients are set up daily with 34% being less frequent (e.g., only Monday, Wednesday, and Friday). Figure 15 describes the timer settings for adherence alerts. On average, 58% of patients prefer morning for the daily self-assessment with 32% setting in the afternoon, and 10% setting in the evening. The average time from alert to call was 39 minutes.

Clinical alerts and calls

Diabetes management needs BG monitoring at regular intervals to keep BG on target and prevent long-term health complications. BG levels change in response to food and hence it becomes necessary to understand fasting and after food (post-prandial) blood sugar levels. If the BG level is measured at any point in time without taking into account food consumption levels, it is called random blood glucose level. Usually, self-monitoring involves random BG sample. CnC monitors the patient's BG level in a similar way as the BP. Clinical alerts are generated if the BG level falls below the lower specified limit and if it exceeds the specified upper limit, which is classified as low and high alert types. Another parameter monitored is if the BG level exceeds the specified upper limit for three consecutive days.

Of all the BG readings per patient, on average, the clinical alert rate for any type of BG alert was 10% (SD \pm 15) (Figure 16). The mean high BG alert was 10% (SD \pm 16), and low BG alert was 4% (SD \pm 6). Of all the BG readings per patient, the mean green, yellow, and red alert was 8% (SD \pm 11), 4% (SD \pm 7), and 2% (SD \pm 4), respectively (Figure 17). Converting these rates to the percentage of clinical alerts, on average, 80% (SD \pm 21) of clinical alerts were classified as green alerts (i.e., no immediate intervention needed).





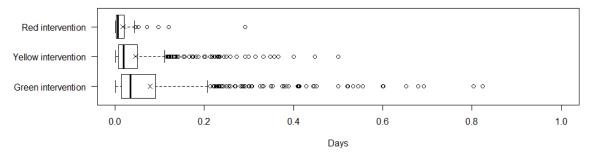


Figure 17. BG Clinical Severity Classified by Follow up Calls by Trained Nurses

3.2.3 PRIMARY CARE PHYSICIANS INVOLVED WITH TELEMONITORING

Table 2 depicts the summary of physician characteristics for those who participated in home telemonitoring services. There were a total of 76 physicians who prescribed home telemonitoring services with a total of 2,527 patients during the study period. Most of their clinics are in urban areas, with 71% in McAllen, 16% in Dallas, and 7% in San Antonio and Houston each. On average, a physician monitored 21 (SD \pm 24) patients in a given month, with a total of 34 (SD \pm 41) unique patients, on average, for the whole study period. On average, physicians have been working with CnC for 17 (SD \pm 10) months. Of 76 physicians, all prescribed BP monitoring service for their eligible patients, a total of 2,462 patients. There was a total of 66 physicians who prescribed BG monitoring service for a total of 930 BG patients.

		BP			BG		Overall		
	Total N	Mean (STD) or %		Total N	Mean (STD) or %		Total N	Mean (STD) or %	
# of Patients in each month	76	20.6	23.2	66	9.2	10.5	76	21.1	23.5
# of Patients in total	76	33.1	40.4	66	14.5	16.9	76	34.0	40.6
# of Months Physician had Patients	76	16.9	9.5	66	16.1	8.8	76	17.0	9.5
Residence Area									
McAllen	54	71.1%		47	71.2%		54	71.1%	
Dallas	12	15.8%		11	16.7%		12	15.8%	
San Antonio	5	6.6%		4	6.1%		5	6.6%	
Houston	5	6.6%		4	6.1%		5	6.6%	
Urban-Rural Classification									
Urban	73	96.1%		64	97.0%		73	96.1%	
Suburban/Rural	3	3.9%		2	3.0%		3	3.9%	

Table 2. Primary care physician characteristics for BP & BG

3.3 SERVICE INTEGRATION WITHIN PRIMARY CARE

In order to understand how telemonitoring systems have been integrated into Texan clinics, a mixed-methods qualitative study has been conducted with clinics who have adopted the Coordination Centric (CnC) telemonitoring system. The objective of the study was to understand the context in which the remote health information is being used by clinicians to identify the constraints (barriers and facilitators) that lead to inefficiencies and disruptions that may be imposed on the clinician's workflow by the integration of the telemonitoring system.

Findings from the study were analyzed and organized following the Systems Engineering Initiative for Patient Safety (SEIPS) model of work system and patient safety (Carayon et al., 2006). According to this framework the CnC clinicians' work system was analyzed based on five main components: (1) people (healthcare providers, patients, and staff; e.g., medical assistants), (2) tasks (activities performed which can be characterized by their difficulty, complexity, and sequence), (3) tools and technologies (artifacts used to perform tasks, which can be characterized by their function, usability, accessibility, and level of automation), (4) physical environment, and (5) organizational conditions (elements inherent to the organizational structure). This multidimensional focus facilitates the characterization of the interaction between the work system components. The feedback loop structure of the SEIPS models (Figure 18) provides insight on how such interactions impact healthcare processes and outcomes, which in turn, will shed light on potential barriers (undesired process performance and outcomes) imposed on system elements as well as opportunities for improvement. For this particular analysis, no elements related to the Environment component were identified from the interviews and observations; therefore, this work system component was not included in the model. The preliminary analysis is based on data collected from five clinics in Texas, two located in Dallas-Fort Worth and three located in McAllen. A particularity of the two clinics located in Dallas-Fort Worth is that the physicians also provide home visiting services. Therefore, in the study, it was possible to observe the in-clinic activities, but also observe their workday during their visits to homebound patients. A contextual inquiry method was used that consisted of observations of the clinical workflow of the clinics, in addition to conducting semistructured interviews with physicians, medical assistants and other staff members involved in performing direct or indirect activities related to the telemonitoring system. Three, out of the five clinics, were used as settings for the observational studies. However, stakeholder interviews were conducted in all five clinics. A total of three physicians and eight medical assistant and staff members were interviewed. The main findings from the observations and the interviews have been categorized by work system component and are discussed below.

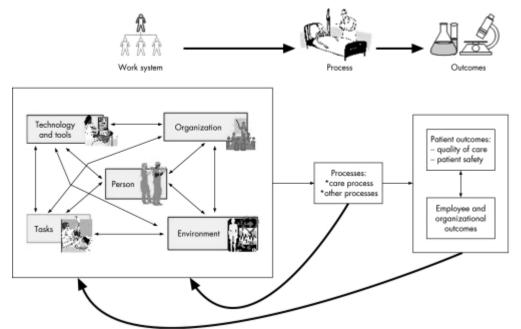


Figure 18. SEIPS model of work system and patient safety (from Carayon et al., 2006)

3.3.1 IMPACT ON PEOPLE

The People component of the system has been divided into three primary stakeholders: health providers, patients, and staff (e.g., medical assistants). *Health Providers and Staff*: The findings suggest that lack of experience with telemonitoring technologies may result in added complexity during the integration into clinical workflow. Having previous experience and familiarity with telemonitoring systems helps health providers and staff members to understand the value and impact of such technologies and would contribute to facilitating the integration. Telemonitoring service providers play a vital role in ensuring successful initial transition and acceptance by providing training to physicians and staff members. Factors such as the physician age, number of years of experience in the medical field, the size of the clinic, and characteristics of the patient population being served, may influence the physician willingness to

accept and adhere to new technologies, such as telemonitoring. For example, our findings show that older physicians resist transitioning to Electronic Health Records (EHR) compared to their younger colleagues. While the generalizability of such finding to other clinics should be validated, resistance to change among established clinics with deep-rooted values and processes has been well-documented (Landaeta, Hyon Mun, Rabadi, & Levin, 2008).

Patients: patients play an important role in the integration process. Regarding adoption, evidence from our study suggests improvements in patient acceptance of telemonitoring over time. At the early adoption stage, most clinics have received many complaints from the patients due to frequent follow-up calls from the CnC staff. It was unclear from the interviews if patients were complaining about the adherence calls from CnC non-clinical staff for missed readings or clinical calls from clinical staff at CnC when readings are out of range. In such cases, the patients would visit the clinic to return the equipment and ask to be dis-enrolled from the program. Clinics report that this situation has diminished in most cases since the program has matured. Another contributor to integration is the addition of a review process for the telemonitoring reports. Our findings suggest that patients' varying conditions contribute to large variability and unpredictability for the time it takes to complete reviews. For example, reviewing the telemonitoring reports of patients from specific patient populations, such as disabled patient or patients with chronic conditions, maybe a more time-consuming task. Another challenge for integration is the imbalance between patients and healthcare providers' expectations about the nature of the telemonitoring service. In particular, physicians tend to consider that some patients have unrealistic expectations of their health providers. For example, one of the physicians mentioned that patients with Medicaid and Medicare think of their doctors as their "concierge doctors," with an obligation to be available for them at any moment, as desired. Regardless of such differences, physicians consider a continuous monitoring program with a 24/7 lifeline for diabetic and high blood pressure patients to be beneficial not only for the patients but also for the physicians.

3.3.2 IMPACT ON TASKS

The addition, remote patient monitoring programs may impose a new set of activities and responsibilities on the healthcare professionals and staff members. If such tasks are not understood and designed properly, the additional workload imposed by the program may overweigh the benefits. While we noticed large variabilities in how telemonitoring technologies were implemented, three themes of resource allocation configurations were observed or mentioned by interviewees: (1) no staff member involved in the process; the physician perform all the activities related to the processing and charting of CnC weekly reports, (2) multiple staff members (e.g., medical assistants), in addition to the physician, involved in the process, performing the same activities at different times, and (3) multiple staff members (e.g., medical assistants), in addition to the physician, involved in the process; each one responsible of performing specific tasks in the process. As a consequence, each clinic has a different flow of activities to process the telemonitoring weekly reports. Some clinics do not have a standard structure to process the incoming weekly reports in terms of frequency and time, and the ones that have an established process, still confront issues, such as unbalanced workload.

3.3.3 IMPACT ON TECHNOLOGY AND TOOLS

An important consideration for the integration of new technologies is investigating the impact on the utility of existing technology and tools. One such issue apparent in the findings from interviews is the integration of the telemonitoring capabilities with other technologies. According to the providers, integrating the telemonitoring system portal (the electronic interface where the physician and staff access the telemonitoring reports) with the EHR would improve the telemonitoring report processing by reducing visual fatigue and saving time. One physician mentioned that having to deal with two interfaces (CnC Portal and EHR) when processing a report and charting patient data caused divided attention issues which contribute to confusion and fatigue. According to this physician, integrating the CnC Portal with EHR could save up to 10 minutes per patient when charting. Another opportunity identified is the possibility of integrating more than one telemonitoring modality to improve the quality of service provided to the patients. One of the physicians mentioned that he would like to have the option of adopting other types of telemedicine, such as real-time live conference, to communicate with patients about their health status once he has reviewed their weekly report. Finally, while remote access and portability are favored among providers and in particular during home visits, reliable internet connectivity remains a challenge for verifying the telemonitoring reports on the road.

3.3.4 IMPACT ON ORGANIZATIONAL CONDITIONS

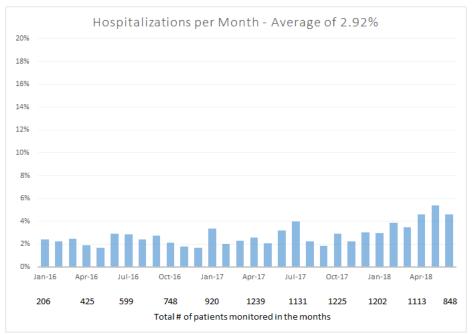
Organizational context of changes to activities, processes, and roles needs to be understood to ensure effective integration of telemonitoring. Our preliminary findings suggest that physicians and staff members (e.g., medical assistants) generally do not share a common understanding of the challenges implied by the integration of a telemonitoring technology. When asked about the impact of integrating a telemonitoring system on their clinic, physicians seem to not perceive a big negative impact in their workflow. One physician mentioned: "It is not different from reading a nurse's note. It is seamless. I do not even feel it." As a consequence, enrolling more patients in the telemonitoring program is not perceived as a burden. On the other hand, medical staff and assistants acknowledge that enrolling more patients might have a negative impact on the administrator/staff workflow in particular due to additional administrative work such as medical transcription imposed.

Integrating telemonitoring technologies to paper-oriented clinics also constraints to the staff regarding the management and continuity of information flow, if not complemented with other health information technologies such as the EHR. Paper-oriented clinics manage too much paperwork. Usually, the staff members' desks are covered with papers, files, and clinical folders. This imposes a challenge in the management and continuity of information flow. Medical assistants, from one paper-oriented clinic visited, expressed that they consider that complementing the telemonitoring portal with the use of the EHR facilitate their work and the processing of the telemonitoring reports.

The method of communication used to send the telemonitoring reports to clinics, and the frequency those reports are sent are two important contextual factors that need to be

understood in the integration process. For example, in the CnC telemonitoring system, medical assistants and physicians receive a weekly telemonitoring report email for each individual patient, in addition to other emails they receive from CnC. While clinicians prefer patient reports to be emailed, the high volume of emails received at different times may result in confusion about whether certain emails have been processed or not. Our findings suggest that clinicians favor receiving all the reports (for several patients) in a single batch each day to avoid processing lapses.

3.4 OUTCOMES ON HEALTH AND COST OF CARE



3.4.1 OUTCOMES FROM TELEMONITORING

Figure 19. Hospitalizations tracked at CnC using the notes from the adherence calls

The adherence calls are also how CnC staff learn more about what is going on with the patients. For example, they may find out that the patient is hospitalized or died and thus not taking readings. Such information learned during the adherence call is written up into notes, similar to medical notes, in the CnC system. An analysis of these notes for hospitalizations based on a total number of patients monitored each month is given in Figure 19 below. The total number of patients monitored each month at CnC, depicted under the graph, has grown significantly over time from 206 in Jan 2016 to a max of 1283 in September 2017. There was a reduction in patients at the end of the study period with a reduction of 226 patients in May 2018 ending on 848 patients in June 2018, the last month of the study period. Hospitalization rates are calculated each month by taking the monitored patients who are detected as being hospitalized over the total number of patients monitored that month. It ranges from 1.7% to 5.4% with an average of 2.9%. We note that the outcomes captured through these adherence calls are a

lower bound as there is a limit to the data collected in this manner because not all events would be captured this way. Also, it is important to remember that hospitalization rates depend heavily on the clinical characteristics of the patients being monitored, which fluctuates over time. Thus, without a baseline for the patient population, the interpretation of these results are limited. For a more rigorous outcome analysis, including a comparison group of similar patients who are not being monitored, we are currently in the process of obtaining data from a local hospital who is likely to have more comprehensive data for a subpopulation of these patients in South Texas. We plan to include the hospital outcomes analysis with comparison groups in the next release of the technical report.

4. CONCLUSION

4.1 SUMMARY OF RESULTS

We analyzed data for 2,527 patients that were monitored by 76 physicians between January 2016 to October 2018 by one telemonitoring company in Texas. Our preliminary analysis suggests that these patients are, on average, slightly over 70 (SD \pm 12), mostly female, live in urban areas in the McAllen region, and have one primary physician monitoring them during the study period. On average, the patients monitored for BP were authorized for 291 (SD ± 233) days, with 46% (SD ± 27) adherence alert rate (i.e., non-clinical alerts required to obtain daily readings) and 75% (SD ± 21) adherence rate (i.e., days with actual reading). Only 33% of patients have been monitored for BP for longer than one year. In comparison, the patients monitored for BG were authorized for 285 (SD ± 241) days on average, with 41% (SD ± 26) adherence alert rate and 70% (SD ± 23) adherence rate. 33% of them were monitored for more than one year. On average, patients had 44% (SD ± 26) of the BP monitored days flagged automatically as being out of range while 10% (SD ± 15) of BG monitored days were flagged automatically. A follow-up call by a trained nurse indicated that most of these clinical alerts did not need immediate intervention with a mean of 85% (SD ± 15) for BP clinical alerts and 80% (SD \pm 21) for BG clinical alerts being classified as green alerts. The primary physicians, on average, monitored 21 (SD \pm 24) patients each month with a total of 34 (SD \pm 41) patients during the study period.

Our preliminary findings from the interviews with physicians and their clinic staff suggest that there is a large variability between the clinics in roles involved with telemonitoring, specific tasks and review processes. While such variability is expected, clinics may benefit from specific guidelines and standardized best practices to avoid issues such as unbalanced workload, process inefficiencies, and unnecessary interruptions to workflow. An important consideration for the integration of new technologies is investigating the impact on the utility of existing technology and tools. Our findings suggest that clinicians perceive the integration of home telemonitoring with Electronic Health Records to associate with major efficiency gains. Other important enablers include reliable internet connectivity, improved portability (e.g., for home visits), as well as integration with other telehealth modalities such as real-time visits. Other organizational variables such as differing perceptions of the technology between physicians and

their staff, additional processes imposed such as medical transcription, and the impact on paper-oriented clinics should be investigated further to avoid process lapses and for seamless integration with primary care. Even with these challenges, we learned that physicians do consider continuous monitoring program for diabetic and high blood pressure patients to be beneficial for patients and providers and broadly stated the technology enjoys high acceptance.

We are in the process of obtaining and evaluating health outcomes and cost data for telemonitoring as well as additional stakeholder feedback to be included in the next updated release of this report.

4.2 IMPLICATIONS

Texas Medicaid program providing home telemonitoring services to eligible patients has seen a rise in clients over the years. With the scheduled sunset of the pilot program in September 2019, Texas will have to deliberate on whether to continue the pilot program, establish a permanent program, change policies on reimbursement, or discontinue reimbursing home telemonitoring for Medicaid patients in Texas. Additionally, in 2018, Medicare started allowing for billing of home telemonitoring with the CPT 99091 code. The new policy allows for billing of the provisioning of the equipment to deploy the equipment and \$59/month for physicians to monitor the vital signs. In 2019, Medicare published three new CPT codes, CPT 99453, 99454, and 99457, for billing of home telemonitoring services in detail. CPT 99453 can be used for set-up of equipment and patient education, CPT 99454 is used for device supply with daily recording or programmed alert transmission, and CPT 99457 is used for 20 minutes or more of healthcare professional time in a calendar month requiring interactive communication with the patients.

Although the Medicaid population is different from the Medicare population, and the exact requirements for an effective system may be different, the nature of the system will still be very similar. Telemonitoring of daily vital signs is a collaborative care model that engages many stakeholders to improve health outcomes and cost by taking timely preventative action and better managing chronic conditions. The stakeholders include patients, caregivers, physicians, clinic staff, providers (e.g., hospitals and home health agencies) and telemonitoring companies that must all work together in a coordinated manner to be effective. Orchestrating this web of stakeholders to take timely action requires a well-designed hybrid human-computer interactive system. Real-time computer systems that automatically monitor vital signs that are outside predefined ranges are merely one component of telemonitoring. Understanding of needs, expectations, of human elements and their interaction with technology as well as other organizational issues is key to the success of future telemonitoring systems.

Our preliminary findings with (1) on average, 75% (SD \pm 21) for BP and 70% (SD \pm 23) for BG adherence alert rates to obtain daily readings and (2) on average, 85% (SD \pm 15) for BP and 80% (SD \pm 21) for BG clinical alerts being classified during follow up calls by trained nurses as not needing immediate clinical intervention suggest the importance of reimbursement policies that allow for both clinical and non-clinical dedicated call centers with trained personnel to

efficiently process the automatic alerts. In addition, more research is needed to build systems that can assist physicians to set the acceptable range to be more personalized using personal historical data, as well as detect in real time changes in patient condition that require changes to these personal ranges. Without such support, clinical users of automated alert systems in health settings may suffer from "alert fatigue" caused by excessive number of real-time warnings for potential problems (Carspecken, Sharek, Longhurst, & Pageler, 2013; Embi & Leonard, 2012; Kesselheim, Cresswell, Phansalkar, Bates, & Sheikh, 2011; Nanji et al., 2014; Roshanov et al., 2013; Saverno et al., 2011). As a result, clinicians may pay less attention to or even ignore other critical clinical duties. Thus, the key to designing cost-effective human-computer systems that have lasting impact on the health outcomes and costs through telemonitoring will require further research in (1) designing effective human processes, both clinical and non-clinical, to augment the computer systems to troubleshoot equipment and communications problems, coach patients, and assess the real clinical nature of the abnormal readings and (2) designing better personalized alert systems that fine-tune and generate parsimonious warnings to reduce alert fatigue while still capturing all important alerts that need timely intervention, and (3) understanding adoption and implementation barriers and opportunities. Such research will require access to real integrated data from physicians, providers, and telemonitoring companies.

REFERENCES

- 1. Ali, M. K., Shah, S., & Tandon, N. (2011). Review of electronic decision-support tools for diabetes care: A viable option for low- and middle-income countries? *Journal of Diabetes Science and Technology*, *5*(3), 553-570. doi:10.1177/193229681100500310
- 2. Alvarado, M. M., Kum, H. C., Coronado, K. G., Foster, M. J., Ortega, P., & Lawley, M. A. (2017). Barriers to remote health interventions for type 2 diabetes: a systematic review and proposed classification scheme. *Journal of medical Internet research*, 19(2). doi: 10.2196/jmir.6382.
- 3. American Diabetes Association, .. (2018, March 22). *Statistics About Diabetes*. Retrieved from American Diabetes Association: http://www.diabetes.org/diabetesbasics/statistics/?loc=db-slabnav
- 4. Angeles, R. N., Howard, M. I., & Dolovich, L. (2011). The effectiveness of web-based tools for improving blood glucose control in patients with diabetes mellitus: A meta-analysis. *Canadian Journal of Diabetes; Canadian Journal of Diabetes, 35*(4), 344-352. doi://doi.org/10.1016/S1499-2671(11)54011-0
- 5. Baron, J., McBain, H., & Newman, S. (2012). The impact of mobile monitoring technologies on glycosylated hemoglobin in diabetes: A systematic review. *Journal of Diabetes Science and Technology*, 6(5), 1185-1196. doi:10.1177/193229681200600524
- 6. Benjamin, E. J., Blaha, M. J., Chiuve, S. E., Cushman, M., Das, S. R., Deo, R., . . . American Heart Association Statistics Committee and Stroke, Statistics Subcommittee. (2017). Heart disease and stroke statistics-2017 update: A report from the american heart association. *Circulation*, *135*(10), e603. doi:10.1161/CIR.00000000000485

- 7. Bowles, K. H., Dykes, P., & Demiris, G. (2015). The use of health information technology to improve care and outcomes for older adults. *Research in Gerontological Nursing*, *8*(1), 5-10. doi:10.3928/19404921-20121222-01
- 8. Brooks, E., Turvey, C., & Augusterfer, E. F. (2013). Provider barriers to telemental health: Obstacles overcome, obstacles remaining. *Telemedicine Journal and E-Health: The Official Journal of the American Telemedicine Association, 19*(6), 433-437. doi:10.1089/tmj.2013.0068
- 9. Carayon, P., Schoofs Hundt, A., Karsh, B., Gurses, A. P., Alvarado, C. J., Smith, M., & Flatley Brennan, P. (2006). Work system design for patient safety: The SEIPS model. *Qual Saf Health Care, 15*, i50. doi:10.1136/qshc.2005.015842
- 10. Carspecken, C. W., Sharek, P. J., Longhurst, C., & Pageler, N. M. (2013). A clinical case of electronic health record drug alert fatigue: Consequences for patient outcome. *Pediatrics*, *131*(6), e1970. doi:10.1542/peds.2012-3252
- 11. Centers for Disease Control and Prevention, .. (2018, March 14). *Diabetes Home*. Retrieved from Centers for Disease Control and Prevention: cdc.gov/diabetes/data
- 12. Dalton, J. E. (2008, Web-based care for adults with type 2 diabetes. *Canadian Journal of Dietetic Practice and Research,* , 185. Retrieved from <u>http://ezproxy.library.tamu.edu/login?url=http://search.ebscohost.com/login.aspx?direct=true&db=edsbl&AN=RN241023896&site=eds-live</u>
- 13. Economic Research Service, United States Department of Agriculture (USDA). (n.d) Rural-Urban Continuum Codes Documentation. Retrieved on: January 3, 2019 from <u>https://www.ers.usda.gov/data-products/rural-urban-continuum-codes/documentation/</u>
- 14. El-Gayar, O., Timsina, P., Nawar, N., & Eid, W. (2013). A systematic review of IT for diabetes self-management: Are we there yet? *International Journal of Medical Informatics*, *82*(8), 637-652. doi://doi.org/10.1016/j.ijmedinf.2013.05.006
- 15. Embi, P. J., & Leonard, A. C. (2012). Evaluating alert fatigue over time to EHR-based clinical trial alerts: Findings from a randomized controlled study. *Journal of the American Medical Informatics Association, 19*, e148. Retrieved from http://dx.doi.org/10.1136/amiajnl-2011-000743
- 16. Farmer, A., Gibson, O. J., Tarassenko, L., & Neil, A. (2005). A systematic review of telemedicine interventions to support blood glucose self-monitoring in diabetes. *Diabetic Medicine*, *22*(10), 1372-1378. doi:10.1111/j.1464-5491.2005.01627.x
- Greenwood, D. A., Young, H. M., & Quinn, C. C. (2014). Telehealth remote monitoring systematic review: Structured self-monitoring of blood glucose and impact on A1C. *Journal of Diabetes Science and Technology, 8*(2), 378-389. doi:10.1177/1932296813519311
- 18. Hammett, J., Sasangohar, F., & Lawley, M. (2018). Home Telemonitoring Platforms for Adults with Diabetes Mellitus: A Narrative Review of Literature. *Proceedings of the Human Factors and Ergonomics Society Annual Meeting*, 62(1), 508–512. https://doi.org/10.1177/1541931218621116
- 19. Health and Human Services Commission. (2016, December). *Telemedicine, Telehealth, and Home Telemonitoring Services in Texas Medicaid*. Retrieved from

https://hhs.texas.gov/sites/default/files/documents/laws-regulations/reportspresentations/2016/telemedicine-telehealth-home-telemonitoring-services-tx-medicaiddec2016.pdf

- 20. Health and Human Services Commission. (2018, December). *Telemedicine, Telehealth, and Home Telemonitoring Services in Texas Medicaid*. Retrieved from https://hhs.texas.gov/sites/default/files/documents/laws-regulations/reports-presentations/2018/sb-789-telemedicine-telehealth-hts-medicaid-dec-2018.pdf
- 21. Health Resources and Services Administration. (2019, January). *Telehealth Programs*. Retrieved from https://www.hrsa.gov/rural-health/telehealth/index.html
- Jaana, M., & Pare, G. (2007, Home telemonitoring of patients with diabetes: A systematic assessment of observed effects. *Journal of Evaluation in Clinical Practice*, , 242. Retrieved from http://ezproxy.library.tamu.edu/login?url=http://search.ebscohost.com/login.aspx?di rect=true&db=edsbl&AN=RN205086570&site=eds-live
- 23. Jarvis-Selinger, S., Chan, E., Payne, R., Plohman, K., & Ho, K. (2008). Clinical telehealth across the disciplines: Lessons learned. *Telemedicine and E-Health, 14*(7), 720-725. doi:10.1089/tmj.2007.0108
- 24. Kesselheim, A. S., Cresswell, K., Phansalkar, S., Bates, D. W., & Sheikh, A. (2011). Clinical decision support systems could be modified to reduce 'Alert fatigue' while still minimizing the risk of litigation. *Health Affairs, 30*(12), 2310-2317. doi:10.1377/hlthaff.2010.1111
- 25. Koopman, R. J., Wakefield, B. J., Johanning, J. L., Keplinger, L. E., Kruse, R. L., Bomar, M., . . . Mehr, D. R. (2014). Implementing home blood glucose and blood pressure telemonitoring in primary care practices for patients with diabetes: Lessons learned. *Telemedicine and E-Health, 20*(3), 253-260. doi:10.1089/tmj.2013.0188
- 26. Landaeta, R., Hyon Mun, J., Rabadi, G., & Levin, D. (2008). *Identifying sources of resistance to change in healthcare*doi:10.1504/IJHTM.2008.016849
- 27. Lee, S. W. H., Chan, C. K. Y., Chua, S. S., & Chaiyakunapruk, N. (2017). Comparative effectiveness of telemedicine strategies on type 2 diabetes management: A systematic review and network meta-analysis. *Scientific Reports,* 7(1), 12680. doi:10.1038/s41598-017-12987-z
- 28. Liang, X., Wang, Q., Yang, X., Cao, J., Chen, J., Mo, X., . . . Gu, D. (2011). Effect of mobile phone intervention for diabetes on glycaemic control: A meta-analysis. *Diabetic Medicine*, *28*(4), 455-463. doi:10.1111/j.1464-5491.2010.03180.x
- 29. Marcolino, M. S., Maia, J. X., Alkmim, M. B. M., Boersma, E., & Ribeiro, A. L. (2013). Telemedicine application in the care of diabetes patients: Systematic review and metaanalysis. *Plos One, 8*(11), e79246. doi:10.1371/journal.pone.0079246
- Montori, V. M., Helgemoe, P. K., Guyatt, G. H., Dean, D. S., Leung, T. W., Smith, S. A., & Kudva, Y. C. (2004, Telecare for patients with type 1 diabetes and inadequate glycemic control: A randomized controlled trial and meta-analysis. *Diabetes Care -Alexandria Va-,*, 1088. Retrieved from <u>http://ezproxy.library.tamu.edu/login?url=http://search.ebscohost.com/login.aspx?di</u> <u>rect=true&db=edsbl&AN=RN149201098&site=eds-live</u>

- Nanji, K. C., Slight, S. P., Seger, D. L., Cho, I., Fiskio, J. M., Redden, L. M., . . . Bates, D. W. (2014). Overrides of medication-related clinical decision support alerts in outpatients. *Journal of the American Medical Informatics Association, 21*(3), 487-491. Retrieved from http://dx.doi.org/10.1136/amiajnl-2013-001813
- 32. Polisena, J., Tran, K., Cimon, K., Hutton, B., McGill, S., & Palmer, K. (2009). Home telehealth for diabetes management: A systematic review and meta-analysis. *Diabetes, Obesity and Metabolism, 11*(10), 913-930. doi:10.1111/j.1463-1326.2009.01057.x
- Roshanov, P. S., Fernandes, N., Wilczynski, J. M., Hemens, B. J., You, J. J., Handler, S. M., . . . Haynes, R. B. (2013). Features of effective computerised clinical decision support systems: Meta-regression of 162 randomised trials. *Bmj, 346*, f657. doi:10.1136/bmj.f657
- 34. Sasangohar, F., Davis, E., Kash, B. A., & Shah, S. R. (2018). Remote patient monitoring and telemedicine in neonatal and pediatric settings: Scoping literature review. *J Med Internet Res, 20*(12), e295. doi:10.2196/jmir.9403
- 35. Saverno, K. R., Hines, L. E., Warholak, T. L., Grizzle, A. J., Babits, L., Clark, C., . . . Malone, D. C. (2011). Ability of pharmacy clinical decision-support software to alert users about clinically important drug—drug interactions. *Journal of the American Medical Informatics Association, 18*(1), 32-37. Retrieved from http://dx.doi.org/10.1136/jamia.2010.007609
- Stowell, E., Lyson, M. C., Saksono, H., Wurth, R. '. C., Jimison, H., Pavel, M., & Parker, A. G. (2018). Designing and evaluating mHealth interventions for vulnerable populations: A systematic review. Paper presented at the *Proceedings of the 2018 CHI Conference on Human Factors in Computing Systems,* Montreal QC, Canada. 15:17. doi:10.1145/3173574.3173589 Retrieved from http://doi.acm.org/10.1145/3173574.3173589
- 37. Texas Medicaid & Healthcare Partnership (TMHP), .. (2019, January). *Texas Medicaid Provider Procedure Manual volume 2 Provider Handbooks: Telecommunication Services Handbook.* Retrieved from Texas Medicaid & Healthcare Partnership (THMP): http://www.tmhp.com/Manuals_PDF/TMPPM/TMPPM_Living_Manual_Current/2_Telecommunication_Srvs.pdf
- Verhoeven, F., Tanja-Dijkstra, K., Nijland, N., Eysenbach, G., & Van Gemert-Pijnen, L. (2010). Asynchronous and synchronous teleconsultation for diabetes care: A systematic literature review. *Journal of Diabetes Science and Technology, 4*(3), 666-684. doi:10.1177/193229681000400323
- Zheng, K., Haftel, H. M., Hirschl, R. B., O'Reilly, M., & Hanauer, D. A. (2010). Quantifying the impact of health IT implementations on clinical workflow: A new methodological perspective. *Journal of the American Medical Informatics Association*, *17*(4), 454-461. Retrieved from <u>http://dx.doi.org/10.1136/jamia.2010.004440</u>

APPENDIX

Table 3. Acronym Directory

	Acronym Directory
BG	Blood Glucose
BP	Blood Pressure
CnC	Coordination Centric
ED	Emergency Department
EHR	Electronic Health Records
HHSC	Texas Health and Human Services Commission
FDA	Food and Drug Administration
MSA	Metropolitan Statistical Areas
RUCC	Rural Urban Continuum Codes
SEIPS	The Systems Engineering Initiative for Patient Safety
USDA	United States Department of Agriculture