May 22, 2017

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, District of Columbia 20201

Sent via ONC-PGHD-Policy@hhs.gov

RE:  Comments of the Connected Health Initiative Regarding ‘Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health Data in Care Delivery and Research through 2024: Draft White Paper for a PGHD Policy Framework’

To Whom It May Concern:

We write on behalf of the Connected Health Initiative (CHI)\(^1\) to provide input on the draft white paper for a patient-generated health data (PGHD) policy framework, *Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health Data in Care Delivery and Research through 2024: Draft White Paper for a PGHD Policy Framework* (Draft White Paper). The CHI appreciates the Office of the National Coordinator for Health Information Technology (ONC) providing additional time to allow the CHI to contribute its views on the Draft White Paper.

The CHI represents a broad consensus of stakeholders across the healthcare and technology sectors whose mission is to support the responsible and secure use of connected health innovations throughout the continuum of care to improve patients’ and consumers’ experience and health outcomes. We seek to partner with the Department of Health and Human Services (HHS) in realizing the benefits of an information and communications technology-enabled American healthcare system.

\(^1\) See [http://www.connectedhi.com/](http://www.connectedhi.com/).
Ample evidence exists, and continues to grow, which identifies telehealth and remote monitoring (RM) of PGHD as cornerstones of advanced healthcare systems, particularly with respect to acute and chronic care consultations. The benefits of increased adoption and use of connected health include improved care, reduced hospitalizations, prevention of complications, and improved satisfaction, particularly for the chronically ill. A prominent example of the benefit of RM can be seen in the virtual chronic care management by the Department of Veterans Affairs, which found the use of RM led to a substantial decrease in hospital and emergency room use.² A growing body of clinical evidence documents the cost saving benefits of RM. A recent study predicted that RM will result in savings of $36 billion globally by 2018, with North America accounting for 75 percent of those savings.³ Both patient outcomes and cost savings are important considerations within the PGHD framework. To assist ONC, we have appended to this letter a non-exhaustive list of studies demonstrating the value of telehealth and RM to patients with acute and chronic conditions.

After careful consideration of the Draft White Paper, we offer the following input:

- From a process standpoint, the CHI is concerned with the methods used to complete the Draft White Paper. The CHI understands that Accenture, funded by a grant, sought input from select parties chosen by Accenture, on which the content of the Draft White Paper is based. The CHI believes that input for policy documents developed by the Federal government should be sought publicly through the Federal Register to ensure transparency and accessibility to any interested and/or impacted stakeholder. We welcome the request for public input at this phase in the development of the Draft White Paper, but we maintain that broad input should have initially been sought to outline the Draft White Paper’s direction and content before a detailed draft was shared. Further, public comments should be sought through the Federal Register, and ample time should be provided for input.


Generally, we appreciate the Draft White Paper’s recognition of PGHD and its integral role in improved patient care. We believe the argument supporting PGHD’s value and contribution to improved care and lower healthcare costs in the continuum of care have been adequately made, which is why we question why digital health technology pilots funded through ONC as part of the effort to develop a PGHD framework. Although such efforts on their face may seem commendable, we fear those resources could have been better utilized. Such pilots were unnecessary to validate the argument that additional studies are needed to determine PGHD’s utility. As detailed infra, we have appended to this letter a non-exhaustive list of studies demonstrating the value of telehealth and RM to patients with acute and chronic conditions. What should have been the focus of this effort is to qualify the existing evidence of telehealth and RM. With ongoing skepticism and lingering questions about the utility of PGHD by the Center for Medicare and Medicaid Services (CMS), the Congressional Budget Office (CBO), the Medicare Payment Advisory Commission (MedPAC), and other governmental actors, creating technology pilots for the sake of developing a framework where efficacy and value has been clearly established seems wasteful and counter-productive.

The CHI appreciates the Draft White Paper’s detailed discussion on the benefits of PGHD but also believes that the recommendations within the paper should be more concrete. The Draft White Paper’s recommendations do not present many concrete deliverables, despite the fact that numerous barriers exist today that directly inhibit the incorporation of PGHD into the continuum of care, an issue about which the CHI recently wrote to HHS Secretary Tom Price. Without confronting these well-documented barriers, the utility of the PGHD framework is significantly limited.

The ONC’s development of a PGHD framework has the potential to serve as an important catalyst for greater use of PGHD in the continuum of care. However, the report does not clearly explain the role of the ONC in the development and implementation of such a framework, particularly in light of ONC’s uncertain future as the new administration considers how best ONC should continue its work. This important issue needs strong leadership and clearly defined directives to bring the benefits of telehealth and RM to more patients and consumers.

4 This CHI letter to HHS Secretary Price is accessible at: http://bit.ly/2rM38SD.
We appreciate the efforts of ONC in developing a PGHD framework, and we urge the careful consideration of the views expressed herein. We encourage you to contact the undersigned with any questions or ways in which the CHI can be of assistance in this endeavor.

Sincerely,

Brian Scarpelli  
Senior Policy Counsel  
Connected Health Initiative  
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Attached: CHI evidence base of telehealth and remote monitoring studies
Key Clinical Studies Demonstrating the Benefits of Connected Health Technologies

CHRONIC CONDITION MANAGEMENT

Audit of the Veterans Health Administration Home Telehealth Program: Over 15,000 patients
On March 09, 2015 the VA Office of Inspector General released an Audit which showed that the Home Telehealth Program increase patient access and reduced costs by reducing the number of admissions. For example, before the program there were 2,365 admissions over six months by the over 15,000 patients who participated in the Home Telehealth Program. After the program there were 1,773 admissions for the following six months. This equates to about 8 fewer hospital admissions for every 100 patients in this program.


Telehealth and the VA - FY2013 Report
In FY2013, 608,900 (11%) of veterans received some element of their health care via telehealth. This amounted to 1,793,496 telehealth episodes of care. 45% of these patients lived in rural areas.

Home Telehealth Services: Helps patients with chronic conditions
• Provided care for 144,520 veterans
• 59% reduction in bed days of care
• 35% reduction in hospital readmissions
• Saves $1,999 per annum per patient
• 84% patient satisfaction

Store-and-Forward Telehealth: Remote scanning, then send to specialist
• Served 311,396 veterans
• 95% patient satisfaction
• Saves $38.41 per consultation
Clinical Video Telehealth: Real-time video consultation that covers over 44 specialties

- 94% patient satisfaction
- Saves $34.45 per consultation

TeleMental Health

- Over 278,000 encounters to 91,000 patients
- 1.1 million patient encounters since FY2003
- Reduced bed days of care by 38%
- Nearly 7,500 patients with chronic mental health conditions are now living independently thanks to TeleMental Health

The number of veterans receiving care through telehealth is climbing by 22% each year.


Veterans Administration: Study Size: Over 17,000 patients

"Routine analysis of data obtained for quality and performance purposes from a cohort of 17,025 CCHT patients shows the benefits of a 25% reduction in numbers of bed days of care, 19% reduction in numbers of hospital admissions, and mean satisfaction score rating of 86% after enrolment into the program. The cost of CCHT is $1,600 per patient per annum, substantially less than other NIC programs and nursing home care. VHA's experience is that an enterprise-wide home telehealth implementation is an appropriate and cost-effective way of managing chronic care patients in both urban and rural settings.”

“Care Coordination/Home Telehealth: the systematic implementation of health informatics, home telehealth, and disease management to support the care of veteran patients with chronic condition”


Primary Care E-Visit v. Physician Office Visit: Study Size 8,000 Office and E-Visits

From The Washington Post, 1/21/2013: “A new study suggests that “e-visits” to health-care providers for sinus infections and urinary tract infections (UTIs) may be cheaper than in-person office visits and similarly effective.”
Randomized Control Trial of Telehealth and Telecare: Study Size 6,191 patients, 238 GP practices

“The early indications show that if used correctly telehealth can deliver a 15% reduction in A&E visits, a 20% reduction in emergency admissions, a 14% reduction in elective admissions, a 14% reduction in bed days and an 8% reduction in tariff costs. More strikingly they also demonstrate a 45% reduction in mortality rates.”

“Whole System Demonstrator Programme, Headline Findings – December 2011”, Department of Health, United Kingdom

Reduced Hospitalizations of Nursing Facility Residents

A study that introduced telemedicine in a Massachusetts for-profit nursing home chain, during the period October 2009 – September 2011, demonstrates the cost-effectiveness of utilizing telemedicine to reduce potential re-hospitalizations for nursing facility patients. The study’s findings show that savings to Medicare from using telemedicine to reduce re-hospitalizations for nursing facility patients exceed the investment in the telemedicine equipment.

- The findings of the study suggest that the nursing facilities that were more engaged in off-hours telemedicine coverage could generate cost savings for Medicare that exceeded the facility’s investment in the telemedicine service.
- The average savings to Medicare for a nursing facility that participated and was engaged with telemedicine, was $151,000 per nursing facility per year, relative to the less-engaged facilities.
- During the two-year period, the rate of hospitalizations per 1,000 resident days declined across the pre- and post-intervention periods for both the treatment and the control groups.
- The difference in the hospitalizations in the treatment group was 4.4 percentage points lower.

**Integrated Telehealth And Care Management Program For Medicare Beneficiaries With Chronic Disease Linked To Savings**

A study from the Health Affairs found significant savings among patients who used the Health Buddy telehealth program, which integrates a telehealth tool with care management for chronically ill Medicare beneficiaries. Specifically, patients who utilized the Health Buddy Program saw spending reductions of approximately 7.7–13.3 percent ($312–$542) per person per quarter.

September 2011: [http://content.healthaffairs.org/content/30/9/1689.abstract](http://content.healthaffairs.org/content/30/9/1689.abstract)

**Rural Hospitals and Communities Save Money Through Telemedicine Program**

A report from NTCA-The Rural Broadband Association explores how much money a rural hospital and community can save by using a telemedicine program. The report analyzes savings in travel costs, lost wages, hospital workers' wages, and lab and pharmacy revenues that can stay local by allowing patients to stay in their own communities rather than travel to larger metropolitan areas for care.

The report finds that on average a rural community can save $31,000 in travel costs and lost wages, per hospital per year. Rural hospitals can on average save more than $81,000 a year in doctors' wages, while generating revenue through local MRIs, and other lab and pharmacy work.


**Telemedicine Saves Patients Time and Money**

Scholars at the University of California Davis studied results and data of 18 years of inpatient and outpatient visits, ending in 2013. The scholars found that the 19,246 interactive video visits over 18 years saved patients approximately nine years of travel time, 5 million miles, and $3 million in related costs. Each patient using telemedicine for treatment saved on average four hours driving time, 278 miles and $156 in travel costs over the period studied.

Impact of a University-Based Outpatient Telemedicine Program on Time Savings, Travel Costs, and Environmental Pollutants
Dullet, Navjit W. et al.
Value in Health , Volume 0 , Issue 0 ,
Remote Patient Monitoring of Heart Failure Patients, Meta analysis: Study Size 4,264 patients
"Remote monitoring programmes reduced rates of admission to hospital for chronic heart failure by 21% (95% confidence interval 11% to 31%) and all-cause mortality by 20% (8% to 31%); of the six trials evaluating health related quality of life three reported significant benefits with remote monitoring.”

Telemonitoring or structured telephone support programmes for patients with chronic heart failure: systematic review and meta-analysis, Robyn Clark, Sally Inglis, Finlay McAlister, John Cleland, Simon Stewart, MJ (British Medical Journal), doi:10.1136/bmj.39156.536968.55 (published 10 April 2007)]
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1865411/

Remote Patient Monitoring of Heart Failure Patients: Meta analysis: Study Size 6,258/ 2,354 Patients
"RPM covers a significant protective clinical effect in patients with chronic HF compared with usual care."

http://content.onlinejacc.org/article.aspx?articleid=1140154

Telehome Monitoring Program: 1,000 Patients Enrolled
"Research at the Heart Institute has shown telehome monitoring at the Heart Institute has cut hospital readmission for heart failure by 54 percent with savings up to $20,000 for each patient safely diverted from an emergency department visit, readmission and hospital stay.”

University of Ottawa Heart Institute, February 24, 2011, Press Release.
http://www.heartandlung.org/article/S0147-9563(07)00084-2/fulltext
Remote Patient Monitoring at St. Vincent’s Hospital

"Impact: In less than two years, preliminary results show that the care management program implemented by St. Vincent Health and facilitated by the Guide platform reduced hospital readmissions to 5 percent for patients participating in the program – a 75 percent reduction compared to the control group (20 percent), and to the national average (20 percent)."


Program Evaluation of Remote Heart Failure Monitoring: Healthcare Utilization Analysis in a Rural Regional Medical Center

"HF patients enrolled in this program showed substantial and statistically significant reductions in healthcare utilization during the 6 months following enrollment, and these reductions were significantly greater compared with those who declined to participate but not when compared with a matched cohort…The findings from this project indicate that a remote HF monitoring program can be successfully implemented in a rural, underserved area. Reductions in healthcare utilization were observed among program participants, but reductions were also observed among a matched cohort, illustrating the need for rigorous assessment of the effects of HF remote monitoring programs in healthcare systems."


Program Evaluation of Remote Heart Failure Monitoring: Healthcare Utilization Analysis in a Rural Regional Medical Center

Background: Remote monitoring for heart failure (HF) has had mixed and heterogeneous effects across studies, necessitating further evaluation of remote monitoring systems within specific healthcare systems and their patient populations. “Care Beyond Walls and Wires,” a wireless remote monitoring program to facilitate patient and care team co-management of HF patients, served by a rural regional medical center, provided the opportunity to evaluate the effects of this program on healthcare utilization.

Materials and Methods: Fifty HF patients admitted to Flagstaff Medical Center (Flagstaff, AZ) participated in the project. Many of these patients lived in underserved and rural communities, including Native American reservations. Enrolled patients received mobile, broadband-enabled remote monitoring devices. A matched cohort was identified for comparison.
Results: HF patients enrolled in this program showed substantial and statistically significant reductions in healthcare utilization during the 6 months following enrollment, and these reductions were significantly greater compared with those who declined to participate but not when compared with a matched cohort. Conclusions: The findings from this project indicate that a remote HF monitoring program can be successfully implemented in a rural, underserved area. Reductions in healthcare utilization were observed among program participants, but reductions were also observed among a matched cohort, illustrating the need for rigorous assessment of the effects of HF remote monitoring programs in healthcare systems.


DIABETES MANAGEMENT

Early Results Support Efficacy and Clinical efficiency of Diabetes Management Decision support software for Blood Glucose Control: Two cohorts of 43 comparative cases

Preliminary results from an ongoing study by Rimidi indicate that the decision support software, Diabetes+Me, helps to ensure a safe but meaningful reduction in A1c and therefore reduction in event rate as well as overall healthcare costs. Diabetes+Me has not only lead to improved benefits to patients, but has also allowed Desert Oasis healthcare, the facility who is conducting the study, to expand the scalability of its already successful diabetes management program without having to make the expensive investment of hiring additional healthcare providers.

Mobile Phone Personalized Behavior Coaching for Diabetes: Study Size 163 patients over 26 Practices

“Conclusions – The combination of behavioral mobile coaching with blood glucose data, lifestyle behaviors, and patient self-management individually analyzed and presented with evidence-based guidelines to providers substantially reduced glycated hemoglobin level over 1 year.”

Cluster-Randomized Trial of a Mobile Phone Personalized Behavioral Intervention for Blood Glucose Control, Charlene Quinn, Michelle Shardell, Michael Terrin, Eric Barr, Soshana Ballew, Ann Gruber-Baldini, Diabetes Care. Published Online July 25, 2011: http://care.diabetesjournals.org/content/34/9/1934.long

Mobile Phone Diabetes Management: Study Size 30 patients from 3 group practices

“Conclusions: Adults with type 2 diabetes using WellDoc’s software achieved statistically significant improvements in A1c. HCP and patient satisfaction with the system was clinically and statistically significant.”

Testing Diabetic Retinopathy with Telemedicine Found Successful
A study in *JAMA Internal Medicine* finds that telemedicine is an effective method to test for diabetic retinopathy (DR) in Los Angeles. The practice of teleretinal DR screening was applied in the Los Angeles County Department of Health Services, the largest publicly operated county safety net in the United States. The use of telemedicine for DR screening kept patients from needing approximately 14,000 specialist visits, wait times decreased by 89.2 percent and DR screening annual rates increased by more than 16 percent.

http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2612116

RESPIRATORY AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE MANAGEMENT

Content-Driven Telehealth System Coupled with Care Management: Study Size Medicare patients enrolled in CMS’ Health Buddy Program demonstration from 2006-2010
The Health Buddy Program is a content-driven telehealth system combined with care management designed to enhance patient education, self-management, and timely access to care. “The Health Buddy Program was associated with 23% lower quarterly all-cause hospital admissions and 40% lower quarterly respiratory-related hospital admissions compared to baseline for intervention beneficiaries vs. controls. In subgroup analyses, patients who engaged in the intervention during the study period (n=247) demonstrated significantly lower quarterly hospital admissions for chronic obstructive pulmonary disease exacerbations.

CONCLUSIONS: A content-driven telehealth system combined with care management has the potential to improve health outcomes in Medicare beneficiaries with chronic obstructive pulmonary disease.”


Home Telehealth for Patients with Severe COPD: 60 patients
Telehealth is an important part of the need for innovative models of care for patients with severe COPD and frequent acute exacerbations. In a cluster assignment, controlled trial study design, 60 patients were recruited: 30 in home telehealth (TH) and 30 in conventional care (CC). Results: “After 7-months of monitoring and follow-up, there was significant reduction in ER visits (20 in HT vs 57 in CC), hospitalizations (12
vs 33), length of hospital stay in (105 vs 276 days), and even need for non-invasive mechanical ventilation (0 vs 8, all p < 0.05)


**Tele-assistance (TA) in chronic respiratory failure patients: 240 patients (101 with COPD)**

Chronic respiratory patients requiring oxygen or home mechanical ventilation experience frequent exacerbations and hospitalizations with related costs. Patients were randomized into two groups: an intervention group (1-year TA) and control group (conventional care). “Compared with controls, the TA group experienced significantly fewer hospitalizations (-36%), fewer GP calls (-65%) and acute exacerbations (-71%). After deduction of TA costs, the average overall cost for each patient was 33% less than for usual care.”


**Home telemonitoring program: 369 patients with at least one COPD exacerbation per year prior to enrollment**

The study was designed to evaluate the effects of home telemonitoring on healthcare utilization in patients with COPD. “Of these, 71.5% had a reduction in number of ED visits and exacerbations requiring hospitalization after enrollment in the program. The average number of hospital admissions, ED visits, and total exacerbations were all reduced (0.41 ± 1.68, 0.15 ± 1.65, and 0.56 ± 2.3, respectively; all with p < 0.01).”


**Telehealth Program for CPAP Adherence: 122 patients**

This study evaluated the effectiveness of coaching labor requirements of a web-based automated telehealth (TH) messaging program compared with standard of care (SOC) in newly diagnosed patients with obstructive sleep apnea. “There was a significant reduction in the number of minutes coaching [by respiratory therapists] required per patient in the TH vs SOC group (23.9 ± 26 vs. 58.3 ± 25, 59% reduction; p < 0.0001).”

More than 2 million patients on continuous positive airway pressure (CPAP) for obstructive sleep apnea (OSA) are being monitored at home using AirView. Key parameters of treatment effectiveness can be determined remotely at the patient level to adjust therapy or troubleshoot and correct device problems, or at the population level to
efficiently measure adherence levels and track frequency of complications like mask leak. Adherence to therapy can be significantly improved through the use of remote patient monitoring and patient engagement technologies.1,2,3


**Telemedicine Versus Face-to-Face Evaluations by Respiratory Therapists**

The study aimed to determine how well respiratory assessments for ventilated neonates and children correlated when performed simultaneously by 2 RTs face-to-face and via telemedicine.

“Telemedicine evaluations highly correlated with face-to-face for 10 of 14 aspects of standard bedside respiratory assessment.”


**MEDICATION ADHERENCE FOR CHRONIC CONDITIONS**

**Case Study: Mobilizing Your Medications: An Automated Medication Reminder Application for Mobile Phones and Hypertension Medication Adherence in a High-Risk Urban Population**

**Background:** Hypertension frequently accompanies diabetes mellitus, worsening prognosis and complicating medical care for patients. Low medication adherence with multiple medications is a major factor in the inadequate achievement of blood pressure treatment goals. Widespread access to mobile phones offers a new opportunity to communicate with patients and enhance disease self-management.

**Methods:** We recruited 50 high-risk urban patients with hypertension, who are using at least two prescription medications for hypertension, into an open-label trial using medication reminder software on a mobile phone. Medication adherence was assessed by review of pharmacy refill rates before, during, and after availability of the medication reminder software (pre-activation, activation, and post-activation phase, respectively).
Results: Forty-eight patients completed the study. All subjects were insured by Medicaid, 96% were African-American, and the majority had diabetes mellitus. The proportion of days covered for each study phase was as follows: pre-activation phase = 0.54, activation phase = 0.58, and post-activation phase = 0.46. A significant difference was found between the activation and post-activation phases (p = .001). The increase in measured adherence between the pre-activation and activation phases approached significance (p = .057). Forty-six patients completed the pre- and post-Morisky medication adherence survey. The median score rose from 2.0 at baseline to 3.0 at study completion (p < .001). Average blood pressure and level of control during study period improved significantly after initiation of the study and remained improved from baseline through the course of the study. The 48 subjects who completed the study reported a high level of satisfaction with the medication reminder application at the final study visit.

Conclusions: A mobile-phone-based automated medication reminder system shows promise in improving medication adherence and blood pressure in high-cardiovascular-risk individuals.


**BLOOD PRESSURE MANAGEMENT**

**Using simple telehealth in primary care to reduce blood pressure: a service evaluation** (n=364) with 124 intervention patients. “Conclusions: Simple telehealth is acceptable and effective in reducing patients’ BP. In future, poorly controlled patients could be targeted to maximize BP reductions or broader use could improve diagnostic accuracy and accessibility for patients who struggle to regularly attend their GP surgery.”

http://bmjopen.bmj.com/content/2/6/e001391