



## Tele-transitions of care. A 12-month, parallel-group, superiority randomized controlled trial protocol, evaluating the use of telehealth versus standard transitions of care in the prevention of avoidable hospital readmissions

Kimberly Noel\*, Samuel Yagudayev, Catherine Messina, Elinor Schoenfeld, Wei Hou, Gerald Kelly

Stony Brook Medicine, Department of Family, Population and Preventive Medicine, Stony Brook, NY, 11794, USA

### ARTICLE INFO

#### Keywords:

Telehealth  
Telemedicine  
Readmissions  
Telecare  
Remote patient monitoring

### ABSTRACT

**Introduction:** Comprehensive transitions of care, reduce dangerous hospital readmissions. Telehealth offers promise, however few guidelines aid clinicians in introducing it in a feasible way while addressing the needs of a multi-comorbid population. Physician adoptability remains a significant barrier to the use of Telehealth due to data overload, concerns for disruptive workflows and uncertain practices. The methods proposed aid clinicians in implementing Telehealth training and research with limited resources to reach patients who need clinical surveillance most. This study introduces a new workflow for addressing tele-transitions of care, using risk stratification, remote patient monitoring, and patient-centered virtual visits. We propose a new communication tool which facilitates adoption. We take a clinically meaningful approach in assessing avoidable hospital readmissions, which can lead to further quality improvements and improved patient care.

**Methods:** This study design is a parallel-group, superiority, randomized controlled trial in which 180 patients are enrolled in the standard of care or Telehealth arms and evaluated for 30-days post hospitalization. The Telehealth group receives daily vitals surveillance with a "teledoc", a senior resident physician, who performs weekly virtual visits. The endpoint is 30-day hospital readmission. Patient data is collected on hospital utilization, patient self-management, physician and patient experience.

**Discussion:** Our protocol introduces a novel study design with existing clinical trainees, to provide comprehensive tele-transitions of care to reduce avoidable readmissions.

### 1. Introduction

Telehealth offers great promise in addressing the triple aim objectives [1], while helping reduce avoidable readmissions. In the advent of new data sources and technologies, clinical practice must evolve to ensure high patient satisfaction and quality care. The first 30 days after hospital discharge offers an important opportunity for telehealth intervention allowing for daily surveillance of vitals, weekly virtual visits and review of all available electronic data [2]. This practice of Telemedicine may potentially reduce dangerous adverse events through improved patient–provider communication, medicine reconciliation, patient education, and assurance of patient hemodynamic stability. Many Telehealth studies thus far, have had inconsistent findings in regards telemedicine's impact on readmissions [3–8]. The lack of evidence is likely due to the paucity of studies, the lack of standardization in telehealth interventions, as well as a focus on evaluation of telehealth

to reduce all cause readmissions for a subgroup of patients with a specific admission diagnosis [9]. We propose, that Telehealth, as primarily a tool of surveillance and communication, should be evaluated for patients with multiple co-morbidities, with a primary outcome of avoidable readmissions. Avoidable readmission is defined as a hospital readmission due to violation of evidenced based Transitions of Care notably 1) medication error 2) lack of clinical follow up 3) lack of appropriate response to clinical “red flags” and 4) lack of appropriate patient-centered documentation or the HIE. It is clear from published studies that preventable readmissions are due to failure of overall clinical management, not simply admission diagnosis management [10] and that Telehealth, has the most beneficial impact on mixed chronic conditions, using multi-function interventions [7,9].

The aim of this paper is to share our research and clinical processes, to help overcome the barrier to the adoption of telemedicine practice and research [11–13]. We introduce a feasible, replicable approach

\* Corresponding author.

E-mail address: [kimberly.noel@stonybrookmedicine.edu](mailto:kimberly.noel@stonybrookmedicine.edu) (K. Noel).

<https://doi.org/10.1016/j.conctc.2018.08.006>

Received 11 June 2018; Received in revised form 26 July 2018; Accepted 14 August 2018

Available online 17 August 2018

2451-8654/ Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

**Table 1**  
World health organization trial registration data set.

Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov NCT03528850
Date of registration in primary registry	18 May 2018
Secondary identifying numbers	IRB 970227
Source of monetary or material support	Stony Brook Medicine Information Technology
Primary sponsor	Stony Brook Medicine Information Technology
Secondary sponsor(s)	None
Contact for public queries	Kimberly Noel, MD, MPH Phone: [631 638 7949] Email: [Kimberly.Noel@StonyBrookmedicine.edu]
Contact for scientific queries	Kimberly Noel, MD, MPH Stony Brook Medicine, Stony Brook, New York, United States
Public title	Stony Brook Telehealth Trial
Scientific title	Stony Brook Telehealth Study. Tele-transitions of Care. An Approach to Reduce 30-day Readmission Using Tele-Health Technology; A Randomized Controlled Trial
Countries of recruitment	United States
Health condition(s) or problem(s) studied	Multi-comorbid disease in the Post-hospitalization period
Intervention(s)	Telehealth: 30 days Biometric Surveillance of blood pressure, heart rate, oxygen saturation and weight. Weekly virtual visits with a telehealth physician and weekly surveys during the 30 day period.
Key inclusion and exclusion criteria	Inclusion criteria: adult patients ( $\geq 30$ years), patients hospitalized and discharged to the care of the Family Medicine clinical practices from Stony Brook University Hospital, patients able to provide consent for their own care, English speakers (able to comprehend and speak English), patients with good cognitive function (as evidence by ability to answer a mild cognitive screen (age, telephone, current date, name of facility), patients living within reasonable commute to the Family Medical Group clinics, patients with a life expectancy greater than 6 months, patients with a clinical disposition to home after hospital discharge, patients that are able to turn on the telehealth technology and follow prompts. Patients with two or more diseases Exclusion criteria: Uninsured patients, Patients whose physical limitations prohibit the use of the telehealth equipment, Patients involved in another research study, Pregnant patients (patients actively trying to conceive), Admission for a psychiatric primary diagnosis
Study type	Interventional Allocation: randomized Intervention model: parallel assignment Masking: None Primary purpose: prevention
Date of first enrollment	June 1, 2017
Target sample size	180
Recruitment status	Recruiting
Primary outcome(s)	Readmissions (HIE and Electronic Medical Record Data)
Key secondary outcomes	Emergency Department Utilization (Electronic Medical Record data), Patient Satisfaction (Survey data), Medication Adherence (Patient Self Report), Biometric Reading Adherence (Vendor Portal Data), Adverse Health Events (Physician Survey), Physician Satisfaction (Physician Survey)
Ethics Review	IRB Approved Trial, 970227 Date of Approval Date: 02/06/2017
Completion Date	June 1, 2018

using clinical trainees and direct involvement of the patient's primary care provider (PCP). This protocol follows the SPIRIT guidelines to establish a transparent, thorough and guideline based study methodology [14]. The results of this trial will be disseminated by publication in peer reviewed medical journals, conference presentations, national meetings and with faculty, staff and the patients studied.

## 2. Objective

Our objective is to provide reliable evidence as to whether Telehealth interventions using remote patient monitoring, weekly virtual visits and access to the HIE, will reduce avoidable readmissions in comparison to standard of care.

## 3. Overview

This trial was a 12-month, parallel-group, superiority randomized controlled trial to evaluate the effect of Telehealth on avoidable readmissions. 180 multi-comorbid patients who fulfilled the eligibility criteria, were randomized to receive either Telehealth or Standard of Care (Table 1). The standard of care upon hospital discharge, was the provision of a discharge summary and patient instructions encouraging follow up with the PCP within 7–14 days and scheduled specialist appointments as indicated. A clinical summary with detailed instructions were provided by the discharge nurse. The Telehealth intervention involved the provision of a smart phone device and Bluetooth-enabled blood pressure monitoring cuff, weighing scale, and pulse oximeter (Fig. 1). Telehealth patients measured their vitals daily using the tele-

equipment and had weekly virtual visits with a transition of care physician (teledoc). Upon consent, patients participated in the trial for the length of thirty (30) days following hospital discharge. The teledoc in this trial, was a senior resident physician of the family, population and preventive medical division. The virtual visits and remote monitoring was performed by the resident who, in turn, reported the patient status to the PCP. The role of the teledoc can be fulfilled by a trained resident, fellow, nurse-practitioner or a primary care physician.

The intervention began two days after hospital discharge, when the patient received the delivered “tele-kit” and began daily vitals. The teledoc then began once daily surveillance of vitals, conducted weekly virtual visits, and wrote detailed Electronic Medical Record (EMR) documentation with the use of validated risk stratification measures [15,16] as well as data from the HIE.

We hypothesized that in comparison to the “standard care” that:

1. Preventable hospital readmissions will be reduced through patient centered virtual visits, daily biometric surveillance, and increased data access.
2. Patient satisfaction during the transition of care period will be improved
3. Adverse healthcare outcomes will be reduced

The primary outcome of the study was to determine the effect of telehealth on avoidable hospital readmissions within 30 days of the index hospitalization discharge as defined by clinical review of two independent physicians according to the definition aforementioned, as well as calculation of overall unplanned hospital readmission. In

# Telemedicine Device Specs

Telemedicine Tablet Monitor	Manufacturer	Model	Certification
	LG	G-Pad 7 in.	FCC Cleared - VZW
	LG	VK 815 8 in.	FCC Cleared - VZQ
Blood Pressure Monitor	Manufacturer	Model	Certification
	A&D Medical	UA-767PBT	FDA Class II
	Fora Care	P20	FDA Class II
Pulse Oximeter	Manufacturer	Model	Certification
	NONIN Medical	ONYX II 9560 BT Smart 3230	FDA Class II
Weight Scale	Manufacturer	Model	Certification
	A&D Medical	UC-321PBT	FDA Class I, FCC
	Fora Care	ForaW310	FDA Class II

Fig. 1. Telemedicine devices.

addition, we have collected data in order to provide secondary analyses on the effect of telehealth on emergency department utilization, patient satisfaction, qualitative patient and physician experience, patient self-management and self-efficacy attitudes (Table 1).

#### 4. Setting

This study was performed at Stony Brook Medicine, which is a 603-bed teaching institution on the northern part of Long Island, New York. The hospital mostly services the population of Suffolk County with an annual admission of 31,715 patients. Less than one percent of all admissions are uninsured. The family medicine department is serviced by two clinics with 16 Family medicine primary care providers. The practice serves 32,000 patients annually, and currently does not serve uninsured patients (whom are referred to our affiliated FQHCs and our free student run clinic not officially part of the Family Medicine practice).

#### 5. Inclusion/Exclusion criteria

Inclusion criteria: adult patients ( $\geq 30$  years), patients hospitalized and discharged to the care of the Family Medicine clinical practices from Stony Brook University Hospital, patients able to provide consent for their own care, English speakers (able to comprehend and speak English), patients with good cognitive function (as evidence by ability to answer a mild cognitive screen (age, telephone, current date, name of facility), patients living within reasonable commute to the Family

Medical Group clinics, patients with a life expectancy greater than 6 months, patients with a clinical disposition to home after hospital discharge, patients that are able to turn on the telehealth technology and follow prompts. Patients with two or more diseases.

Exclusion criteria: Uninsured patients, Patients whose physical limitations prohibit the use of the telehealth equipment, Patients involved in another research study, Pregnant patients (patients actively trying to conceive), Admission for a psychiatric primary diagnosis.

#### 6. Data collection

Study data was collected and managed using REDCap [17] electronic data capture tools hosted at Stony Brook Medicine. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. REDCap software allowed the team to seamlessly incorporate a randomization schema in the process of enrollment. After meeting the inclusion criteria, the software followed a schema unknown to the researcher to randomly select consented participants into appropriate arms of the trial.

## 7. Data analysis

All analyses will be performed with a per protocol population, which is having conducted 30-day survey. We will use chi-squared test for binary outcomes, and T-test/Wilcoxon rank sum test for continuous outcomes. Multivariable analyses will be based on logistic regression for binary outcomes and linear regression for continuous outcomes. We will examine the residual to assess model assumptions and goodness-of-fit. For timed endpoints such as readmission we will use the Kaplan-Meier survival analysis followed by multivariable Cox proportional hazards model for adjusting for baseline variables. We will calculate Relative Risk (RR) and RR Reductions (RRR) with corresponding 95% confidence intervals to compare dichotomous variables, and difference in medians will be used for additional analysis of continuous variables. P-values will be reported to four decimal places with p-values less than 0.001 reported as  $p < 0.001$ . Up-to-date versions of SAS (Cary, NC) and SPSS (Chicago, IL) will be used to conduct analyses. For all tests, we will use 2-sided p-values. We will use the Bonferroni method to appropriately adjust the overall level of significance for multiple primary outcomes, and secondary outcomes.

## 8. Ethics/Approval to Participate/Data confidentiality and access

Patient data security has been of utmost importance due to potential risks of utilizing audio-visual technology in medical practice. Data collection, transmission and storage have been tested and approved by institution's specialists in Information Technologies and Biomedical Informatics.

Furthermore, the Stony Brook University School of Medicine Institutional Review Board (IRB) reviewed and approved this study (970227) to ensure protection of human subjects in this study. The data is stored and secured in the EMR, and a HIPAA compliant database provided by the telehealth vendor, as well as in REDCap. All smartphones are password protected, allowing only the patients and their caregivers to access the phone. Transmitted data includes only study identifiers, and all documentation is conducted in the EMR. All data security measures are outlined in all recruitment and consent materials.

## 9. Patient enrollment

Patient enrollment and randomization occurred at the bedside (Table 2). All patients were consented for the HIE in addition to the trial, and were risk stratified through an EMR data based validated algorithm. The care management team was notified of all study participants in order to inform the telehealth team of hospital discharge. Upon

**Table 2**  
Schedule of enrollment, interventions, and assessments.

Timepoint**	Study period						
	Enrolment	Allocation	Post-allocation				Close-out
	$-t_1$	0	Week 1	Week 2	Week 3	Week 4	$t_x$
Screening consent:							
Eligibility screen	X						
Informed consent	X						
Baseline Questionnaire	X						
Allocation		X					
Interventions:							
Treatment Biometric Surveillance							
Treatment Weekly Surveys			X	X	X		X
Control							X
Assessments:							
Readmissions			X	X	X	X	X
Emergency Room Utilization			X	X	X	X	X

hospital discharge the patient received the telehealth equipment by a vendor service to their home within 48 h.

## 10. Randomization

Computer-generated random number allocation sequence was used with a block size of 3 to reduce predictability of a random sequence.

## 11. Sample size and size of treatment effect that should be detectable

In order to increase power, given a low recruitment capacity, the study was planned so that sixty (60) patients were randomized to the Telehealth group and one hundred and twenty patients (120) were randomized to the Non-Telehealth group. Sample size was calculated for 80% power and type 1 error of 0.05 based on chi squared test. Readmission risk was approximated for an estimated difference of 20% (as cited by Medicare data on readmissions Jencks et al. NEJM. 2009) to 5% using high quality transition of care and telehealth services.

## 12. Risk stratification

The bedside risk stratification was done by an internally and externally validated *High Risk Readmission Tool* across many different hospital systems. This tool identified patients at High Risk for Readmission via a risk score grouped as high, moderate, and low. Normalizing the readmission risk score converts it into a more universally used scale (0–100 scale) that is easier for clinicians to understand and use. The scores are calculated by using a proprietary algorithm by Cerner<sup>®</sup> that includes about 40 + data points from groups, based on the patient history and admitting physical exam, diagnosis related group codes, patient demographics, procedures, utilization, lab tests, medications, and exploratory variables. The tool was validated by a public academic center, Advocate Health Care [16].

Further risk stratification, will be performed for exploratory analysis after the study period, using a validated machine learning algorithm [15] by our Biomedical Informatics team. This will be a useful comparison to the Cerner<sup>®</sup> tool in predicting future readmission risk after 30 days.

## 13. Biometric surveillance

The patient followed prompts from the smart phone to register vitals daily, using a blood pressure cuff, pulse oximeter and digital scale (Fig. 1). The teledoc determined the parameters of the vitals depending

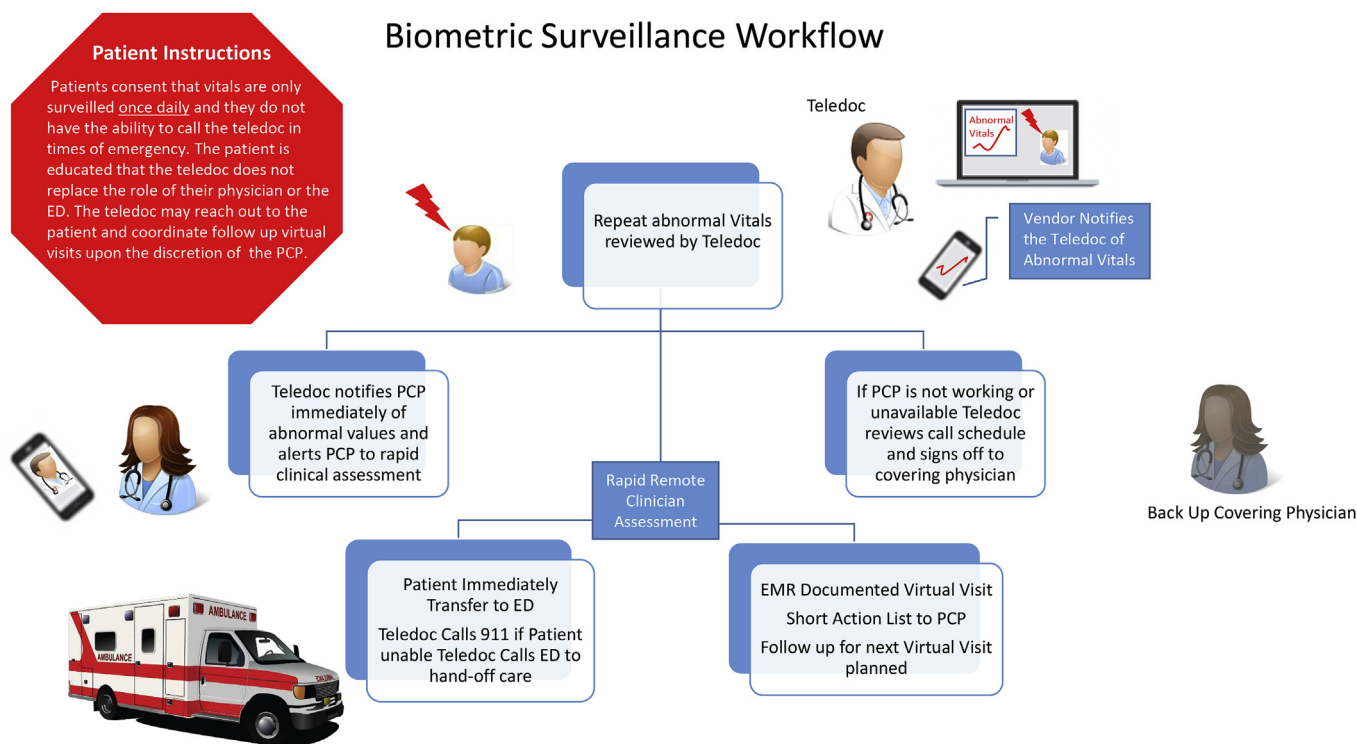


Fig. 2. Biometric surveillance workflow.

on the patient clinical history and status. The telehealth vendor, notified the teledoc of any abnormal values (Fig. 2).

#### 14. Virtual visits

The weekly virtual visit technique is based on the theoretical framework of the Coleman Transition of Care Model [18], and best practices of “Whole-Person” transitional care from the Agency of HealthCare Research and Quality (AHRQ) [19].

The Coleman model focuses on timely follow up with a primary care provider, medication self-management, use of a dynamic patient-centered record, and knowledge and monitoring of red flags that could indicate clinical decompensation of a patient [18]. The “Whole-Person” transition of care focuses on comprehensive assessments of the patient, incorporating potential social determinants of adverse health outcomes and interdisciplinary care coordination. These models are incorporated into the content of the virtual visits that allow for thorough assessments.

Prior to the virtual visit, the primary care physician (PCP) was alerted by email from the study team of the dates of scheduled virtual visits as to be available for hand-off afterwards. The teledoc began evaluation of the patient vitals obtained once daily, reviewed clinical orders, medications, radiology, labs, and previous clinical notes, including the automated readmission risk score from the internal EMR prior to the first encounter. The teledoc verified that no further hospitalizations or emergency room visits were present in the HIE. After the review of the objective EMR and HIE data, the teledoc text notified the PCP prior to an encounter, then began synchronous two-way audio-video conferencing with the patient, which mirrors the interaction of an in-person interaction (Figs. 3 and 4). The teledoc then performed a detailed medicine reconciliation focusing on prevention of medication errors, ensuring adequate review of potential barriers for medicine adherence. The patient was coached on self-management, and instructed to recite the indication for each medication. A joint preliminary patient-centered plan was agreed upon by the telehealth provider and the patient. The visit was then completed with a data

collection survey using REDCap. Thorough documentation was recorded in the EMR using a modified Situation-Background-Assessment-Recommendation (SBAR) framework (19) (Figs. 3–6). In this structure, communication is effectively conveyed through an Assessment/Plan section organized in a severity stratified problem based format. A short Action List (Fig. 5) was then created for telephone communication to the PCP.

A clinical plan was then offered to the primary care doctor for consideration, the primary care doctor authorized all final medication changes or treatment plans. The patient was then notified of the finalized medical plan by the teledoc by phone. The teledoc monitored vitals once daily from the vendor portal. The vendor notified the teledoc with abnormal values through text messaging. The teledoc then applied a personalized evaluation of abnormal vitals, with either a notification for the patient to go to the emergency room, instruction for the patient to come into the clinic for in person evaluation, or instruction to continue adherence to the plan until the next scheduled virtual visit. All abnormal values were communicated to the PCP by the teledoc (Fig. 2). If the PCP was unavailable, the teledoc signed off to the covering physician. Additional telehealth visits were conducted to assess the patient’s clinical status per the discretion of the teledoc and PCP.

#### 15. Limitations

This feasibility study introduced a novel physician led, patient-centered telehealth intervention using the latest available data at Stony Brook Medicine. There are several limitations to the study methodologies employed that should be considered. Generalizability must be taken into account when evaluating our design, given that Stony Brook Medicine is a large academic center with advanced biomedical informatics and Information Technology resources and residents available for telehealth training. The time dedicated and level of clinical training or expertise for the role of the teledoc should be taken into account, furthermore the volume of patients followed by the Teledoc must be tailored to clinical experience and aptitude. Larger well powered, multi-

### Telehealth Trial Timeline

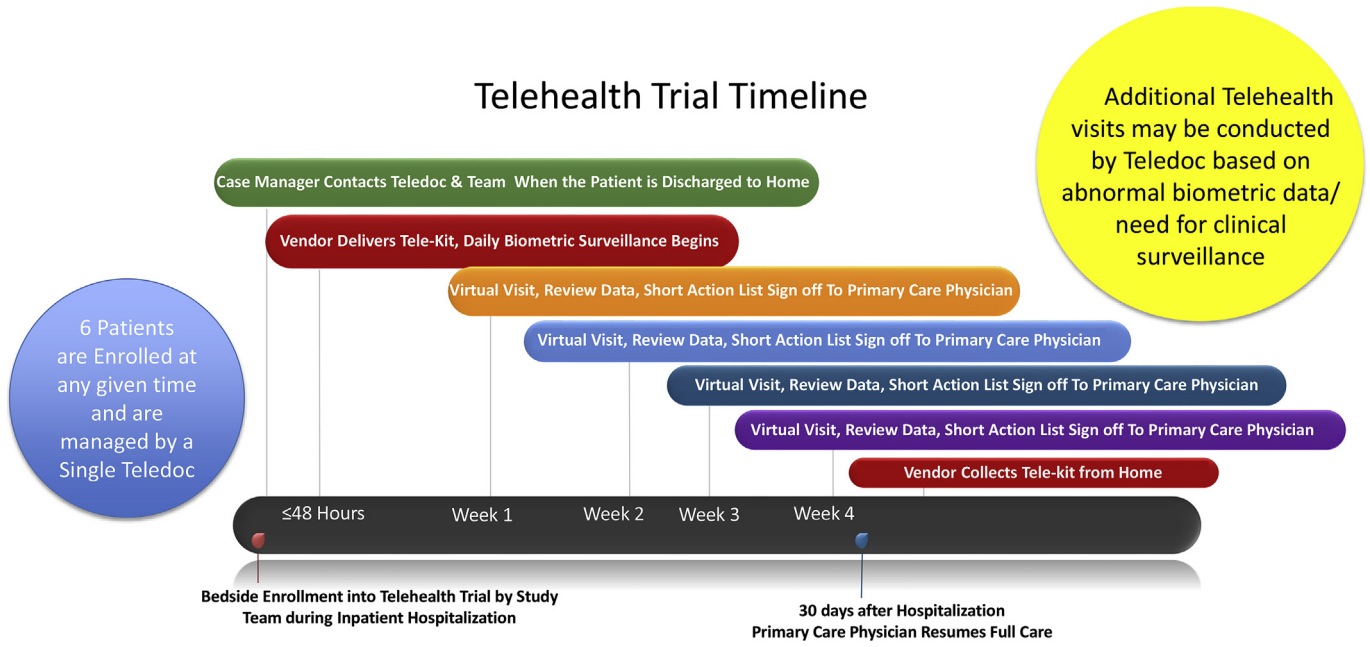


Fig. 3. Remote patient monitoring and data transfer.

institutional trials are required to make definitive conclusions regarding the ability of the intervention to reduce hospital readmissions. However, despite these limitations, we believe the methods discussed are valuable to researchers evaluating telehealth utilization.

### 16. Discussion

Telehealth offers promising opportunities to address patient needs

in the community after hospitalization. Understanding the role of telehealth, incorporating data analytics in this period, is an important goal of this study. Regular virtual evaluations incorporating all available patient data, may further improve healthcare delivery, reduce medical error, and improve patient self-management post hospital discharge. Furthermore, this study design offers opportunities in Telehealth practice for trainees through an enhanced longitudinal continuity of care model rather than infrequent episodic care, which provides a

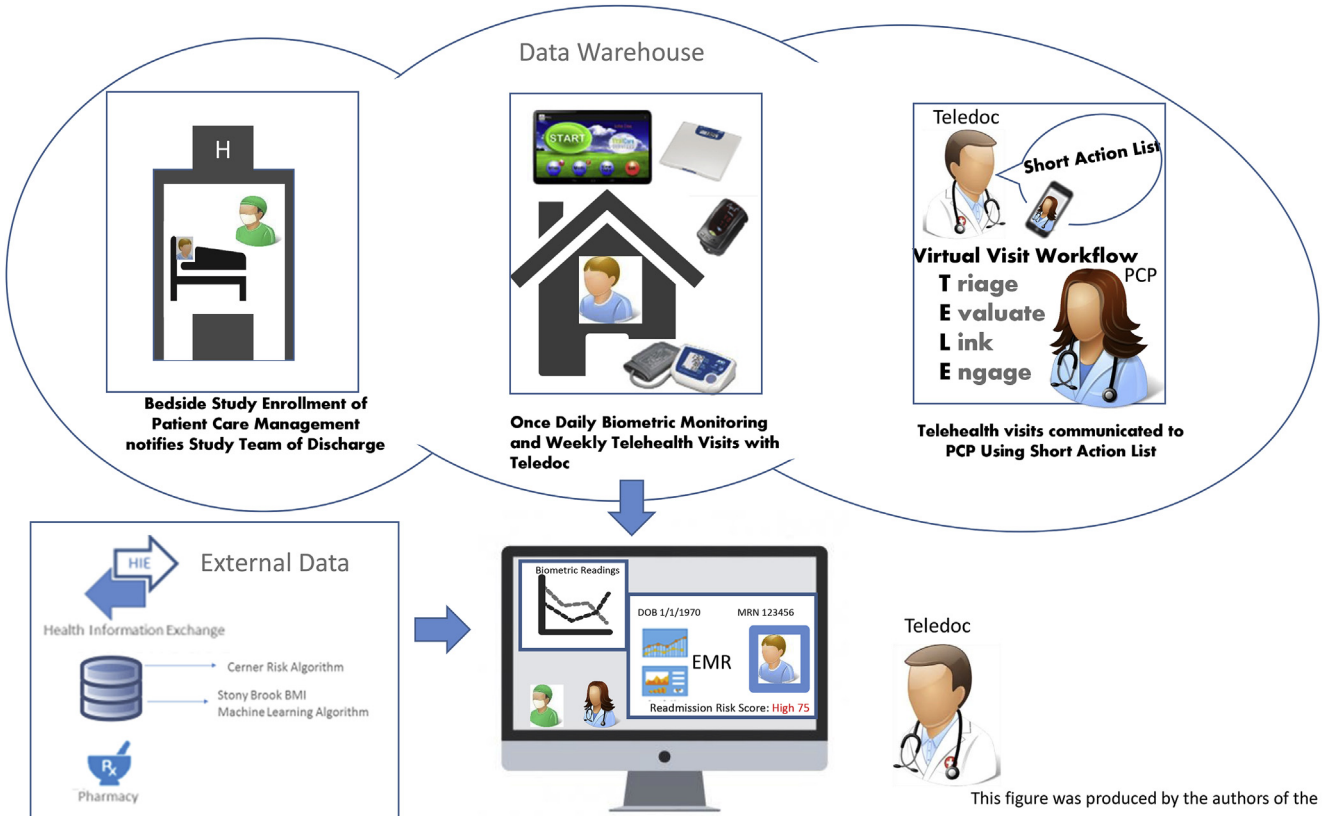


Fig. 4. TELE acronym and short action list for clinicians.

This figure was produced by the authors of the article



provided to the study participants and clinical and administrative stakeholders of the trial.

### Ethical statement

Our study and all of its components were approved by the Stony Brook University Institutional Review Board.

### Source of support

None, the telehealth vendor was paid for by The Stony Brook University Hospital.

### Contribution

All authors listed above have contributed to this work equally.

### Declarations

The protocol data and information in this study may be obtained through correspondence with [kimberly.noel@stonybrookmedicine.edu](mailto:kimberly.noel@stonybrookmedicine.edu).

### Conflicts of interest

The authors: Dr. Kimberly Noel, Dr. Shamuël Yagudayev, Dr. Gerald Kelly, Dr. Catherine Messina, Dr. Elinor Schoenfeld, and Dr. Wei Hou, declare to possess no conflict of interest and no competing financial interests exist.

### Acknowledgements

We would like to acknowledge Drs. Joel Saltz, Janos Hajagos, Steven Feldman, Iris Granek, Dorothy Lane, Howard Sussman, Daniel VanArsdale, Manal Soliman, Christina Hamm, Khaula Tauqeer, Boris Gilyadov, Valarie Luck, Sabina Rebis, Sabrina Trammel, Rachel Wong, Patricia Ng, Ms. Jere Freeman, Ms. Lynn Lettieri, Ms. Denise Reilly, Elizabeth Cerato, NY Care Information Gateway and Mr. Chris and Dave Gaur of Vital Care Services for their contribution to this study.

### References

- [1] D.M. Berwick, T.W. Nolan, J. Whittington, The triple aim: care, health, and cost,

- Health Aff. 27 (3) (2008) 759–769.
- [2] B.A. Kash, J. Baek, E. Davis, T. Champagne-Langabeer, J.R. Langabeer 2nd, Review of successful hospital readmission reduction strategies and the role of health information exchange, *Int. J. Med. Inf.* 104 (2017) 97–104.
- [3] C. Feltner, C.D. Jones, C.W. Cené, et al., Transitional care interventions to prevent readmissions for persons with heart failure: a systematic review and meta-analysis, *Ann. Intern. Med.* 160 (11) (2014) 774–784.
- [4] S. Stevens, Preventing 30-day readmissions, *Nurs. Clin.* 50 (1) (2015) 123–137.
- [5] B.J. Wakefield, M.M. Ward, J.E. Holman, et al., Evaluation of home telehealth following hospitalization for heart failure: a randomized trial, *Telemed. J. e Health: Offic. J. Am. Telemed. Assoc.* 14 (8) (2008) 753–761.
- [6] A.A. Louis, T. Turner, M. Gretton, A. Baksh, J.G.F. Cleland, A systematic review of telemonitoring for the management of heart failure, *Eur. J. Heart Fail.* 5 (5) (2003) 583–590.
- [7] A.L. Leppin, M.R. Gionfriddo, M. Kessler, et al., Preventing 30-day hospital readmissions: a systematic review and meta-analysis of randomized trials, *JAMA internal medicine* 174 (7) (2014) 1095–1107.
- [8] S. Emani, Remote monitoring to reduce heart failure readmissions, *Curr. Heart Fail. Rep.* 14 (1) (2017) 40–47.
- [9] A.M. Totten, D.M. Womack, K.B. Eden, et al., AHRQ Comparative Effectiveness Technical Briefs. Telehealth: Mapping The Evidence For Patient Outcomes From Systematic Reviews, Agency for Healthcare Research and Quality (US), Rockville (MD), 2016.
- [10] J. Donzé, S. Lipsitz, D.W. Bates, J.L. Schnipper, Causes and patterns of readmissions in patients with common comorbidities: retrospective cohort study, *BMJ Br. Med. J. (Clin. Res. Ed)* 347 (2013).
- [11] P.J. Hu, P.Y. Chau, Physician acceptance of telemedicine technology: an empirical investigation, *Top. Health Inf. Manag.* 19 (4) (1999) 20–35.
- [12] M.A. Moore, M. Coffman, A. Jetty, K. Klink, S. Petterson, A. Bazemore, Family physicians report considerable interest in, but limited use of, telehealth services, *J. Am. Board Fam. Med. JABFM* 30 (3) (2017) 320–330.
- [13] H. Tanriverdi, C.S. Iacono, Diffusion of telemedicine: a knowledge barrier perspective, *Telemed. J.* 5 (3) (1999) 223–244.
- [14] A.-W. Chan, J.M. Tetzlaff, P.C. Göttsche, et al., SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials, *BMJ Br. Med. J. (Clin. Res. Ed.)* (2013) 346.
- [15] M.J. Sigakis, E.A. Bittner, J.P. Wanderer, Validation of a risk stratification index and risk quantification index for predicting patient outcomes: in-hospital mortality, 30-day mortality, 1-year mortality, and length-of-stay, *Anesthesiology* 119 (3) (2013) 525–540.
- [16] S.A. Choudhry, J. Li, D. Davis, C. Erdmann, R. Sikka, B. Sutariya, A public-private partnership develops and externally validates a 30-day hospital readmission risk prediction model, *Online J. public health informatics* 5 (2) (2013) 219.
- [17] P.A. Harris, R. Taylor, R. Thielke, J. Payne, N. Gonzalez, J.G. Conde, Research Electronic Data Capture (REDCap) - a metadata-driven methodology and workflow process for providing translational research informatics support, *J. Biomed. Inf.* 42 (2) (2009) 377–381.
- [18] E.A. Coleman, C. Parry, S. Chalmers, S.J. Min, The care transitions intervention: results of a randomized controlled trial, *Arch. Intern. Med.* 166 (17) (2006) 1822–1828.
- [19] Quality AfHra (Ed.), Designing and Delivering Whole-person Transitional Care, 2017 Rockville, MD.