Implementation Guide

Electronic Administration of Patient Reported Outcomes using mHealth Platform in Emergency Department Patients with Nonmedical Opioid Use

October 2020

Kathryn Hawk, MD, MHS[1], Caitlin Malicki, MPH[1], Jeremiah Kinsman, MPH, NREMT[1], Gail D'Onofrio, MD, MS[1], Andrew Taylor, MD, MHS[1], Arjun Venkatesh, MD, MBA[1,2]

[1]Department of Emergency Medicine, Yale University School of Medicine, New Haven, CT
[2]Center for Outcomes Research and Evaluation, Yale New Haven Hospital, New Haven, CT

Yale SCHOOL OF MEDICINE

National Institute on Drug Abuse (NIDA)
Clinical Trials Network (CTN) Dissemination Initiative

Acknowledgements

This research was supported by the U.S. Department of Health and Human Services (HHS) Office of the Secretary Patient Centered Outcomes Research Trust Fund (PCORTF) under IDDA# ASPE-2018-001 and NIDA UG1DA015831-18S2. HHS contract # HHSN271201700059C partially supported the development of this implementation guide. The content does not necessarily reflect the official position of the National Institute on Drug Abuse, National Institutes of Health, Department of Health and Human Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. government.

Table of Contents

Overview

Purpose of This Guide

This guide was developed by investigators at Yale University as part of a project designed to build data capacity for patient-centered outcomes research. It provides an overview of the collection of patient reported outcomes (PROs) from emergency department (ED) patients with nonmedical opioid use using a novel mobile health (mHealth) platform and is designed to aid in the design and conduct of similar projects at other institutions.

Background

The ED offers an important opportunity to identify patients with opioid use disorder (OUD), and initiate treatment and care pathways. However, effectively connecting ED patients with OUD to follow-up care after discharge from the ED remains a challenge and novel approaches to support patients and enhance connection with treatment and resources are urgently needed. Given the rise in mHealth tools, this study explored the feasibility and acceptability of electronically collecting PROs from ED patients with nonmedical opioid use to enhance care in the ED and transitions of care.

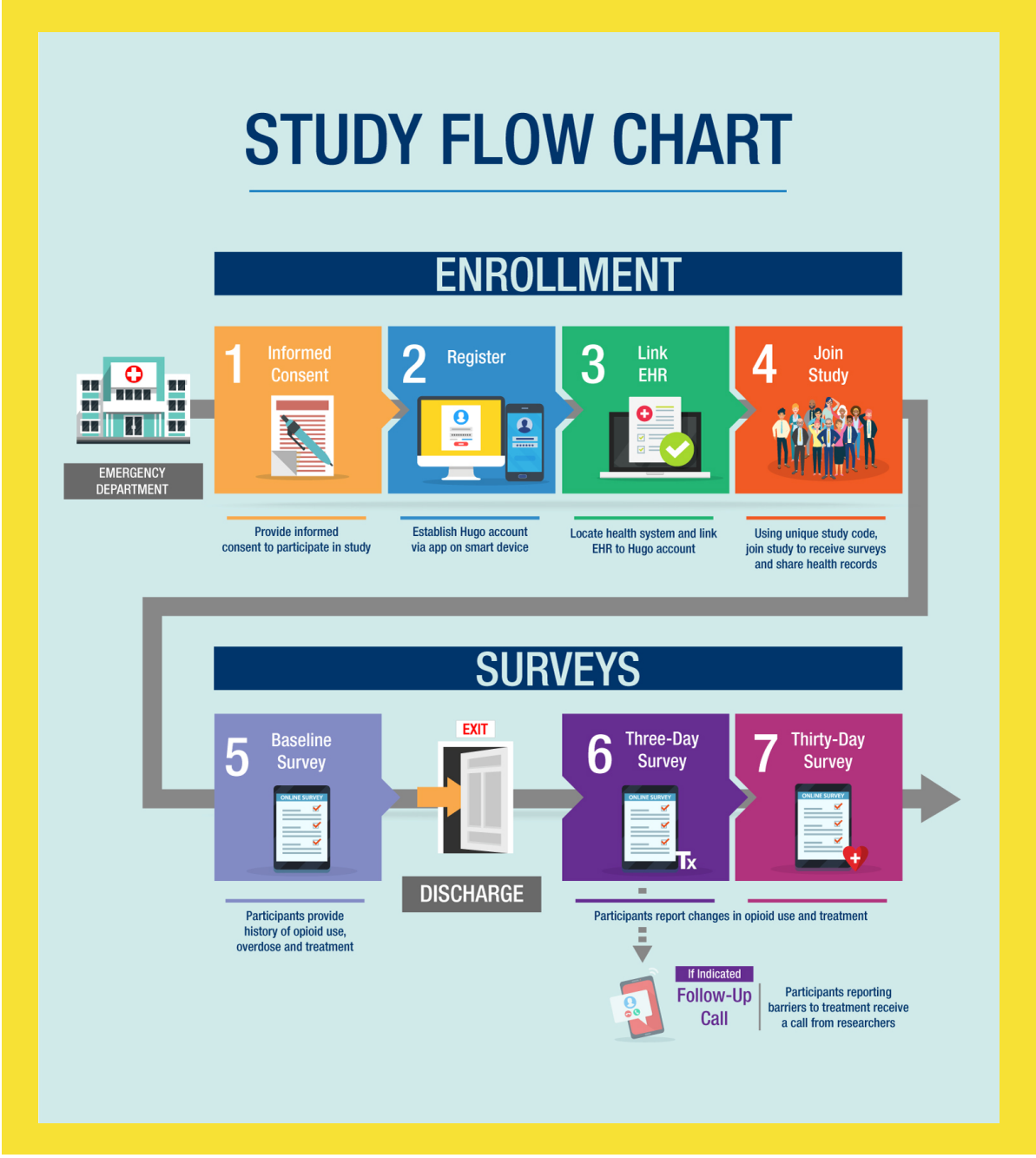
Study Overview

A single-site pilot study to test the feasibility and acceptability of electronic PRO survey distribution among ED patients with nonmedical opioid use, OUD or opioid overdose. The study was conducted between June 2019 and February 2020 at Yale New Haven Hospital (YNHH), a tertiary urban academic ED in New Haven, Connecticut. Participants were screened by a trained research assistant (RA) using a short and standardized substance use questionnaire and eligible participants were offered participation in the study. Following informed consent, participants were asked to enroll in an mHealth platform, share electronic health records (EHR) with researchers, and complete electronic surveys of PROs at baseline, three days and thirty days post ED discharge. Surveys were distributed through Hugo Health (Hugo), a cloud-based platform that engages patients as data partners and automates a process that enables patients to easily and securely access and share their health information—including medical records, pharmacy data and survey data such as PROs—directly from a patient's mobile devices or computer.

The study's primary objective was feasibility testing to determine whether ED patients with OUD, nonmedical opioid use or opioid overdose were willing to share their electronic health data with researchers and complete PROs delivered by a mobile-based technology platform. The secondary objective was to collect and measure PROs to better understand factors associated with OUD referrals and treatment. An additional exploratory aim included pilot testing the integration of PRO responses into the YNHH ED clinical workflows.

Study Set-Up

- **Protocol Development** - The study protocol was developed by the research team in collaboration with a steering committee comprised of experts in addiction medicine, emergency medicine and health informatics. Broadly, the protocol encompassed study objectives, study design and outcomes, sample size and study population, assessment and duration, safety reporting and analyses. Surveys were developed using available OUD-related PROs deemed suitable for electronic completion within a 30-day window. Study flow is depicted below and the full study protocol can be found online at: https://datashare.nida.nih.gov/



- **Study Team** - The study team was comprised of a primary investigator (PI), two co-investigators, two project managers and two part-time RAs. Investigators were faculty members in the Yale Department of Emergency Medicine with expertise in addiction medicine, emergency medicine administration and health informatics. Project managers were research associates in the Yale Department of Emergency Medicine, both with Masters in Public Health and extensive experience in the management of human subjects research. RAs were nursing students at the Yale School of Nursing, who were hired for a six-month period to recruit for the study. RA job requirements included experience with human subjects research and patients with substance use disorder. When the number of enrolled subjects was less than anticipated, we enrolled a third part-time RA and staggered shifts to maximize recruitment.

- **Institutional Review Board** - As a single site study, this study was submitted for approval by the Yale University Institutional Review Board (IRB) through an electronic IRB portal. The IRB application included a number of materials, including study protocol, consent form, a quick-screen form, screening log, surveys (baseline, 3-day and 30-day), and a call log. The application also included a privacy policy and security statement from Hugo, which outlined how protected health information (PHI) is accessed, managed and shared through the application. Once approved, the study was listed on www.clinicaltrials.gov.

- **Contracts** - Yale University set up a consulting contract with Hugo. While Hugo was an established vendor at Yale University, professional services and consulting agreements were required for this specific project. Hugo subcontracted with the gift card company, Tremendous, and integrated distribution of gift cards within their system.

- **Office Space and Supplies** - Prior to study implementation, we ordered a study cell phone, laptop, and iPad for use by RAs. We also arranged for workspace in the research office, located in the ED for RAs to use while screening patients and making phone calls. The office contained a study-specific locked file cabinet to store electronics, consent forms and any materials with PHI.

- **Manuals and Guides** - Prior to study implementation, manuals, checklists, scripts and troubleshooting guides were developed to walk RAs through study procedures and offer solutions to common challenges that might be encountered during the recruitment and enrollment process. Troubleshooting materials were later adapted so they could be sent home with or emailed to study participants who had challenges with the Hugo App or accessing their EHR. A selection of these supplemental materials can be found at the end of this guide (Appendix A and B).

- **Hiring and Training** - Prior to study launch, part-time RAs were hired through the Yale School of Nursing for a six-month period with a maximum of 16 hours a week, per Yale University guidelines. Approximately one week before enrollment, RAs completed comprehensive trainings that included review of human subjects research, study protocol and materials, data collection, mock enrollment, and a tour of the YNHH ED. We also ensured that RAs had access to necessary locations (ED office and locked file cabinets) and electronic systems (email, Hugo, Qualtrics, secure file transfer, etc).

- **Data Collection** -

    - *Hugo Health* – In collaboration with web developers at Hugo, we created a study dashboard for subject management, which included reporting on surveys and linkage with EHR. Via the dashboard, surveys and distribution timing were programmed and tested prior to implementation for user experience and reporting. For the purpose of this project, the unique randomized code automatically assigned to Hugo participants was used as the study ID.

    - *Qualtrics* – The Qualtrics Survey Tool was used to electronically collect information captured in case report forms (screening forms and call logs). For all relevant forms, the study ID assigned in Hugo was entered to ensure linkage between Qualtrics and Hugo data.

    - *Microsoft Excel* – A participant monitoring file was used by RAs to document and manage communications with study participants. The file was password-protected and maintained on a secure Yale server.

- **Subject Payments** - Electronic gift cards were distributed through the company, Tremendous, and programmed to trigger upon completion of PRO surveys sent by Hugo. After completion of a survey, participants were given the option to receive their gift cards electronically by text or email (instant delivery) or by mail (within one week).

- **Integration in ED** - Prior to launch, we emailed ED clinical staff to share study details and introduce the study team. Signs were also posted in the ED, which included a brief description of our study and our contact information for referrals or questions. We also collaborated with other research staff in the Yale Department of Emergency Medicine to coordinate recruitment and avoid co-enrolling participants in active research studies.

Implementation

- **Workflow** - With oversight and direction from project managers, RAs were responsible for screening, enrollment and continued communication with study participants. Following enrollment, the participant monitoring file was used to track required actions for participants, such as registering with Hugo, linking EHR and completing the baseline, three-day and thirty-day survey. Project managers flagged incomplete actions in this file and RAs were responsible for following up with participants regarding troubleshooting and survey reminders. A similar model could be used to facilitate clinical follow-up in the ED setting, as patients often require close tracking and warm handoffs for transitions of care to reduce the harms of care fragmentation. Historically, follow-up communication with discharged ED patients has been infrequent or based on ad hoc tools, such as paper checklists or basic spreadsheets, which lack the ability to capture patient outcomes, standard care transition information or support follow-up planning. The use of workflows that mirror industry customer relationship management tools may be better suited to ensuring improved patient contact following ED discharge.

- **Recruitment** - RA hours initially ranged from 6am-11pm, depending on availability, and were adjusted based on effectiveness of recruitment. Overall, early morning shifts were least effective and hours were realigned with evening shifts when there were higher numbers of eligible patients. During down time, RAs input data into Qualtrics and sent reminders to participants for survey completion.

- **Data Monitoring** - Project managers routinely downloaded data from Hugo and Qualtrics, merging the information using the Hugo study ID, to enable tracking and reporting. Data was saved in Microsoft Excel on a secure server throughout the course of the study. A CONSORT diagram was developed to monitor screening, enrollment and completion rates and reviewed during weekly meetings to help inform progress and areas for improvement.

- **Team Meetings** - Weekly team meetings were held with the principal investigator, project managers and RAs to review the CONSORT diagram, call log, and help troubleshoot challenges.

- **Modifications** - Throughout the course of the study, a number of changes were implemented to increase enrollment and address challenges encountered. Most notably, the study protocol was modified to include admitted and/or psychiatric patients, since many patients in the ED were admitted for psychiatric care before successfully completing enrollment. A third RA was hired mid-study to help increase enrollment and implemented use of an electronic system to assign and manage shifts. We set up a study-specific email and texting system to improve efficiencies in communication with participants. The study team continually worked with inpatient clinicians if patients were admitted to the hospital.

Analysis and Reporting

- **Data Analysis** - Upon completion of the study, Hugo shared participant EHR data via secure file transfer. EHR data was merged with the participant monitoring file, survey responses and Qualtrics reports, using the Hugo study ID. Once complete, data was de-identified and analyzed using SAS software.
- **Lessons Learned** - The study team documented a list of successes, challenges and lessons learned throughout the study, which was later used for qualitative analysis and reporting. A complete summary of these findings can be found in related publications but in short, successes included overall willingness to share EHR with researchers, high participation rate (101 of 130 eligible participants enrolled), high completion rate for baseline survey completed in ED (97%), and successful linkage of EHR with Hugo (81%). Implementation challenges included short engagement window during ED visit, limited patient access to smartphones and computers, insufficient device storage to download the Hugo app, forgotten emails and passwords, multi-step verification processes for account set up, receiving sensitive patient information unrelated to the study during follow-up communications, and low follow-up rates (49% and 42% completion rates for three and thirty day surveys, respectively). However, it's important to note that low completion rates were expected for electronic surveys post-discharge from the ED in this population, as discussed in study manuscripts.
- **Dissemination** - The study's primary and secondary objectives (feasibility testing and PROs, respectively), were reported in separate manuscripts. A list of publications can be found online at: http://ctndisseminationlibrary.org/protocols/ctn0081.htm

Additional Information

For additional details about this project, please contact:

Kathryn Hawk at Kathryn.hawk@yale.edu.

Note: Hugo Health is continually enhancing functionality, and expanding capabilities of its novel technology platform. Some of the guidelines and screenshots in this document may be outdated. Many of the lessons learned may have informed subsequent product updates. For the most current information regarding the Hugo platform, please visit https://hugo.health or reach out directly to Hugo Health at info@hugo.health.

Appendices

Appendix A: Enrollment checklist

Enrollment checklist

Study Title: CODE PRO

What you will need:

- Consented study participant with ability to check their email
- Username and password for each patient portal, pharmacy & device participant will connect
- Participant's app store password for Hugo app (optional)

STEP 1: Create Hugo Account & Share with Study

- ☐ Search app store for Hugo Health & download app
- ☐ Tap sign up or Get Started, enter first name, last name, email, & study code: **CODE-PRO1,** and create a password. (*study code not case sensitive and hyphen appears automatically; password: min 8 characters; at least one upper & lower case letter and a number*)
- ☐ Check email for account activation email, and follow instructions to activate
- ☐ Sign into app using email and newly created password to accept privacy policy
- ☐ Tap 'Share with Study' to complete the enrollment process
- ☐ Enter a mobile phone number to have surveys delivered by text message
- ☐ Sign in to the Hugo researcher admin panel, then the associated patients tab and enter the 'survey trigger date' (enrollment date)
- ☐ Help study participant complete baseline survey

STEP 2: Connect Patient Portals (MyChart)

- ☐ Select connect data sources in Hugo app, & tap add health records
- ☐ Search the list for health system & tap login
- ☐ Have participant enter MyChart username and password & 'Authorize Connection'
- ☐ Repeat for any additional portals

STEP 3: Connect Pharmacy and Devices *(if any)*

- ☐ Return to data source screen in Hugo app, & tap add pharmacy
- ☐ Select Walgreens or CVS
- ☐ Have participant enter pharmacy username and password & 'Authorize Connection'
- ☐ Enter answers to any security questions
- ☐ Repeat if participant has both Walgreens and CVS accounts

Appendix A: Enrollment checklist

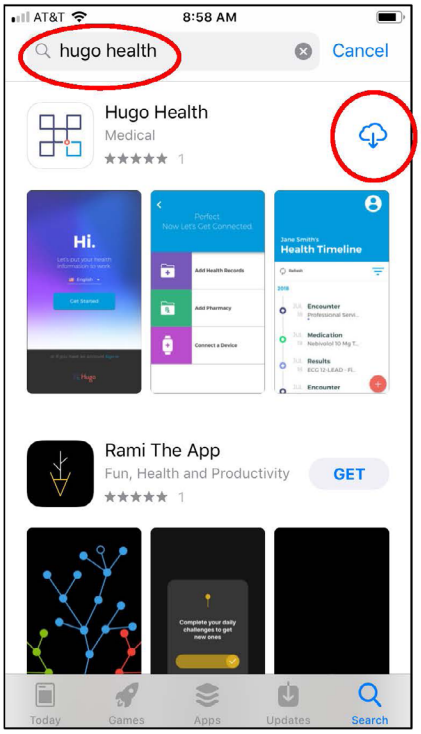
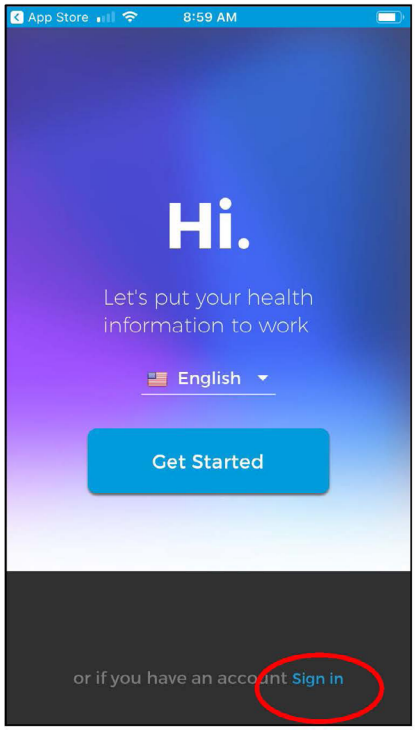
STEP 4: Download/install Hugo app on additional devices *(optional)*

- ☐ Search app store for Hugo Health
- ☐ Download app
- ☐ Enter email & password created in step 1

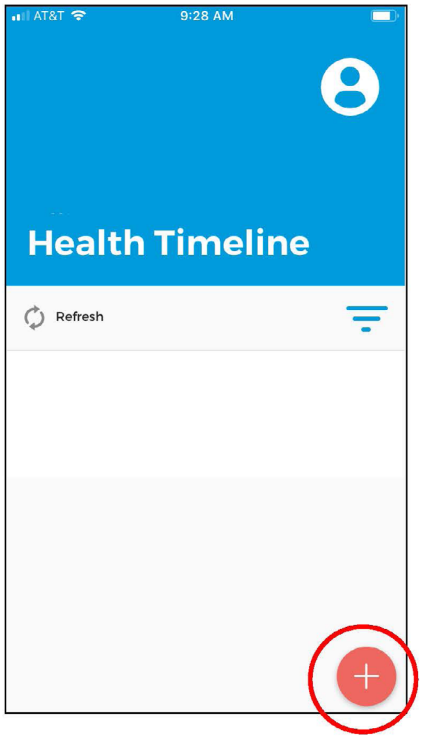
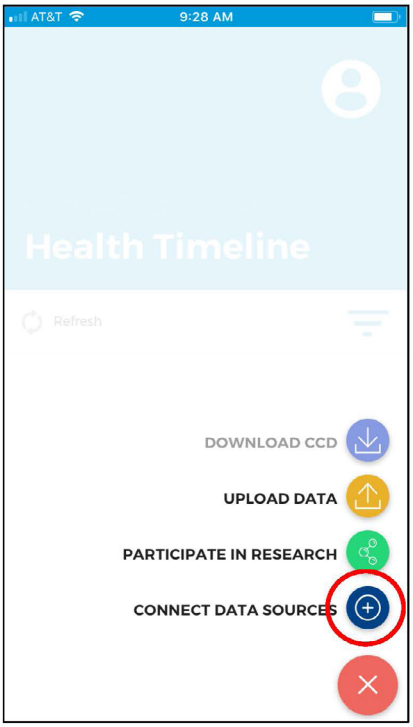
Hugo Contacts:

Support: *admin@hugosupport.com*

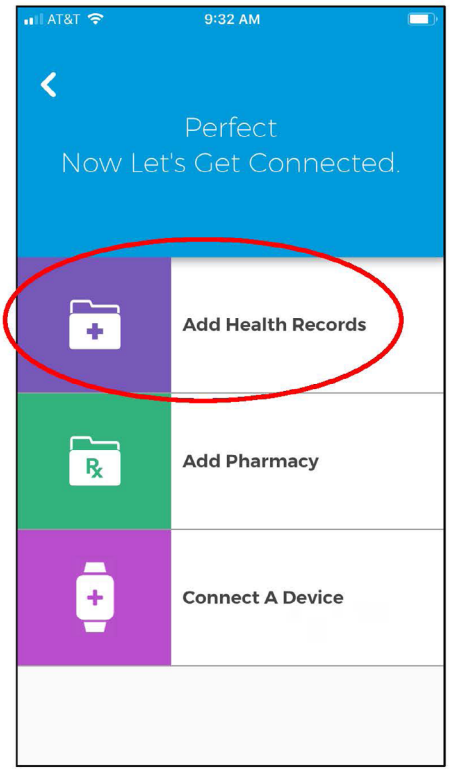
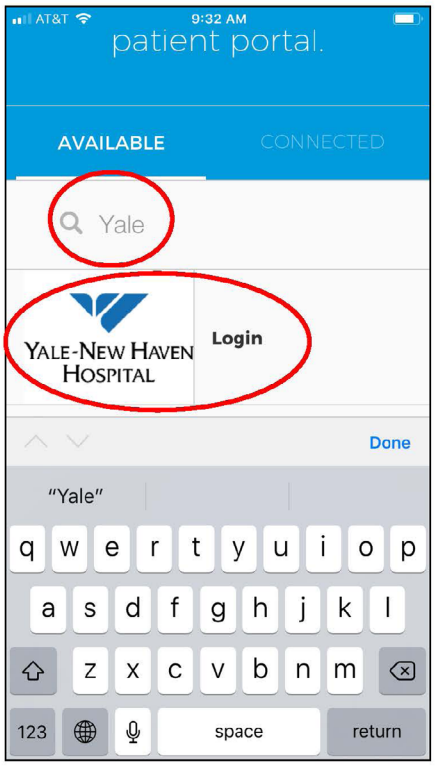
Appendix B: Instructions for Linking MyChart Account with Hugo

Instructions for Linking your MyChart Account with Hugo Health	
Step 1: Open the App Store (if using iPhone) or Google Play Store (if using Android)	
Step 2: Search for "Hugo Health" Step 3: Download the "Hugo Health" app Step 4: Open the "Hugo Health" app 	Step 5: Click "Sign in" on the bottom right. 

Appendix B: Instructions for Linking MyChart Account with Hugo

Step 6: Click the red circle with plus sign icon on the bottom right	Step 7: Click the "Connect Data Sources" icon
	

Appendix B: Instructions for Linking MyChart Account with Hugo

Step 8: Click “Add Health Records”	Step 9: Search for “Yale” Step 10: Click “Yale New Haven Hospital – Login”
	

Appendix B: Instructions for Linking MyChart Account with Hugo

Step 11: Enter your Yale New Haven Hospital – MyChart username and password; if you can't remember your MyChart username or password, go to https://mychart.ynhhs.org/MyChart-PRD/, and click "Forgot Username?" and/or "Forgot Password?"

Step 12: Click "Authorize Connection"