Trial Protocol and Statistical Analysis Plan

Effect of Expansion of Abbreviations and Acronyms on Patient Comprehension of their Health Records: A Randomized Controlled Trial

Coordinating Investigator

Ruth Masterson Creber, PhD, RN
Department of Population Health Sciences
425 E 61st St, New York, NY, 10065
rmc2009@med.cornell.edu
+1 646 962 2435

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This version is effectively equivalent to the original trial protocol, with small revisions made upon reviewer request to improve clarity for the reader.

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### Abbreviations and Acronyms

| Abbreviation | Description |
|--------------|-------------|
| CARD         | Clinical Abbreviation Recognition and Disambiguation |
| CONSORT      | Consolidated Standards of Reporting Trials |
| COVID        | Coronavirus Disease |
| EHR          | Electronic Health Record |
| EMPI         | Enterprise-wide Master Patient Index |
| HIPAA        | Health Insurance Portability and Accountability Act of 1996 |
| HPI          | History of Present Illness |
| ISO          | International Organization for Standardization |
| MRN          | Medical Record Number |
| NY           | New York |
| NYHA         | New York Heart Association |
| REDCap       | Research Electronic Data Capture |
| U.S.         | United States |
Synopsis

Title
Effect of Expansion of Abbreviations and Acronyms on Patient Comprehension of their Health Records: A Randomized Controlled Trial

Keywords
Abbreviations, Acronyms, Personal Health Records, Patient Portals, Consumer Health Informatics, Patient Access to Records

Sponsor
Department of Population Health Sciences, Division of Health Informatics, Weill Cornell Medicine, New York, NY, USA

Sites
1 geographic area, 3 urban hospitals

Schedule
February 2020 – August 2021: Data Collection
September – December 2021: Data Analysis
January – March 2022: Dissemination

Design
Prospective, two-arm, parallel, individually randomized controlled trial

Objectives
(1) To better characterize the extent of miscommunication due to abbreviations in health records
(2) To evaluate the need for potential solutions such as automated abbreviation expansion

Intervention
Study control is abbreviations and acronyms, and study intervention is expansion of abbreviations and acronyms. Patients will be computer-randomized to the control or intervention in a 1:1 ratio.

End Points
The primary end point is objective comprehension, or whether the participant can define the abbreviation or expansion (binary yes or no variable), as judged by a trained recruitment coordinator according to pre-specified definitions. We will not assess any secondary end points.

Sample Size
Our planned sample size of 60 patients will provide 80% power to detect a 33 percentage point difference in our primary outcome at the 5% significance level. This sample size relies on a comprehension rate of 89% for the intervention and 56% for the control group, based on prior predictions by clinician experts.

Analyses
A two-sided unequal variances t-test with a significance threshold of $P<0.05$ will be used to examine for differences in overall comprehension scores between study groups. Fisher’s exact test of independence will be used to test for differences in comprehension rates between abbreviated and expanded versions of each term. As a secondary analysis, association of baseline characteristics with abbreviation and acronym comprehension in the control group will be assessed.
1. Background and Objectives

1.1. Background

A decade ago, only 10% of U.S. healthcare organizations used an electronic health record (EHR), whereas more than 99% do today.1–4 The rapid adoption of EHRs has radically transformed health communication. Previously, health records primarily consisted of providers handwriting notes in paper charts, rarely seen by outsiders. Today, EHRs integrate data, information, and knowledge from dozens of sources, viewable by providers, patients, and caregivers alike. Accordingly, more patients can instantly access their health records online than ever before, and millions of patients accessed their personal health information online last year.5–8

Comprehension of personal health information is challenging for most patients,9–13 but has the potential to prevent medical errors,14–19 increase shared decision-making,20–25 and improve health outcomes.26,27 According to federal policy, hospitals must allow patients to view, download, and transmit their own health information.28,29 As a result, the percentage of healthcare organizations offering online patient portals increased from 43% in 2013 to 92% in 2015.30,31 This transparency has been hailed as the next "blockbuster drug" and "healthcare revolution."9 Arguably, one promising form of transparency is giving patients their doctors' notes. Over 22 million U.S. individuals accessed their doctors' notes in early 2018, a year-over-year increase of more than 120%.32 Access to notes helps patients take medications as prescribed, be better prepared for future visits, and better understand their illness conditions.5,33–39

Unfortunately, tools to help patients comprehend, interpret, and use their health information have not evolved concomitantly.40–43 In our previous research, we determined that clinical abbreviations and acronyms (hereby "abbreviations") present a major barrier to patient comprehension of their health records, especially their doctors' notes.44–46 In one previous study,44 we determined that abbreviations cause more misunderstanding than any other barrier, including medical terms and health literacy. In a preliminary study, we assessed the abbreviation content of admissions notes, and determined that abbreviations constitute 30-50% of the words. In the most extreme case, one note began with an entire sentence of acronyms: '50 y/o f w/hx b/l SO pw/ LLQP' (50 year old female with a history of bilateral salpingo-oophorectomy presents with left lower quadrant pain).

Therefore, it is unsurprising that abbreviations frequently cause patients to misunderstand notes. Patients' misunderstanding may reduce the potential benefits of transparency, increase miscommunication, decrease satisfaction, increase doctors' legal liability, and ultimately harm the patient-doctor relationship.47,48 Because current interventions show extremely limited ability to improve patient's comprehension of abbreviations,49 any advances in our understanding of the problem and our ability to automatically expand acronyms should have major clinical significance and far-reaching consequences such as better shared decision-making and improved health outcomes.

1.2. Long-Term Goal

Our long-term goal is to develop methods to improve patient comprehension of their health records, focusing specifically on clinical abbreviations. Expanding abbreviations in text is a first step towards fully semantically representing personal health information to all viewers.
1.3. Study Objectives

The overall objective is to establish patient comprehension of abbreviations vs. expansions in clinical text, using several control mechanisms to isolate the main effect of expansion. This assessment is intended to:

(1) characterize the extent of miscommunication due to abbreviations in health records;
(2) evaluate the need for potential solutions such as automated abbreviation expansion.

We hypothesized that abbreviation expansion would improve patient comprehension of abbreviations in clinical text. As a secondary analysis, the study will determine associations between comprehension of abbreviations and common characteristics, including education level, socioeconomic status, and health literacy.

1.4. Control of Confounding

The following control mechanisms will be used to isolate the main effect:

- **Control for prior health system exposure**: Patients at the same level of care will be recruited. Specifically, we will recruit primarily heart failure patients that have been recently hospitalized, as this very sick population experiences a high need to quickly comprehend their personal health information.

- **Control for clinical context and prior knowledge of medical jargon**: Patients with the same illness condition will be recruited. Specifically, we have chosen to recruit heart failure patients. Heart failure is a highly prevalent chronic illness that impacts over 6.5 million Americans.⁵⁰,⁵¹

- **Control for difficulty of comprehension**: We will include abbreviations of varied difficulty for patients to comprehend, as rated by participating clinicians prior to the design and recruitment of the trial. No abbreviations that clinicians deem overly difficult to comprehend will be included.

- **Control for written context**: We will present abbreviations and expansions in a short paragraph similar to the History of Present Illness (HPI) section of doctors' notes. The participant will read the entire paragraph before comprehension of each abbreviation or expansion is assessed.
2. Study Design

2.1. General

This study is a prospective, two-arm, parallel, individually randomized controlled trial designed to establish patients' objective comprehension (primary outcome) of abbreviations vs. expansions in clinical text. Patients will be individually randomized to receive either abbreviations (control group) or expansions (intervention group).

2.2. Participants

Table 2.1 describes the eligibility criteria for participation. The subject population is 60 diagnosed adult heart failure patients (confirmed by clinical exam, echocardiographic evidence, or cardiologist expert opinion), who receive primary care at one of three institutions: Columbia University Medical Center, Weill Cornell Medical Center, and New York University Langone Health.

We will recruit a purposive sample on age, sex, and race as per the institutions' adult heart failure population demographics on 1 July 2019. Potential participants will be identified by their attending cardiologist and invited to participate by the research coordinator. The attending cardiologists will not be involved in any study procedures, including data collection and randomization, and will not have access to the results except in aggregation.

| Table 2.1. Eligibility Criteria |
|-------------------------------|
| **Inclusion Criteria**         | **Exclusion Criteria**                 |
|--------------------------------|----------------------------------------|
| Adult (21 years or older)      | Healthcare professional (MD, DO, RN, etc.) |
| Confirmed diagnosis of heart failure | No telephone number or email address               |
| Able to read and speak English | Severe cognitive impairment or clinical diagnosis of dementia |
| Willing and able to provide informed consent | Major psychiatric illness, including active psychosis |
| Receives primary care from participating provider | Other illness that would preclude participation |

2.3. Baseline Data

All baseline data will be recorded in REDCap. REDCap is a secure, HIPAA-compliant web application for building and managing online surveys and databases. REDCap is specifically geared to support online or offline data capture for research studies and operations.

Table 2.2 describes the baseline data that will be collected. Demographic characteristics included age, gender, race, ethnicity, and preferred language, and socioeconomic characteristics included educational attainment, insurance type, financial resources, and disability status. To estimate health literacy, we use the 3-item Brief Health Literacy Screener.52
| Data Field     | Question Text                                      | Coded Responses                                                                 |
|---------------|---------------------------------------------------|--------------------------------------------------------------------------------|
| mrn_empi      | Please enter patient’s EMPI number:               | Text (10 digit EMPI)                                                           |
| survey_taker  | Who is completing this survey?                    | 1 Researcher                                                                   |
|               |                                                   | 2 Patient                                                                      |
| location      | Where was the participant recruited?              | 1 Inpatient                                                                    |
|               |                                                   | 2 Outpatient                                                                   |
| institution   | Where does the participant receive primary care?  | Text (prefilled institution)                                                   |
| age           | What is your age?                                 | Text (number, minimum 18, maximum 110)                                         |
| gender        | What gender do you identify as?                   | 1 Male                                                                         |
|               |                                                   | 2 Female                                                                       |
|               |                                                   | 3 Other                                                                        |
| gender_other  | Please specify "Other":                           | Text (required)                                                                |
| race          | What race do you identify as?                     | 1 White                                                                        |
|               |                                                   | 2 Black                                                                        |
|               |                                                   | 3 Asian                                                                        |
|               |                                                   | 4 Native American                                                              |
|               |                                                   | 5 Mixed                                                                        |
|               |                                                   | 6 Other                                                                        |
|               |                                                   | 7 Unsure/prefer not to answer                                                   |
| race_other    | Please specify "Other":                           | Text (required)                                                                |
| ethnicity     | What ethnicity do you identify as?                | 1 Hispanic/Latino                                                              |
|               |                                                   | 2 Not Hispanic/Latino                                                           |
|               |                                                   | 3 Unsure/prefer not to answer                                                   |
| language_spoken| What is your preferred language to speak?         | 1 English                                                                       |
|               |                                                   | 2 Spanish                                                                      |
|               |                                                   | 3 Cantonese                                                                    |
|               |                                                   | 4 Mandarin                                                                     |
|               |                                                   | 5 Russian                                                                      |
|               |                                                   | 6 Other                                                                        |
| languagespoken_other| Please specify "Other":                    | Text (required)                                                                |
| language_read | What is your preferred language to read and write?| 1 English                                                                       |
|               |                                                   | 2 Spanish                                                                      |
|               |                                                   | 3 Cantonese                                                                    |
|               |                                                   | 4 Mandarin                                                                     |
|               |                                                   | 5 Russian                                                                      |
|               |                                                   | 6 Other                                                                        |
| languagespoken_other| Please specify "Other":                   | Text (required)                                                                |
| language_read | What is your preferred language to read and write?| 1 English                                                                       |
|               |                                                   | 2 Spanish                                                                      |
|               |                                                   | 3 Cantonese                                                                    |
|               |                                                   | 4 Mandarin                                                                     |
|               |                                                   | 5 Russian                                                                      |
|               |                                                   | 6 Other                                                                        |
### Education

**What is the highest level of education that you completed?**

1. I have never attended school
2. Eighth grade
3. Some high school
4. High school
5. Some college
6. Associates degree
7. Bachelor’s degree
8. Master’s degree
9. Doctoral degree
10. Unsure/prefer not to answer

### Health Insurance

**Do you currently have health insurance?**

1. Yes
2. No
3. Not sure

### Insurance Type

**What kind of health insurance do you have?**

1. Insurance through employer
2. Self purchased insurance
3. Medicare
4. Medicaid
5. Other program
6. Not sure what type of insurance

### Financial Resources

**Do you feel you have enough financial resources to make ends meet?**

1. More than enough
2. Enough
3. Not enough

### Disability

**Do you have a disability?**

1. Yes
2. No

### Disability Type

**Which of the following describes your disability?**

1. Problems with physical mobility
2. Problems with hearing
3. Problems with seeing
4. Other

### Disability Other

**Please specify “Other”:**

Text (required)

### Health Literacy 1

**How often do you have problems learning about your medical condition because of difficulty understanding written information?**

1. Never
2. Occasionally
3. Sometimes
4. Often
5. Always

### Health Literacy 2

**How confident are you with filling out medical forms by yourself?**

1. Extremely
2. Quite a bit
3. Somewhat
4. A little bit
5. Not at all

### Health Literacy 3

**How often do you have someone help you read hospital materials?**

1. Never
2. Occasionally
3. Sometimes
4. Often
5. Always
2.4. Intervention

This study is designed to compare comprehension of abbreviations vs. expansions in clinical text. We have used the following process to identify abbreviations for inclusion in the randomized trial:

- Using the Clinical Abbreviation Recognition and Disambiguation (CARD) framework,53 we identified the 20 most common abbreviations found in advanced heart failure notes, excluding those abbreviations judged as highly obscure by participating clinicians (n=6).

- Participating clinicians rated these 20 abbreviations and their corresponding expansions as easy, moderate, or difficult for patients to comprehend. We then choose 10 of the 20 abbreviations of varied difficulty and their corresponding expansions for inclusion in the randomized trial.

Table 2.3 displays the included abbreviations and corresponding clinician ratings.

| Clinical Text        | Difficulty Score (out of 12) | Estimated Comprehension (% of patients) | Interpretation |
|----------------------|------------------------------|----------------------------------------|----------------|
| Abbreviations        |                              |                                        |                |
| hrs                  | 0                            | 100%                                   | Easy           |
| MD                   | 1                            | 92%                                    | Easy           |
| BP                   | 3                            | 75%                                    | Easy           |
| ED                   | 3                            | 75%                                    | Easy           |
| yo                   | 5                            | 58%                                    | Moderate       |
| pt                   | 5                            | 58%                                    | Moderate       |
| HF                   | 6                            | 50%                                    | Moderate       |
| hx                   | 9                            | 25%                                    | Difficult      |
| HTN                  | 10                           | 17%                                    | Difficult      |
| MI                   | 11                           | 8%                                     | Difficult      |
| Expansions           |                              |                                        |                |
| hours                | 0                            | 100%                                   | Easy           |
| medical doctor       | 0                            | 100%                                   | Easy           |
| blood pressure       | 0                            | 100%                                   | Easy           |
| emergency department | 0                            | 100%                                   | Easy           |
| year old             | 0                            | 100%                                   | Easy           |
| patient              | 0                            | 100%                                   | Easy           |
| heart failure        | 0                            | 100%                                   | Easy           |
| history              | 2                            | 83%                                    | Easy           |
| hypertension         | 2                            | 83%                                    | Easy           |
| myocardial infarction| 9                            | 25%                                    | Difficult      |

Categories: 75-100% is easy, 50-75% is moderate, and <50% is difficult.
We will present abbreviations or expansions in a short paragraph similar to the History of Present Illness section of doctors' notes (Figure 2.1). This will control for written context and stimulate real-life interpretation of abbreviations or expansions as closely as possible. The paragraph will be short to minimize time burden on participants. Text size will be 20 point font to ensure legibility as per National Institution of Aging recommendations.

(a) A 44 yo man, former smoker with a hx of gout, HF, and HTN, presents to the ED with chest pain. Pt states that his pain began about 2 hrs ago. BP is 154/96. The MD is concerned for MI.

(b) A 44 yo man, former smoker with a hx of gout, HF, and HTN, presents to the ED with chest pain. Pt states that his pain began about 2 hrs ago. BP is 154/96. The MD is concerned for MI.

Figure 2.1. Paragraphs with abbreviations or expansions
(a) Versions to be displayed to participants during the randomized trial
(b) Versions highlighted according to clinicians' perceptions ( easy, moderate, difficult)

2.5. Randomization

Prior to launching recruitment, an independent statistician will randomly assign groups using a computer-generated block randomization algorithm of size 6. Groups will be assigned in a 1:1 ratio.

Two coordinators will enroll participants and collect data. REDCap will conceal each participant's allocation until directly after baseline data collection. Blinding after assignment is not possible due to the obvious nature of the intervention.

2.6. Outcome

The primary outcome will be objective comprehension, assessed using the International Organization for Standardization Method for Testing Comprehension (ISO 9186) as previously adapted for oral administration by an objective observer. ISO 9186 is a well-known standardized protocol for assessing objective comprehension.

Briefly, the coordinator primes participants to the task (Figure 2.2) and reads the paragraph aloud. Then, the coordinator asks participants to verbally explain each abbreviation's or expansion's meaning as per ISO 9186. If the response is incomplete or incorrect, the coordinator can only say "tell me more," to prevent them from biasing the response.
We will consider the response correct if the participant can describe the abbreviation or expansion, as determined by the coordinator. The coordinators will discuss the potential scope and depth of adequate responses prior to recruitment to ensure standardization, and any unclear classifications will be discussed by the research team.

Next, I'm going to ask you to read a paragraph.
You may not understand every word in this paragraph and that's ok.
Our goal is to find out what you don't understand, so we can make it more understandable in the future.

[Participant reads paragraph with either abbreviations or expansions]

Now, I'm going to ask you what some of the words mean.
Even if it seems obvious, just say it.
If you don't know, it's okay to say "I don't know."

[Ask about meaning of each abbreviation or expansion]

**Figure 2.2.** Introductory script to ISO 9186 protocol. Actions depicted in [gray]

### 2.7. Procedures

**Table 2.4** describes the study procedures. In an important update as per version 2.0, participants will be now recruited by phone in addition to in-person at the outpatient clinic or inpatient unit. Recruitment by phone will be used when necessary to comply with local COVID restrictions. We will rigidly adhere to local restrictions to prevent unnecessary coronavirus infections in this vulnerable patient population.

| Procedure   | Description                                                                 |
|-------------|-----------------------------------------------------------------------------|
| Prescreening | Patient is prescreened for eligibility and invited to participate by their cardiologist |
| Consent     | Participant provides verbal informed consent (by phone) or written informed consent (in-person) |
| Baseline    | Participant completes baseline questionnaire and health literacy screening |
| Allocation  | Participant assigned to either the abbreviation group (control) or expansion group (intervention) |
| Assessment  | Objective comprehension is assessed as per the ISO 9186 protocol |

### 2.8. Adherence to Guidelines

This study will be performed in accordance with World Medical Association Declaration of Helsinki. The Weill Cornell Medicine Institutional Review Board has approved the trial and all participants will provide informed consent. We will conduct and report this trial in accordance with CONSORT.56

Notably, this trial was not classified as a clinical trial under the NIH definition at the time it was funded, so it was not registered prospectively. However, the journal has asked that it be registered retrospectively as they have determined this study to meet the ICMJE definition of a clinical trial. Accordingly, the trial has been retrospectively registered with ClinicalTrials.gov (NCT05297942).
3. Statistical Analysis

3.1. Data Management

The coordinator will enter baseline data and outcome data electronically into REDCap at the time of collection. The coordinators will be trained in the ISO 9186 protocol and a pre-standardized REDCap survey will be used throughout to ensure that data collection is standardized. Data transfer between REDCap and computers for statistical analysis will be HIPAA-compliant and the data will be stored in a secure server environment.

3.2. Sample Size Calculation

Based on the clinician ratings, the estimated comprehension of expansions is 89% and the estimated comprehension of abbreviations is 56%. Therefore, we have anticipated a comprehension rate of 89% for the intervention and 56% for the control group. Our planned sample size of 60 patients will provide 80% power to detect this 33 percentage point difference in our primary outcome at the 5% significance level. We will stop recruitment once 60 participants have completed the trial.

3.3. Main Analysis

We will use a two-sided unequal variances t-test with a significance threshold of $P<0.05$ to analyze differences in overall comprehension (primary outcome) between study groups based on a summary (count) score of the total number of abbreviated or expanded terms comprehended by the patient. Fisher’s exact test of independence with a significance threshold of $P<0.05$ will be used to examine differences between abbreviated and expanded versions of each individual term. Uncertainty will be estimated using standard 95% confidence intervals.

We will conduct bivariate analyses to assess whether baseline characteristics differ by group. Nominal variables will be compared using Fisher’s exact tests, while ordinal and numerical variables will be compared using Wilcoxon rank-sum tests. Participants will be analyzed according to their original allocation. One goal of the study design is to avoid missing data, and we do not anticipate having missing data. However, in the event of missing data, we will use multiple imputation methods. Analyses will be performed in R Version 3.6.3.57

3.4. Subgroup Analysis

We will conduct a subgroup analysis of control group participants to assess potential predictors of objective comprehension of abbreviations. First, correlation (for numerical baseline variables) and t-test or ANOVA (for categorical baseline variables) will be used to determine relationships between individual baseline characteristics and summary (count) scores for the total number of abbreviations comprehended. Based on this preliminary analysis, multiple Poisson regression models may be used to predict summary comprehension scores using selected baseline characteristics ($P<0.15$ in the bivariate analyses).
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