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PROTOCOL

Title: ContextCare: A randomized pilot trial of AI-simplified discharge summaries to improve patient comprehension

Short Title: ContextCare

Authors:

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1.0 Background

Timely and accurate discharge communication is critical for continuity of care, yet all too often discharged patients leave the hospital unable to explain their diagnosis, treatment, or follow-up plan. This gap contributes greatly to missed appointments and increased hospital readmission rates. According to Medicare, the United States national health insurance program, 15% of patients discharged from the hospital are readmitted within 30 days, of which 1 in 4 of those readmissions is potentially preventable [1]. Challenges in the discharge process extend beyond individual patient outcomes and strain the healthcare system as a whole, with unplanned readmissions costing an estimated $20 billion annually in the United States [1]. Additionally, the gap in discharge communication has led to increased drug adverse reactions and medication reconciliation errors, especially for high-risk populations. For example, older adults are one population at an increased risk for drug-related problems (DRPs), including inappropriate prescribing, poor adherence, and adverse drug reactions due to poor discharge communication, with DRPs accounting for 9–15% of hospitalisations [2]. A study by Parekh et al. reported that 37% of older patients experienced a DRP within eight weeks of discharge, with roughly half potentially preventable [2].

A major determinant to this discontinuity in healthcare is the lack of patient adherence to discharge summaries provided by their physician. Discharge summaries are required to include relevant physician identification, reason(s) for admission, diagnosis or diagnoses at time of discharge, and a summary of the treatment(s) received [3]. Discharge summaries, however, lack consistency amongst physicians in their layout, the material included, and overall thoroughness [4]. The delivery of discharge information is commonly rushed and overwhelming, creating difficulties in patient retention and understanding. This issue disproportionately affects individuals with limited health literacy skills or those facing societal barriers to care [5–7].

Health literacy directly correlates to patient comprehension and adherence of discharge summaries [8]. Fundamentally, health literacy is defined by a patient’s ability to understand and apply health information, and it is estimated that approximately 60% of adults and 88% of seniors in Canada struggle with understanding, evaluating, communicating, and using health information [9]. In conjunction with low health literacy, many patients report leaving the hospital without fully understanding their discharge instructions or feeling confident in managing their care at home. Discharge materials are often written using complex medical terminology and may not be tailored to patients' health literacy needs, reducing comprehension, engagement, and adherence to recommended care [10]. Digital applications to deliver simplified instructions to patients do currently exist and assist patients in understanding their healthcare journey. However, a novel approach is the use of a clinician-facing platform that leverages artificial intelligence (AI) to generate personalized, plain-language discharge summaries tailored to patients' clinical information and health literacy needs. This study aims to describe the development and testing of ContextCare, an application that delivers AI-simplified discharge summaries intended to increase patient comprehension.

We hypothesize that patients who receive simplified, and personalized discharge summaries via AI will demonstrate higher comprehension, as measured by the teach-back method, compared to those who receive standard discharge summaries. This is because standard discharge summaries often use complex medical language that can be difficult for patients with low health literacy or

language barriers to understand. We aim to assess the baseline health literacy levels of participants using ContextCare compared to the standard of care that consists of verbal and printed instructions.

2.0 Objectives

Primary Objective:

1. To evaluate whether AI-simplified discharge summaries generated by the ContextCare platform improve patient comprehension of discharge instructions compared to standard discharge care, as measured by the teach-back method.

Secondary Objectives:

1. To assess feasibility of implementing ContextCare within routine discharge workflows.
2. To assess baseline health literacy levels of participants using the Newest Vital Sign (NVS) tool.
3. To evaluate patient satisfaction with discharge communication.

3.0 Methods

3.1 Study Design

The project implementation comprises three stages:

Stage 1

A minimum viable product (MVP) will be developed, integrating a combination of traditional and artificial intelligence for natural language processing (NLP). The deliberate use of an AI-assisted coding platform allows for content experts to be empowered to directly code the application. The prototype accepts unaltered, unformatted discharge summaries and creates simplified, documents and multimedia content.

Stage 2

Before the randomized trial, the study team will conduct a pre-study pilot on approximately 10 patients to test workflow feasibility and application functionality in the real-world discharge environment. During this phase, research staff will identify eligible patients, access discharge summaries, de-identify the discharge content, and process the summaries through ContextCare. The generated ContextCare summaries will be reviewed by the study team for internal testing purposes only and will not be released to patients or used in clinical care. Patients will continue to receive standard discharge summaries. Data from this phase will be used only to evaluate workflow feasibility, technical performance, and operational issues, and will not be included in the primary trial analysis.

Stage 3

Following successful completion of the pre-study pilot, a randomized pilot study will be conducted to evaluate the app's effectiveness. Participants include adult patients discharged from Scarborough Health Network (SHN). The control group will receive discharge summaries and the intervention group which receives simplified discharge summaries via the ContextCare app. Patient health literacy will be assessed using Newest Vital Sign (NVS) and Brief Health Literacy Screen (BHLS). Primary outcomes will include comprehension measured via teach-back method, and patient satisfaction. Secondary outcomes include medication adherence, hospital readmission rates, and follow-up appointment attendance.

This study will be conducted as a prospective, randomized controlled trial (RCT) to evaluate the impact of the ContextCare AI-assisted discharge simplification tool on patient comprehension, recall, and health outcomes.

Data will be collected in three phases:

Phase 1: Pre-discharge health literacy assessment (Newest Vital Sign, NVS)

- A nutrition label is shown to patients accompanied by 6 questions [11].
    - A score > 4 indicates low health literacy
    - A score < 4 indicates high health literacy
- 0–1 = high likelihood of limited literacy
- 2–3 = possibility of limited literacy
- 4–6 = adequate literacy

Phase 2: Post-discharge comprehension between the experimental and control group will be assessed with the teach-back method in a semi-structured interview and time required to explain the discharge summaries will be recorded

- Control Group: Standard discharge process (verbal and printed summary from hospital staff)
- Experimental Group: ContextCare AI-assisted discharge process, which includes upload of original summary (PDF), automatic simplification using OpenAI API, (e.g., audio in patient language), and output in preferred format (text or audio)

Phase 3: Patient satisfaction with clarity, and usability (5-Point Likert Scale)

3.2 Participant Characteristics

Inclusion Criteria:

- age ≥18 years,
- medically stable for discharge,
- Has a completed discharge summary available,
- Independently able to participate in consent,
- able to understand the consent form in English,

Exclusion Criteria:

- Age <18 years;
- Medically unstable or acute illness preventing discharge;
- Has a Legally Authorized Representative (LAR)/Substitute Decision Maker (SDM) for diseases including but not limited to: impaired vision and/or hearing, impaired speech;
- Discharge summary unavailable at time of discharge.

Patients will be selected consecutively under standard discharge conditions, ensuring representation across a typical general medicine population. No restrictions will be placed on cultural and linguistic background or first language, as the study aims to evaluate the adaptability of the ContextCare platform across diverse patient profiles.

3.3 Health Literacy, Discharge Summary, Teach-Back Method

Health Literacy

Health literacy is defined as an individual's ability to access, understand, and use health information to make informed health decisions [12]. In this study, health literacy will be assessed using the Newest Vital Sign (NVS), a validated tool that evaluates literacy and numeracy based on a nutrition label and six associated questions. For later analysis, patient subgroups will be recorded. They will be assigned into low and adequate health literacy groups based on their NVS scores, using established cutoffs (0–1 = high likelihood of limited literacy, 2–3 = possibility of limited literacy, 4–6 = adequate literacy) [13].

Discharge Summary
A discharge summary is the formal document provided to patients upon hospital discharge that summarizes their diagnosis, treatments received, medications prescribed, blood test results, follow-up instructions, and return-to-care guidelines. In this study, patients will receive either a standard hospital discharge summary, or an AI-simplified summary generated by ContextCare, which adapts content based on the patient's language, and preferred information format.

Teach-Back Method
The teach-back method is an evidence-based technique used to assess a patient's understanding of medical and discharge information [14]. It evaluates patients' recall and verifies their understanding of discharge instructions by asking them to repeat their care plan in their own words [14]. A key benefit of this method is that healthcare providers can identify and correct inaccurate information or misinterpretations in real time [14].

A 2020 study by Mahajan et al. aimed to determine the direct and short-term impact of the teach-back method as well as feasibility for routine use in the Emergency Department (ED) [15]. The results demonstrated that teach-back can improve patient recall and comprehension of discharge information in all domains (diagnosis, treatment, follow-up care, return instructions) directly following ED discharge [14]. Nearly half of patients in the control group had incomplete comprehension after standard discharge, compared to one tenth of the patients after teach-back in the intervention group.

Similar to Mahajan et al., patients in this study will be asked to recall and explain, in their own words, key aspects of their discharge information across four domains: diagnosis, treatment plan, follow-up care, and return instructions. Each response will be scored using a 4-point comprehension scale (1 = none, 4 = complete), for a maximum possible score of 16. All participants will receive discharge information under one condition only (either standard or AI-simplified) depending on their randomized group assignment (1:1 ratio). This between-subjects design, stratified by literacy level, allows for comparison of effectiveness across both content type (standard vs. AI) and patient profile (low vs. high literacy).

3.4 ContextCare Intervention
Participants in the intervention group will receive their discharge summary simplified by the ContextCare app. The platform automatically:

- Extracts information from uploaded PDF discharge summaries
- Simplifies medical jargon using large language models (LLMs).
- Tailors output by language, and preferred explanation format.
- Structures content under clear headers: Your Care Plan, Your Medications, Follow-up Appointments, When to Seek Help.
- Outputs summaries with optional audio.
- Includes an interactive chat box for follow-up questions about the discharge summary.
- Prompt Engineering: *"You are a health communication assistant for a culturally diverse hospital. Your job is to simplify discharge summaries for patients in plain, clear language, tailored to their preferred language and format of information."* May be subject to change.

- Demographic data and clinical information in the app (age, sex, diagnosis, treatment plan) will be collected from discharge summaries and electronic health records (EHR) and language preference, and preferred information format will be collected through patient selection in the app.

All patients will undergo a teach-back session immediately after discharge instructions are given. Trained research assistants will prompt patients to recall information from each domain and assign scores accordingly.

3.5 Video Recording of Interaction

As part of this study, the discharge interaction and teach-back assessment may be video recorded. The recording will capture the interaction between the participant and the research assistant and may include the participant's voice and image. Video recordings will be used solely for research purposes:

- It will support evaluation of participant teach-back responses by trained evaluators.
- Improve consistency and reduce bias in scoring by allowing evaluators to independently review and assess teach-back responses while remaining blinded to the participant's study group assignment.
- Participation in video recording will be explained during the informed consent process.
- Video recordings will not be used for any purpose outside of this study. Additional information regarding the storage, confidentiality, and handling of video recordings is provided in Section 6.0 (Ethical Considerations).

4.0 Outcome Measures

The **primary outcome** of this study is patient comprehension of discharge instructions, assessed using the teach-back method.

Comprehension will be evaluated using a structured questionnaire across four domains:

- Diagnosis: “What was the medical explanation for your complaints?”
- Treatment: “What is the treatment?”
- Follow-up: “What are the follow-up appointments?”
- Return Instructions: “Which symptoms are a reason for you to revisit a doctor?”

Each domain will be scored on a 4-point scale:

- 1 = none
- 2 = minimal
- 3 = partial
- 4 = complete comprehension

The total comprehension score will range from 4 to 16, with higher scores indicating better understanding.

Secondary outcomes include:

1. Health Literacy
    a. Assessed at baseline using the Newest Vital Sign (NVS) tool
    b. Used to evaluate its association with comprehension outcomes
2. Patient Satisfaction
    a. Measured immediately after the teach-back assessment using a 5-point Likert scale:
    b. “How clear and helpful was the discharge information you received?”
        i. 1 = Not at all clear
        ii. 2 = Slightly clear
        iii. 3 = Somewhat clear
        iv. 4 = Mostly clear
        v. 5 = Extremely clear
3. Post-Discharge Recall
    a. Assessed within 24–48 hours via follow-up phone call or in-person check
4. Clinical Outcomes
    a. Hospital readmission within 30 days
    b. Follow-up appointment attendance
    c. Self-reported medication adherence

5.0 Statistical Analysis

5.1 Quantitative Data

Stage 1 and Stage 2
Descriptive statistics will be reported for the pre-study pilot.

Stage 3
Descriptive statistics will be used to report baseline demographics and health literacy levels of the participants. SPSS and/or R will be used.

The total comprehension based on the teach-back method assessment will be calculated. A one-way analysis of variance (ANOVA) will be performed to identify whether the control group's comprehension of the discharge summaries differs from the experimental group. To determine whether the effect of ContextCare on comprehension interacts with health literacy levels, a two-way ANOVA will be performed. The two factors to be used are the intervention groups (traditional vs ContextCare discharge process) and health literacy levels (low or high).

A sample size of 52 was calculated using G*Power [15,16] for a two-tailed one-way ANOVA with effect size f of 0.4, power of 0.8, and 0.05 alpha. Similarly, a sample size of 52 was calculated for a two-tailed two-way ANOVA with the same input parameters and a numerator degree of freedom of 1.

If the assumptions for the one-way ANOVA are violated, a Mann-Whitney U test will be performed. If the assumptions for the two-way ANOVA are violated, separate one-way ANOVAs may be performed on the factors mentioned above. Other non-parametric tests may be considered if appropriate.

5.2 Qualitative Data

Thematic analysis described by Braun and Clarke [17] will be used to analyze and report qualitative data. Two members of the team will independently review semi-structured interview responses to elucidate themes that arise from subjective or qualitative feedback.

6.0 Ethical Considerations

Strict ethical standards will be upheld throughout the study to ensure participant privacy and confidentiality. Prior to any information being processed through the ContextCare platform, all discharge summaries assigned to the intervention group will undergo a multi-stage de-identification process. First, protected health information (PHI) will be de-identified using Scarborough Health Network's (SHN) locally hosted web review interface, which incorporates the nophi PII/PHI redaction engine. This command-line tool detects and removes protected health information according to the 18 HIPAA Safe Harbor identifiers and provides verification that all identifiable information has been removed before further processing.

Following the initial de-identification, the discharge summary will undergo a second de-identification stage within the ContextCare platform using Microsoft Presidio, an open-source software development kit (SDK) designed to detect and anonymize personally identifiable information (PII) in text, images, and structured data. This second screening serves as an additional safeguard by identifying any remaining identifiers not captured during the initial redaction process. Only after both stages confirm that no protected health information remains will the de-identified discharge summary be transmitted to the OpenAI API for simplification. OpenAI's API will be used solely to simplify the readability of discharge summaries within a closed-loop platform and will not receive identifiable patient information.

Research data, including participant study ID, language preference, randomized group assignment, health literacy scores, teach-back comprehension scores, and patient satisfaction responses, will be stored separately in a secure, access-restricted Google Sheets database accessible only to authorized members of the research team. The ContextCare platform will not permanently store simplified discharge summaries or de-identified discharge text. All de-identified information processed by the platform will be irrecoverable following completion of each study session, with the exception of the printed discharge summary (standard or simplified) provided directly to the participant. The ContextCare platform will only process discharge summaries for participants randomized to the intervention group; discharge summaries from participants assigned to the control group will not be uploaded into the platform.

A Master Linking Log (MLL) connecting participant identities with study IDs will be maintained separately by the Principal Investigator in a secure, access-restricted location for study administration purposes (e.g., participant withdrawal). This file will not be used for data analysis. Study data will be used solely for the purposes outlined in this protocol and will not be used for secondary analyses or future research.

As part of this study, the discharge interaction and teach-back assessment may be video recorded following written informed consent. These recordings may include the participant's voice and image and will be used solely for research purposes to support standardized evaluation of teach-back responses and improve consistency of scoring by trained evaluators who are blinded to participant group assignment. Video recordings will be stored securely on password-protected institutional servers with access restricted to authorized members of the research team. The recordings will not be used for educational, promotional, or any other secondary purposes and

will be retained and securely destroyed in accordance with Scarborough Health Network's data retention policies.

Additionally, equitable access to the application for those facing technological barriers will be explored through possible partnerships with community health centres where mobile devices with the app pre-downloaded will be made available to patients. The application also allows users to customize how they want their information to be delivered (audio, visual, different language, etc.), ensuring simple app navigation for all patients.

7.0 References

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