Novel Text-Message Interventions to Improve Surgical Outcomes

Introduction

Problem & Scope

Post-operative follow up with patients is critical to providing high quality and cost effective care. Nationally, 5.7% of 498,875 operations resulted in preventable 30-day readmission due to poor follow-up care, commonly resulting in surgical site infection (SSI)[1,2]. Specifically, Medicare data from 2015 indicates that Grady Memorial Hospital drastically underperformed both national and Georgia standards in regards to 30-day readmissions (16.7%), serious post-operative complications, and quality of post-discharge care[3,4]. Overall, 20% of Medicare patients are readmitted within 30 days, but 75% of these readmissions are preventable with better care transitions and follow-up[5,6].

The current standard of care includes patients receiving verbal instructions from a physician and a stack of papers with post-discharge protocols. Patients often leave confused, resulting in high 30-day readmission rates and poor patient care post-discharge. They're paying higher healthcare costs, missing work every time they're readmitted, and living with the very real fear that they won't get help in time from our healthcare system when they need it most.

More importantly, even outside the transitional period, self-caring for complex illness can be difficult and isolating, and sustainable methods to supplement care outside of the hospital have been hard to come by. Furthermore, the information required to identify high-risk patients is hard to find in their medical records and following-up with those patients requires significant time, resources, and personnel. Grady Memorial Hospital currently has no automated or systematic mechanism for following up with patients, largely contributing to their underperformance in most recent CMS ratings.

Medication adherence represents a crucial area for follow-up, as it is a major determinant of high-quality outcomes for post-operative care. Over 50% of patients in the U.S. either forget to or don't correctly take their prescription medications. Non-adherence causes nearly 10% of all hospital admissions in the U.S. and 125,000 annual deaths, at a total cost of $290 billion per year[7]. In hospital unit economics, that's an additional $2000 per-patient spent in excess physician visits per year[8]. Specifically in the context of surgical care, studies indicate that poor medication adherence accounts for nearly one-third of post-operative complications, warranting intervention[9].

Among patients, forgetfulness is the most frequently reported reason for non-adherence. In a survey of 10,000 patients, the most common reported reason for missing medications was forgetfulness (24%), followed by perceived side effects (20%), high drug costs (17%), and perception that a prescribed medication would have little effect on their disease (14%). The majority of the factors contributing to non-adherence could therefore be resolved by longitudinally addressing forgetfulness and misconceptions about medication effectiveness, options for treatment, and side effects[10]. Status quo efforts to improve adherence include patient education counseling by pharmacists and involving family members in patient care, neither of which have demonstrated an impactful reduction in short-term hospital readmissions[11].

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[10] Boskovic, Jelena, et al. "Patient self-reported adherence for the most common chronic medication therapy." *Scandinavian journal of public health* 41.4 (2013): 333-335.

[11] Sarangarm, Preeyaporn, et al. "Impact of Pharmacist Discharge Medication Therapy Counseling and Disease State Education Pharmacist Assisting at Routine Medical Discharge (Project PhARMD)." *American Journal of Medical Quality* 28.4 (2013): 292-300.

Specific Aims

We propose using Memora Health, a platform that leverages mobile messaging as a medium for advancing preventive care, to improve the quality of post-operative care delivered to patients and subsequently improved quality of life and patient satisfaction scores. Our goals and **concrete metrics for success** include:

1. We hypothesize the use of SMS-based condition-specific surveys prompting patients to provide pain scores and pictures of their surgical sites to help increase early detection of surgical site infection (SSI). This can be assessed qualitatively based on physician surveys and quantitatively by identifying the number of cases in which preemptive intervention takes place.
2. We hypothesize that the use of personalized, SMS-based medication reminders will improve overall medication adherence for patients. This will be quantitatively measured using responses to adherence reminders and qualitatively measured using an abridged version of the Morisky Medication Adherence Scale (MMAS-4)[12].
3. We hypothesize that access to an interactive SMS platform will improve both quality of care, by providing increased patient confidence in self-management of their condition, and patient satisfaction. This data is collected using pre- and post-study surveys that includes questions from the Care Transitions Measure (CTM-5)[13], Surgical Care Survey[14], and a modified version of the RAND-36 Health Related Quality of Life (HRQoL) survey[15].

Patient Reported Outcome Measures (PROMs) represent a literature-validated mechanism that allow our team to quantify data including medication adherence and patient satisfaction while providing information to clinicians that allows them to minimize confounding factors. Rather than using the full question sets for each survey, we've elected to take relevant questions from each and merge them into a custom survey that allow us to collect data regarding patient care as well as data our team can use for internal quality improvement purposes.

Our primary endpoints, which we hope to address through this study, include medication adherence and patient satisfaction scores with intervention and overall care. Secondary endpoints, for which trends can be ascertained from this study and reinforced by a complementary phase II study, include assessments of patient self-management and 30-day readmissions related to the condition they're being tracked for.

Methodology

Memora Health is a communications and analytics platform that allows providers to automate text messages to patients, including post-discharge checklists, time-sensitive medication reminders, and responsive medication information. Patients receive automated medication reminders and condition-specific surveys (i.e. pain scale, surgical site irritation, bleeding, etc.) while also having the ability to text in questions about their medications, discharge protocols, or condition. Questions that a patient may text in are automatically handled by a natural language processing engine, providing them with immediate and specific responses. All messaging content is handcrafted using principles of cognitive heuristics, while remaining below 8th-grade Flesch-Kincaid reading level for patient accessibility across the socioeconomic spectrum. The surgical staff at Grady Memorial Hospital will review all messaging content prior to patient enrollment.

While the platform is entirely SMS-facing for patients, physicians see a comprehensive patient analytics dashboard to assess patient progress over time. Physicians can track metrics, such as pain level, redness, etc., over time, examine medication adherence trends, and look at patient messaging history. The platform also has a risk assessment algorithm built in which uses a combination of a patient's text messages indicating symptoms or concerns they may have and automatically emails an alert to a physician if it seems as if the patient may be at risk, prompting the physician to check in with the patient. This is intended towards improving preemptive identification of SSI and is geared towards the secondary endpoint of reducing the preventable readmission rate identified above.

Specifically, the research team has had a chance to use the Memora Health platform with other patient populations and has found successful data thus far. Pilot data has been collected from over 100 users and the platform is on track to be exposed to over 1,000 patients and 250 clinicians through the development process and phase I studies with other departments. To date, we've had a chance to work with NYP-Cornell Emergency Medicine, Brigham & Women's Hospital Diabetes, BWH Pain Management, and BWH Neurology. The data collected thus far indicates:
- Greater than 83% of users find care management advice useful to help manage their respective conditions

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[13] "Care Coordination Measures Atlas Update." *Agency for Healthcare Research & Quality*. U.S. HHS: Agency for Healthcare Research and Quality.
[14] "Surgical Care Survey." *Agency for Healthcare Research & Quality*. U.S. HHS: Agency for Healthcare Research and Quality.
[15] Hays, R. D. "Measure of Health-Related Quality of Life." *RAND-36*. RAND.

- 100% of users find the content easy to read and understand
- 100% of patients were comfortable with the frequency of messages they received
- 100% of patients appreciated the interactive capability that we've built using a natural language processing engine
- Over 71% of patients stated they felt comfortable discussing health information with our SMS content due to the fact that the content we send is humanized

Expanding the scope of this data to encompass post-operative care would allow for platform validation in a high-impact use case and provide data on a condition for which SMS-based follow-up is yet to be tested.

Impact on Healthcare Delivery

SMS messaging has shown a significant positive impact on fostering desired behavior change among patients. A 2016 meta-analysis of academic studies pooling over 2700 patients showed that SMS reminders nearly doubled both short- and long-term medication adherence and patient motivation in various acute and chronic diseases, including Type II Diabetes[16], cardiovascular disease[17], HIV[18], and schizophrenia[19], across the socioeconomic spectrum. Additionally, SMS reminders significantly improved patient satisfaction, with more than 93% of patients finding messages 'very helpful' in regards to improving their adherence, 90% claiming they would like to continue receiving messages, and 92% mentioning that they would recommend SMS-based interventions to family and friends[20]. This data eases concerns about patient alert fatigue. This study aims to function as a proof of concept study for post-operative follow-up via SMS, something that is yet to be tested. Our team believes that while existing data is promising, post-operative follow-up represents a much higher risk use case and corresponding data could have much greater implications, warranting this study.

Communities traditionally underserved in healthcare can be most effectively reached via mobile technology. In 2013, mobile phone penetration had been estimated at 86% among American households earning less than $30,000 per year, 93% of which regularly send text messages[21]. In the same demographic, only 59% have access to a desktop or laptop, while just 47% have broadband at home, validating SMS as the best method for automated interventions[22].

SMS is the ideal delivery mechanism for two reasons: 1) universal mobile reach, we can reach populations that don't have smartphones yet, and 2) the highest-risk patients don't keep fitness apps on their home screens, but their messaging icon is almost always front and center. Additionally, these SMS interventions have a 98% read rate, better than any smartphone app on the market[21].

Mobile text communication can be a subtle, cost-efficient, and effective way to engage patients in desired behavioral changes to improve appointment attendance, medication adherence, and self-care management of disease. As the healthcare system transitions to a focus on improving health outcomes, engaging patients in the management of their health is critical. SMS text messaging is a low-cost way to facilitate engagement and enhance the health literacy of individuals living with chronic conditions and other health challenges.

Our vision is an improved infrastructure across care delivery through a centralized platform that allows the most innovative medications and care strategies to be as effective and accessible as they can be, and providing each and every patient with the health literacy and care support that they deserve.

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[16] Vervloet, Marcia, et al. "SMS reminders improve adherence to oral medication in type 2 diabetes patients who are real time electronically monitored." *International journal of medical informatics* 81.9 (2012): 594-604.
[17] Patel, Samir, et al. "Mobilizing your medications: an automated medication reminder application for mobile phones and hypertension medication adherence in a high-risk urban population." *Journal of diabetes science and technology* 7.3 (2013): 630-639.
[18] Horvath, Tara, et al. "Mobile phone text messaging for promoting adherence to antiretroviral therapy in patients with HIV infection." *The Cochrane Library* (2012).
[19] Montes, Jose Manuel, et al. "A short message service (SMS)-based strategy for enhancing adherence to antipsychotic medication in schizophrenia." *Psychiatry research* 200.2 (2012): 89-95.
[20] Huang, Hsiu-Ling, et al. "Effects of and satisfaction with short message service reminders for patient medication adherence: A randomized controlled study." *BMC medical informatics and decision making* 13.1 (2013): 127.
[21] Duggan, M. "*Cell phone activities 2013".* Pew Research Center. September 2013. http://www.pewinternet.org/2013/09/19/cell-phone-activities-2013/.
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Study Details

Grady Memorial Hospital experiences a high influx of patients in the surgical department, making it difficult for physicians and nurses to allocate adequate time to each post-discharge follow-up. Using Memora Health, this study aims to use text messaging as a platform for automating this, improving medication adherence, follow-up care, and patient satisfaction. This pilot will:

1. Enroll **200 patients** into a randomized controlled trial.
2. Prove that the Memora Health platform's post-discharge text message reminders **improve medication adherence, preemptive identification of SSI, and patient satisfaction scores**.
3. **Engage patients** with personalized post-operative care management advice and assess provider/patient user experience

We aim to conduct a randomized controlled trial with 200 patients where 50% of the total patient population receives text-message based follow-up in regards to medication adherence, side effects, and general post-op survey questions while 50% of the population is maintained with standard of care (control). This allows for determination of statistical significance (n > 30 in each group) in confirming effectiveness of the platform as per the metrics defined above. Random assortment of n>30 patients per group allows for us to assume that the study population is representative of the population that stands to potentially benefit from this research. Accounting for approximately a 50% attrition rate during the course of the study, we hope to gather at least 100 complete data sets to assess our primary endpoints. While the sample size is likely not sufficiently powered to detect small changes in readmissions over 30 days or self-management improvements, trends can nevertheless be ascertained.

The simplicity of our approach - using text messaging to reach patients - allows our platform to reach **patients of all socioeconomic strata** that visit Grady. Nearly 90% of the US population has cellphones and 80% regularly send text messages, facilitating large-scale patient adoption. Prompting patients to give simple 'Yes/No' responses to adherence reminders and 'A/B/C' or '1-10' responses to surveys minimizes barriers to adoption & maximizes engagement. A platform this accessible and simplistic for patient use is yet to be used for post-operative follow-up, making this a pioneer study for mHealth interventions in surgical care. Sample screenshots demonstrating the various features of the platform can be found here: https://www.dropbox.com/sh/gvwuaw81flwal2o/AACgEKy0vF7vzONzedWm25sya?dl=0

Preliminary inclusion criteria include the patient being above 18 years of age, having a working camera-enabled cell phone that can send and receive SMS and MMS over the next three months, being able to read and write fluently in English, and being discharged with a prescription of an antibiotic or short-term steroid. Preliminary exclusion criteria include the patient being deceased prior to discharge, transferred to another hospital, has occupancy in a nursing home, has a terminal illness with less than 6-month expected survival. Specific inclusion and exclusion criteria regarding comorbid conditions and restrictions based on types of surgery will be determined upon greater discussion between the faculty advisor, care coordination team at Grady, and research team.

The **implementation of the pilot** involves enrollment of patients who are being discharged in the next 7 days and abide by inclusion and exclusion criteria. Once a patient confirms that they would like to join the messaging intervention, they will be randomly assigned to a group and the following information will be collected: name, medication, dosing regimen, phone number, and condition. A tablet will be used to collect this data and signatures on consent forms. Both control and test group will receive a monthly questionnaire via SMS to assess self-care management as well as patient satisfaction with the intervention, and with their overall care. Both control and test group will also be tracked via EHR to determine relevant re-presentation data, and medication adherence data will be taken from the physician-facing dashboard of the Memora Health platform.

Test group patients will receive medication reminders as per the prescribed frequency and receive condition-specific surveys once a week. Patients will have the opportunity to respond to all surveys and reminders for up to 2 hours, after which point their response would be nullified to avoid skew. This data will be instantly uploaded to the aforementioned physician portal, which can be viewed in real time by any of member of the research team. If a patient is non-responsive for greater than 48 hours, they will automatically receive a message asking if they're doing okay to assure that any adverse event is captured by the platform. If a patient ever texts in a concerning statement regarding their condition, they're immediately given appropriate instructions and notified to contact the on-call physician or nurse. Additionally, the physician receives an immediate email alert indicating the patient may be at risk of an adverse event, prompting preemptive intervention.

The **pilot timeframe is 1 year**: 3 months for IRB approval and server registration with Grady IT; 8 months for patient enrollment; 1 months for post-study data analysis and mining to compute readmission rates, statistical significance, and medication adherence levels. In 2015, Grady physicians performed 10,122 studies[23]. Accounting for inclusion/exclusion criteria and the 8-month period allocated to patient enrollment, approximately 3,000 patients would be eligible for enrollment. Accounting for a patient acceptance rate of 25% for study enrollment, the research assistant will have to approach approximately 800 of these patients (~25%), which is feasible over an 8-month period, given the nature of this intervention. The research team has already started drafting an early version of the IRB and looks to get it expedited, making it feasible to have it approved within the 3-month period. Server registration is a short process and can be accomplished in under 2 weeks, based on experience of doing so at NewYork-Presbyterian.

The PI and faculty advisor will work together for completion of IRB approval and assuring deadlines are met. While this represents an ambitious timeframe, the experience of the research team in writing IRBs and conducting similar studies with the Memora Health platform beforehand has us confident in this timeline.

Challenges during rollout and implementation include patient enrollment and long-term engagement. While a patient may enroll, it's expected several will stop responding over the course of the trial. Attempting to provide as much targeted advice as possible and sending engaging content aims to mitigate this. Additionally, aiming to enroll 200 patients accounts for patient drop-off and still assures that a strong sample size of data is collected to evaluate primary endpoints and begin formulating hypotheses regarding secondary endpoints. Another challenge pertains to patients at Grady switching phone numbers due to prepaid lines. Maintaining consistent communication with patients and directly contacting them after 48 hours of non-responsiveness, as mentioned above, helps to mitigate this. The last burden involves collection of relevant patient data from the EHR for post-study data analysis. By having members on the research team who are employed at Grady and working with the full surgical team helps assure that the correct data is found and extracted in a timely manner. Additionally, we look to work with the Grady IT team to assist with the post-study data mining process.

<u>**Anticipated Results**</u>

Aim 1: We hypothesize the use of text-message follow-ups for patient reported signs and symptoms of surgical site infection (SSI) would result in earlier detection and intervention of the most common surgical complications resulting in unplanned 30-day readmission. We hypothesize that SMS-based follow-up will **improve early detection of SSI by 10%,** consistent with literature values for alternative remote care management interventions. We hope that this indirectly results in an absolute reduction in readmissions of 1%. While this readmissions reduction is difficult to validate given the sample size, we hope to collect preliminary data to warrant a larger scale phase II study to examine this secondary endpoint.

Aim 2: We hypothesize the use of text-message medication reminders will help increase medication adherence and indirectly reduce the risk of post-operative complications. We hypothesize that SMS-based medication reminders will be validated as a tool to **increase medication adherence with statistical significance** as validated by MMAS-8 and patient reported adherence data.

Aim 3: We hypothesize that the use of personalized SMS content will improve the patient experience and reduce loss to follow up. Current rates of loss to follow up are nearly 35% in our test clinic. We hypothesize SMS reminders will **reduce loss to follow up by 5% and increase patient satisfaction scores with statistical significance** as validated by the CTM-5 and HRQoL.

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[23] "Grady Memorial Hospital." *Healthcare Rankings*. U.S. News & World Report