Effect of Personalized Care Management Program on Hospital Inpatient Stays among High Utilizers: A Randomized Clinical Trial

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The study will be conducted in compliance with the protocol, ICH-GCP and any applicable regulatory requirements.

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PROTOCOL SUMMARY	
Study Title	**Effect of Personalized Care Management on Hospital Inpatient Stays among High Utilizers: A Randomized Clinical Trial**
Study Design	Parallel group randomized controlled trial evaluating inpatient encounters
Study Objectives	The Multiple Visit Patient (MVP) program was rolled out to the first cohort of 600 patients in January 2019, and 46 additional patients were added in August 2019. Pre-post descriptive results show that the 2019 MVP cohort had 50% lower inpatient hospital admissions in 2019 than in 2018. While this is a promising outcome, without a randomized controlled trial (RCT) causal inferences cannot be made about the effect of the MVP program. Regression to the mean is a competing potential reason for observing the rate decrease, with high utilizers having lower hospital use over time even in the absence of any interventions. Thus, the Population Health leadership seeks to conduct a definitive trial to rigorously evaluate the MVP program effectiveness. Primary Objective: To evaluate the effectiveness of enrollment in the MVP care management program compared to usual care on reducing 12-month total inpatient hospital utilization among patients with high past volume of hospital inpatient stays. The Secondary Objectives are to (1) evaluate the effect(s) of participation in the MVP program on: • 6-month inpatient hospital utilization • 6-month and 12-month Combined IP and OBS hospital stays at Atrium Health facilities • 6-month and 12-month Combined IP and OBS hospital stays at AH and other facilities • 6-month and 12-month IP hospital stays that are readmission eligible (using CMS criteria) • 6-month and 12-month Readmissions • 6-month and 12-month ED visits • 6-month and 12-month Mortality • 6-month and 12-month Hospital bed days (length of stay, IP) • 6-month and 12-month Hospital charges (2) assess variability in MVP program treatment effects associated with predefined patient and program factors, including: ▪ insurance status ▪ age, gender, race and ethnicity ▪ English as second language ▪ type of program (e.g., ACM, etc.) ▪ community characteristics ▪ clinical characteristics (e.g., CCI)

	The exploratory analysis aims are to evaluate the effect of participation in the MVP program features on • 6-month and 12-month primary care visits scheduled and attended / no show to a scheduled appointment • 6-month and 12-month Healthy Days at Home • 6-month and 12-month paid amount for the Medicare patient subgroup

Inclusion / Exclusion Criteria	**Inclusion criteria:**
	• Adults (18 years old or older)
	• Patients with 4 or more inpatient hospital visits across Atrium Health Metro hospitals in 2019
	
	Exclusion criteria:
	• Existing MVP participants (enrolled in the 2019 MVP program cohort)
	• Patients who at the time of identification for the MVP program are
	  o enrolled in a Levine Cancer Institute navigator program
	  o enrolled in hospice or palliative care
	  o attributed to a primary care provider at another healthcare system (e.g., Novant)
	• Patients whose primary residence is a skilled nursing facility

Study Procedures	The list of patients with four or more inpatient hospital visits in 2019 will be pulled from the Atrium Health electronic data warehouse (EDW) by IAS Clinical Quality Analytics, and eligibility for the MVP program of patients on this list will be determined by the Population Health's Care Management team based on predefined eligibility criteria. IAS CORE will randomize eligible participants into one of two groups: 1) MVP program; or 2) usual care. Population Health's Multiple Visit Patient (MVP) care management program aims to manage health and lower hospital utilization among patients with a history of high inpatient hospital stays at Atrium Health. Patients eligible for the program have four or more inpatient visits over the 12-month period prior to enrollment. Once enrolled, each MVP program participant receives on-going support from an assigned MVP care manager and larger care management team, including the following core program components: (1) customized care plan developed for each patient at the time of enrollment (2) routine, virtual health monitoring and collaborative care management team-based review (3) personalized navigation and coordination across multidisciplinary Atrium Health services, as needed (4) education, health coaching, and support via telephonic and in-person interactions, as needed The control group will receive usual care.

	Upon completion of the 12-month period during which outcomes data will be accrued, the study will evaluate whether 12-month participation in the MVP program care management program, compared to usual care, reduced inpatient hospital use.
Statistical Analysis	Analyses will include all patients meeting the inclusion and exclusion criteria. The effect of the MVP program (intervention) on primary and secondary outcomes will be estimated using multivariable regression analysis, including generalized linear models and Poisson regression models. Results will be presented as marginal effects and odds ratios where applicable, with 95% confidence intervals.

LIST OF ABBREVIATIONS

ACM	Ambulatory Care Management
AH	Atrium Health
AIM	Advanced Illness Management
CCNC	Community Care of NC
CCB	Community Care Bridge
CCP	Community Care Partners
CORE	Center for Outcomes Research and Evaluation
ED	Emergency Department
EDW	Enterprise Data Warehouse
HNHC	High-need high-cost
IP	Inpatient
MVP	Multiple Visit Patient
NC	North Carolina
OBS	Observation
SOP	Standard Operating Procedures

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1. OBJECTIVES

1.1. Hypothesis

The MVP care management program, compared to usual care, leads to a decrease in inpatient hospital stays among patients with a historical high volume of hospital inpatient stays.

1.2. Primary Objective

Primary Objective: To evaluate the effectiveness of enrollment in the MVP care management program compared to usual care on reducing 12-month total inpatient hospital utilization among patients with a historical high volume of hospital inpatient stays.

1.3. Secondary Objectives

The Secondary Objectives are to

(1) evaluate the effect(s) of participation in the MVP program on:
- 6-month inpatient hospital utilization
- 6-month and 12-month Combined IP and OBS hospital stays at Atrium Health facilities
- 6-month and 12-month Combined IP and OBS hospital stays at AH and other facilities
- 6-month and 12-month IP hospital stays that are readmission eligible (using CMS criteria)
- 6-month and 12-month 30-day readmission rate among patients who had at least one encounter during the time frame
- 6-month and 12-month ED visit rate
- 6-month and 12-month Mortality rate
- 6-month and 12-month Hospital bed days (length of stay, IP)
- 6-month and 12-month Hospital charges

(2) assess variability in MVP program treatment effects associated with predefined patient and program factors, including:
- insurance status
- age, gender, race and ethnicity
- English as second language
- type of care management program (e.g., ACM, etc.)
- community characteristics
- clinical characteristics (e.g., CCI)

1.4. Exploratory Analyses

The exploratory analysis aims are to evaluate the effect of participation in the MVP program features on

- 6-month and 12-month primary care visits scheduled and attended / no show to a scheduled appointment
- 6-month and 12-month Healthy Days at Home
- 6-month and 12-month paid amount for the Medicare patient subgroup

2. BACKGROUND

A large portion of US health care costs is attributed to a small group of high-need, high-cost (HNHC) patients. The Agency for Healthcare Research and Quality recently examined nationwide Medical Expenditure Panel Survey data from 2014 and reported that 1% of US civilian population was accountable for more than 20% of health care spending, and 5% of the population for 50% (Dzau, et al. 2017, Mitchell, 2016). Similar patterns are seen at the health system level; Johnson et al. (2015) found that 3% of patients in an integrated safety-net health system accounted for 30% of charges.

To address HNHC patients' costs and high medical care utilization, health systems have been implementing a variety of care management programs as part of population health initiatives. The rise of these programs has been prevalent especially for Accountable Care Organizations (ACOs) and other value-based payment contracts (Peck et al., 2018). In general, these programs are characterized by establishing teams of clinicians and social workers who coordinate patients' medical care and address social determinants of health through referrals to community resources. The programs vary widely in theoretical foundations for interventions and individual features, which are a mix of medical and social services, and can have either episodic or longitudinal focus (Anderson, et al., 2015, Bodenheimer, 2013). There is not a consensus definition of the HNHC patient, thus selection criteria for these programs vary. One approach is based on clinical and functional characteristics of the patient, and the other approach identifies eligible patients as "super-utilizers" who accumulated a high number of ED visits and hospital admissions, with some programs using a combination of the two approaches (AHRQ, 2019, Johnson et al., 2015, Mann, et al., 2013).

Evaluations of care management programs for HNHC patients have been conducted using pre-post analysis and randomized controlled trials, both have shown mixed results (Baker, et al., 2018, Naylor et al, 2011). Recently, Powers, et al. (2020) conducted a randomized trial to evaluate CareMore Health's complex care management program on utilization of HNHC Medicaid patients between March 2017 and February 2018. Patients were screened based on a set of clinical and past healthcare use characteristics and randomized to receive the chronic care management program or usual care. Those randomized into the program were contacted by phone, and those who chose to enroll completed a comprehensive assessment and received a tailored care plan. The complex chronic program team consisted of a community health work, social worker and a primary care physician (PCP). The authors found that patients randomized to receive complex care management had fewer total inpatient bed days (59% decrease) and fewer inpatient admissions (44% decrease) over a 12-month period. Healthcare costs were also lower in the group who received care management, mostly driven by the decrease in inpatient utilization. On the other hand, in the recent randomized controlled trial conducted to evaluate the Camden Coalition of Healthcare Providers hotspotting

program, Finkelstein, et al. (2020) found no effect of a promising care management program on HNHC patients' readmission rates 180 days after discharge. Nor did the authors find an effect on any other hypothesized outcomes. Similar to CareMore, patient eligibility was based on a complex set of clinical and past utilization characteristics. In the evaluation of Camden's program, patients were enrolled on a rolling base while in the hospital, and upon return home they received help from a multidisciplinary team of clinicians, social and community workers.

Several published studies used the pre-post approach (Lynch, et al., 2016). Pre-post analysis can, however, misleadingly suggest huge benefits of the program, while the decrease in utilization is simply an observation of regression to the mean; in other words, utilization would drop with or without the program. Johnson, et al. (2015) confirms this phenomenon. The authors found that at the individual level, person's high utilizer status changed over time, with less than 50% of super-utilizers remaining in the high utilization category seven months after being identified as high utilizers, and only 28% a year later. Finkelstein, et al. (2020) addressed the importance of conducting a randomized trial evaluation instead of a pre-post analysis. While a pre-post analysis using the same data as the RCT showed a 38 % decrease in readmissions for the intervention group, the RCT results implied that this decrease could not be attributed to the Camden hotspotting program.

Another approach applied in care management program evaluations is a pre-post design with a comparable control group created in absence of an RCT (Thompson, et al., 2018, Sevak, et al., 2018). Thompson, et al. (2018) evaluated a community navigator program where eligibility was determined based on having 11+ encounters (ED, IP and OBS) during a 12-month period and primary residence at a specific zip code. The cohort received help from community navigators for one year. The authors created a control group that met the 11+ encounters criteria for super-utilizers but had residence in different zip codes. The authors found that that patients participating in the program had a 13% larger reduction in hospital encounters and 8% reduction in hospital days than the control group.

The components of the MVP program at AH were adopted from the approach promoted by A. Boutwell, MD, Collaborative Healthcare Strategies (2018). Multi-visit utilization in the past is considered a manifestation of co-occurring medical, behavioral, and social needs, likely unmet or not adequately addressed. Care managers are trained to identify underlying causes for high utilization through listening and asking patient questions beyond clinical diagnoses and looking for patterns in care seeking (e.g., problems with logistics, sense of urgency, uncertainty, or convenience). The MVP program aims to engage the patient, develop trusting relationships, offer recommendations tailored to patient while avoiding "over-medicalization," and over time help the patient achieve stability. An example of the program implementation is the MAX series for Medicaid patients with high past utilization in New York State. Both inpatient and ED utilization for participants in the MAX series decreased after the program introduction; the evaluation method, however, was pre-post analysis (New York State Department of Health, 2017).

Evidence of effectiveness of care management programs varies because of differences in program features, outcomes studied, the underlying studied population eligibility and characteristics (e.g., all patients, Medicaid, patients with heart failures), and statistical methods employed for evaluation (from pre-post to randomized trials). Randomized trials such as this are needed to make causal inferences on a care management programs effectiveness, ability to identify subgroups of patients who benefit most from the programs, and to identify impactful program features.

3. RATIONALE

The AH MVP program was established by the Population Health's Care Management group to address the complex needs of patients with the highest volume of inpatient hospital visits at AH. Care management initiated its work with the first cohort of 600 MVP patients in January 2019. An additional 46 patients were added in August 2019. Pre-post descriptive results showed that the 2019 MVP cohort's inpatient hospital rate was lower in 2019 than in 2018. While this is a promising outcome, without a randomized controlled trial (RCT) causal inferences cannot be made about the effect of the MVP program. Regression to the mean is a competing potential reason for observing the rate decrease, with high utilizers having lower hospital use over time even in the absence of any interventions. Thus, the Population Health leadership seeks to conduct a definitive trial to rigorously evaluate the MVP program effectiveness.

The randomized trial will allow us to make causal inferences regarding the effect of the MVP program on hospital utilization and isolate this effect from the regression to the mean phenomenon. It will also address identification of patients who most benefit from the program by sociodemographic characteristics, economic indicators of communities where they live, and clinical characteristics. The insights gained from the RCT will (1) inform strategic decisions on how AH effectively deploys limited care management resources to its patients; (2) provide generalizable knowledge using a rigorous RCT framework to improve care management programs beyond AH; and (3) generate robust real-world data as input to develop a novel machine learning model to advance high risk patient segmentation.

This research project is a parallel group, randomized trial of a care management program which seeks to evaluate inpatient hospitalization and utilization of other acute care services during a 12-month period. The evaluation of this intervention has been designed to integrate into routine care and minimize frontline staff burden by deploying a pragmatic evaluation in a real-world setting.

4. SUBJECT SELECTION

4.1. Subjects Accrual and Randomization

1. The list of patients meeting the inclusion criteria will be pulled from AH electronic data warehouse (EDW).
2. Based on chart review, patients not eligible for the MVP program due to exclusion criteria will be removed from the list. Programmatic subgroups will be identified among eligible patients
    (1) Ambulatory Care Management (ACM) and Advanced Illness Program (AIM)
    (2) Community Care Partners (CCP) and Community Care of NC (CCNC)
    (3) Community Care Bridge (CCB)
3. Patients remaining on the list will be randomized 1:1 to Usual Care or MVP referral using stratification to maintain balance across defined programmatic subgroups.
4. The Care Management team will monitor and reach out to patients identified for enrollment in the MVP program during the study period. Patients assigned to usual care will not be enrolled into the MVP program.

4.2. Inclusion/Exclusion Criteria

4.2.1. Inclusion Criteria

Eligible patients in the analyses must meet each of the following criteria:

- 18 years of age or older
- 4 or more inpatient hospital visits across Atrium Health Metro hospitals in 2019

4.2.2. Exclusion Criteria

- Existing MVP participants (enrolled in the 2019 MVP program cohort)
- Patients who at the time of identification for the MVP program are
  - Actively enrolled in a Levine Cancer Institute oncology navigation program
  - Actively receiving hospice or palliative care
  - Attributed to a primary care provider at an outside healthcare system (e.g. Novant)
- Patients whose primary residence is skilled nursing facility

4.3. Evaluable Population

Patients included in the evaluable population for this project, will have their data inform the final outcomes assessment. All patients who meet the inclusion and exclusion criteria in both groups will be assessed for the primary outcome (intent to treat).

AH Care Management will enroll patients assigned to the 2020 MVP program cohort on a predetermined date, flagging the MVP program participants as “active” in the care management’s data application (PatientPing).

5. OVERALL DESIGN

5.1. Variables

5.1.1. Primary Outcome Variable

The primary outcome variable **is the number of inpatient (IP) hospital encounters over a 12-month period.**

- IP encounter is defined as an admission to an AH acute care hospital.

5.1.2. Secondary Outcome Variables

- The number of IP hospital encounters over a 6-month period.

All secondary outcome variables listed below are cumulative over 6-month and 12-month periods.

- Combined number of IP and OBS hospital encounters at AH hospitals
- Combined number of IP and OBS hospital encounters at both AH + non-AH hospitals
- Among patients with at least 1 encounter during the study period, 30-day all-cause non-elective inpatient readmission rate to any AH hospital
- Among patients with at least 1 encounter during the study period, 30-day all-cause non-elective inpatient readmission rate to the same AH hospital as the index encounter
- Emergency Department encounters
- Mortality
- Hospital bed days (IP)
    - This is the total length of stay (LOS) in days (discharge date – admission date) for acute care inpatient utilization.
- Cost of Care - Hospital charges
    - Total accrued hospital billed charges for inpatient encounter at Atrium Health primary enterprise acute care facilities.

5.1.3. Exploratory Outcome variables

All exploratory outcome variables listed below are cumulative over 6-month and 12-month periods

- Primary care visits and primary care visits scheduled but not kept (no shows)
- Healthy Days at Home
    - This is a measure of quality of life (Burke, et al. 2019). It measures the number of days spent at home during a predefined time period.
- Cost of Care - Paid Amount for the Medicare patient subgroup

5.1.4. Main Explanatory Variable of Interest: Intervention Identifier

The MVP program is the intervention (treatment group).

Bivariate identifier variable = 1 if the patient was randomly assigned to the MVP program and is flagged “active” in PatientPing Care Management application; 0 otherwise

5.1.5. Explanatory Variables (Covariates) Description

Covariates will include:

- Demographic characteristics (e.g. age, race, gender)
- Clinical characteristics (e.g. Charlson comorbidity index score)
- Past medical services utilization
- Insurance type
- English as second language
- Type of care management program received (programmatic subgroup)
- Discharge location characteristics
- Community characteristics (e.g. % under federal poverty level)

5.2. MVP Program - Intervention Description

Population Health's Multiple Visit Patient (MVP) care management program aims to manage health and lower hospital utilization among patients with a history of high inpatient hospital stays at Atrium Health. Patients eligible for the program have four or more inpatient visits over the 12-month period prior to enrollment. Once enrolled, each MVP program participant receives on-going support from an assigned MVP care manager and larger care management team, including the following core program components:

- customized care plan developed for each patient at the time of enrollment
- routine, virtual health monitoring and collaborative care management team-based review
- personalized navigation and coordination across multidisciplinary Atrium Health services, as needed
- education, health coaching, and support via telephonic and in-person interactions, as needed

Screening and care manager assignment. A list of patients with four or more inpatient hospital visits in 2019 will be pulled from the Atrium Health electronic data warehouse (EDW). The care management team will review eligibility for the MVP program. The list of eligible participants will be randomized using parallel block randomization approach into the 2020 MVP program cohort (intervention) and the control group.

Eligibility for the program is based on past utilization, with patients with 4 or more inpatient visits over a 12-month period qualifying for the program. To identify the new MVP cohort, the list of patients with highest volume of inpatient hospital visits is generated by Clinical Analytics. The care management leadership team then reviews the chart of each patient on the list to determine eligibility and assigns the patient to the appropriate care management group. The number of patients accepted to the MVP program is constrained by the care management group's capacity. Existing MVP enrollees continue to receive care from their currently assigned team. Patients are assigned to a distinct care management group based on insurance/care needs:

i. Ambulatory Care Management (ACM)
    - Commercial insurance

- Medicare only
- Medicare with Medicaid as second
- Uninsured outside of Mecklenburg and Union counties
- Non CA II Medicaid

ii. Community Care Partners (CCP)
- Medicaid CA II
    a. Priority list (determined by the Medicaid state program)
    b. Provider preferred
- Community Care of NC (CCNC)
    a. Medicaid CA II that are not being managed by CCP (ie Mecklenburg, Union, Anson counties)

iii. Community Care Bridge (CCB)
- Uninsured in Mecklenburg and Union counties

iv. Advanced Illness Management (AIM)
- Patients with a limited prognosis but for whom hospice is not yet an option. This program is part of Continuing Care.

Program Start Point. Patients in the intervention group are enrolled in the MVP program at one time point determined by Care Management leadership. The start point is marked by an "Active" indicator in the Patient Ping app. From that point, the assigned care manager starts receiving "pings," which are real time updates alerting the care manager about the MVP patient's hospital utilization (IP, OBS, ED). The MVP care manager checks on the patient, communicates with providers and helps coordinate care and the transition to home.

Initial Assessment and Customized Plan. Shortly after the program start date, each MVP care manager calls patients assigned to her/him to conduct a full assessment. The case manager continues to try to reach the patient, and there is no limit for the number of attempted phone calls over a period of time. The assessment contains review of medications, upcoming appointments, social determinants of health (living arrangements, financial), and a PHQ9 survey. The care manager assesses a patient's motivation to change, provides education, solicits questions about health, and how the patient wants to be contacted. The care manager uses the assessment to create a customized plan for each patient.

MVP program features: Care managers are alerted via Patient Pings when a patient is admitted to hospital or has an ED encounter.

- If a patient is admitted to a hospital, the care manager consults the inpatient case manager and calls the patient if needed
- During monthly huddles, care management reviews charts of patients who had an acute care encounter during the past 30 days.
    - In general, if a patient had 0 hospital stays in the previous month, care managers do not make any calls.
    - There are no home visits.

- Face-to-face visits may take place if the patient is admitted to a facility at a close proximity to the care manager.

The relationship between a patient and a care manager varies. Care managers strive to identify MVP drivers and resources needed (clinical, financial, social), coordinate medical care and draw on resources from community programs. Community resource referrals depend on the county and availability (e.g., Mecklenburg county has more resources for transportation, food pantry, access to specialists than rural counties). The goal is to engage the patient, develop trusting relationships, offer recommendations tailored to patient, help the patient avoiding unnecessary medical utilization, and over time help the patient achieve stability.

5.3. Usual Care

Patient's post-discharge usual care depends on the inpatient care management assessment at last hospital admission. Patients can be discharged to home and receive no further care, or home with home health, or to a skilled nursing facility (SNF) or another type of Continuing Care facility. Patients can be referred to AIM, hospice, and Community Care Partners by the inpatient care manager. Patient can be referred to Ambulatory Care Management for care management also via telehealth, by a PCP or the Transitions Clinic.

5.4. Patient Graduation from the MVP program

Participation in the MVP program ends if the care manager stops monitoring the patient's health and stops reaching out to the patient. Reasons include:

a) Patient died
b) Patient relocated
c) Patient was incarcerated

The below reasons do not result in ending the MVP participation. Instead, the MVP care manager continues to quietly monitor the patient's health and coordinate services if needed but does not reach out directly to the patient.

a) Patient no longer wishes to participate
b) Patient enrolled in palliative/hospice care while enrolled in the MVP program
d) Patient moved to nursing home or assisted living while enrolled in the MVP program

5.5. Continuation of the Intervention

Patients enrolled in the MVP program may continue participating after the study period has ended.

6. DATA COLLECTION AND REPORTING

Data will be obtained from several sources:

- Electronic medical record and billing datamarts
    i. Patient demographics and health characteristics
    ii. Medical care utilization: hospital IP and OBS, ED
    iii. Social determinants of health in the hospital discharge questionnaire
    iv. Charges
    v. Paid amount for the subset of Medicare patients (Part A and B)
    vi. Mortality
- HealtheCare
    i. Care Management assessment
- PatientPing (third party care management vendor)
    i. non-AH hospital IP and OBS
    ii. non-AH ED utilization

Data will be retrieved by an application specialist on the research team. Data will be retrieved retrospective to a patient's completion of the intervention or usual care arm of the study.

6.1. Power Analysis

The outcome of interest is the number of IP hospital encounters over a 6-month period. The research (alternative) hypothesis is that the enrollment in the MVP program will lead to a larger decrease in IP encounters compared to usual care; the null hypothesis is no change in the percentage decrease across both arms of the study.

In order to determine the outcome variable value for the power analysis we used historical data of IP hospital encounters for patients enrolled in the MVP program in 2019 whom we expect to be similar to MVP enrollees in this study. To determine the sample size we considered the Care Management's requested size of 600 enrollees in the MVP program cohort. We estimated that the MVP program will serve 146 existing enrollees, who are not eligible for the study, and 454 new enrollees, who are eligible for the study. We used the following inputs for the power analysis: the average number of IP encounters was 6.5 in 2018, and it decreased 54% in 2019. We assumed that there are equal variances in both the treatment group and the control group and performed the calculations with a standard deviation of 0.45. We assumed there are 910 patients in the study population, with 454 patients randomized in the treatment group (MVP program) and 454 patients randomized in the control group (usual care). We assumed that the attrition rate due to death and relocation is 35%, resulting in 295 patients per group.

The sample size of 295 (in each group) achieves 80% power to reject the null hypothesis of equal percentage decreases in both groups when the mean difference is 10.4% points with a standard deviation of 0.45. In other words, with our sample size we would have the statistical power to detect a 10.4% point

reduction in IP hospital encounters for the MVP group compared to the control group. The 10.4% point difference (between the 54% drop for the MVP group compared to 43.6% drop for the control group) translates into a 21.3% relative reduction in the number of IP hospital encounters thanks to the MVP program. The level of significance is 0.05; a two-sided two sample t test was used (assuming the outcome follows a normal distribution). The sample size calculation was performed using the PASS software (2020).

6.2. Statistical analysis

Analyses will include all patients meeting the inclusion and exclusion criteria. All analyses will follow the intention-to-treat ("ITT") principle, such that patients will be analyzed based on the assignment of their primary care site to the MVP program or usual care.

Descriptive statistics will be calculated to screen all variables for accuracy and to examine distributions. Balance in baseline characteristics between the groups will be assessed.

The primary and secondary outcomes will be estimated as functions of *Treatment* (intervention / MVP program identifier) covariates $\boldsymbol{X}$:

$$Y_i = \beta_0 + \beta_1 (Treatment) + \boldsymbol{\beta_2 X}_i + \varepsilon_i$$

where

- β_1 is the parameter of interest and measures the Intent to Treat: the causal effect of being randomized into the treatment group (in this study we expect the intent to treat and treatment to be almost the identical).
- X are covariates, uncorrelated with Treatment, but they can aid in the precision of the estimate; $\boldsymbol{\beta_2}$ are the corresponding parameter estimates. The covariates will include patient's demographic and clinical characteristic, past utilization, insurance type, type of program management, community characteristics, care management groups, and discharge location.

Generalized linear models will be used. Results will be presented as marginal effects (continuous and count outcomes) and odds ratios (binary outcomes). Wald test will be used to assess the statistical significance of the independent variable. The level of significance is set to 0.05. Appropriate model diagnostics will be performed on each model to assess fit. Data will be analyzed using SAS Enterprise Guide 7.1 (SAS Institute Inc., Cary, NC, USA) and the R programming environment.

6.3. Data Collection Dates

All participants in the MVP cohort will be enrolled at the same time and flagged as "active" status in the PatientPing application. Data accrual will take place during 365 days from the date of patient enrollment.

7. STUDY GOVERNANCE

This research trial will be conducted at Atrium Health. It will be run jointly by the Center for Outcomes Research and Evaluation (CORE) and Population Health. Alica Sparling, PhD will serve as principal investigator on behalf of CORE. Barb DeSilva, MPH, MSN (Care Management, Population Health) will serve as the clinical co-principal investigator. The Executive Committee (EC) will consist of leaders from the System involved in the trial, quality improvement, and implementation (Table 2). The EC will have the overall responsibility of trial oversight and direction. The EC will support dissemination of project findings and next steps. The EC will receive progress reports from the team. When appropriate, ad hoc committee meetings will be scheduled to discuss pressing concerns.

Table 2. Executive Committee	
Ruth Krystopolski	Atrium Health Executive Leadership – Population Health
Andrew McWilliams	Atrium Health Executive Leadership – CORE Medical Director

8. SAFETY RISKS AND REPORTING

The data collection and intervention for this project presents no more than minimal risk to patients. The MVP program is currently offered at Atrium Health, the first 2019 cohort was enrolled in the program in January 2019. This study is evaluating the existing MVP program for the new 2020 MVP cohort of eligible patients. The implementation of the MVP program and its components are considered part of regular ongoing patient care within Atrium Health. The addition of an evaluation design that aligns with existing patient care thus confers minimal additional risk to patients.

The data collection and intervention for this project presents no more than minimal risk to patients. There is always the risk of disclosure of a patient's private health information (PHI) or medical information. However, the processes identified in this protocol to enable the execution of this project, do not increase inherent risk of disclosure. Atrium Health utilizes several hard and soft safety controls in the protection of patient information and medical records. Security controls include, but are not limited to, multiple system firewalls, access restrictions to patient records and information, locked offices and buildings housing research and patient data, and multiple layers of username and password protected computer and system access. Statistical tools and programs that are developed are stored on secure restricted access file shares. Programs have versioning controls turned on and access to the file shares are restricted. Access is granted through a request process that requires multiple authorizations and is controlled centrally by our Information and Analytics Service Department.

The CORE project team will ensure that appropriate handling of patient PHI follows standard Atrium Health procedure. Confidentiality will be maintained according to ICH E6; 4.8.10, part 0: "Records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the study trial are published, the patient's

identity will remain confidential.' In the event of PHI disclosure, the appropriate internal departments will be informed and processed per legislation and privacy regulations.

8.1. Data Quality Assurance

This study will be organized, performed, and reported in compliance with the study protocol, standard operating procedures (SOPs) of the CORE and Atrium Health, and other applicable regulations and guidelines (e.g. GCP).

8.2. Safety Reporting to the IRB

All events occurring during the conduct of a protocol and meeting the definition of a reportable safety event per the IRB guidelines, will be reported to the IRB within 10 working days of the Investigator learning of the event, per their requirements.

Major protocol deviations that result in a threat to subject safety or the integrity of the study will be reported to the IRB per their requirements.

8.3. Data Monitoring by the Sponsor

The conduct of this project will abide by standard operating procedures set forth by both Atrium Health and CORE. The Principal Investigators, statistician, and other team members will meet as needed to review enrollment and retention, study progress, and validity/integrity of the data. Documentation of these meetings will be kept with study records.

9. RESEARCH COMPLETION

The Principal Investigators have the right to close the project at any site at any time.

For any closure, the following applies:

- Closure should occur only after consultation between involved parties.
- In case of a partial study closure, patients still participating in the MVP program, or those who are considered in follow-up, must be taken care of in an ethical manner.

The study will be considered complete when one or more of the following conditions is met:

- The data collection period is complete.
- The IRB or Principal Investigator discontinues the study.
- The Principal Investigator defines an administrative or clinical cut-off date.

Upon study completion, a final report will be presented to the Executive Committee and all key stakeholders. The final report will detail all findings including primary, secondary and post-hoc outcomes. The team will also prepare a manuscript for publication focused on outcomes and feasibility of implementation of the MVP program.

10. ETHICAL AND LEGAL ISSUES

10.1. Ethical and Legal Conduct of the Study

The procedures set out in this protocol, pertaining to the conduct, evaluation, and documentation of this study, are designed to ensure that the Investigators abide by Good Clinical Practice (GCP) guidelines and under the guiding principles detailed in the Declaration of Helsinki. The study will also be carried out in keeping with the applicable local laws and regulation(s).

Documented approval from appropriate agencies (e.g. IRB) will be obtained before the start of the study, per GCP, local laws, regulations, and organizations.

Strict adherence to all specifications laid down in this protocol is required for all aspects of study conduct; the Investigators may not modify or alter the procedures described in this protocol.

Modifications to the study protocol will not be implemented without consulting the Principal Investigator and the IRB, as applicable. The Principal Investigator must assure that all study personnel, including co-investigators and other study staff members, adhere to the study protocol and all applicable regulations and guidelines regarding research both during and after study completion.

The Principal Investigator will be responsible for assuring that all the required data will be collected and properly documented.

10.2. Confidentiality

All records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available.

10.3. Disclosure of Data

The Principal Investigator, his associates and co-workers, and the appropriate regulatory agencies may use the information and data included in this protocol as necessary for the conduct of the study. Information contained in this study, and data and results from the study are confidential and may not be disclosed without the written permission of the Principal Investigator.

11. RETENTION OF RECORDS

Essential documentation including all IRB correspondence, will be retained for at least 2 years after the investigation is completed. Documentation will be readily available upon request.

12. PUBLICATION POLICY

The Principal Investigator or designee must send any draft manuscript, abstract, or conference presentation to members of the project Executive Committee for feedback and transparency, prior to submission of the final version. The Principal Investigator will be responsible for all relevant aspects regarding data reporting and publication.

The Principal Investigator or designee will ensure that the information and results regarding the study will be made publicly available on the internet at www.clinicaltrials.gov.

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