

**Can Refinements to Effective Transitional Care Services Improve Outcomes? Results
from a Pragmatic, Randomized Controlled Trial**

Study Protocol and Statistical Analysis Plan

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Objectives

The National University Hospital System is piloting a new care coordination program named CareHub. We aim to evaluate the effect of CareHub (compared to usual care) on resource utilization (using hospital administrative records), as well as patient and caregiver quality of life (using survey data).

CareHub includes the streamlining of post-discharge care, providing more structured and regular telephone support and checks, having a call center where tele-consultation will be available, early identification and preparation for post-discharge care by a multi-disciplinary team. We hypothesize that CareHub will improve outcomes of patients at high risk of readmission.

Background

NUHS has a variety of transitional / post-discharge care programs into which patients may be enrolled. Each of these programs is run by a different hospital team, so a patient may have to liaise with many parties for their post-discharge care. NUHS is currently piloting an improved post-discharge care program called CareHub. The pilot will run from 20 April 2016 – May / June 2017. CareHub is designed to streamline post-discharge care and better coordinate current programs for patients at high risk of readmission. The novel features of CareHub are (a) Provision of a single point of contact for all the patient's needs, to help patients and their families navigate the healthcare system as well as various programs available in the hospital and community. CareHub staff identify patients and start working with the care team during the inpatient phase, and will follow the patient through to the post-discharge phase (b) More structured and regular telephone support and checks, to help ease the hospital-to-home transition, as well as to provide more opportunity to verify that patients are adhering to their recommended treatment (c) A call center which will operate during office hours, where tele-consult will be available from CareHub staff (d) A consolidated multi-disciplinary discharge plan, based on the input of all healthcare workers caring for the patient. These include CareHub staff, ward doctor and nurse, heart failure care manager, and allied health professionals, as required (e) Early identification and preparation for post-discharge care. Healthcare workers listed in (f) will participate in a daily in-patient multi-disciplinary ward huddle, to discuss the patient's condition and start early preparation for post-discharge care. The two main features of CareHub that are likely to improve patient outcomes are structured telephone support (STS) and care coordination. Recent systematic reviews of randomized trials found that tele-monitoring / STS reduced hospital readmission rates and improved patients' health-related quality of life (Kronick et al. 2014; Louis et al. 2003; Inglis et al. 2015; Clark et al. 2007). However, the variation in effectiveness was large, perhaps due to differences in institutional context and implementation between studies. In addition, while STS appears to be cost effective, few studies in the literature have carried out cost-effectiveness analyses using prospectively collected data. Compared to tele-monitoring

and STS, fewer randomized trials have studied the effect of care coordination on post-discharge outcomes of cardiac patients. These studies found conflicting results on the effectiveness of care coordination, in part due to variation in institutional context as well as the types of intervention provided (Peikes et al, 2009; Harrison et al.,2002; Naylor et al, 2004). In all, the available evidence suggests that the two main features of CareHub are likely to result in positive changes to patient outcomes as well as reductions in resource utilisation.

Design

Inclusion and Exclusion Criteria and Consenting

The sample will include all cardiac patients who are eligible for CareHub, and were admitted to Wards 63 / 64 (post-cardiac surgery recovery wards) at NUH during the CareHub pilot. Recruitment for this pilot will be from 20 April 2016 – end November 2016, and the CareHub team will provide 6 months of post-discharge support.

All patients meeting a pre-defined minimum LACE score will be enrolled into the program and randomly assigned to CareHub or Usual Care (the existing package of post-discharge care services). All patients between 18 and 99 years of age will be included. Patients below 18 years of age will be excluded. Patients that do not consent or are unable to consent to the program will be excluded.

We will aim for a balanced design, as far as possible, in which the number of patients in the Usual Care and CareHub groups will be equal.

Written informed consent will be sought from patients admitted to Wards 63 /64 by a ward nurse that is not part of the study team. Request for informed consent will be delivered in the primary language of the patient (English, Mandarin Chinese or dialect, Malay or Tamil).

Individuals who agree to participate in the survey will be eligible for a lottery consisting of 10 prizes of \$10 each. The lottery will take place in May 2017. Winners will be informed by phone and the prize will be mailed to them. The lottery is meant as partial compensation for participants' time spent answering the survey. We choose the lottery, rather than a guaranteed sum due to budget constraints. The amount of the lottery is set at the low amount of \$10 to avoid undue influence of patients' decisions regarding survey participation.

Sample size

NUHS estimates that the total size of the population during the 6 month period to be approximately 1000 patients, of which 250 will be enrolled in CareHub, with a corresponding 250 in the control group. For the survey, due to resource constraints, we aim to randomly survey a total of 400 pairs of patients and their caregivers. 200 from CareHub and the rest from the control group.

The control group is anticipated to be a robust control because NUH randomly allocates the pool of eligible patients into CareHub and existing care. Table 1 summarizes the minimum detectable standardized effect size (MDE) for outcomes measured by the survey based on a 5% (2-sided) Type 1 error rate, different survey response rates, and different levels of statistical power for survey respondents. The MDE for outcomes captured by hospital administrative data will be lower (i.e. better) than those in the 100% response column, because administrative data are available for a larger group of patients.

Table 1

Total no. of patients in the CareHub and non- CareHub groups responding to the survey (response rate)	400 (100%)	300 (75%)	200 (50%)	120 (30%)
	Minimum detectable effect sizes			
80% power	0.28	0.32	0.40	0.52
90% power	0.32	0.38	0.46	0.60

Assumptions: (i) Survey response rates from the treatment and control groups are the same
(ii) Outcome variable is a continuous variable

Methods

Data

De-identified data will be extracted from the administrative and patient records. We will verify part of the administrative data, such as readmission rates, with a national database maintained by the Ministry of Health, that includes reportable readmissions data. We will also conduct a short survey to gauge patient and patient family satisfaction as another outcome measure.

We will use deidentified patient-related data from administrative databases of all public health institutions (PHIs) over the period Oct 2015 – Jun 2017. We sought and have obtained a waiver of informed consent for retrospective use of patients' administrative data. Our use of deidentified patient-related data from administrative databases from PHIs other than NUH has been approved by the Ministry of Health (MOH). We will collect additional data from patients and caregivers using surveys that we plan to carry out over the phone just after discharge, as well as one, two and six months after discharge. Each survey should take around 15 minutes. Consent for the follow surveys will be obtained as discharge.

Data on patients' compliance behaviors will be obtained during their scheduled specialty outpatient clinic visits, including a pill count, and clinical indicators such as HbA1C, fasting lipids, blood pressure, height, weight, ambulatory status.

Outcome measures

Our primary measures are length of stay at readmission, number of readmissions within 90 days, number of visits to the specialty outpatients clinics, the number of emergency department visits (planned and unplanned) post-discharge, and patient satisfaction.

Statistical Analysis Plan

Inpatient and discharge data will come from the National University Hospital, Singapore. Other data on health service utilization outside the NUH system will come from the Ministry of Health omnibus dataset.

We will compare the outcome variables between the control (non-CareHub) and treatment (CareHub) groups using t-tests, Chi-square tests and hazard models depending on the variable type.

We will also control for any differences in baseline characteristics of patients (e.g. in comorbidities and types of healthcare interventions received) and caregivers in the control and treatment groups by regression analyses. We acknowledge that we will face the multiple comparisons problem (i.e. as more outcomes are considered, it becomes increasingly likely that the control and treatment groups will differ on at least one outcome by random chance alone) by examining such many outcome variables.

We will consider the following methods to counteract the problem of multiple corrections: Bonferroni correction; comparing the number of outcomes with significant differences to the total number of outcomes examined; creating an index that combines certain outcome variables.

We will also be performing a cost-effectiveness analysis that compares the relationship between difference in costs and selected outcomes across the treatment and control groups. Examples of outcomes include number of readmissions or unplanned readmissions and quality adjusted life years.

All statistical analyses will be performed with Stata 13.0.