Describing the usefulness and efficacy of discharge interventions: predicting 30 day readmissions through application of the cumulative complexity model (protocol).

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Background

Introduction

Hospital readmissions, particularly among the elderly, are common and costly[1]. They are one of the most important causes of preventable health expense in the United States. Thus, policymakers and reimbursement strategists have established the reduction of hospital readmission rates as a national priority[2-4]. The CMS’ Hospital Readmissions Reduction Program officially began assigning financial penalties in October, 2012 [4, 5]. In an effort to improve care quality and avoid financial penalties, a number of predictive models have been developed to better understand the cause of readmissions and a variety of peridischarge interventions have been established to reduce their incidence.

Predictive models have been devised to identify patients at high risk of readmission, but they do not often identify modifiable risk factors [6-8]. Most models focus on patient characteristics only and may fail to fully consider the complexities of a patient’s experience, including socioeconomic concerns, the relative vulnerability of the patient, and the impact of the intervention itself. Indeed, currently available readmission risk prediction models generally perform poorly and are often limited in applicability [6, 9, 10].

Many peridischarge interventions have been found to successfully reduce the rates of hospital readmissions and health care costs[11-15], but often outcomes are variable[16, 17]. A recent systematic review by Hansen, et al found no single intervention alone to be effective and suggested only bundled interventions have value[18]. The inconsistency in evidence is probably due to the complexity and variability of both patients and interventions, and the fact that most synthesized information is based on studies with too much heterogeneity[17, 19-21]. In many cases, the lack of comparable studies has made firm conclusions impossible. The meta-analytic data that does exist is informed by rough categorizations based of the activities that comprise interventions [18, 20]. However, intervention value may need to be assessed in other ways[8]. No attempt has been made to assess the efficacy of interventions based on their patient-centeredness or their sensitivity to post-discharge patient vulnerability, despite considerable face validity.

Because the post-discharge period has been described as a period of extreme physiologic and psychologic vulnerability[22], it seems possible that interventions in this context may be particularly disruptive to the patient and could result in decompensation when important factors are not taken into consideration [23]. No attempts have been made to apply predictive models to interventions themselves.

*The Cumulative Complexity Model*
The *cumulative complexity model*[24] is a functional, patient-centered tool that may have usefulness in improving the predictability of outcomes when applied to discharge interventions, even in the context of diverse patient and disease factors. The model may be able to shed light on the essential characteristics of successful interventions.

The cumulative complexity model can be summarized as a description of the patient experience that depends on the balance between *workload* and *capacity*[24]. Workload, in this context, includes all of the activities required from and responsibilities placed on a patient. Workload becomes overwhelming when it is too high and this may result in intervention failures. Capacity can be thought of as the ability of the patient to be well, empowered, and equipped and is affected by disease factors, social issues, matters of support, and education, among other things. Increasing a patient's capacity is likely to increase the odds of therapeutic success.

**Objective**

The objective of this study and review is to systematically determine the usefulness of the cumulative complexity model as a tool for predicting the efficacy of various interventions targeted at reducing 30-day hospital readmission rates. If the model proves successful, it will provide much needed guidance and perspective to stakeholders interested in reducing readmissions, designing successful interventions, and improving and individualizing care.

**Methods**

**Eligibility Criteria**

Studies that will be considered eligible for review must assess the effectiveness of any peri-discharge intervention at reducing hospital readmission rates. The studies must evaluate these interventions in adults (age>18) acutely admitted to the hospital for any medical or surgical diagnosis for at least 24 hours. Eligible studies must also report outcomes as risks of all-cause readmission to the hospital at 30 days (RR or OR) but may have longer follow-up. In order to increase the ability to assess magnitudes of intervention effect indirectly, controls of any type will be considered acceptable. Eligible study designs will be restricted to randomized controlled trials. Retrospective studies will be excluded from analysis, as will studies that assess the effect of disease specific treatment or diagnostic strategies on readmission rates. Studies that assess interventions employed on admission, carried out throughout the hospital stay, or that are otherwise not primarily targeted at the hospital to home interface will be considered ineligible. Studies published before 1990, that admitted children or any patients for obstetric or psychiatric diagnoses, or exclusively evaluated in-hospital (ICU) readmissions will also be excluded.

**Search Strategy**

Electronic searches of PubMed, Ovid MEDLINE, Ovid EMBASE, EBSCO CINAHL, and SCOPUS will be searched for relevant studies. Keywords and MESH terms will be determined by an expert research librarian in collaboration with the lead author. Hand searching references from recent reviews and included studies and consultation with experts will also be used to identify eligible studies.
**Selection**

Two reviewers will independently consider the potential eligibility of each RCT abstract and title that results from the search strategy outlined above; disagreements will justify full text retrieval for evaluation and consensus. Full text versions of all potentially eligible studies will also be requested for further evaluation. In full text screening, two reviewers will work independently and blindly to identify the final selection of eligible studies. Prior to this, they will calibrate their judgments using a small set of reports. Disagreements will be resolved by consensus and, if necessary, by arbitration. Agreement will be measured using the kappa or phi statistics, as appropriate (the latter is appropriate when the distribution of agreement is extreme).

**Subgroups**

We will conduct subgroup analyses based on the number and types of trials generated from the search. We anticipate analyses based on patient characteristics such as index diagnosis and age (CHF, elderly, general medical, etc). Other subgroup or sensitivity analyses based on study characteristics may be required (i.e. for risk of bias). When possible, we will also analyze the difference in effect of targeting various interventions to specific populations (pharmacy consult applied only in populations with polypharmacy vs. all patients, etc). This analysis will be used to estimate the effect of relevance in intervention application.

**Intervention Categorization and Rating**

Authors from included studies will be contacted via email if the intervention is not well described in the paper. They will be asked to provide more detailed descriptions of the interventions used in their studies. These descriptions will then be standardized in language and transcribed into a web-based survey system (SurveyMonkey, Google Forms, etc) so that the interventions can be blind and categorized. The intervention rating survey will be administered to two investigators familiar with the cumulative complexity model and the clinical application of discharge interventions. These raters must not have participated in study selection (thus they will be blinded to the study and the outcome associated with the intervention). Raters will work independently after calibrating their judgments of interventions. They will be asked to evaluate each intervention based on “the degree to which the intervention increases or decreases patient workload” and “the degree to which the intervention decreases or increases patient capacity.” A 9 point scale (ratings from 1 to 9) will be used. If a rater feels the intervention resulted in “no change” from baseline in regards to workload or capacity, he or she will be asked to select a value of “5.” Ratings will be averaged between the two investigators.

**Data Extraction**

Data extractors, working independently, will collect primary data from the included trials through use of a web-based program (DistillerSR). The extracted data will include patient characteristics, primary outcomes (RR or OR of all-cause 30 day hospital readmission), interventions and controls, and factors associated with study quality. Data will also be extracted related to the number of people involved in intervention delivery, the number of contacts that occur, the number of components involved in the
intervention, and the location of the intervention activity (inpatient vs outpatient). Discrepancies in data collection will be adjudicated by consensus.

As a proxy for assessing the patient relevance of interventions, extractors will also be asked to determine whether the intervention is designed for specific application in the population studied.

Quality

To assess the methodological quality of randomized trials we will determine how the randomization sequence was generated and how or if allocation was concealed. We will look for important imbalances at baseline and determine which groups, if any, were blinded. The number lost to follow up, whether analyses were by intention to treat, and how missing data were dealt with will all be considered.

Analysis

The outcomes of the re-categorized interventions (relative risk of 30 day readmission) will be used to generate meta-analytic estimates of treatment effect when possible. This data will then be assessed for association with intervention ratings and characteristics.