

Title:

Effectiveness of the Supportive and Palliative Care Review Kit (SPARK) for Cancer Patients in the Acute Hospital

NCT ID: not assigned yet

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Statistical analysis plan

Data collection

A waiver of individual patient consent will be sought for the collection of health services utilization data from the electronic health records, as this will present no more than minimal risk of harm to participants. Electronic health data will be kept confidential and stored in a secure location. All data will be anonymized prior to statistical analysis.

Patient quality of life, measured by patient questionnaires, will not be measured because this was found to be infeasible in our pilot study. In the inpatient hospital setting, patients were physically ill with acute problems such as pain, leading to low recruitment and data completion rate.

Specific aim 1: To analyze the effect of the SPARK model on hospital length of stay and health services utilization. The following data will be extracted from the electronic health records: dates of hospital admission and discharge for the index admission and all subsequent admissions, dates of all subsequent Emergency Department attendances, and date of referral to community palliative care services.

Specific aim 2: To determine the access to palliative care. The receipt of different forms of palliative care from the palliative care doctor/nurse will be recorded. This may include direct care as well as indirect input e.g. specific advice regarding medication dose for that particular patient or suggestion of an appropriate source of support in the community for the patient.

Data analysis

Specific aims 1 and 2: Mixed-effect linear regression will be used to compare differences in (log-transformed) length of stay (primary outcome) and hospital-free days in the last 6 months of life between ‘spark intervention’ and ‘usual care’ groups controlling for (team- and patient-level) clustering and time effect. Similarly, mixed-effect logistic regression will be used to compare the proportion of patients who receive direct palliative care in the usual care model versus the SPARK model. A separate analysis will also be done for patients who receive any specific form of palliative care (direct or indirect).

Sample size calculation

It is estimated that each of the 4 clusters will have an average of 300 stage 4 cancer patient admissions per 4-month period, giving a total of 6000 admissions over the 20-month study period.

Based on results from our pilot study, we estimated the mean hospital length of stay to be about 6 days and the standard deviation to be 7. We estimated the intra-cluster coefficient arising from multiple admissions per person to be 0.2 and that each patient would have an average of 2 admissions during the study period. Therefore, the design effect arising from multiple admissions per person is 1.2 and 300 patient admissions would give an “effective sample size” of 250 admissions per 4-month period, or a total “effectiveness sample size” of 5000 admissions over the study period. Assuming the coefficient of variation between clusters to be about 0.25, the sample size of totally 6000 admissions as aforementioned would provide 80% power at 5% two-sided type 1 error rate to detect a mean difference of 1 day in hospital length of stay in the stepped-wedge design in table 1.