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

NCT ID: not assigned

Date of document: 31 October 2017

Study protocol

## Abstract


Introduction

There is a rising need for palliative care services in Singapore due to a rapidly ageing population and an increasing incidence of cancer. Current existing resources are inadequate – novel models of care are needed to expand access to palliative care without requiring significantly more specialist palliative care manpower.

Oncologist-driven referrals to a palliative care consultation service is the norm worldwide, including Singapore. This results in variable access to palliative care due to differences in referral practices. Palliative care involvement is also often delayed. In this study, we propose to test Supportive and Palliative care Review Kit (SPARK) – a novel integrated model of care in which the palliative care team co-rounds with the medical oncology team.

Specific Aims and Hypothesis

This study aims to evaluate the impact of SPARK compared to usual care. We hypothesize that SPARK will result in more advanced cancer patients having access to palliative care, and at the same time operate at lower net cost. We also hypothesize that the improved efficiency of SPARK will result in shorter hospital length of stay for stage 4 cancer patients.

Methods

A cluster randomized trial with step wedged design will be used to compare SPARK to usual care. Data will be collected on health services utilization and access to palliative care services. Net costs will also be compared between SPARK and usual care. Semi-structured interviews with patients and healthcare professionals will be used to explore differences in experiences of healthcare provision between both models of care.

Importance

Singapore has a rising prevalence of cancer patients who require palliative care input, but only a minority are able to access it at present. If the SPARK model of care proves to be a scalable and cost-effective way of expanding access to palliative care, more cancer patients can benefit from palliative care.

## Specific aims and hypotheses

The overall aim of this proposed study is to evaluate the impact of the Supportive and Palliative care Review Kit (SPARK) model of care compared to usual care on health services utilization, access to palliative care, net costs and the experiences of both patients and healthcare providers. SPARK is an integrated palliative care and medical oncology co-rounding model of care for cancer patients in the acute hospital setting. We plan to develop and comprehensively assess this model using a prospective cluster randomized controlled trial and semi-structured interviews.

The study specific aims and hypotheses are:

Specific aim 1: To determine the effectiveness of SPARK on hospital length of stay (primary outcome) and other health service utilization metrics

Hypothesis: The SPARK model of care will reduce hospital length of stay compared to usual care, due to earlier involvement of palliative care in the course of hospital admission and consequently swifter relief of problems that prompted the hospitalization.

Other metrics of health service utilization will also be explored, including hospital-free days and visits to the Emergency Department in the last 6 months of life, and number of days to hospital readmission within 30 days.

Specific aim 2: To assess the relationship between the SPARK model of care and access to palliative care services

Hypothesis: The SPARK model will be associated with a greater proportion of cancer patients who receive any form of palliative care input during their hospital admission.

## Background and significance

Palliative care, according to the World Health Organization, is an approach that improves the quality of life of advanced cancer patients and their families, through early identification, assessment and treatment of pain and other problems, physical, psychosocial and spiritual. (1) Concurrent palliative care and oncology care for advanced cancer patients results in improved quality of life, better symptom control and perhaps even longer survival. (2-7) International organizations recommend that palliative care should be integrated with oncology – the question that remains is how this integration should occur to optimize health outcomes. (7-9)

According to published literature, only 5-11% of stage 4 cancer inpatients in the acute hospital setting receive palliative care. (10, 11) Predominant models of care rely on direct delivery of care by specialist palliative care healthcare professionals, and there is insufficient manpower to extend this labor-intensive service to more cancer patients. (12) Even in resource-rich United States, the estimated gap between current supply and hypothetical demand is 6,000-18,000 individual physicians. (13, 14)

In Singapore, a rapidly ageing population and increasing incidence of cancer means a rising need for palliative care services that cannot be fully met by current models of care. (15-18) In the acute hospital setting, an unscheduled admission for a stage 4 cancer patient indicates that palliative care may be beneficial. (19) Our previous study showed that 84% of cancer inpatients had stage 4 cancer and that unscheduled admissions accounted for 82% of total admissions, yet only 21% received a palliative care review. (20) In recent years, anecdotal evidence suggests that home hospice services have been forced to restrict referrals and even close services temporarily to new referrals due to insufficient manpower. To extend palliative care services to more cancer patients, it will be inadequate to simply increase manpower within current service models – the need for large numbers of extra manpower cannot be met.

Singapore urgently needs a model of care that can expand access to palliative care for more cancer patients without requiring a lot more palliative care manpower. Therefore, the focus of our research is not whether palliative care improves patient outcomes – that has already been affirmed in recent research. The overall research question addressed by this proposed study is whether the SPARK model of care is a better way of delivering integrated palliative care to cancer patients in the acute hospital setting.

We propose a cluster randomized controlled trial to test the SPARK model of care for cancer inpatients in the acute hospital setting. This is novel in our institution because palliative care is currently delivered only as a separate consultation service – the most common model worldwide. (21) In the SPARK model, palliative care doctors and nurses are integrated with the oncology team, supporting them in their delivery of basic palliative care, seamlessly stepping in and out to deliver specialist palliative care directly to patients when needed. (22-25) With this approach, it is anticipated that there will be more efficient collaborative working between the oncology and palliative teams.

In the short term, our proposed study responds to an urgent need to expand access to palliative care for advanced cancer patients, in a model that does not require a large increase in specialist palliative care manpower. In the long term, scalable and effective models of care need to be developed for the exponentially rising need for palliative care in Singapore and across the world.

## Methods

### Study setting

The study will take place in Singapore General Hospital, a 1597-bedded acute hospital with more than 78,000 admissions per year. About 5,000 hospital admissions per year are cancer patients under the care of the Division of Medical Oncology (DMO), of which 80% are advanced cancer patients. This service is the largest public provider of cancer care in Singapore.

### Current model of service

The current model of service is a consultation service with oncologist-driven referrals. A cancer patient admitted to hospital may have pain or other physical symptom problems such as breathlessness, or psychosocial and spiritual issues. The oncology team usually manages them first-line, and would refer to the palliative care team for further management only if the problems were unresolved after oncology management. Upon a referral from the oncologist, the palliative care team will review the patient and make suggestions for patient management, but the oncology team still takes primary responsibility for the patient's care. In the current model, about **20%** of cancer inpatients are referred to the palliative care team.

### The SPARK model of care

In the SPARK model of care, a specialist palliative care physician and nurse join the DMO team as integrated members. The patient's issues are managed collaboratively by the palliative care and oncology healthcare professionals. The form of palliative care provided will depend on the needs of individual patients and may include expert advice given to the oncology team, screening assessments for unidentified problems, or direct provision of palliative care for complex issues. It is anticipated that **more** patients admitted under the care of the integrated palliative oncology team will receive some varying degree of palliative care input as needed, whether directly or indirectly through support given to the oncology nurses and doctors.

### Study design

Cluster-randomized trial with stepped-wedge design, unblinded due to practical challenges of blinding. There will be 4 teams (clusters) within the DMO inpatient service, each comprising a team of senior consultant physicians, middle level and junior doctors, and oncology nurses. This follows current team structures. During the intervention period, a palliative care physician and nurse will join the team as integrated members.

The study will be conducted over 20 months from January 2018 to August 2019, with each cluster crossing over from 'usual care' to 'spark intervention' at 4-month intervals. Each cluster will be randomly assigned a specific timing of crossing over.

Table 1

| | Jan-Apr 2018 | May-Aug 2018 | Sep-Dec 2018 | Jan-Apr 2019 | May-Aug 2019 |
|---|---|---|---|---|---|
| Cluster 1 | control | intervention | intervention | intervention | intervention |
| Cluster 2 | control | control | Intervention | intervention | intervention |
| Cluster 3 | control | control | control | Intervention | intervention |
| Cluster 4 | control | control | control | control | intervention |

### Study patients

All hospital admissions with stage 4 cancer under the care of the oncology team will be included.

**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. (30) 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).

Specific aim 3: A net cost analysis of SPARK will be undertaken from the perspective of the restructured health system. It is possible that total labour costs are greater for SPARK but that costs per patient are lower because SPARK allows for seeing more patients. This difference, whether positive or negative, represents differences in direct labour costs. Because this is a new model of care, this cost will not be reflected in the billing data. However, the billing data can be used to quantify other differences that may result from SPARK, such as savings through reductions in length of stay. Using the billing data, we will again quantify total and per capita cost differences between SPARK and usual care. The net costs of SPARK will be quantified by adding per capita labour cost differences to per capita billing cost differences. If negative, then SPARK is cost saving. If positive, then SPARK is more expensive.

**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. (31)

## References


1. WHO Definition of Palliative Care. http://www.who.int/cancer/palliative/definition/en/ (last accessed 3 January 2017)

2. Temel J, Greer J, Muzikansky A, et al. Early palliative care for patients with metastatic non-small-cell lung cancer. N Engl J Med 2010;363:733-42.

3. Zimmermann C, Swami N, Krzyzanowska M, et al. Early palliative care for patients with advanced cancer: a cluster-randomised controlled trial. Lancet 2014;383:1721-30.

4. Bakitas M, Tosteson T, Li Z, et al. Early Versus Delayed Initiation of Concurrent Palliative Oncology Care: Patient Outcomes in the ENABLE III Randomized Controlled Trial. J Clin Oncol 2015;33:1438-45.

5. Dionne-Odom JN, Azuero A, Lyons KD, et al. Benefits of Early Versus Delayed Palliative Care to Informal Family Caregivers of Patients With Advanced Cancer: Outcomes From the ENABLE III Randomized Controlled Trial. J Clin Oncol 2015;33:1446-52.

6. May P, Garrido MM, Cassel JB, et al. Prospective Cohort Study of Hospital Palliative Care Teams for Inpatients With Advanced Cancer: Earlier Consultation Is Associated With Larger Cost-Saving Effect. J Clin Oncol 2015;33:2745-52.

7. Nickolich MS, El-Jawahri A, Temel JS, LeBlanc TW. Discussing the Evidence for Upstream Palliative Care in Improving Outcomes in Advanced Cancer. Am Soc Clin Oncol Educ Book 2016;35:e534-8.

8. Hui D, Bruera E. Models of integration of oncology and palliative care. Ann Palliat Med 2015;4:89-98.

9. Smith T, Temin S, Alesi E, et al. American Society of Clinical Oncology provisional clinical opinion: the integration of palliative care into standard oncology care. J Clin Oncol 2012;30:880-7.

10. Mulvey CL, Smith TJ, Gourin CG. Use of inpatient palliative care services in patients with metastatic incurable head and neck cancer. Head Neck 2016;38:355-63.

11. Uppal S, Rice LW, Beniwal A, Spencer RJ. Trends in hospice discharge, documented inpatient palliative care services and inpatient mortality in ovarian carcinoma. Gynecol Oncol 2016;143:371-378.

12. Block S, Billings J. A need for scalable outpatient palliative care interventions. Lancet 2014;383:1699-700.

13. Calton BA, Alvarez-Perez A, Portman DG, et al. The Current State of Palliative Care for Patients Cared for at Leading US Cancer Centers: The 2015 NCCN Palliative Care Survey. J Natl Compr Canc Netw 2016;14:859-66.

14. Lupu D, American Academy of H, Palliative Medicine Workforce Task F. Estimate of current hospice and palliative medicine physician workforce shortage. J Pain Symptom Manage 2010;40:899-911.

15. Population Refernce Bureau. World Population Data Sheet. 2016. http://www.prb.org/pdf16/prb-wpds2016-web-2016.pdf (Last accesssed 3 January 2017)

16. Department of Statistics, Ministry of Trade and Industry, Singapore. Population trends. 2016. http://www.singstat.gov.sg/docs/default-source/default-document-library/publications/publications_and_papers/population_and_population_structure/population2016.pdf (Last accessed 3 January 2017)

17. Ministry of Health, Singapore. Trends in Cancer Incidence in Singapore 2010-2014. https://www.nrdo.gov.sg/docs/librariesprovider3/default-document-library/cancer-trends-report-2010---2014_web.pdf?sfvrsn=0 (Last accessed 3 January 2017)

18. Lien Centre for Palliative Care. Report on the National Strategy for Palliative Care. 2011.

19. Rocque G, Barnett A, Illig L, et al. Inpatient hospitalization of oncology patients: are we missing an opportunity for end-of-life care? J Oncol Pract 2013;9:51-4.

20. Zhu X, Neo P, Peh TY, et al. Is there an unmet need for palliative care in cancer patients admitted to hospital? In: ASCO Annual Meeting Proceedings, 2015:123.

21. Hui D, Bruera E. Integrating palliative care into the trajectory of cancer care. Nat Rev Clin Oncol 2016;13:159-71.

22. Cheng M, King L, Alesi E, Smith T. Doing palliative care in the oncology office. J Oncol Pract 2013;9:84-8.

23. Hoverman J. If palliative care is the answer, what is the question? J Oncol Pract 2013;9:55-6.

24. Quill T, Abernethy A. Generalist plus specialist palliative care--creating a more sustainable model. N Engl J Med 2013;368:1173-5.

25. Rangachari D, Smith T. Integrating palliative care in oncology: the oncologist as a primary palliative care provider. Cancer J 2013;19:373-8.

26. Creswell JW, Plano Clark VL. Designing and conducting mixed methods research, 2nd ed. Los Angeles: SAGE Publications, 2011.

27. Fetters MD, Curry LA, Creswell JW. Achieving integration in mixed methods designs-principles and practices. Health Serv Res 2013;48:2134-56.

28. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ 2008;337:a1655.

29. Higginson IJ, Evans CJ, Grande G, et al. Evaluating complex interventions in end of life care: the MORECare statement on good practice generated by a synthesis of transparent expert consultations and systematic reviews. BMC Med 2013;11:111.

30. Hussey MA, Hughes JP. Design and analysis of stepped wedge cluster randomized trials. Contemp Clin Trials 2007;28:182-91.

31. Hemming K, Girling A. A menu-driven facility for power and detectable-difference calculations in stepped-wedge cluster-randomized trials. Stata Journal 2014;14:363-380.