

Received 4/14/11
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Requirements to submit AOI:

A comprehensive review of previously published data has been completed.: Yes
The specific aims are clear and focused.: Yes
The investigator has appropriate experience and expertise to develop the concept proposal; if not, has identified a mentor or senior co-investigator.: Yes
The investigator agrees to develop an initial draft of the concept proposal within 6 weeks of approval of the AOI and to finalize the concept proposal within 6 months.: Yes

Project Title: Cost-effectiveness of Colorectal Cancer Screening Among Survivors Treated with Abdominal Radiation Therapy
Planned research population (eligibility criteria): Survivors treated with radiation therapy to abdomen, pelvis, or TBI (the cohort at risk). The outcome of interest is CRC as a second cancer.
Proposed specific aims: The overall objective is to conduct a quantitative analysis to inform colorectal cancer (CRC) screening guidelines for survivors. Specifically, 1. To estimate the effectiveness (numbers needed to screen, life years gained) and cost-effectiveness (cost per life year gained) of CRC screening among childhood cancer survivors treated with abdominal/pelvic RT. We will use CRC incidence data for specific strata of age/sex/abdo RT dose, derived from the CCSS, as transition state inputs into Markov models of CRC screening.
Will the project require non-CCSS funding to complete?: No
If yes, what would be the anticipated source(s) and timeline(s) for securing funding?:
This is one of 3 projects being proposed in a CIHR grant (Deadline JUNE 1): "Reducing the Burden of Second Malignancies for Childhood Cancer Survivors: A Stratified Medicine Approach"

Does this project require contact of CCSS study subjects for . . .

Additional self-reported information: Yes

Biological Samples: No

Medical record data: No

If yes to any of the above, please briefly describe.: If feasible, data regarding inflammatory bowel disease and/or a history of GI comorbidity. This would facilitate restricting the analysis to patients with no other indications for colonoscopy.

What CCSS Working Group(s) would likely be involved? (Check all that apply)

Second Malignancy: Secondary

Chronic Disease:

Psychology / Neuropsychology:

Genetics:

Cancer Control: Primary

Epidemiology / Biostatistics:

To describe the anticipated scope of the study, please indicate the specific CCSS data to be included as outcome (primary or secondary) or correlative factors. (Check all that apply)

Late mortality:

Second Malignancy: Primary

Health Behaviors

Tobacco:

Alcohol:

Physical activity:

Medical screening: Secondary

Other:

If other, please specify:

Psychosocial

Insurance: Correlative Factors

Marriage:

Education: Correlative Factors

Employment:

Other:

If other, please specify:

Medical conditions

Hearing/Vision/Speech:

Hormonal systems:

Heart and vascular:

Respiratory:
Digestive: Primary, Correlative Factors
Surgical procedures: Correlative Factors
Brain and nervous system:
Other:
If other, please specify:

Medications

Describe medications:

Pregnancy and offspring:
Family History: Correlative Factors

Psychologic/Quality of Life

BSI-18:
SF-36:
CCSS-NCQ:
PTS:
PTG:
Other:
If other, please specify:

Chronic conditions (CTCAE v3):
Health status:

Demographic

Age: Correlative Factors
Race:
Sex: Correlative Factors
Others:
If others, please specify:

Cancer treatment

Chemotherapy: Correlative Factors
Radiation therapy: Correlative Factors
Surgery: Correlative Factors

Anticipated sources of statistical support

CCSS Statistical Center:

Local institutional statistician: Yes

If local, please provide the name(s) and contact information of the statistician(s) to be involved.: Cecilia Cotton, U of Waterloo <http://sas.uwaterloo.ca/Faculty/Cotton.shtml>

Will this project utilize CCSS biologic samples?: No

If yes, which of the following?

Buccal cell DNA:

Peripheral blood:

Lymphoblastoid cell lines:

Second malignancy pathology samples:

Other requiring collection of samples:

If other, please explain:

Other general comments: Current COG Guidelines recommend consideration of CRC screening among patients receiving prior abdo/pelvic RT. We propose to use CCSS data as the basis to create models of CRC risk. These estimates will then be used in Markov models to evaluate different possible CRC screening strategies.