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Project Requirements and Description

Requirements to submit AOI (all answers must be "yes" to proceed)

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	Late Cardiovascular Disease Risk Prediction among Childhood Cancer Survivors and Scalable Clinical Informatics Tools for Electronic Health Record Integration

Planned research population (eligibility criteria)

For Aim 1, our planned research population will be all CCSS participants in the original and expanded cohorts with completed treatment exposure data. As our CV outcomes of interest are all potentially life-threatening, individuals who report the development of these conditions within 5 years of diagnosis will be excluded from analysis. And similar to past efforts, we will attempt to validate any updated model (if there are any changes to predictors) in an external cohort (e.g., NWTS, SJLIFE, and Dutch LATER).

For Aims 2 and 3, the EHR-based tool based on the final prediction model will be implemented at Seattle Children's Hospital and expanded to at least one other CCSS site to assess scalability.

Proposed specific aims

Using data from the Childhood Cancer Survivorship Study (CCSS), we will:

Specific Aim 1: Update the previous CVD prediction models (i.e., Chow et al, JCO 2014 and 2017) based on proportional hazards models and a time-dependent receiver operating characteristic (ROC) curve approach to predict individual CV outcomes (i.e., myocardial infarction, congestive heart failure, and stroke) following childhood cancer treatment as associated with baseline treatment and demographic factors. We will assess if sex and age at time of initial cancer treatment remain influential predictors, given interim changes to the COG cardiomyopathy surveillance recommendations, which do not factor either characteristic in its risk stratification.

Specific Aim 2: Using a human-centered design approach, leverage discrete demographic and treatment exposure data in the EHR to create an EHR-based version of the updated CCSS CVD prediction models as a tool to enhance clinical decision support and population health management.

Hypothesis: a) Data elements included in the final updated prediction models will be readily available in discrete format within the EHR, and will be feasible to implement an EHR tool with high fidelity to manual use of the risk calculator b) Compared with the web-based platform, the EHR-tool will be highly accessible, yield a greater system usability score (based on the technology acceptance model for human-centered design), reduce provider time, and improve task analysis for implementation among providers.

Specific Aim 3: Implement the EHR-based late CVD risk prediction tool at another CCSS institution to evaluate its interoperability and scalability.
Hypothesis: The EHR-based late CVD risk prediction tool will be feasible and scalable at another CCSS institution with similar fidelity and acceptability.

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?

Does this project require contact of CCSS study subjects for:

Additional self-reported information	No
Biological samples	No
Medical record data	No

If yes to any of the above, please briefly describe.

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

	Primary	Secondary
Second Malignancy		
Chronic Disease	✓	
Psychology/Neuropsychology		
	Primary	**Secondary**
Genetics		
Cancer Control		
Epidemiology/Biostatistics		✓

Outcomes or Correlative Factors

	Primary	Secondary	Correlative Factors
Late Mortality		✓	
Second Malignancy			

Health Behaviors

	Primary	Secondary	Correlative Factors
Tobacco			
Alcohol			
Physical Activity			
Medical Screening			
Other			

If other, please specify

Psychosocial

	Primary	Secondary	Correlative Factors
Insurance			
Marriage			
Education			
Employment			
Other			

If other, please specify

Medical Conditions

	Primary	Secondary	Correlative Factors
Hearing/Vision/Speech			
Hormonal Systems			
Heart and Vascular	✓		
Respiratory			
Digestive			
Surgical Procedures			
Brain and Nervous System			
Other			

If other, please specify

Medications

Describe medications

Psychologic/Quality of Life

	Primary	Secondary	Correlative Factors
BSI-18			
SF-36			
CCSS-NCQ			
PTS			
PTG			
Other			

If other, please specify

Other

	Primary	Secondary	Correlative Factors
Pregnancy and Offspring			
Family History			

	Primary	Secondary	Correlative Factors
Chronic Conditions (CTCAE v3)			
Health Status			

Demographic

	Primary	Secondary	Correlative Factors
Age			✓
Race			
Sex			✓
Other			

If other, please specify

Cancer Treatment

	Correlative Factors
Chemotherapy	✓
Radiation Therapy	✓
Surgery	

Anticipated Sources of Statistical Support

CCSS Statistical Center	Yes
Local Institutional Statistician	No

If local, please provide the name(s) and contact information of the statistician(s) to be involved.

Will this project utilize CCSS biologic samples? No

If yes, which of the following?

If other, please explain

Other General Comments

Primary Senior Mentor: Eric Chow

Agree

I agree to share this information with St. Jude

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