STREAMLINING MULTISITE ETHICS REVIEWS: LESSONS FROM THE "CANCER IN YOUNG PEOPLE IN CANADA" PROGRAM

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INTRODUCTION

The Cancer in Young People in Canada (CYP-C) surveillance program was launched in 2009 to contribute to the control of cancer in children, adolescents, and young adults in Canada. CYP-C includes diagnostic, treatment, and outcome data from all children diagnosed and/or treated at one of seventeen pediatric oncology centers across the country (Figure 1 and Table 1). Multisite ethics approval was required for the CYP-C program.

Figure 1: Pediatric oncology centers participating in the CYP-C program

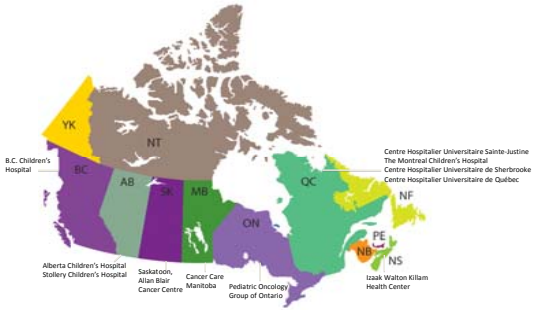


Table 1: Data collected by the CYP-C program

Demographics	Diagnostic Details	Time to Treatment	Treatment	Other
Sex	Date of diagnosis Diagnosis	First health care professional contacted	Treatment plan and start date	Organ transplant (date)
Date of birth	ICDO-M, ICDO-T and ICCC codes	Date first health care professional contacted	Treatment completion details	Complications
Age at diagnosis	Stage at diagnosis Risk	Dates first seen by: oncologist, surgeon, and/or specialist	Chemotherapy and dose	Hospitalizations
Province	Grade		Surgery details	Relapse
Postal code	Chromosomal testing Metastases and site(s)			
Ethnicity			Radiation (intent, type, site) Hematopoietic stem cell transplantation	Vital status Height and weight

METHODS

CYP-C is a minimal risk study that meets the Tri-Council Policy Statement criteria for a waiver of consent (Box 1). A CYP-C research ethics board (REB) review committee was established in December 2009 to streamline multi-site REB approvals (Box 2). Twelve separate REB applications were submitted by participating hospitals and the Health Canada REB between December 2009 and September 2010. Data on time to study approval and REB-issued change requests were collected and analysed.

Box 1: How CYP-C meets the Tri-Council Policy Statement criteria for a consent waiver

- The research involves no more than minimal risk to the subjects
- The waiver is unlikely to adversely affect the rights and welfare of the subjects
- The research could not practicably be carried out without the waiver or alteration
- Whenever possible and appropriate, participants are provided with pertinent information after participation
- The waived consent does not involve a therapeutic intervention

Adapted from article 3.8 of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Second Edition

Box 2: Steps taken to streamline the multisite ethics reviews for the CYP-C program

- The CYP-C research ethics board review committee met on a monthly basis to review REB applications completed at each participating pediatric oncology center.
- The committee prepared guidelines on how to approach REB applications for CYP-C based on the Tri-Council Policy Statement principles.
- The committee provided personalised feedback on each REB application.
- Relevant resources were centrally disseminated and posted on an electronic, password protected portal.
- The committee received regular updates on the status of the applications and assisted with answering REB questions until full approval was secured.

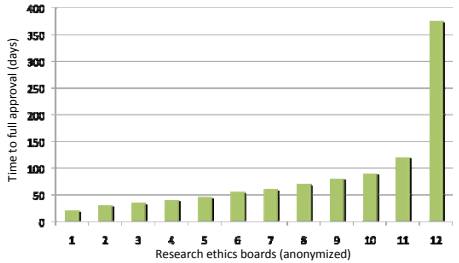
RESULTS

Seven out of the twelve centers (58 %) received uncontested REB approval. Of the remaining five centers that were granted conditional REB approval, most requested information pertained to non-local changes (Table 2). Three of the five remaining centres provided REB approval after additional information was provided. For the remaining two centres, further negotiating was required over requested changes before REB approval was given. By the end of 2010, all centres had secured full ethics approvals. The time taken for full approval varied greatly among the REBs (Range = 13 to 364 days; Median = 74 days, Mean = 43 days) (Figure 2). Delays in receiving ethics approval delayed the commencement of data collection by 4 months.

Table 2: Local and non local changes requested by research ethics boards

Non local changes or comments	No. of times requested	Local changes or comments	No. of times requested
Information on recruitment	3	Letter of support from sponsor	2
Request for updated study documents	2	Local changes to patient information sheet	2
Information on legal authority to conduct surveillance	2	Limits on postal code data collection due to regional considerations	1
Information on inclusion of vulnerable populations	1	Request for annual report on data use at the center	1
Changes to the request for a consent waiver	1	Information on local process for resolving patient complaints	1
Information on storage of personal information	1		

Figure 2: Time to full ethics approval by research ethics boards



CONCLUSIONS

The CYP-C program overcame some of the challenges of requiring multisite ethics approval by the establishment of an REB review committee. Notably, the emphasis on establishing channels of communication between the REBs and local researchers and continual efforts in streamlining ethics reviews proved highly successful. Still, ethics approvals from all the centres was achieved at considerable administrative and logistical cost and led to delays in the launch of the study. A consistent, balanced, and timely approach to receiving ethical approval for multi-site studies is recommended. The effort will ameliorate the administrative and financial burden of ethics reviews, yield timely research, and improve consistency in decision making among REBs.

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The Cancer in Young People in Canada (CYP-C) program is a national, population-based research initiative, studying all children diagnosed with cancer in Canada. CYP-C collects data on cancer cases, treatments, complications and outcomes with the aim of better understanding the causes of cancer, improving cure rates, enhancing the quality and accessibility of care, and minimizing late effects. The program is a partnership between the Public Health Agency of Canada and the C[17] Council, the network of all the seventeen paediatric cancer hospitals across the country.