

Pediatric Best Case Series

Enclosed in this document are the following study materials.

1. An explanatory letter (page 1) for the CAM provider.
2. An explanatory letter (page 2) to be distributed to potentially eligible patients/families.
3. An information release form (page 3) that would be completed by the oncologist and patient in order to release patient information to the study team.
4. A report form (page 4) to be completed by the patient/family (section 1) and the oncologist (section 2) before submission to the study team.
5. A poster advertising the study (page 5) that may be posted in the CAM provider's office in order to inform patients of the study.

Project Details: *for providers*

Since 1991, the National Cancer Institute (NCI) in the United States has had a "Best Case Series Program" that collects information on CAM therapies and products that have been shown to improve outcomes for patients with cancer. At the moment, the NCI does not have any information on CAM therapies or products that have been successful in children with cancer. The purpose of this study is to identify such cases. If we find that there is enough interest and response to this project our next step would be to partner with NCI to develop a registry to collect childhood best cases. Ultimately, the goal is to identify CAM therapies that deserve more in-depth clinical trials.

What are we asking of you?

This project asks interested CAM providers to advertise the study in their waiting rooms.

We are asking CAM practitioners who are currently treating or have treated pediatric cancer patients to inform these patients and families about this study and to provide interested patients with the information letter and case report form.

Criteria for patient participation in this study:

1. A child diagnosed with cancer between 1990 and 2006?
2. Use of any form of CAM during or after conventional cancer treatments
3. Remarkable outcome such as shrinking or disappearance of tumour, extended survival, or significantly improved quality of life (i.e. reduction in cancer symptoms, treatment side effects, overall wellness, etc)

Eligible patients will be asked to complete section 1 of the report form, and to ask their treating physician to complete section 2.

If you would like to participate please access the attached poster and patient forms.

For further information please contact:

Denise Adams, Project Coordinator;

University of Alberta, Edmonton, Alberta, Canada

Phone: 780-492-4181; Fax: 780-407-2105; denise.adams@ualberta.ca

Study Investigators: Sunita Vohra MD, Stollery Children's Hospital, Edmonton, AB; Paul Grundy MD, Stollery Children's Hospital, Edmonton, AB; Susan Sencer MD, Children's Hospitals and Clinics of Minnesota, Minneapolis, MN; Anne Leis PhD, University of Saskatchewan, Saskatoon, SK

Since 1991, the National Cancer Institute (NCI) in the United States has had a “Best Case Series Program” that collects information on complementary and alternative medicine (CAM)¹ that has helped patients with cancer. At the moment, the NCI does not have any information on CAM that has helped children with cancer. The purpose of this study is to identify such cases.

At this time, we are inviting interested patients or their immediate family members who answer yes to all of the following criteria to take part:

1. Were you a child diagnosed with cancer between 1990 and 2006?
2. Did you use any form of CAM during or after your conventional cancer treatments?
3. Did you have a remarkable outcome such as shrinking or disappearance of your tumour, a longer life, or significantly improved quality of life (did you feel much better than what was expected?).

If you answered yes to all of these questions, and wish to take part, you will be asked to fill out section 1 of the study form and to ask your doctor to fill out section 2. That is all you will be asked to do, you will not have to do anything else for this study. No identifying information such as your name or address should be included on this form. Please ask your doctor to return this form to the contact person listed below and on the form. *Please note that the submission of this form implies that you have agreed to participate in the study.*

If we find that there is enough interest and response to this project, our next step would be to partner with NCI to develop a registry to collect childhood best cases. Ultimately, the goal is to identify CAM therapies that deserve more research, thus making their benefits better known.

Personal records relating to this study will be kept confidential. Any research data collected about you during this study will not identify you by name, nor will any published material.

There are no known risks associated with this study. You do not have to take part in the study at all, and you can quit at any time. No one will be mad at you if you decide you don't want to do this, or if you decide to stop part way through. You should tell your doctor that you want to quit.

If you have concerns about your rights as a study participant, you may contact the Patient Relations Office of Capital Health, at 407-1040. This office has no affiliation with the study investigators.

Please consider participating in this novel pilot project! For further information or to submit your “Best Case” please contact:

Denise Adams, Project Coordinator;
University of Alberta, Edmonton, Alberta, Canada
denise.adams@ualberta.ca
Phone: 780-492-4181; Fax: 780-407-2105

Study Investigators:

Sunita Vohra MD, Stollery Children's Hospital, Edmonton, AB **Telephone: (780) 407-2106**
Paul Grundy MD, Stollery Children's Hospital, Edmonton, AB
Susan Sencer MD, Children's Hospitals and Clinics of Minnesota, Minneapolis, MN
Anne Leis PhD, University of Saskatchewan, Saskatoon, SK

¹Complementary and alternative medicine is commonly defined as a “broad field that includes all health systems and practices outside of the mainstream health system”. CAM involves the use of practices (e.g., acupuncture, chiropractic, and massage therapy) and/or natural health products (e.g., Echinacea, St. John's Wort).

PEDIATRIC BEST CASE SERIES
A Study of CAM use in Pediatric Oncology

CONFIRMATION OF EXPRESSED WISHES FOR RELEASE OF PATIENT INFORMATION

DATE: _____

TO: Pediatric Best Case Series: A Study of CAM use in Pediatric Oncology

Project Coordinator

University of Alberta

Edmonton, Alberta

Canada

Email: denise.adams@ualberta.ca

Phone: 780-492-4181

Fax: 780-407-2105

I _____ confirm that the release to the Pediatric Best Case Series: A Study of CAM use in Pediatric Oncology of all pertinent individually identifying health information of myself or my child (if patient is under 18 years of age) is consistent with my expressed wishes.

Physician Information: Dr. _____

Address/Email/Phone/Fax: _____

Name of Patient: _____

DOB: _____

Address: _____

Signature of Patient: _____

Signature of Parent/Guardian: _____

If patient is under 18 years of age.

CARE Pediatric Best Case Series

SECTION 1: To be completed by the PATIENT(if over 18 years of age) or LEGAL GUARDIAN:

Eligibility Checklist:

- Was the patient diagnosed with cancer between 1990 and 2006?
- Was the patient under 18 years old when diagnosed?
- Did the patient use any forms of Complementary and Alternative Medicine (CAM) therapies or products during or after conventional cancer treatment?
 - o For example: acupuncture, massage therapy, Echinacea
- Did the patient experience any unexpected positive outcome (i.e. tumour shrinkage, extended survival, improved quality of life)?

If you checked all of the above statements the patient is eligible to participate in our novel pilot project!

Please complete the table below and then provide the form to the patient's doctor for completion.

Age at Diagnosis:	Gender:	Diagnosis:
CAM Therapy eg. <i>acupuncture</i>		
Description eg. <i>needling to lower back</i>		
Start Date eg. <i>01/01/02</i>		
End Date eg. <i>02/02/03</i>		
Frequency eg. <i>weekly</i>		
Patient Outcome: Please select one or more of the following. <input type="checkbox"/> Tumour regression <input type="checkbox"/> Extended survival <input type="checkbox"/> Improved quality of life.		

SECTION 2: To be completed by the patient's treating PHYSICIAN:

Please complete the table below and fax to the Study Coordinator at 780-407-2105. Please include dates where possible.

Diagnosis: <i>Please verify above diagnosis.</i>
Anticipated Prognosis:
Patient Outcome: <i>Please confirm and comment on patient reported outcome.</i>
Conventional Treatment: <i>(ie. chemo/radiation/surgery)</i>
Physician Contact Information:



Complementary and Alternative
Research and Education Program

Stollery Children's Hospital, University of Alberta

...are you a childhood **cancer** survivor?

...did you use **Complementary and Alternative** treatments?

...did your **recovery go better** than was expected?

If you answered yes to the above questions, or did so on behalf of your child, you may be able to participate in CARE's Pediatric Best Case Series: A Study of Complementary and Alternative Medicine use in Pediatric Oncology. For more information, please ask your CAM provider or contact the study coordinator, Denise Adams, denise.adams@ualberta.ca.