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# BMJ Open

## French translation and validation of the Symptom Screening in Pediatrics Tool (SSPedi)

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Complete List of Authors:	Larouche, Valérie; CHU de Québec-Université Laval, Department of Pediatrics Revon-Rivière, Gabriel; Hospital Timone, Department of Pediatric Hematology and Oncology Johnston, Donna; Children's Hospital of Eastern Ontario, Division of Hematology/Oncology Adeniyi, Oluwatoni; Children's Hospital of Eastern Ontario, Division of Hematology/Oncology Giannakouros, Panagiota; CHU de Québec-Université Laval, Department of Pediatrics Loves, Robyn; Hospital for Sick Children Research Institute, Child Health Evaluative Sciences Tremblay, Jenna-Lee; Children's Hospital of Eastern Ontario, Division of Hematology/Oncology Plenert, Erin; Hospital for Sick Children Research Institute, Child Health Evaluative Sciences Dupuis, Lee; Hospital for Sick Children Research Institute, Child Health Evaluative Sciences; Hospital for Sick Children, Department of Pharmacy Sung, Lillian; Hospital for Sick Children, Division of Haematology/Oncology; Hospital for Sick Children Research Institute, Child Health Evaluative Sciences
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3 TITLE: French translation and validation of the Symptom Screening in Pediatrics Tool (SSPedi)  
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9 AUTHORS: Valérie Larouche, MD FRCPC<sup>1</sup>; Gabriel Revon-Rivière, MD<sup>2</sup>; Donna Johnston, MD,  
10 FRCPC, FAAP<sup>3</sup>; Oluwatoni Adeniyi<sup>3</sup>; Panagiota Giannakouros<sup>1</sup>; Robyn Loves, HBSc<sup>4</sup>; Jenna-  
11  
12 Lee Tremblay<sup>3</sup>; Erin Plenert, MPH<sup>4</sup>; L. Lee Dupuis, RPh, PhD<sup>4,5</sup>; Lillian Sung, MD, PhD<sup>4, 6</sup>  
13  
14  
15  
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17

18 AFFILIATIONS:

19  
20 <sup>1</sup>Department of Pediatrics, Centre Mère-Enfant Soleil du CHU de Québec-Université Laval,  
21  
22 2705 Boulevard Laurier, Québec, Québec, G1V 4G2, Canada  
23

24 <sup>2</sup>Department of Pediatric Hematology and Oncology, La Timone Children's Hospital, APHM, 265  
25  
26 Rue Saint-Pierre, Marseille, 13005, France  
27

28 <sup>3</sup>Division of Hematology/Oncology, Children's Hospital of Eastern Ontario, 401 Smyth Road,  
29  
30 Ottawa, Ontario, K1H 8L1, Canada  
31

32 <sup>4</sup>Program in Child Health Evaluative Sciences, The Hospital for Sick Children, Peter Gilgan  
33  
34 Centre for Research and Learning, 686 Bay Street, Toronto, Ontario, M5G 0A4, Canada  
35

36 <sup>5</sup>Department of Pharmacy, The Hospital for Sick Children, 555 University Avenue, Toronto,  
37  
38 Ontario, M5G 1X8, Canada  
39

40 <sup>6</sup>Division of Haematology/Oncology, The Hospital for Sick Children, 555 University Avenue,  
41  
42 Toronto, Ontario, M5G 1X8, Canada  
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CORRESPONDING AUTHOR:

Lillian Sung MD, PhD

Division of Haematology/Oncology

The Hospital for Sick Children

555 University Avenue

Toronto, Ontario

M5G 1X8

Telephone: 416-813-5287

Fax: 416-813-5979

Email: [lillian.sung@sickkids.ca](mailto:lillian.sung@sickkids.ca)

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WORD COUNTS: 1,767

## ABSTRACT

**Objectives:** Symptom Screening in Pediatrics Tool (SSPedi) is a validated approach to measuring bothersome symptoms for English- and Spanish-speaking children with cancer and pediatric hematopoietic stem cell transplantation recipients. Objectives were to translate SSPedi into French, and among French-speaking children receiving cancer treatments, to evaluate understandability and cultural relevance.

**Methods:** Forward translation was performed by four medical translators. After confirming that back translation was satisfactory, we enrolled French-speaking children with cancer and pediatric hematopoietic stem cell transplantation recipients at four centers in France and Canada.

**Primary and Secondary Outcome Measures:** Understandability was evaluated by children themselves who self-reported degree of difficulty, and by two adjudicators who rated incorrectness. Assessment of cultural relevance was qualitative. Participants were enrolled in cohorts of 10.

**Results:** There were 30 children enrolled. Participants were enrolled from Marseille (n=10, 33%), Ottawa (n=1, 3%), Quebec City (n=11, 37%) and Toronto (n=8, 27%). No child reported that it was hard or very hard to complete French SSPedi in the last cohort of 10 participants. Changes to the instrument itself were not required. After enrollment of 30 respondents, the French translation of SSPedi was considered finalized based upon self-reported difficulty with understanding, adjudicated incorrect understanding and cultural relevance.

**Conclusions:** We translated and finalized SSPedi for use by French-speaking children and adolescents receiving cancer treatments. Future work should begin to use the translated version to conduct research and to facilitate clinical care.

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3 **STRENGTHS AND LIMITATIONS OF THIS STUDY**  
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- 5       ▪ Conduct at multiple centers
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- 7       ▪ Multiple approaches to assessing understandability
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- 9       ▪ Use of external adjudicator
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- 11       ▪ Limited by conduct in only two countries
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## BACKGROUND

Children with cancer and pediatric hematopoietic stem cell transplantation (HSCT) recipients commonly experience severely bothersome symptoms.(1-3) The Symptom Screening in Pediatrics Tool (SSPedi) is a reliable and valid approach to measuring bothersome symptoms in English-speaking children 8-18 years of age receiving cancer treatments.(4) SSPedi was developed because of the need for a short and simple symptom screening and assessment tool for clinical utilization in children receiving cancer treatments.(5)

SSPedi requires about two to three minutes to complete and it includes the following 15 symptoms considered most important to children and their guardians: disappointed or sad, scared or worried, cranky or angry, problems thinking, body or face changes, tiredness, mouth sores, headache, other pain, tingling or numbness, throwing up, hunger changes, taste changes, constipation and diarrhea. SSPedi also allows children to record additional bothersome symptoms not already listed.

We previously translated SSPedi into Spanish and clarified the procedures we would adopt generically for SSPedi translation and validation. Canada is a bilingual (French and English) country. We therefore next chose to translate SSPedi into French. Objectives were to translate SSPedi into French, and among French-speaking children receiving cancer treatments, to evaluate understandability and cultural relevance of the translation.

## METHODS

### Translation of SSPedi from English to French:

Translation of SSPedi into French included forward translation, reconciliation, back translation and back translation review. Methods followed the principles for the translation and cultural adaptation process from the The Professional Society for Health Economics and Outcomes Research (ISPOR) Task Force.(6)



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5 We convened a translation panel composed of the Toronto-based research team (RL,  
6 EP, LD, LS), the four forward translators, and the investigators and interviewers from enrollment  
7 sites where the translation was tested (VL, GRR, DJ, PG, OA).  
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11 The initial forward translation of SSPedi was performed independently by four  
12 professional medical translators who are native French speakers. We planned to have two  
13 translators from each country in which the translation would be tested. Two translators had  
14 previously resided in France while the other two had always resided in Canada. Two were  
15 currently residing in Quebec (primary provincial language is French) and two were currently  
16 residing in Ontario (primary provincial language is English). In addition to translating the SSPedi  
17 tool, the translators also translated the synonym list, which provides alternative words for each  
18 SSPedi symptom to assist participants who need help understanding an item. The translation  
19 panel met through WebEx to reconcile the four forward translations, with the goal of producing a  
20 single translated version of the tool. Discrepancies between the translated versions of SSPedi  
21 were identified and resolved by consensus, with input from French-speaking investigators. Once  
22 the panel was satisfied with the translated version of the tool, it was sent to a new, independent  
23 translator for back translation.  
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39 The back translation was performed by a bilingual native English-speaker with no  
40 previous knowledge of the original English version of SSPedi. The Toronto-based research  
41 team verified that the back translation did not contain mistranslations or inaccuracies. This  
42 version was approved by all members of the translation panel prior to testing with patients.  
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### 49 **Cognitive Interviewing to Evaluate Understandability and Cultural Relevance**

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51 Eligible participants were native French-speaking children with cancer and pediatric  
52 HSCT recipients who were 8-18 years of age at the time of the interview. We excluded those  
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3 who were not able to participate in the interview because of cognitive, visual or hearing  
4 limitations as judged by a member of the patient's healthcare team.  
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7         The evaluation of translated SSPedi was performed using in-person interviews. All  
8 interviews were conducted by trained personnel who are fluent in the target language. All  
9 interviews were audio-recorded and adjudicated by the Toronto-based team. The goals of  
10 cognitive interviewing were to determine whether children self-reported that SSPedi items  
11 (introduction, response scale and individual symptoms) were hard to understand, whether  
12 children were incorrect in their understanding of SSPedi items as adjudicated by an external  
13 rater, and whether translated SSPedi was culturally appropriate.  
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22         Initially, the child participant or their guardian completed a demographic questionnaire.  
23 Next, each participant was given time to complete the translated version of SSPedi in the  
24 presence of the interviewer. The entire tool or specific items could be read aloud if requested by  
25 the participant. Then the participant was asked how easy or hard SSPedi was to complete  
26 overall using a 5-point Likert scale ranging from 1 = "very hard" to 5 = "very easy". To assess  
27 cultural relevance, the participant was asked whether any of the questions did not make sense  
28 to them in thinking about their day-to-day life, as someone living in their country.  
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37         Next, the SSPedi instructions and the response options were presented and evaluated  
38 separately. The instructions were read aloud and the participant was asked to rate how easy or  
39 hard it was to understand them using the same 5-point Likert scale previously described. Next,  
40 using cognitive interviewing and pre-specified probes, the interviewer assessed whether the  
41 participant was correct in their understanding of the instructions and, specifically, the concept of  
42 bother. Understanding of the degree of bother, in other words, the response options, was also  
43 assessed. Adjudicator-assessed understanding was rated on a 4-point Likert scale ranging from  
44 1 = "completely incorrect" to 4 = "completely correct".  
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53         Then, each of the 15 SSPedi items were presented and evaluated separately. First, the  
54 individual SSPedi item was read aloud. Second, the participant was asked to rate how easy or  
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3 hard that item was to understand using the same 5-point Likert scale previously described. We  
4 focused on the number who rated an item as very hard or hard to understand (score of 1 or 2 on  
5 the 5-point scale). Third, using cognitive interviewing and pre-specified probes, the interviewer  
6 assessed whether the participant was correct in their understanding of each item using the 4-  
7 point Likert scale previously described. We focused on the number that were completely or  
8 mostly incorrect (score of 1 or 2 on the 4-point scale).  
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16 Inevaluable interviews were those where: (a) a participant could not understand the  
17 questions posed during cognitive interviews (not the SSPedi items themselves); or (b) the  
18 interviewer failed to probe the participant during the cognitive interview (thus not permitting  
19 evaluation of correct understanding). Upon completion of the interview, the audiotape was sent  
20 to Toronto. The Toronto-based adjudicator listened to the transcripts to identify inevaluable  
21 interviews and, for evaluable interviews, to independently rate the participant's extent of  
22 understanding of translated SSPedi. Discrepancies between the assessments of the Toronto-  
23 based adjudicator and in-country interviewer were resolved by a third Toronto-based reviewer.  
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33 The Toronto-based research team met after each group of five interviews were  
34 completed to review participant responses and decide whether the translated version of SSPedi  
35 or the synonym list of terms required modification. Formal evaluation of outcomes were  
36 performed after each cohort of 10 participants and these occurred with the entire translation  
37 panel by WebEx. Modification was required when at least two participants among the last cohort  
38 of 10 participants: (a) found an item hard or very hard to understand; (b) were completely or  
39 mostly incorrect in their understanding of an item; (c) other comments suggested changes were  
40 required, including those related to cultural relevance. To be finalized, the translated version of  
41 SSPedi must not have required any substantive changes in the last cohort of 10 participants  
42 interviewed.  
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## RESULTS

Between September 24, 2018 and June 21, 2019, we identified 49 children and enrolled 30 participants before the French translation of SSPedi was finalized. Figure 1 illustrates the flow diagram of participant identification and enrollment. Table 1 shows the demographic characteristics of the three cohorts of 10 participants enrolled to this study. The number of participants who were 8-10, 11-14 and 15-18 years of age were 8 (27%), 11(37%) and 11 (36%) respectively. Participants were enrolled from Marseille, France (10, 33%), Toronto, Canada (8, 27%), Ottawa, Canada (1, 3%) and Quebec City, Canada (11, 37%).

**Table 1: Demographic Characteristics of Participants Evaluating the French Translation of SSPedi**

	Cohort 1 (n=10)	Cohort 2 (n=10)	Cohort 3 (n=10)
Age in Years			
8-10	1	3	4
11-14	6	2	3
15-18	3	5	3
Male Sex	6	6	7
Diagnosis			
Leukemia	2	0	1
Lymphoma	2	0	1
Solid tumor	3	2	5
Brain tumor	3	8	3
Metastatic Disease	5	5	3
On Active treatment	6	9	9
Hematopoietic Stem Cell Transplantation	1	0	0
Inpatient at Interview	4	5	2
Attending School	9	5	8
Sites of Enrollment			
Marseille, France	5	1	4
Ottawa, Canada	0	0	1
Québec City, Canada	0	8	3
Toronto, Canada	5	1	2
Confident Speaking French			
Not at all	0	0	0
Not very	0	0	0
Somewhat	0	1	1
Confident	1	2	0
Very confident	9	7	9

Confident Reading French			
Not at all	0	0	0
Not very	0	0	0
Somewhat	0	2	0
Confident	4	4	1
Very confident	6	4	9

Abbreviation: SSPedi – Symptom Screening in Pediatrics Too

Table 2 shows understandability by SSPedi item in terms of self-reported difficulty with understanding (number finding an item hard or very hard to understand) and adjudicated incorrect understanding (number interpreting an item mostly or completely incorrectly). Changes made during the first two iterations were only modifications to the synonym list and the instrument itself did not require modification. For the last cohort of 10 participants interviewed, none of the respondents reported that it was hard or very hard to complete French SSPedi overall. One found a single item hard to understand (changes in how your body or face look) and one was incorrect in their understanding of an item (mouth sores). Among all 30 participants, no issues in terms of cultural relevance were raised. None of the participants identified important missing symptoms from SSPedi. The finalized version of the French translation of SSPedi is shown as Figure 2.

**Table 2: Self-reported Difficulty and Rater-Adjudicated Incorrectness in Understanding the French Translation of SSPedi\***

SSPedi Item	Cohort 1 (n=10)		Cohort 2 (n=10)		Cohort 3 (n=10)	
	Hard*	Incorrect**	Hard*	Incorrect**	Hard*	Incorrect**
SSPedi Instructions	0	0	1	0	0	0
SSPedi Items:						
Feeling disappointed or sad	0	0	1	0	0	0
Feeling scared or worried	0	0	0	0	0	0
Feeling cranky or angry	1	0	0	0	0	0
Problems with thinking or remembering things	0	0	0	0	0	0

Changes in how your body or face look	0	0	1	0	1	0
Feeling tired	0	0	0	0	0	0
Mouth sores	0	0	1	2	0	1
Headache	0	0	0	0	0	0
Hurt or pain (other than headache)	0	0	0	0	0	0
Tingly or numb hands or feet	0	0	0	1	0	0
Throwing up or feeling like you may throw up	0	0	0	0	0	0
Feeling more or less hungry than you usually do	0	0	0	0	0	0
Changes in taste	0	0	0	0	0	0
Constipation (hard to poop)	0	1	0	1	0	0
Diarrhea (watery, runny poop)	0	0	0	0	0	0
Response Scale	NA	0	NA	0	NA	0

Abbreviation: SSPedi – Symptom Screening in Pediatrics Tool; NA – not assessed

\*How hard or easy each section was to understand as rated by participants - the number who rated the section as hard or very hard to understand is shown

\*\*Participant understanding of each section as rated by the in-country interviewer and a

Toronto-based adjudicator - the number who were rated as mostly or completely incorrect is shown

## DISCUSSION

We reported the process for translating and validating the French translation of SSPedi. The final version was well-understood by the target audience, namely French-speaking children with cancer and HSCT recipients. The translation of patient-reported outcomes to other languages is important to reduce disparities and ensure all children can benefit from approaches to improve quality of life.

We enrolled 30 participants in this study and required that at least 10 participants evaluate the translated version of SSPedi to be fit for use as-is before finalization. Although several instruments have been translated and validated using fewer participants (7-9), we felt it was important to enroll a modest number to increase confidence in its assessment. We also used at least two adjudicators of understanding to improve this assessment.

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3 While translation of a self-report symptom assessment tool for children receiving cancer  
4 treatments 8-18 years of age is important, it will also be important to extend translation to other  
5 French-speaking respondents. These include proxy-respondents, either in the setting of children  
6 8-18 years of age with illness acuity or impairments that preclude self-reporting of symptoms, or  
7 in the setting of younger children. Such an instrument is available in English.(10) Similarly,  
8 translation of a symptom screening tool for younger children is also important. While such a tool  
9 has been developed for children 4-7 years of age,(11) it has not yet been validated in English.  
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13 The strengths of this research include its multi-center conduct and multiple approaches  
14 to assessing understandability. Audio-recording interviews and use of an external adjudicator is  
15 another strength that enhances rigor of the research. However, the study is limited by its  
16 conduct in only two Francophone countries; evaluation in other French-speaking nations may  
17 not necessarily yield the same results due to linguistic and cultural differences.  
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21 In conclusion, we translated and finalized SSPedi for use by French-speaking children  
22 and adolescents receiving cancer treatments. Future work should begin to use the translated  
23 version to conduct research and to facilitate clinical care.  
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## AUTHOR CONTRIBUTORSHIP

LD and LS developed the study concept and design. EP, RL, GRR, PG, OA, and JT were involved in data collection. LS drafted the manuscript. All authors VL, GRR, DJ, OA, PG, RL, JT, EP, LD, and LS participated in data interpretation, reviewed, revised, and approved the manuscript.

## COMPETING INTERESTS

The authors declare that they have no competing interests.

## FUNDING

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## DATA SHARING

The datasets used or analyzed during the current study are available from the corresponding author on reasonable request.

## ETHICAL APPROVAL

This study has research ethics board approval from The Hospital for Sick Children Research Ethics Board (#1000057560) and all other participating sites. Written informed consent and assent were obtained from all study participants.



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**FIGURE LEGEND**

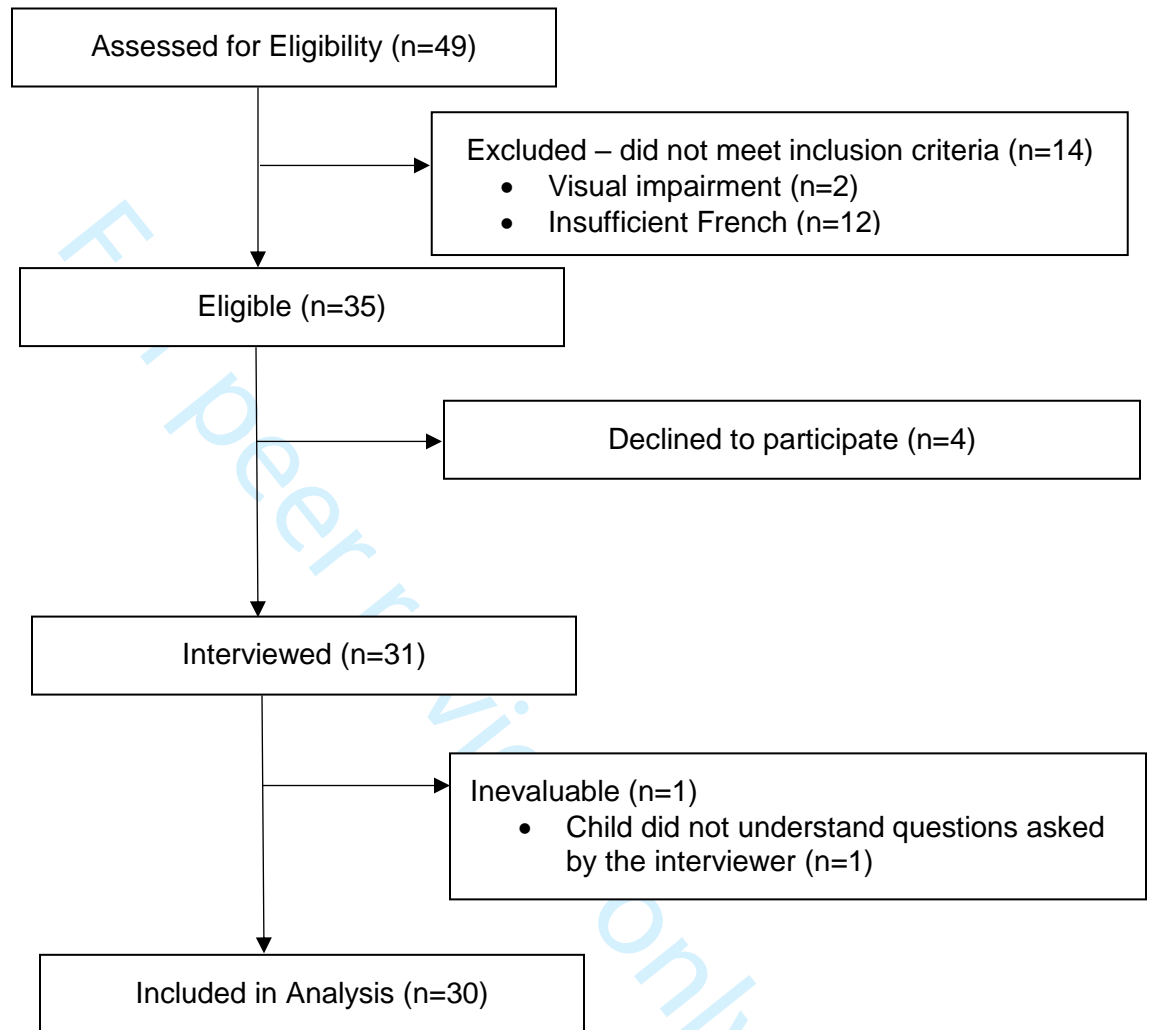
Figure 1: Flow Diagram of Participant Identification and Enrollment

Figure 2: French Translation of SSPedi

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**Figure 1: Participant Identification and Enrollment Flow Diagram**

## SSPedi: Évaluation des symptômes en pédiatrie

À quel point ces choses ont été dérangeantes **hier ou aujourd'hui**? Fais une marque dans le cercle qui correspond le mieux à ta réponse:

	Pas du tout dérangeant	Un peu	Moyen	Beaucoup	Énormément dérangeant
Déception ou tristesse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Peur ou inquiétude	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Mauvaise humeur ou colère	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Difficulté à réfléchir ou à te souvenir de certaines choses	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Changement d'apparence (corps ou visage)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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Mains ou pieds qui picotent ou sont engourdis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Vomissements ou envie de vomir	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Plus faim ou moins faim que d'habitude	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Changements du goût	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Constipation (difficulté à faire caca)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Diarrhée (caca mou ou liquide)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Écris ci-dessous les autres choses qui te dérangent dernièrement.

# BMJ Open

## Translating the Symptom Screening in Pediatrics Tool (SSPedi) into French and Among French-speaking Children Receiving Cancer Treatments, Evaluating Understandability and Cultural Relevance in a Multiple-Phase Descriptive Study

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13 AUTHORS: Valérie Larouche, MD<sup>1</sup>; Gabriel Revon-Rivière, MD<sup>2</sup>; Donna Johnston, MD<sup>3</sup>;  
14 Oluwatoni Adeniyi<sup>3</sup>; Panagiota Giannakouros<sup>1</sup>; Robyn Loves, HBS<sup>4</sup>; Jenna-Lee Tremblay<sup>3</sup>;  
15 Erin Plenert, MPH<sup>4</sup>; L. Lee Dupuis, RPh, PhD<sup>4,5</sup>; Lillian Sung, MD, PhD<sup>4,6</sup>  
16  
17  
18  
19  
20  
21

22 AFFILIATIONS:

23  
24 <sup>1</sup>Department of Pediatrics, Centre Mère-Enfant Soleil du CHU de Québec-Université Laval,  
25 2705 Boulevard Laurier, Québec, Québec, G1V 4G2, Canada  
26  
27

28 <sup>2</sup>Department of Pediatric Hematology and Oncology, La Timone Children's Hospital, APHM, 265  
29 Rue Saint-Pierre, Marseille, 13005, France  
30  
31

32 <sup>3</sup>Division of Hematology/Oncology, Children's Hospital of Eastern Ontario, 401 Smyth Road,  
33 Ottawa, Ontario, K1H 8L1, Canada  
34  
35

36 <sup>4</sup>Program in Child Health Evaluative Sciences, The Hospital for Sick Children, Peter Gilgan  
37 Centre for Research and Learning, 686 Bay Street, Toronto, Ontario, M5G 0A4, Canada  
38  
39

40 <sup>5</sup>Department of Pharmacy, The Hospital for Sick Children, 555 University Avenue, Toronto,  
41 Ontario, M5G 1X8, Canada  
42  
43

44 <sup>6</sup>Division of Haematology/Oncology, The Hospital for Sick Children, 555 University Avenue,  
45 Toronto, Ontario, M5G 1X8, Canada  
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## CORRESPONDING AUTHOR:

Lillian Sung MD, PhD

Division of Haematology/Oncology

The Hospital for Sick Children

555 University Avenue

Toronto, Ontario

M5G 1X8

Telephone: 416-813-5287

Fax: 416-813-5979

Email: [lillian.sung@sickkids.ca](mailto:lillian.sung@sickkids.ca)

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## ABSTRACT

**Objectives:** Symptom Screening in Pediatrics Tool (SSPedi) is a validated approach to measuring bothersome symptoms for English- and Spanish-speaking children with cancer and pediatric hematopoietic stem cell transplantation recipients. Objectives were to translate SSPedi into French, and among French-speaking children receiving cancer treatments, to evaluate understandability and cultural relevance.

**Methods:** We conducted a multi-phase, descriptive study to translate SSPedi into French. Forward translation was performed by four medical translators. After confirming that back translation was satisfactory, we enrolled French-speaking children with cancer and pediatric hematopoietic stem cell transplantation recipients at four centers in France and Canada.

**Primary and Secondary Outcome Measures:** Understandability was evaluated by children themselves who self-reported degree of difficulty, and by two adjudicators who rated incorrectness. Assessment of cultural relevance was qualitative. Participants were enrolled in cohorts of 10.

**Results:** There were 30 children enrolled. Participants were enrolled from Marseille (n=10, 33%), Ottawa (n=1, 3%), Quebec City (n=11, 37%) and Toronto (n=8, 27%). No child reported that it was hard or very hard to complete French SSPedi in the last cohort of 10 participants. Changes to the instrument itself were not required. After enrollment of 30 respondents, the French translation of SSPedi was considered finalized based upon self-reported difficulty with understanding, adjudicated incorrect understanding and cultural relevance.

**Conclusions:** We translated and finalized SSPedi for use by French-speaking children and adolescents receiving cancer treatments. Future work should begin to use the translated version to conduct research and to facilitate clinical care.

### STRENGTHS AND LIMITATIONS OF THIS STUDY

- Multi-center conduct
- Multiple approaches to assessing understandability
- Use of external adjudicators
- Limited by conduct in only two countries

For peer review only

## BACKGROUND

Children with cancer and pediatric hematopoietic stem cell transplantation (HSCT) recipients commonly experience severely bothersome symptoms.(1-3) The Symptom Screening in Pediatrics Tool (SSPedi) is a reliable and valid approach to measuring bothersome symptoms in English-speaking children 8-18 years of age receiving cancer treatments.(4) SSPedi was developed because of the need for a short and simple symptom screening and assessment tool for clinical utilization in children receiving cancer treatments.(5) SSPedi requires about two to three minutes to complete and it includes the following 15 symptoms considered most important to children and their guardians: disappointed or sad, scared or worried, cranky or angry, problems thinking, body or face changes, tiredness, mouth sores, headache, other pain, tingling or numbness, throwing up, hunger changes, taste changes, constipation and diarrhea. SSPedi also allows children to record additional bothersome symptoms not already listed.

We conducted a multi-center study in Canada and the United States to evaluate the psychometric properties of SSPedi. SSPedi was reliable (internal consistency and test re-test and inter-rater reliability), valid (construct validity) and responsive to change in 502 English-speaking children 8-18 years of age receiving cancer therapies.(4) More specifically, the intraclass correlation coefficients were 0.88 (95% CI 0.82 to 0.92) for test re-test reliability, and 0.76 (95% confidence interval (CI) 0.71 to 0.80) for inter-rater reliability between children and parents. Mean difference in SSPedi scores between groups hypothesized to be more and less symptomatic was 7.8 (95% CI 6.4 to 9.2;  $P<0.001$ ).(4) Construct validity was demonstrated as all hypothesized relationships among measures were observed. SSPedi was responsive to change; those who reported they were much better or worse on a global symptom change scale had significantly changed from their baseline score (mean absolute difference 5.6, 95% CI 3.8 to 7.5;  $P<0.001$ ).

We previously translated SSPedi into Spanish (personal communication, Lillian Sung, January 9, 2020) and clarified the procedures we would adopt generically for SSPedi translation

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3 and evaluation. Canada is a bilingual (French and English) country. We therefore next chose to  
4 translate SSPedi into French. Objectives were to translate SSPedi into French, and among  
5 French-speaking children receiving cancer treatments, to evaluate understandability and cultural  
6 relevance of the translation.  
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## 11 12 13 **METHODS**

14  
15 We conducted a multi-phase, descriptive study to translate SSPedi into French. This study was  
16 approved by The Hospital for Sick Children's Research Ethics Board (#1000057560) and the  
17 Research Ethics Boards of all participating sites. Written informed consent and assent were  
18 obtained from all study participants. For children providing assent, guardians also provided  
19 informed consent.  
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### 28 **Translation of SSPedi from English to French**

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30 Translation of SSPedi into French included forward translation, reconciliation, back  
31 translation and back translation review. Methods followed the principles for the translation and  
32 cultural adaptation process from The Professional Society for Health Economics and Outcomes  
33 Research (ISPOR) Task Force.<sup>(6)</sup>  
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39 We convened a translation panel composed of the Toronto-based research team (RL,  
40 EP, LD, LS), the four forward translators, and the investigators and interviewers from enrollment  
41 sites where the translation was tested (VL, GRR, DJ, PG, OA). The Toronto-based research  
42 team included one pediatric oncologist, one pediatric pharmacist, one clinical research manager  
43 and one research student.  
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49 The initial forward translation of SSPedi was performed independently by four  
50 professional medical translators who are native French speakers. We planned to have two  
51 translators from each country in which the translation would be tested. Two translators had  
52 previously resided in France while the other two had always resided in Canada. Two were  
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3 currently residing in Quebec (primary provincial language is French) and two were currently  
4 residing in Ontario (primary provincial language is English). In addition to translating SSPedi,  
5 the translators also translated the synonym list, which provides alternative words for each  
6 SSPedi symptom. The translation panel met through WebEx meetings to reconcile the four  
7 forward translations, with the goal of producing a single translated version of the tool.  
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9 Discrepancies between the translated versions of SSPedi were identified and resolved by  
10 consensus, with input from French-speaking investigators.  
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18 Once the panel was satisfied with the translated version of the tool, it was sent to a new,  
19 independent translator for back translation. The back translation was performed by a bilingual  
20 native English-speaker with no previous knowledge of the original English version of SSPedi.  
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22 The Toronto-based research team verified that the back translation did not contain  
23 mistranslations or inaccuracies. Next, this version was approved by all members of the  
24 translation panel prior to testing with patients.  
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### 32 **Cognitive Interviewing to Evaluate Understandability and Cultural Relevance**

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35 Eligible participants were native French-speaking children with cancer and pediatric  
36 HSCT recipients who were 8-18 years of age at the time of the interview. We excluded those  
37 who were not able to participate in the interview because of cognitive, visual or hearing  
38 limitations as judged by a member of the patient's healthcare team.  
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44 The evaluation of translated SSPedi was performed using in-person interviews. All  
45 interviews were conducted by trained personnel who are fluent in the target language. All  
46 interviews were audio-recorded and adjudicated by the Toronto-based team. The goals of  
47 cognitive interviewing were to determine whether children self-reported that SSPedi items  
48 (introduction, response scale and individual symptoms) were hard to understand, whether  
49 children were incorrect in their understanding of SSPedi items as adjudicated by an external  
50 rater, and whether translated SSPedi was culturally appropriate.  
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3 Initially, the child participant or their guardian completed a demographic questionnaire.  
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5 Next, each participant was given time to complete the translated version of SSPedi in the  
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7 presence of the interviewer. The entire tool or specific items could be read aloud if requested by  
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9 the participant. Then the participant was asked how easy or hard SSPedi was to complete  
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11 overall using a 5-point Likert scale ranging from 1 = “very hard” to 5 = “very easy”. To assess  
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13 cultural relevance, the participant was asked whether any of the questions did not make sense  
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15 to them in thinking about their day-to-day life, as someone living in their country.  
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18 Next, the SSPedi instructions and the response options were presented and evaluated  
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20 separately. The instructions were read aloud and the participant was asked to rate how easy or  
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22 hard it was to understand them using the same 5-point Likert scale previously described. Next,  
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24 using cognitive interviewing and pre-specified probes, the interviewer assessed whether the  
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26 participant was correct in their understanding of the instructions and, specifically, the concept of  
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28 bother. Understanding of the degree of bother, in other words, the response options, was also  
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30 assessed. Adjudicator-assessed understanding was rated on a 4-point Likert scale ranging from  
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32 1 = “completely incorrect” to 4 = “completely correct”.  
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35 Then, each of the 15 SSPedi items was presented and evaluated separately. First, the  
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37 individual SSPedi item was read aloud. Second, the participant was asked to rate how easy or  
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39 hard that item was to understand using the same 5-point Likert scale previously described. We  
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41 focused on the number who rated an item as very hard or hard to understand (score of 1 or 2 on  
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43 the 5-point scale). Third, using cognitive interviewing and pre-specified probes, the interviewer  
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45 assessed whether the participant was correct in their understanding of each item using the 4-  
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47 point Likert scale previously described. We focused on the number that were completely or  
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49 mostly incorrect (score of 1 or 2 on the 4-point scale).  
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52 Inevaluable interviews were those where: (a) a participant could not understand the  
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54 questions posed during cognitive interviews (not the SSPedi items themselves); or (b) the  
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56 interviewer failed to probe the participant during the cognitive interview (thus not permitting  
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3 evaluation of understanding). Upon completion of the interview, the audiotape was sent to  
4 Toronto. The Toronto-based adjudicator listened to the transcripts to identify inevaluable  
5 interviews and, for evaluable interviews, to independently rate the participant's extent of  
6 understanding of translated SSPedi. Discrepancies between the assessments of the Toronto-  
7 based adjudicator and in-country interviewer were resolved by a third Toronto-based reviewer.  
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14 The Toronto-based research team met after each group of five interviews were  
15 completed to review participant responses and decide whether the translated version of SSPedi  
16 or the synonym list of terms required modification. Formal evaluation of outcomes was  
17 performed after each cohort of 10 participants and these occurred with the entire translation  
18 panel by WebEx meetings. Modification was required when at least two participants among the  
19 last cohort of 10 participants: (a) found an item hard or very hard to understand; (b) were  
20 completely or mostly incorrect in their understanding of an item; (c) other comments suggested  
21 changes were required, including those related to cultural relevance. To be finalized, the  
22 translated version of SSPedi must not have required any substantive changes in the last cohort  
23 of 10 participants interviewed. There was no attempt to compare findings between French-  
24 speaking children from Canada and France.  
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### 39 **Patient and Public Involvement**

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41 No patients were involved in study design or conduct apart from being participants in the  
42 research.  
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## 47 **RESULTS**

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49 Between September 24, 2018 and June 21, 2019, we identified 49 children and enrolled  
50 30 participants before the French translation of SSPedi was finalized. Figure 1 illustrates the  
51 flow diagram of participant identification and enrollment. Table 1 shows the demographic  
52 characteristics of the three cohorts of 10 participants enrolled to this study. The number of  
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participants who were 8-10, 11-14 and 15-18 years of age were 8 (27%), 11(37%) and 11 (37%) respectively. Participants were enrolled from Marseille, France (10, 33%), Ottawa, Canada (1, 3%), Quebec City, Canada (11, 37%) and Toronto, Canada (8, 27%).

**Table 1: Demographic Characteristics of Participants Evaluating the French Translation of SSPedi**

	Cohort 1 (n=10)	Cohort 2 (n=10)	Cohort 3 (n=10)
Age in Years			
8-10	1	3	4
11-14	6	2	3
15-18	3	5	3
Male Sex	6	6	7
Diagnosis			
Leukemia	2	0	1
Lymphoma	2	0	1
Solid tumor	3	2	5
Brain tumor	3	8	3
Metastatic Disease	5	5	3
On Active treatment	6	9	9
Hematopoietic Stem Cell Transplantation	1	0	0
Inpatient at Interview	4	5	2
Attending School	9	5	8
Sites of Enrollment			
Marseille, France	5	1	4
Ottawa, Canada	0	0	1
Québec City, Canada	0	8	3
Toronto, Canada	5	1	2
Confident Speaking French			
Not at all	0	0	0
Not very	0	0	0
Somewhat	0	1	1
Confident	1	2	0
Very confident	9	7	9
Confident Reading French			
Not at all	0	0	0
Not very	0	0	0
Somewhat	0	2	0
Confident	4	4	1
Very confident	6	4	9

Abbreviation: SSPedi – Symptom Screening in Pediatrics Tool

Table 2 shows understandability by SSPedi item in terms of self-reported difficulty with understanding (number finding an item hard or very hard to understand) and adjudicated incorrect understanding (number interpreting an item mostly or completely incorrectly). Changes made during the first two cohorts were only modifications to the synonym list; the instrument itself did not require modification. For the last cohort of 10 participants interviewed, none of the respondents reported that it was hard or very hard to complete French SSPedi overall. One found a single item hard to understand (changes in how your body or face look) and one was incorrect in their understanding of an item (mouth sores). Among all 30 participants, no issues in terms of cultural relevance were raised. None of the participants identified important missing symptoms from SSPedi. The finalized version of the French translation of SSPedi is shown as Figure 2.

**Table 2: Self-reported Difficulty and Rater-Adjudicated Incorrectness in Understanding the French Translation of SSPedi**

SSPedi Item	Cohort 1 (n=10)		Cohort 2 (n=10)		Cohort 3 (n=10)	
	Hard*	Incorrect**	Hard*	Incorrect**	Hard*	Incorrect**
SSPedi Instructions	0	0	1	0	0	0
SSPedi Items:						
Feeling disappointed or sad	0	0	1	0	0	0
Feeling scared or worried	0	0	0	0	0	0
Feeling cranky or angry	1	0	0	0	0	0
Problems with thinking or remembering things	0	0	0	0	0	0
Changes in how your body or face look	0	0	1	0	1	0
Feeling tired	0	0	0	0	0	0
Mouth sores	0	0	1	2	0	1
Headache	0	0	0	0	0	0
Hurt or pain (other than headache)	0	0	0	0	0	0
Tingly or numb hands or feet	0	0	0	1	0	0
Throwing up or feeling like you may throw up	0	0	0	0	0	0
Feeling more or less hungry	0	0	0	0	0	0

than you usually do						
Changes in taste	0	0	0	0	0	0
Constipation (hard to poop)	0	1	0	1	0	0
Diarrhea (watery, runny poop)	0	0	0	0	0	0
Response Scale	NA	0	NA	0	NA	0

Abbreviation: SSPedi – Symptom Screening in Pediatrics Tool; NA – not assessed

\*How hard or easy each section was to understand as rated by participants - the number who rated the section as hard or very hard to understand is shown

\*\*Participant understanding of each section as rated by the in-country interviewer and a Toronto-based adjudicator - the number who were rated as mostly or completely incorrect is shown

## DISCUSSION

We reported the process for translating and evaluating the French version of SSPedi. The final version was well-understood by French-speaking children receiving cancer treatments. The translation of patient-reported outcomes to other languages is important to reduce disparities and ensure all children can benefit from approaches to improve quality of life.

We enrolled 30 participants in this study and required that modifications not be required among the last 10 participants evaluating the translated version of SSPedi. Although several instruments have been translated and validated using fewer participants (7-9), we felt it was important to enroll a modest number to increase confidence in the assessment of understandability. We also used at least two adjudicators of understanding to improve the reliability of this assessment.

While translation of a self-report symptom assessment tool for children receiving cancer treatments 8-18 years of age is important, it will also be important to extend translation to other French-speaking respondents. These include proxy-respondents in the setting of children 8-18 years of age with illness acuity or impairments that preclude self-reporting of symptoms. Such an instrument is available in English.<sup>(10)</sup> Similarly, translation of a symptom screening tool for

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3 younger children is also important. While such a tool has been developed for children 4-7 years  
4 of age,(11) it has not yet been validated in English.  
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7 The strengths of this research include its multi-center conduct and multiple approaches  
8 to assessing understandability. Audio-recording interviews and use of an external adjudicator is  
9 another strength that enhances rigor of the research. However, the study is limited by its  
10 conduct in only two Francophone countries; evaluation in other French-speaking nations may  
11 not necessarily yield the same results. In addition, only one HSCT recipient was included and  
12 thus, further evaluation in this population is warranted.  
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19 In conclusion, we translated and finalized SSPedi for use by French-speaking children  
20 and adolescents receiving cancer treatments. Future work should begin to use the translated  
21 version to conduct research and to facilitate clinical care.  
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29 We thank all the translators who worked with us on this project and whose expertise and  
30 insights greatly assisted the translation and evaluation process.  
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32

## 33 **AUTHOR CONTRIBUTORSHIP**

34 LD and LS developed the study concept and design. EP, RL, GRR, PG, OA, and JT were  
35 involved in data collection. LS drafted the manuscript. All authors VL, GRR, DJ, OA, PG, RL,  
36 JT, EP, LD, and LS participated in data interpretation, reviewed, revised, and approved the  
37 manuscript.  
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## 45 **COMPETING INTERESTS**

46 The authors declare that they have no competing interests.  
47  
48

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50 This research received no specific grant from any funding agency in the public, commercial or  
51 not-for-profit sectors.  
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## 55 **DATA SHARING**

1  
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3 The datasets used or analyzed during the current study are available from the corresponding  
4 author on reasonable request.  
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6  
7 **FIGURE LEGEND**  
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9 Figure 1: Flow Diagram of Participant Identification and Enrollment  
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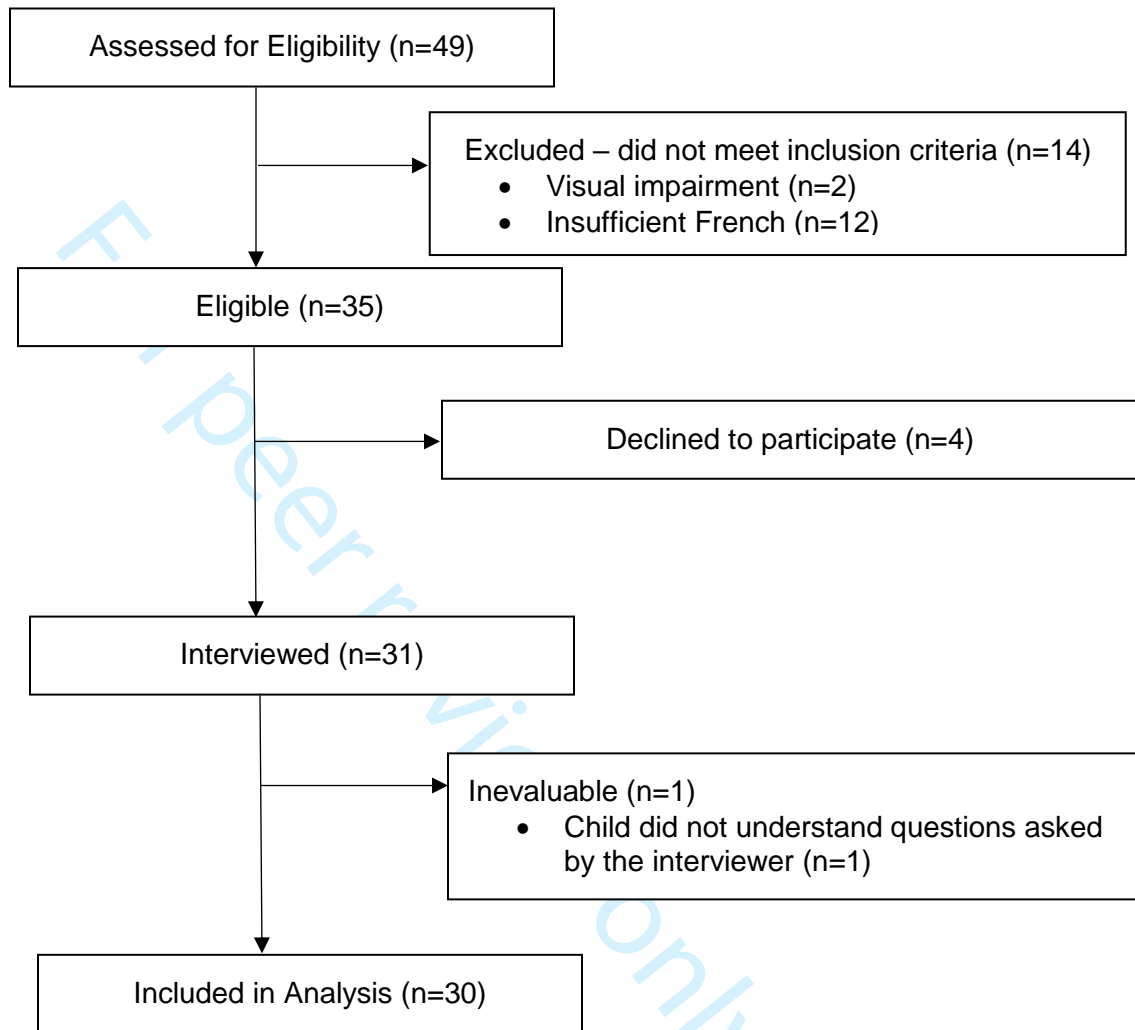
11 Figure 2: French Translation of SSPedi  
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Figure 1: Participant Identification and Enrollment Flow Diagram





## SSPedi: Évaluation des symptômes en pédiatrie

À quel point ces choses ont été dérangeantes **hier ou aujourd'hui**? Fais une marque dans le cercle qui correspond le mieux à ta réponse:

	Pas du tout dérangeant	Un peu	Moyen	Beaucoup	Énormément dérangeant
Déception ou tristesse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Peur ou inquiétude	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Mauvaise humeur ou colère	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Difficulté à réfléchir ou à te souvenir de certaines choses	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Changement d'apparence (corps ou visage)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fatigue	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Plaies dans la bouche	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Mal de tête	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Douleurs (autres que mal de tête)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Mains ou pieds qui picotent ou sont engourdis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Vomissements ou envie de vomir	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Plus faim ou moins faim que d'habitude	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Changements du goût	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Constipation (difficulté à faire caca)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Diarrhée (caca mou ou liquide)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Écris ci-dessous les autres choses qui te dérangent dernièrement.

# BMJ Open

## Translating the Symptom Screening in Pediatrics Tool (SSPedi) into French and Among French-speaking Children Receiving Cancer Treatments, Evaluating Understandability and Cultural Relevance in a Multiple-Phase Descriptive Study

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Complete List of Authors:	Larouche, Valérie; CHU de Québec-Université Laval, Department of Pediatrics Revon-Rivière, Gabriel; Hospital Timone, Department of Pediatric Hematology and Oncology Johnston, Donna; Children's Hospital of Eastern Ontario, Division of Hematology/Oncology Adeniyi, Oluwatoni; Children's Hospital of Eastern Ontario, Division of Hematology/Oncology Giannakouros, Panagiota; CHU de Québec-Université Laval, Department of Pediatrics Loves, Robyn; Hospital for Sick Children Research Institute, Child Health Evaluative Sciences Tremblay, Jenna-Lee; Children's Hospital of Eastern Ontario, Division of Hematology/Oncology Plenert, Erin; Hospital for Sick Children Research Institute, Child Health Evaluative Sciences Dupuis, Lee; Hospital for Sick Children Research Institute, Child Health Evaluative Sciences; Hospital for Sick Children, Department of Pharmacy Sung, Lillian; Hospital for Sick Children, Division of Haematology/Oncology; Hospital for Sick Children Research Institute, Child Health Evaluative Sciences
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Secondary Subject Heading:	Paediatrics
Keywords:	Paediatric oncology < ONCOLOGY, Bone marrow transplantation < HAEMATOLOGY, Paediatric oncology < PAEDIATRICS

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4 French-speaking Children Receiving Cancer Treatments, Evaluating Understandability and  
5 Cultural Relevance in a Multiple-Phase Descriptive Study  
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13 AUTHORS: Valérie Larouche, MD<sup>1</sup>; Gabriel Revon-Rivière, MD<sup>2</sup>; Donna Johnston, MD<sup>3</sup>;  
14 Oluwatoni Adeniyi<sup>3</sup>; Panagiota Giannakouros<sup>1</sup>; Robyn Loves, HBSc<sup>4</sup>; Jenna-Lee Tremblay<sup>3</sup>;  
15 Erin Plenert, MPH<sup>4</sup>; L. Lee Dupuis, RPh, PhD<sup>4,5</sup>; Lillian Sung, MD, PhD<sup>4,6</sup>  
16  
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21

22 AFFILIATIONS:  
23

24 <sup>1</sup>Department of Pediatrics, Centre Mère-Enfant Soleil du CHU de Québec-Université Laval,  
25 2705 Boulevard Laurier, Québec, Québec, G1V 4G2, Canada  
26  
27

28 <sup>2</sup>Department of Pediatric Hematology and Oncology, La Timone Children's Hospital, APHM, 265  
29 Rue Saint-Pierre, Marseille, 13005, France  
30  
31

32 <sup>3</sup>Division of Hematology/Oncology, Children's Hospital of Eastern Ontario, 401 Smyth Road,  
33 Ottawa, Ontario, K1H 8L1, Canada  
34  
35

36 <sup>4</sup>Program in Child Health Evaluative Sciences, The Hospital for Sick Children, Peter Gilgan  
37 Centre for Research and Learning, 686 Bay Street, Toronto, Ontario, M5G 0A4, Canada  
38  
39

40 <sup>5</sup>Department of Pharmacy, The Hospital for Sick Children, 555 University Avenue, Toronto,  
41 Ontario, M5G 1X8, Canada  
42  
43

44 <sup>6</sup>Division of Haematology/Oncology, The Hospital for Sick Children, 555 University Avenue,  
45 Toronto, Ontario, M5G 1X8, Canada  
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## CORRESPONDING AUTHOR:

Lillian Sung MD, PhD

Division of Haematology/Oncology

The Hospital for Sick Children

555 University Avenue

Toronto, Ontario

M5G 1X8

Telephone: 416-813-5287

Fax: 416-813-5979

Email: [lillian.sung@sickkids.ca](mailto:lillian.sung@sickkids.ca)

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## ABSTRACT

**Objectives:** Symptom Screening in Pediatrics Tool (SSPedi) is a validated approach to measuring bothersome symptoms for English- and Spanish-speaking children with cancer and pediatric hematopoietic stem cell transplantation recipients. Objectives were to translate SSPedi into French, and among French-speaking children receiving cancer treatments, to evaluate understandability and cultural relevance.

**Methods:** We conducted a multi-phase, descriptive study to translate SSPedi into French. Forward translation was performed by four medical translators. After confirming that back translation was satisfactory, we enrolled French-speaking children with cancer and pediatric hematopoietic stem cell transplantation recipients at four centers in France and Canada.

**Primary and Secondary Outcome Measures:** Understandability was evaluated by children themselves who self-reported degree of difficulty, and by two adjudicators who rated incorrectness. Assessment of cultural relevance was qualitative. Participants were enrolled in cohorts of 10.

**Results:** There were 30 children enrolled. Participants were enrolled from Marseille (n=10, 33%), Ottawa (n=1, 3%), Quebec City (n=11, 37%) and Toronto (n=8, 27%). No child reported that it was hard or very hard to complete French SSPedi in the last cohort of 10 participants. Changes to the instrument itself were not required. After enrollment of 30 respondents, the French translation of SSPedi was considered finalized based upon self-reported difficulty with understanding, adjudicated incorrect understanding and cultural relevance.

**Conclusions:** We translated and finalized SSPedi for use by French-speaking children and adolescents receiving cancer treatments. Future work should begin to use the translated version to conduct research and to facilitate clinical care.

### STRENGTHS AND LIMITATIONS OF THIS STUDY

- Multi-center conduct
- Multiple approaches to assessing understandability
- Use of external adjudicators
- Limited by conduct in only two countries

For peer review only



## BACKGROUND

Children with cancer and pediatric hematopoietic stem cell transplantation (HSCT) recipients commonly experience severely bothersome symptoms.(1-3) The Symptom Screening in Pediatrics Tool (SSPedi) is a reliable and valid approach to measuring bothersome symptoms in English-speaking children 8-18 years of age receiving cancer treatments.(4) SSPedi was developed because of the need for a short and simple symptom screening and assessment tool for clinical utilization in children receiving cancer treatments.(5) SSPedi requires about two to three minutes to complete and it includes the following 15 symptoms considered most important to children and their guardians: disappointed or sad, scared or worried, cranky or angry, problems thinking, body or face changes, tiredness, mouth sores, headache, other pain, tingling or numbness, throwing up, hunger changes, taste changes, constipation and diarrhea. SSPedi also allows children to record additional bothersome symptoms not already listed.

We conducted a multi-center study in Canada and the United States to evaluate the psychometric properties of SSPedi. SSPedi was reliable (internal consistency and test re-test and inter-rater reliability), valid (construct validity) and responsive to change in 502 English-speaking children 8-18 years of age receiving cancer therapies.(4) More specifically, the intraclass correlation coefficients were 0.88 (95% CI 0.82 to 0.92) for test re-test reliability, and 0.76 (95% confidence interval (CI) 0.71 to 0.80) for inter-rater reliability between children and parents. Mean difference in SSPedi scores between groups hypothesized to be more and less symptomatic was 7.8 (95% CI 6.4 to 9.2;  $P<0.001$ ).(4) Construct validity was demonstrated as all hypothesized relationships among measures were observed. SSPedi was responsive to change; those who reported they were much better or worse on a global symptom change scale had significantly changed from their baseline score (mean absolute difference 5.6, 95% CI 3.8 to 7.5;  $P<0.001$ ).

We previously translated SSPedi into Spanish (personal communication, Lillian Sung, January 9, 2020) and clarified the procedures we would adopt generically for SSPedi translation

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2  
3 and evaluation. Canada is a bilingual (French and English) country. We therefore next chose to  
4 translate SSPedi into French. Objectives were to translate SSPedi into French, and among  
5 French-speaking children receiving cancer treatments, to evaluate understandability and cultural  
6 relevance of the translation.  
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## 11 12 13 **METHODS**

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15 We conducted a multi-phase, descriptive study to translate SSPedi into French. This study was  
16 approved by The Hospital for Sick Children's Research Ethics Board (#1000057560), the  
17 Children's Hospital of Eastern Ontario Research Ethics Board (18/156X), the CHU de Québec-  
18 Université Laval Research Ethics Board (MP-20-2019-4436) and the Committee for the  
19 Protection of People at the Hôpital Timone (#2018-A02299-46) . Written informed consent and  
20 assent were obtained from all study participants. For children providing assent, guardians also  
21 provided informed consent.  
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### 32 **Translation of SSPedi from English to French**

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34 Translation of SSPedi into French included forward translation, reconciliation, back  
35 translation and back translation review, as outlined in Figure 1. Methods followed the principles  
36 for the translation and cultural adaptation process from The Professional Society for Health  
37 Economics and Outcomes Research (ISPOR) Task Force.(6)  
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43 We convened a translation panel composed of the Toronto-based research team (RL,  
44 EP, LD, LS), the four forward translators, and the investigators and interviewers from enrollment  
45 sites where the translation was tested (VL, GRR, DJ, PG, OA). The Toronto-based research  
46 team included one pediatric oncologist, one pediatric pharmacist, one clinical research manager  
47 and one research student.  
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3 The initial forward translation of SSPedi was performed independently by four  
4 professional medical translators who are native French speakers. We planned to have two  
5 translators from each country in which the translation would be tested. Two translators had  
6 previously resided in France while the other two had always resided in Canada. Two were  
7 currently residing in Quebec (primary provincial language is French) and two were currently  
8 residing in Ontario (primary provincial language is English). In addition to translating SSPedi,  
9 the translators also translated the synonym list, which provides alternative words for each  
10 SSPedi symptom. The translation panel met through WebEx meetings to reconcile the four  
11 forward translations, with the goal of producing a single translated version of the tool.  
12 Discrepancies between the translated versions of SSPedi were identified and resolved by  
13 consensus, with input from French-speaking investigators.  
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Once the panel was satisfied with the translated version of the tool, it was sent to a new,  
independent translator for back translation. The back translation was performed by a bilingual  
native English-speaker with no previous knowledge of the original English version of SSPedi.  
The Toronto-based research team verified that the back translation did not contain  
mistranslations or inaccuracies. Next, this version was approved by all members of the  
translation panel prior to testing with patients.

### **Cognitive Interviewing to Evaluate Understandability and Cultural Relevance**

Eligible participants were native French-speaking children with cancer and pediatric  
HSCT recipients who were 8-18 years of age at the time of the interview. We excluded those  
who were not able to participate in the interview because of cognitive, visual or hearing  
limitations as judged by a member of the patient's healthcare team.

The evaluation of translated SSPedi was performed using in-person interviews. All  
interviews were conducted by trained personnel who are fluent in the target language. All  
interviews were audio-recorded and adjudicated by the Toronto-based team. The goals of

1  
2  
3 cognitive interviewing were to determine whether children self-reported that SSPedi items  
4 (introduction, response scale and individual symptoms) were hard to understand, whether  
5 children were incorrect in their understanding of SSPedi items as adjudicated by an external  
6 rater, and whether translated SSPedi was culturally appropriate.  
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11 Initially, the child participant or their guardian completed a demographic questionnaire.  
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13 Next, each participant was given time to complete the translated version of SSPedi in the  
14 presence of the interviewer. The entire tool or specific items could be read aloud if requested by  
15 the participant. Then the participant was asked how easy or hard SSPedi was to complete  
16 overall using a 5-point Likert scale ranging from 1 = "very hard" to 5 = "very easy". To assess  
17 cultural relevance, the participant was asked whether any of the questions did not make sense  
18 to them in thinking about their day-to-day life, as someone living in their country.  
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26 Next, the SSPedi instructions and the response options were presented and evaluated  
27 separately. The instructions were read aloud and the participant was asked to rate how easy or  
28 hard it was to understand them using the same 5-point Likert scale previously described. Next,  
29 using cognitive interviewing and pre-specified probes, the interviewer assessed whether the  
30 participant was correct in their understanding of the instructions and, specifically, the concept of  
31 bother. Understanding of the degree of bother, in other words, the response options, was also  
32 assessed. Adjudicator-assessed understanding was rated on a 4-point Likert scale ranging from  
33 1 = "completely incorrect" to 4 = "completely correct".  
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43 Then, each of the 15 SSPedi items was presented and evaluated separately. First, the  
44 individual SSPedi item was read aloud. Second, the participant was asked to rate how easy or  
45 hard that item was to understand using the same 5-point Likert scale previously described. We  
46 focused on the number who rated an item as very hard or hard to understand (score of 1 or 2 on  
47 the 5-point scale). Third, using cognitive interviewing and pre-specified probes, the interviewer  
48 assessed whether the participant was correct in their understanding of each item using the 4-  
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3 point Likert scale previously described. We focused on the number that were completely or  
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5 mostly incorrect (score of 1 or 2 on the 4-point scale).  
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7 Inevaluable interviews were those where: (a) a participant could not understand the  
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9 questions posed during cognitive interviews (not the SSPedi items themselves); or (b) the  
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11 interviewer failed to probe the participant during the cognitive interview (thus not permitting  
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13 evaluation of understanding). Upon completion of the interview, the audiotape was sent to  
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15 Toronto. The Toronto-based adjudicator listened to the transcripts to identify inevaluable  
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17 interviews and, for evaluable interviews, to independently rate the participant's extent of  
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19 understanding of translated SSPedi. Discrepancies between the assessments of the Toronto-  
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21 based adjudicator and in-country interviewer were resolved by a third Toronto-based reviewer.  
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24 The Toronto-based research team met after each group of five interviews were  
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26 completed to review participant responses and decide whether the translated version of SSPedi  
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28 or the synonym list of terms required modification. Formal evaluation of outcomes was  
29  
30 performed after each cohort of 10 participants and these occurred with the entire translation  
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32 panel by WebEx meetings. Modification was required when at least two participants among the  
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34 last cohort of 10 participants: (a) found an item hard or very hard to understand; (b) were  
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36 completely or mostly incorrect in their understanding of an item; (c) other comments suggested  
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38 changes were required, including those related to cultural relevance. To be finalized, the  
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40 translated version of SSPedi must not have required any substantive changes in the last cohort  
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42 of 10 participants interviewed. There was no attempt to compare findings between French-  
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44 speaking children from Canada and France.  
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### 49 **Patient and Public Involvement**

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51 No patients were involved in study design or conduct apart from being participants in the  
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53 research.  
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## RESULTS

Between September 24, 2018 and June 21, 2019, we identified 49 children and enrolled 30 participants before the French translation of SSPedi was finalized. Figure 2 illustrates the flow diagram of participant identification and enrollment. Table 1 shows the demographic characteristics of the three cohorts of 10 participants enrolled to this study. The number of participants who were 8-10, 11-14 and 15-18 years of age were 8 (27%), 11(37%) and 11 (37%) respectively. Participants were enrolled from Marseille, France (10, 33%), Ottawa, Canada (1, 3%), Quebec City, Canada (11, 37%) and Toronto, Canada (8, 27%).

**Table 1: Demographic Characteristics of Participants Evaluating the French Translation of SSPedi**

	Cohort 1 (n=10)	Cohort 2 (n=10)	Cohort 3 (n=10)
Age in Years			
8-10	1	3	4
11-14	6	2	3
15-18	3	5	3
Male Sex	6	6	7
Diagnosis			
Leukemia	2	0	1
Lymphoma	2	0	1
Solid tumor	3	2	5
Brain tumor	3	8	3
Metastatic Disease	5	5	3
On Active treatment	6	9	9
Hematopoietic Stem Cell Transplantation	1	0	0
Inpatient at Interview	4	5	2
Attending School	9	5	8
Sites of Enrollment			
Marseille, France	5	1	4
Ottawa, Canada	0	0	1
Québec City, Canada	0	8	3
Toronto, Canada	5	1	2
Confident Speaking French			
Not at all	0	0	0
Not very	0	0	0
Somewhat	0	1	1
Confident	1	2	0
Very confident	9	7	9

Confident Reading French			
Not at all	0	0	0
Not very	0	0	0
Somewhat	0	2	0
Confident	4	4	1
Very confident	6	4	9

Abbreviation: SSPedi – Symptom Screening in Pediatrics Tool

Table 2 shows understandability by SSPedi item in terms of self-reported difficulty with understanding (number finding an item hard or very hard to understand) and adjudicated incorrect understanding (number interpreting an item mostly or completely incorrectly). Changes made during the first two cohorts were only modifications to the synonym list; the instrument itself did not require modification. For the last cohort of 10 participants interviewed, none of the respondents reported that it was hard or very hard to complete French SSPedi overall. One found a single item hard to understand (changes in how your body or face look) and one was incorrect in their understanding of an item (mouth sores). Among all 30 participants, no issues in terms of cultural relevance were raised. None of the participants identified important missing symptoms from SSPedi. The finalized version of the French translation of SSPedi is shown as Figure 3.

**Table 2: Self-reported Difficulty and Rater-Adjudicated Incorrectness in Understanding the French Translation of SSPedi**

SSPedi Item	Cohort 1 (n=10)		Cohort 2 (n=10)		Cohort 3 (n=10)	
	Hard*	Incorrect**	Hard*	Incorrect**	Hard*	Incorrect**
SSPedi Instructions	0	0	1	0	0	0
SSPedi Items:						
Feeling disappointed or sad	0	0	1	0	0	0
Feeling scared or worried	0	0	0	0	0	0
Feeling cranky or angry	1	0	0	0	0	0
Problems with thinking or remembering things	0	0	0	0	0	0

Changes in how your body or face look	0	0	1	0	1	0
Feeling tired	0	0	0	0	0	0
Mouth sores	0	0	1	2	0	1
Headache	0	0	0	0	0	0
Hurt or pain (other than headache)	0	0	0	0	0	0
Tingly or numb hands or feet	0	0	0	1	0	0
Throwing up or feeling like you may throw up	0	0	0	0	0	0
Feeling more or less hungry than you usually do	0	0	0	0	0	0
Changes in taste	0	0	0	0	0	0
Constipation (hard to poop)	0	1	0	1	0	0
Diarrhea (watery, runny poop)	0	0	0	0	0	0
Response Scale	NA	0	NA	0	NA	0

Abbreviation: SSPedi – Symptom Screening in Pediatrics Tool; NA – not assessed

\*How hard or easy each section was to understand as rated by participants - the number who rated the section as hard or very hard to understand is shown

\*\*Participant understanding of each section as rated by the in-country interviewer and a Toronto-based adjudicator - the number who were rated as mostly or completely incorrect is shown

## DISCUSSION

We reported the process for translating and evaluating the French version of SSPedi. The final version was well-understood by French-speaking children receiving cancer treatments. The translation of patient-reported outcomes to other languages is important to reduce disparities and ensure all children can benefit from approaches to improve quality of life.

We enrolled 30 participants in this study and required that modifications not be required among the last 10 participants evaluating the translated version of SSPedi. Although several instruments have been translated and validated using fewer participants (7-9), we felt it was important to enroll a modest number to increase confidence in the assessment of understandability. We also used at least two adjudicators of understanding to improve the reliability of this assessment.



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3 While translation of a self-report symptom assessment tool for children receiving cancer  
4 treatments 8-18 years of age is important, it will also be important to extend translation to other  
5 French-speaking respondents. These include proxy-respondents in the setting of children 8-18  
6 years of age with illness acuity or impairments that preclude self-reporting of symptoms. Such  
7 an instrument is available in English.(10) Similarly, translation of a symptom screening tool for  
8 younger children is also important. While such a tool has been developed for children 4-7 years  
9 of age,(11) it has not yet been validated in English.  
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13 The strengths of this research include its multi-center conduct and multiple approaches  
14 to assessing understandability. Audio-recording interviews and use of an external adjudicator is  
15 another strength that enhances rigor of the research. However, the study is limited by its  
16 conduct in only two Francophone countries; evaluation in other French-speaking nations may  
17 not necessarily yield the same results. In addition, only one HSCT recipient was included and  
18 thus, further evaluation in this population is warranted.  
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22 In conclusion, we translated and finalized SSPedi for use by French-speaking children  
23 and adolescents receiving cancer treatments. Future work should begin to use the translated  
24 version to conduct research and to facilitate clinical care.  
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### 30 31 32 33 34 35 36 37 38 39 **ACKNOWLEDGMENTS**

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41 We thank all the translators who worked with us on this project and whose expertise and  
42 insights greatly assisted the translation and evaluation process.  
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### 45 46 **AUTHOR CONTRIBUTORSHIP**

47 LD and LS developed the study concept and design. EP, RL, GRR, PG, OA, and JT were  
48 involved in data collection. LS drafted the manuscript. All authors VL, GRR, DJ, OA, PG, RL,  
49 JT, EP, LD, and LS participated in data interpretation, reviewed, revised, and approved the  
50 manuscript.  
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### 55 56 **COMPETING INTERESTS**

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2  
3 The authors declare that they have no competing interests.  
4

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6  
7 This research received no specific grant from any funding agency in the public, commercial or  
8  
9 not-for-profit sectors.  
10

#### 11 **DATA SHARING**

12  
13 The datasets used or analyzed during the current study are available from the corresponding  
14  
15 author on reasonable request.  
16

#### 17 **FIGURE LEGEND**

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20 Figure 1: Standard Approach for Translation, Validation, and Finalization of SSPedi  
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22 Figure 2: Flow Diagram of Participant Identification and Enrollment  
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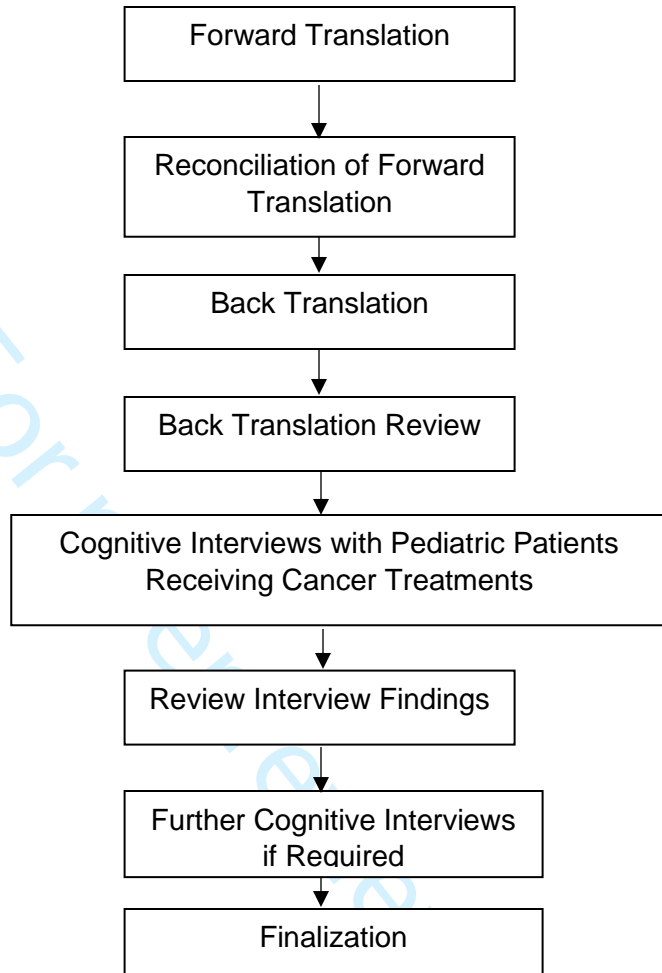
24 Figure 3: French Translation of SSPedi  
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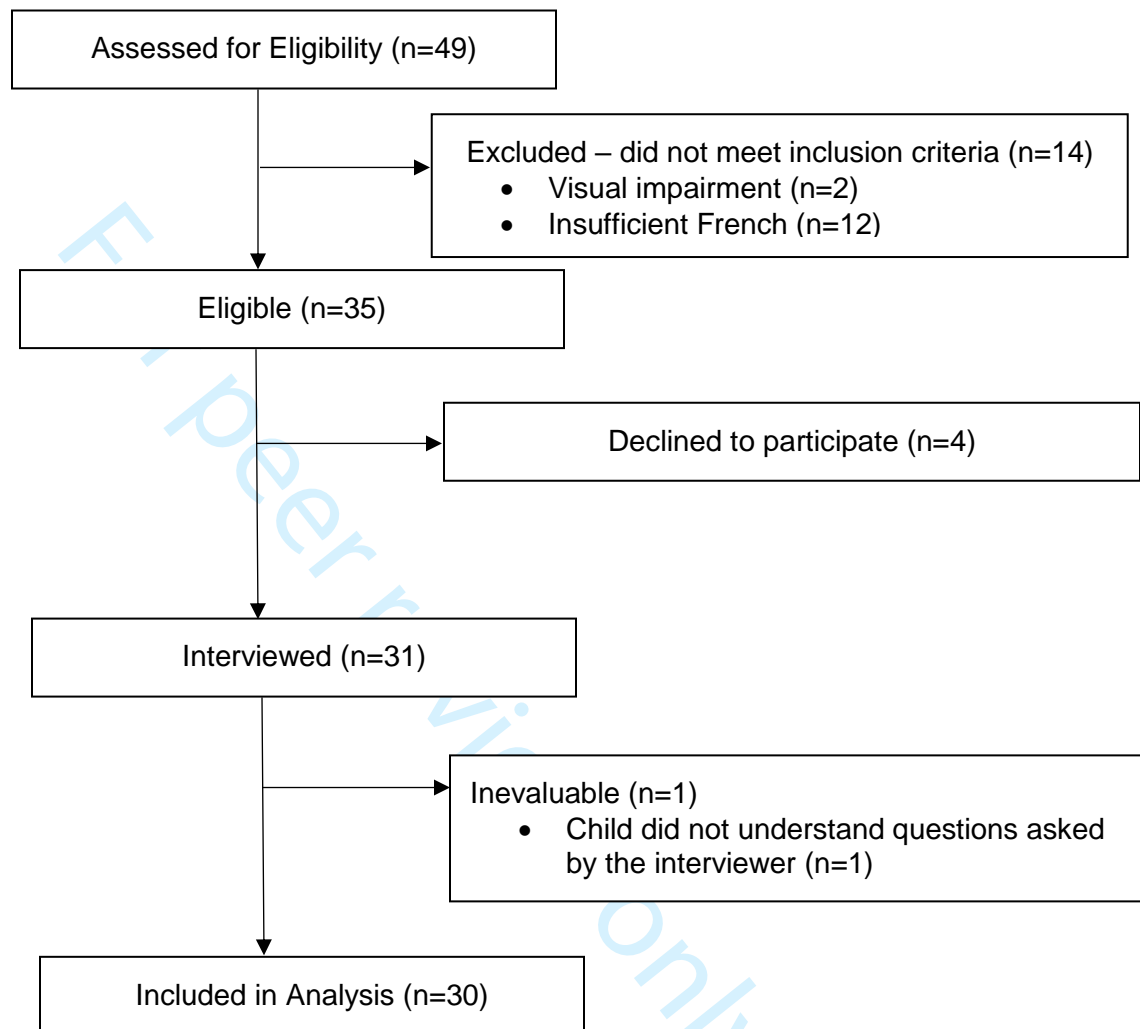
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Figure 1: Standard Approach for Translation, Validation, and Finalization of SSPedi



**Figure 2: Participant Identification and Enrollment Flow Diagram**

## SSPedi: Évaluation des symptômes en pédiatrie

À quel point ces choses ont été dérangeantes **hier ou aujourd'hui**? Fais une marque dans le cercle qui correspond le mieux à ta réponse:

	Pas du tout dérangeant	Un peu	Moyen	Beaucoup	Énormément dérangeant
Déception ou tristesse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Peur ou inquiétude	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Mauvaise humeur ou colère	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Difficulté à réfléchir ou à te souvenir de certaines choses	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Changement d'apparence (corps ou visage)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fatigue	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Plaies dans la bouche	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Mal de tête	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Douleurs (autres que mal de tête)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Mains ou pieds qui picotent ou sont engourdis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Vomissements ou envie de vomir	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Plus faim ou moins faim que d'habitude	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Changements du goût	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Constipation (difficulté à faire caca)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Diarrhée (caca mou ou liquide)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Écris ci-dessous les autres choses qui te dérangent dernièrement.