documents by a professional linguist; 2) verification of the translation against the source documents by a second professional linguist; 3) quality control review for semantics, grammar, syntax, punctuation and reading level; and 4) review by a third linguist to ensure that the translation was complete and read well. The translated documents were revised by the translation service based on feedback from four French-speaking investigators (A-ML, EO, MP-M, LLD).

The French-language PeNAT and supporting documents were then reviewed by three bilingual, pediatric oncology healthcare professionals to ensure that the translated versions reflected the content of the English documents and were likely to be understood by respondents and to capture the intended information from respondents. Each bilingual healthcare professional read both the source (English) and translated documents (French) with the order of document presentation (English versus French) randomized. They then answered a structured questionnaire (Appendix 1) in a face-to-face interview. Any suggestions for revisions that arose during this process were discussed by investigators. The translated documents were revised by the translation service based on this feedback. If significant revisions were made, a second round of reviews by bilingual healthcare professionals was planned. At each stage of this process, the French-language documents were reviewed by investigators to ensure cohesiveness and consistency with the English language documents.

Face validity testing

Eligible patients were age 4 to 18 years, had no cognitive or physical impairments that precluded completion of the PeNAT and were scheduled to receive moderately or highly emetogenic chemotherapy (Dupuis et al., 2011) at SickKids or MCH on an inpatient or outpatient basis. Furthermore, eligible patients spoke French at home. Patients were identified using institutional admission lists or clinic schedules. Sampling was purposive to ensure that children of varied ages were represented. A sample size of seven to 10 participants is considered sufficient to determine understandability (Willis, 2005). Thus, we enrolled patients and their parents until 10 consecutive participants suggested no substantive revisions to the most recent iteration of the French-language PeNAT and indicated the most recent iteration of the French-language documents was easy or very easy to use. Patients were recruited in groups of five. Each patient participated once only and received a gift card as a token of appreciation at the end of the study period.

Within three days after the last day of the study chemotherapy block, a standard questionnaire (Appendix 2) was administered to each patient's parent by a member of the study team, either by telephone or in person. This questionnaire combined solicited information about the parent's use of the French-language PeNAT and supporting documents, with emphasis on ease of use, readability, and clarity with respect to nausea severity. The first half of the questionnaire focused on the PeNAT and consisted of four questions requiring a yes/no response and three open-ended questions to solicit suggestions for improvements to the PeNAT. The second half of the questionnaire addressed the diary and consisted of four open-ended questions soliciting information about strengths and suggestions for improvement and an assessment by the parent about how easy or difficult the diary was to use on a five-point scale (very easy to very hard). The questionnaire took no more than 10 minutes to complete. Patients could also participate in questionnaire completion if they chose.

The investigators reviewed questionnaire responses from the first group of five participants and decided if revisions to the documents were warranted. Recruitment was paused until this decision was made. Revised versions of the French-language PeNAT and supporting documents were to be reviewed by bilingual healthcare professionals, as described above. As a last step, investigators reviewed the final French-language documents to ensure their cohesiveness and consistency with the English language versions.

Use of the PeNAT and Supporting Documents

A study team member taught each participant how to use the French-language PeNAT and supporting documents and then observed the patient's first use of the PeNAT. Patients were then asked to use the French-language PeNAT to assess their nausea severity at least twice daily on each day of the acute phase of an upcoming chemotherapy block that included MEC or HEC. Patients or parents were also asked to use the French-language diary to record the time of each vomit and each administration of an antiemetic agent during this time. The acute phase was defined as starting with the first chemotherapy dose of the chemotherapy block and continuing for 24 hours after the administration of the last chemotherapy dose of the block. A chemotherapy block was defined as the period of consecutive days where chemotherapy is given on each day. Parents were asked to return the completed diaries to the investigators at a future hospital visit.

Data Collection

Patient demographic, chemotherapy, and antiemetic characteristics were collected from the patient's health record. The diaries completed by participants provided information regarding nausea severity, vomiting control, and antiemetic administration.

Analysis

Parent responses to the questionnaire were collated for review. Face validity was considered to have been demonstrated when 10 consecutive participants indicated that the French-language supporting documents were easy or very easy to use and suggested no revisions to the French-language PeNAT.

Descriptive statistics were used to describe patient demographics and extent of acute phase CINV control that they reported. Complete acute phase CINV control was defined as no emetic episodes and no nausea (maximum PeNAT score of 1). Partial acute phase CINV control was defined as one or two emetic episodes in any 24-hour period or a maximum PeNAT score of 2. Failed acute phase CINV control was defined as more than two emetic episodes in any 24-hour period or a maximum PeNAT score of 3 or 4.