COG-ACCL20N1CD: Financial Distress during Treatment for Pediatric Acute Lymphoblastic Leukemia in the United States

FAST FACTS

Eligibility Reviewed and Verified By

_____ MD/DO/RN/LPN/CRA Date _____

_____ MD/DO/RN/LPN/CRA Date _____

Consent Version Dated_____

PATIENT ELIGIBILITY:

Important note: The eligibility criteria listed below are interpreted literally and cannot be waived (per COG policy posted 5/11/01). All clinical and laboratory data required for determining eligibility of a patient enrolled on this trial must be available in the patient's medical research record which will serve as the source document for verification at the time of audit.

___1. Timing

- Parent Study Entry
  Parent study enrollment must occur after Day 1 of the index child's systemic Induction chemotherapy (excluding intrathecal chemotherapy with diagnostic lumbar puncture) and prior to completion of Induction chemotherapy for ALL (i.e., prior to end-Induction remission evaluation).

  Note: It is recommended that parent enrollment occur by Day 25 of the index child's Induction chemotherapy to allow for timely completion of the parent baseline survey. See Section 4.3.1.1 for parent survey timing details.

- Institution Study Entry
  Institution study enrollment must occur only once and on the same day as the institution's first parent study entry.

___2. Consent

Note: Immediately upon study consent, parents must complete the Parent Information/Contact Form found in Appendix III. The information collected in this form is required for OPEN enrollment and completion of the Parent Contact CRF in Medidata/RAVE, both of which must occur on the same day as parent consent to study.

Parents/legal guardians (hereafter "parents") of a child or adolescent with ALL ("index child") will be approached for consent during systemic Induction chemotherapy. As part of this consent discussion, parents will be given an opt-in opportunity to participate in the individual parent interviews as well as to be contacted for future research.

- For each index child, families must identify one (1) parent to complete the surveys at each time point and the opt-in interview, if selected. This person should be one of the child's caregivers and someone who is responsible, at least in part, for paying the child's/adolescent's medical bills and meeting their basic material needs (e.g., clothes, food, and housing).

- For index children with more than one household, families must designate a primary household and, within that household, the one parent who will complete the surveys at each time point and the opt-in interview, provided that the parent has opted-in and is selected for an interview.

- While there may be more than one parent who meets the above criteria, each family must designate only one parent to participate for the duration of the study to ensure that responses are comparable across time points.

___3. Treating Institution

All COG NCORP institutions are eligible for participation in this study upon first parent enrollment.

___4. Age

Parents age 18 years and above are eligible for this study. Index child must be between the ages of 1 and 14.9 years at the time of the parent's enrollment.

___5. Diagnosis

Parents of an index child with newly diagnosed with de novo ALL are eligible for this study.

___6. Language
Parent must speak English or Spanish in order to participate in the consent process and provide consent. The parent's language skills must be sufficient to understand the study requirements and complete the survey and interview questions.

___7. Treatment
At the parent's entry to the study, the index child must be receiving Induction chemotherapy for newly diagnosed ALL at the enrolling institution. The index child may be enrolled in therapeutic clinical ALL trials or receiving ALL therapy per standard of care.

EXCLUSION CRITERIA

___1. Parents of index children with any of the following clinical characteristics will be excluded from the study:
- KMT2A-R (formerly MLL-R) not receiving ALL therapy.
- Mixed-phenotype acute leukemia (MPAL) not receiving ALL therapy.
- Burkitt's leukemia.

TREATMENT PLAN:

Timing
Parent surveys will be administered at three (3) time points, as detailed in the below table.

Time Point	Phase of Index Child's ALL Treatment	Timeframe for Survey Completion
T1 (baseline survey)	Induction therapy	At study entry and no later than 7 days after planned Induction remission evaluation
T2 (follow-up survey)	Maintenance therapy	During Cycle 1 or Cycle 2 (±7 days) of planned Maintenance therapy
T3 (follow-up survey)	End of therapy	During months 0-3 after planned completion of final chemotherapy (±1 month)

Parents of index children who relapse or proceed to stem-cell transplantation or chimeric antigen receptor-T cell (CAR-T) therapy due to high-risk disease or per protocol, will remain enrolled in the study (as long as the baseline parent survey is completed by end of T1). These parents will be asked to complete one (1) follow-up parent survey within 3-6 months of the index child's non-chemotherapy definitive therapy—for a total completion of 2 or 3 parent surveys, depending on the number of surveys completed prior to the index child's change in therapy. Parents who consented to participate in the opt-in interview will still be eligible to participate in the interview; however, we will not include more than three (3) parents who meet this criterion to ensure generalizability of qualitative data.

In the event of an index child's death, the parent will not be asked to complete any further surveys and will be removed from this study.

Parents who do not complete the baseline survey by the end of T1 will be removed from this study and no further study data will be collected. See Section 5.1 for complete off study criteria.