Procedure of informed assent/consent for clinical trials in pediatric Hemato-Oncology: the adolescents' and parents' point of view.

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Objective: Clinical trials require an assent by the adolescents to participate. Few literature data are available on the experiences expressed by adolescents. A study has been conducted to explore the personal views of adolescents and their parents in order to optimize this consent procedure.

Methods: Adolescents (n=10) and their parents (n=15) completed a questionnaire and were interviewed. Qualitative data were coded using NVIVO 8. Quantitative data were analyzed by the statistic program SPSS.

Results:
All adolescents (>13 years) want to be informed about the trial.
The majority of them want to co-decide. They want this from an average of 10 years (SD=2,88) while parents indicate an average of 12,5 years (SD=2,30).
Adolescents believe that their decision should be accompanied by consultations with parents and physicians. Parents are in favour of a unilateral decision only made by themselves (significant difference between adolescents and mothers, p=0,008) or by a physician.
Adolescents and parents experience mostly positive emotions. Important preconditions for the adolescents were: presence of their parents and structured and clear approach by the physician during the IC interview.
The majority of the adolescents wanted information: as much as possible, adapted to their developmental level. There was a significant difference regarding the amount of information: boys wanted more information than girls (p=0,033).
Both adolescents and parents are positive about participating in clinical trials: it's important to improve cancer treatment and it may help others.
Reported suggestions for improvement: no coincidence between IC and the diagnostic interview, more written/oral information for adolescents, …

Conclusion:
Despite this small sample, the results give us an insight into the adolescents' and parents' point of view.
These results are a first step towards the adaptation and the improvement of the departmental guidelines and towards the adjustment of the written information for adolescents about their participation in clinical trials.