



FACTORS INFLUENCE PARENTS' WILLINGNESS TO CONSENT PEDIATRIC CLINICAL TRIAL AND POSSIBLE CNL INTERVENTIONS

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BACKGROUND & SIGNIFICANCE

- Pediatric clinical trials/ studies are facing tremendous difficulties in recruiting participants. Parents refuse to consent to participation which can lead to delays in the research process and greatly impedes the progress of pediatric treatments.
- At Boston Children's Hospital, less than half (49.7%) of all protocols achieved 80% or more of their target enrollment sample size (Denhoff et al., 2015).
- A possible root cause is information asymmetry: a gap of medical knowledge and health literacy between healthcare professionals and patients.
- Nurses as a key role in care team/ research team can help parents better understand the potential risk and benefit for participation and hence increase their willingness to participate.

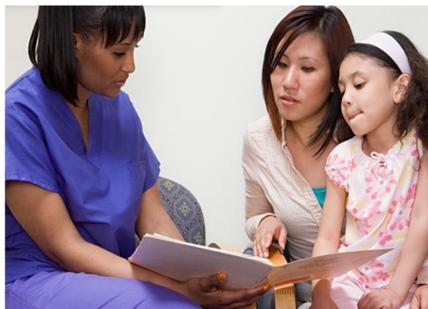
METHODS-Summary of Search

Database: PubMed

Keywords: pediatric, consent, clinical trials, and nurse.

Exclusion criteria: articles published later than 2014.

Results: 6 articles relevant to PICOT topic were selected.



EVIDENCE SUMMARY

Authors	Level of Evidence (Melnik, 2019)	Type of study	Sample Size	Overall Quality (JHNEBP):	Results
Crane et al., 2021	Level 5	Qualitative, empirical phenomenology study	N=11	Good quality	5 aspects were identified as challenging for families: learning about clinical trials, get referred to another institution, difficulty in keep up with research-only procedures, adhering to trial requirements, and difficulty in administering oral medications.
Denhoff et al., 2015	Level 4	Cross-sectional, web-based survey	N=182	Good quality	Protocols that used recruitment in person were 9.07 times (95% CI 2.09 to 39.35; p = 0.003) more likely to achieve 50% of target enrollment when compared to other methods of recruitment.
Drury et al., 2021	Level 5	Qualitative interview study	N=26	Good quality	Factors that most concerning to parents: potential risks of additional procedures; personal benefit and altruism; timing and approach; and trust in the clinical team.
Greenberg et al., 2018	Level 5	Qualitative interview study	N=24	Good quality	Wishes of participation of the child him/herself is an important factor for parents to make decision if their child is old enough to communicate and understand clinical trials participation.
Kaur et al., 2016	Level 5	Qualitative survey study	N=169	High quality	Effective communication and coordination between study team members at the site (74.5%), presence of a research nurse (68.1%) are the top-rated facilitator to recruitments.
Keusch et al., 2014	Level 5	Qualitative interview study	N=23	Good quality	Lack of feedback of study results were the top concerns among participants.

CONCLUSIONS

Factors in increasing parents' willingness to participate:

- 1) Timing of the approach/ recruitment;
- 2) Understanding of study logistics, risk and benefit, and questions regarding the studies are answered at the time of recruiting;
- 3) In-person recruiting with research nurses/ other nursing staff being present during the recruiting process to facilitating logistics, advocate for patients' concerns, and patient education.

PICOT

Among pediatric patients qualified to participate clinical research trails, are parents more willing to consent with additional information given by the care team staff compare to only the consentor/ researcher during the recruiting process?

IMPLICATION FOR NURSING PRACTICE & ROLE OF THE CNL

Role of the CNL:

- Participant centered approach of recruitment: CNL lead training secessions to increase clinical research staff's cultural awareness, sensitivity to appropriate time for recruitment approach is strongly recommended to improve participant's satisfaction and trust toward research team.
- Patient and staff education: adoption of educational tools such as short videos describe the trial and use of other social medias for patient to access trail information at anytime, anywhere.
- Facilitate interdisciplinary communication and team coordination: CNL can lead some changes to team dynamics and logistics to improve research team coordination in providing patient adequate information during recruiting and follow-up care needed.

REFERENCES

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