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Commentary

Challenges with recruitment in pediatric procedural pain research

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It is generally accepted that many procedural pain management (PPM) interventions that are considered clinically effective for infants (such as breastfeeding and skin-to-skin care) and older children (including topical anesthetics and distraction) are ineffective or less effective for toddlers (12-36 months; Pillai Riddell et al., 2011; Harrison et al., 2015 ; Birnie et al., 2018). Existing PPM interventions are largely considered less effective for toddlers than older children due to toddlers' early emotional and cognitive developmental stage (Thrane et al., 2016). This is further complicated by the limited number of validated assessment tools for use among toddlers (McMurtry et al., 2011; Crellin et al., 2018). We designed a study to explore PPM strategy use and efficacy for toddlers in a previously unstudied setting but encountered significant recruitment challenges. Our experiences with this study highlight some universal challenges to recruiting toddlers into PPM studies. In this commentary, we use our study as an illustrative example to discuss considerations for overcoming common recruitment challenges with pediatric procedural pain research.

Low enrollment is a common phenomenon in pediatric research. A web-based survey identified that nearly 31% of pediatric clinical studies were discontinued due to low enrollment, 34% of protocols did not reach 80% of targeted enrollment before closure, and recruitment difficulties caused significant delays for many others (Denhoff et al., 2015). Our study aimed to recruit 50 toddlers undergoing venipuncture from one inpatient and two outpatient pediatric clinics using convenience sampling. Most toddlers who had a physician's order for venipuncture were eligible. The annual inpatient admission rate to the inpatient unit was approximately 200 toddlers. It was assumed this would remain relatively constant. Visit rates for the outpatient clinics were unavailable. Although venipuncture rates were unavailable, unit managers and staff believed the study to be feasible based on perceived venipuncture rates. Combined with the assumption that general pediatric research follows the 15-20% non-consent rate found in pediatric critical care research (Menon et al., 2012), it was anticipated that recruitment would be straightforward and enrollment goals feasible.

In these clinical settings, primary nurses perform venipuncture procedures and were identified as being in an ideal position to identify potential participants. Nurses were asked to notify the primary investigator (PI) of upcoming venipunctures as researchers were not allowed to access patient information before study consent and enrollment. Toddlers' primary nurses were directed to ask caregivers' permission to be approached by the PI who was physically present on the units during the day and on-call by phone at night. Posters were provided for distribution to caregivers and reminder emails were sent to staff. These recruitment methods were deemed feasible to the researchers, nurses, and unit managers.

The study protocol ran for 10 weeks. During this time the PI was never notified of any venipuncture procedures despite extensive study promotion. For approximately half of the research days, no toddlers were present on the units. When toddlers were present, it was reported bloodwork had not been ordered or had been collected in other units. On two occasions it was identified that venipuncture had been performed without PI notification. These nurses reported forgetting about the study, PI absence at night, and staff quickly completing the procedure due to patient clinical instability as barriers to following the established protocol. Resultantly, no toddlers were screened, no consents were obtained, and the study was terminated.

Recruitment methods are considered the most common factors affecting successful study enrollment, with in-person recruitment having been identified as the most important factor (Denhoff et al., 2015). Introduction of the researcher to participants by the healthcare team and short participation duration have also been reported to improve enrollment rates (Denhoff et al., 2015). Each of these factors was identifiable within our research protocol. Intermittent absence of toddlers on the units could only be attributed to unpredictable fluctuations in admissions. Non-consent (i.e. refusal) was not a factor as no opportunities for enrollment arose but reasons for non-consent should be monitored by future researchers and protocols adapted as needed (Menon et al., 2012).

Missed opportunities to enroll participants, restrictive inclusion criteria, and PI unavailability are common recruitment barriers (Denhoff et al., 2015). Our study asked nurses to notify the researcher when an enrollment opportunity presented. This did not occur and resulted in at least two missed enrollment opportunities. Based on this experience, researchers should consider the use of researcher- rather than clinician-driven participant recruitment methods when designing future event-based protocols. For example, in settings using phlebotomy teams, the PI or another study staff member could follow phlebotomists to identify potential participants. Improving nurses' engagement to reduce the frequency of missed enrollment opportunities when staff involvement is essential to study success may also improve enrollment. Researchers should consider involving staff in ways that are appropriate and meaningful to their clinical practice from the outset of the study design (Bowen & Graham, 2013). Highlighting patient- and nursing-specific benefits of possible research outcomes is one way to accomplish this. Throughout our study, nurses reported bloodwork was frequently performed on infants and older children and was often limited to the time of admission for toddlers. However, tight age eligibility criteria were an unavoidable enrollment-limiting factor given our study's purpose. When feasible, restrictive inclusion criteria should be reevaluated for studies experiencing enrollment difficulties (Denhoff et al., 2015). Alternatively, age-specific subgroup analysis from age-diverse samples could be considered. Due to the 24-hour functioning of inpatient units and clinical urgency of venipuncture when ordered in hospitals, having more than one recruiter available for 24-hour on-site presence may also improve recruitment rates. However, these strategies would require larger overall sample sizes and would increase study costs, both in terms of personnel time and expense.

While efforts to reduce painful procedure frequency in young children are appropriate, these practice changes have made clinical research exploring these procedures more difficult to conduct. In our study, it was ultimately identified that our recruitment challenges were attributable to a low frequency of toddler-specific venipuncture. Several factors may explain the low frequency of venipuncture found in our study. The use of unnecessary procedures and diagnostic testing in the Canadian healthcare system is a common problem, with up to 30% of procedures and tests being deemed unnecessary despite existing campaigns to reduce unnecessary testing (Choosing Wisely Canada, 2019). Although the studied organization has not formally partnered with these campaigns, it is possible that healthcare professionals are beginning to reevaluate practices in favor of less invasive diagnostic and monitoring approaches. More research is needed to confirm this finding.

Staff in one of the two outpatient clinics anecdotally discussed a decrease in the routine use

of testing. They stated, historically, any young child presenting with a fever was assessed by a physician, ordered to have a bloodwork panel and in-and-out urinary catheterization was completed to identify infection sources. Staff stated this practice has recently become significantly less common as physicians are opting to use assessment findings in tandem with illness history in place of painful tests and procedures. In the second clinic, staff identified the placement of central venous lines as a priority for children who were expected to undergo long-term treatment and monitoring. Inpatient unit nurses identified that critically ill toddlers requiring frequent bloodwork commonly had central venous lines rapidly placed to reduce venipuncture requirements. Nurses were aware that aspiration from existing intravenous catheters is not best practice for specimen collection but commonly reported this practice as one way they could reduce the pain and distress inflicted on pediatric patients. Additionally, most blood sampling was being completed before admission to the inpatient unit, often when intravenous catheters were placed in the Emergency Department.

Site-specific venipuncture rates before and during the study period were unavailable. To date, no identified studies have explored venipuncture rates in different age groups at outpatient pediatric clinics. Changing healthcare practices, in combination with the limited availability of age- and procedure-specific data, must be therefore considered when designing future single-site study protocols with restrictive enrollment criteria. Venipuncture rate data could be collected before future studies to support protocol feasibility. Limiting data collection to venipuncture procedures may have also affected enrollment rates. Including a variety of painful procedures such as intravenous cannulation, nasogastric tube insertion, and painful dressing changes in procedural pain studies may result in easier recruitment while still providing evidence for PPM efficacy in similar studies with tight age-eligibility criteria.

Due to significant enrollment challenges with a seemingly well-designed protocol, our study, like many others, failed to recruit the targeted number of participants. Future researchers must consider the feasibility of research protocols for each research setting, use multiple recruitment strategies, and be willing to adapt protocols as needed. In the context of changing healthcare practices and a perceived reduction in painful procedures, researchers must continue to develop innovative approaches to participant recruitment and research design, while reducing the number of painful procedures for children of all ages should be a healthcare provider priority.

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