Original Research

Deferred consent model for an observational study in a pediatric emergency department

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Abstract

Background: A limited amount of literature has been published regarding the use of deferred consent for studies involving children. We aim to inform future studies by reporting the results of an observational study in a pediatric emergency department which employed a deferred consent model.

Methods: Over a 14-month period, prospective data was collected on children who presented to the emergency department of the IWK Health Center (Halifax, NS, Canada) and the Alberta Children's Hospital (Calgary, AB, Canada) with blunt abdominal trauma. At presentation in Halifax, parents were offered the option of deferring consent until they could speak to a member of the study team. In Calgary, parents had to decide to consent or not at the time of assessment.

Results: A total of forty potential study participants were approached over the study period. All 8 of the participants in Halifax consented to be enrolled, with 25% choosing to defer consent. In Calgary, where there was no option to defer consent, only 53% provided consent for study enrolment.

Conclusions: A deferred consent model should be considered when designing observational studies in the pediatric emergency department setting. Based on the results of our small study, deferred consent is feasible, an acceptable option for parents, and aided our ability to maximize enrolment. Further research is required to validate our findings.

Introduction

Conducting prospective research studies in the pediatric emergency department (ED) setting is a time-sensitive and resource-intensive endeavor. Particularly in the setting of pediatric trauma research, potential study participants present to the ED infrequently, and at all times of the day. Despite this challenge, key data must be collected at the time of presentation in order to produce valid results[1,2]. Given this, consenting and enrolling participants on an ongoing basis for prospective studies in the ED usually requires research staff to be present around the clock to maximize recruitment and minimize selection bias. However, the feasibility of maintaining such staffing at all times is limited by resource availability. We present the results of a study that used a deferred consent model. This model provided a more feasible approach to recruiting study participants for our observational study in the ED while maintaining research ethics standards[2-4].

Deferred consent has been used successfully in several studies in the United Kingdom and Australia[1,5]. This has yielded positive results from both a participant and an investigator perspective. In the pediatric ED there is a conflict between the requirement for informed consent prior to data collection, which may not be feasible in emergencies, and the need for high-quality prospective evidence to guide clinical decision making[1]. There is also uncertainty regarding the validity of informed consent when it is obtained in the stressful environment of a pediatric emergency; in this case, parents or guardians are unlikely to fully process the study information provided, and so are unlikely to give consent that is fully informed[6]. This is a situation unique to the pediatric ED, and this clinical area has a paucity of published data on obtaining consent. Additionally, the need for initiation of emergent investigations and treatment without delay often leaves little time to obtain consent[7]. In certain cases, obtaining informed consent before starting management could even compromise patient care, particularly in circumstances when a parent or guardian is not initially present[1]. Deferring consent to participation in an observational study avoids delaying emergency interventions while still ensuring fully informed consent to the use of patient data[2].

We designed an observational study to assess the feasibility of running a larger multicenter study which would collect data on clinical predictors of significant injury after pediatric blunt abdominal trauma. The aim of this paper is to present and describe the impact of our deferred consent model using results from this observational study. To our knowledge, this model represents a novel consent process and may serve as a blueprint for future research in the pediatric ED.

Materials and Methods

The authors collected data over a 14-month period on children less than 18 years of age who presented to the ED of either the IWK Health Centre, Halifax, NS, Canada (IWK) or the Alberta Children's Hospital, Calgary, AB, Canada (ACH) with blunt abdominal trauma. The IWK employed a deferred consent model, while the ACH did not. Consent was required to permit collection of clinical variables related to the traumatic event and to allow the study team to follow-up with the parents via telephone in order to rule-out missed injuries should the child be discharged from the ED. The study protocol was approved by the Offices of Research Ethics at the IWK and ACH.

Participants at both sites were flagged by registration or triage staff in the ED for inclusion in the study and a Data Collection Form was placed on each participant's chart. The Data Collection Form was completed by the emergency physician in order to obtain the time-sensitive data regarding their clinical assessment of the trauma. The registration clerk or nursing staff gave the potential participants' parent(s)/guardian(s) an Information and Consent Form (ICF) to review while waiting in the ED. After reviewing the ICF, they could choose to provide written consent to participate or not to participate in the study. At the IWK, parent(s)/guardian(s) were also provided with a third option to defer consent until speaking to a member of the study team (Figure 1). For those who wished to speak to a study team member before giving consent, or for those potential participants who had a completed Data Collection Form without an ICF, a member of the study team contacted them via telephone within four days to obtain informed consent.

For participants who declined to be included in the study, all data collected by the emergency physician on the Data Collection Form, except for the date and time of assessment, age, and gender of the patient, were destroyed. The patient's electronic medical record was not accessed by the study team if consent was not obtained.

For each participant who did consent to inclusion in the study, data from their initial clinical assessment by the emergency physician were inputted into a secure research database. Further clinical data regarding each participant's injury were collected by the study team from the participant's electronic medical record to determine the clinical significance and possible predictors of the injury.

Results

A total of forty children were approached over the 14-month study period: 8 at the IWK, and 32 at the ACH.

Of the eight sets of parent(s)/guardian(s) that reviewed the ICF at the IWK, 6 (75%) provided written consent immediately, and 2 (25%) wished to defer con-

If you are **too busy to decide now or want more time to think about it**, one of the study team members will contact you within 4 days to ask if you are willing to include you/your child's information in the study. **If you decide you want to wait to consent, you do not need to complete this form.**

I have read or had read to me this information and consent form and have had the chance to ask questions which have been answered to my satisfaction before signing my name. I understand the nature of the study and I understand the harms and benefits. I understand that I have the right to withdraw from the study at any time without affecting my care in any way. I have received a copy of the Information and Consent Form for future reference. I freely agree to participate in this research study.

_____
Name of Participant (printed)

_____	_____	_____
Parent/Guardian Name (printed)	**Parent/Guardian Signature**	**Date**

PLEASE CHECK ONE:

☐ **Yes,** I wish to participate ☐ **No**, I do not wish to participate ☐ I would like **more information**

☐ ***Do you wish to receive a lay summary of the results of the study? If so provide your address:***

Email or postal address_____

Figure 1. Excerpt from Information & Consent Form at the IWK Health Centre.

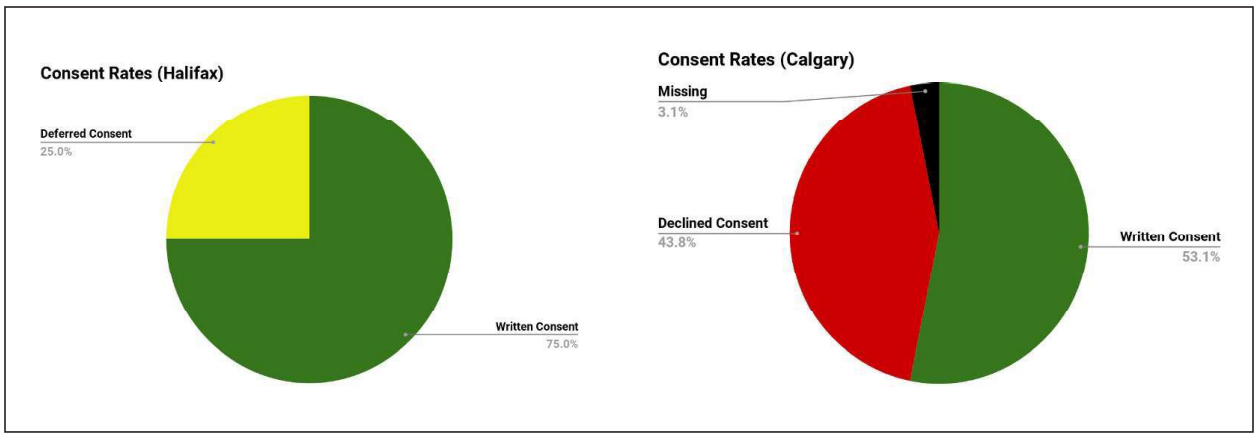

Figure 2. Consent Rates at the IWK Health Centre (Halifax) and the Alberta Children's Hospital (Calgary). The Halifax study site offered a deferred consent option to participants, whereas the Calgary site did not.

sent. After speaking with a study team member via telephone, both participants' parent(s)/guardian(s) ultimately provided consent. No participants denied consent at the IWK, where the deferred consent model was employed.

Of the 32 sets of parent(s)/guardian(s) that reviewed the ICF at the ACH, 17 (53%) provided written consent immediately, 14 (43%) denied consent and 1 (3%) did not complete the form. No participants were able to defer consent as this study site did not employ the deferred consent model (Figure 2).

Discussion

The ED presents many barriers to conducting prospective research. One of the major difficulties was obtaining informed consent prior to the collection of time-sensitive data. ED visits are often an incredibly stressful time for pediatric patients and their families, particularly in the setting of trauma. Reading a consent form and making an informed decision about research participation can be overwhelming in this environment and can lead to a default response of denied consent. Deferred consent provides an opportunity for participants and their families to review study information in a less stressful setting, thereby allowing them to be better informed prior to their consent decision.

Our data demonstrates that a deferred consent model is feasible and ethical. Deferred consent was offered to the 8 potential participants identified at the Halifax site. Of those approached, 6 consented to participate in the study immediately, while the 2 participants who chose to defer consent agreed to participate after speaking with a member of the research team. At the Calgary site, 32 potential participants were identified, each of whom was approached by a research assistant at the time of assessment to either confirm or deny consent. Of those approached, 17 consented to participate in the study immediately, 14 declined to participate in the study, and in one case the form was not completed. At the Calgary site, potential participants and their families did not have the option to defer consent until they were able to speak with a member of the study team. Though we appreciate that this is a small sample size, it is possible that the Calgary site would have seen an improved participation rate had they provided the option for deferred consent. We do acknowledge that we did not explicitly survey participants to gauge their level of satisfaction with the deferred consent process. This would be valuable information to include in a future study.

Another advantage of the deferred consent model is that it reduces the incidence of missing or incomplete consent forms. The protocol approved by the Research Ethics Board at the Halifax site allowed a study team member to contact a participant's guardian within four days should their Data Collection Form be collected with an incomplete or missing ICF. Forms can be easily misplaced or left incomplete in the setting of a busy ED; the deferred consent model helps limit the number of participants missed as a result of this. The Calgary site did not employ the deferred consent model and had to exclude one participant due to an incomplete ICF. The data for this patient would have likely been included at the Halifax site, as deferred consent could have been obtained by contacting the potential participant's guardian within four days of presentation.

The deferred consent model provides a more feasible option when it is not possible to have study team members constantly available to obtain patient consent. This model can minimize the resources required to conduct emergency department research, leading to exciting observational research opportunities.

Finally, though not addressed in our study, the question has been raised as to whether consent is re-

quired at all in the context of observational prospective clinical data collection in the pediatric ED for the purpose of research. In this study, aside from any data obtained from the tool used by the emergency physician to systematically document clinical findings, all data used by the researchers would have ultimately been available from participants' electronic health records. Had we opted to perform this study retrospectively using electronic health records, waiver of consent would have been permitted. However, systematic collection of clinical variables (such as abdominal exam findings) that were to be examined for the purpose of a developing a clinical decision tool would have been limited in a retrospective study. Undoubtedly, the general principles of ethics in research, including doing good (beneficence), doing no harm (non-maleficence), assuring confidentiality and minimizing risk to participants, must be upheld in all research. There is ongoing debate surrounding how to uphold these principles while balancing them with the feasibility of obtaining informed consent and the need for quality prospective research to guide clinical decision making, particularly in the setting of acute care, but that is beyond the scope of this paper[8].

The main limitation of our study is the small number of participants recruited through the Halifax site where the deferred consent model was used. It would be beneficial to use the deferred consent model at a site better staffed to identify potential study participants. This would help to determine whether potential participants would utilize the deferred consent option, and whether this would result in increased consent rates.

Conclusion

When designing observational studies to be conducted in the pediatric emergency department setting, researchers should consider the use of a deferred consent model when approaching children and their parents for recruitment. While some may see deferred consent as aa shortcut and cost-cutting measure, our experience demonstrates that it is, in fact, a feasible option acceptable to parents at a stressful time, and that it may help to increase consent rates. Further research is required to determine the validity and acceptability of using a deferred consent model in a larger study.

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