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Who Speaks for Me? Addressing Variability in Informed Consent Practices for Minimal Risk Research Involving Foster Youth

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Abstract

Background: Youth in protective custody (e.g.. foster care) are at higher risk for poorer physical and mental health outcomes compared with those who are not in custody. These differences may be due in part to the lack of research on the population to create evidence-based recommendations for health care delivery. A potential contributor to this lack of research is difficulties in obtaining informed consent for empirical studies in this population. The objective of this study was to describe the approaches to obtaining informed consent in minimal risk studies of foster youth and provide recommendations for future requirements.

Methods: We conducted a systematic review of the literature to characterize the informed consent approaches in published minimal risk research involving youth in foster care. We searched PubMed, CINAHL, PsychINFO, Embase, ERIC, Scopus, and EBMR. Inclusion criteria were: studies conducted in the United States, included current foster youth, minimal risk, peer reviewed, and published in English. Full text was reviewed, and individuals required to consent and assent were extracted.

Results: Forty-nine publications from 33 studies were identified. Studies required 0 to 3 individuals to consent. Individuals required to give consent included case workers (16, 48%), foster caregivers (12, 36%), biological parents (7, 21%), judges (5, 15%), and guardian ad litems (2, 6%). Twenty-nine (88%) studies required the youth's assent. The studies used 14 different combinations of individuals. One (3%) study utilized a waiver of consent.

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Conclusions: There is no consistent approach for obtaining informed consent for foster youth to participate in minimal risk research. Consent should ideally involve individuals with legal authority and knowledge of the individual youth's interests and should not be burdensome. Consensus regarding consent requirements may facilitate research involving foster youth.

Keywords

foster care; informed consent; child welfare; custody; research

Introduction

Over 430,000 children are in protective custody (e.g. foster care) in the United States (U.S. Department of Health and Human Services, 2016). Retrospective chart reviews suggest that foster children face a wide range of health challenges (AAP Council on Foster Care, 2015; Beal & Greiner, 2015; Chernoff, Combs-Orme, Risley-Curtiss, & Heisler, 1994; Hansen, Mawjee, Barton, Metcalf, & Joye, 2004; Jee & Simms, 2006; Takayama, Wolfe, & Coulter, 1998). Nearly half of foster children have chronic medical conditions (Kavaler F, 1983; Leslie et al., 2005; Steele & Buchi, 2008; Stein et al., 2013) and one-third to one-half have developmental delays/cognitive impairment (Jee et al., 2010). Rates of preventable health issues, including mental health concerns and acute health problems, are also greatly elevated in foster children, particularly among older youth (Simms, Dubowitz, & Szilagyi, 2000). Studies of young people who were emancipated from foster care when they were between 18 and 21 years of age also indicate poorer outcomes: they experience higher rates of sexually transmitted infections, pregnancy, drug use/abuse, and chronic medical conditions compared to young adults who were never in foster care (Courtney, 2005). Young adults formerly in foster care also experience lower access to needed medical care and self-rated quality of health (Courtney, 2005). It is important to identify ways to improve these health outcomes.

Despite identified health disparities, there is a limited evidence base to inform providers of the origin and course of the health problems in foster youth and potential interventions that would improve their lives. Existing research studies are primarily qualitative and descriptive with small sample sizes or analyses of administrative data. Health care providers often face challenges implementing these interventions in children in foster care because the child welfare system itself introduces unique dynamics into the patient's care, such as uncertainty regarding the stability of a given foster placement, the identity of the primary caregiver, and the method of securing consent for treatment (AAP Council on Foster Care, 2015).

The lack of evidence-based treatment recommendations may be due in part to decreased research opportunities related to difficulties obtaining informed consent (Liu, Cox, Washburn, Croff, & Crethar, 2017). Informed consent, the understanding and voluntary agreement to participate in research, is believed to be one of the most important research protections because it protects the autonomy of the subject and thereby ensures that the welfare and interests of the subject are always the highest priority (Gupta, 2013). When the research subject is a child, informed consent is generally provided by the parent(s) or guardian(s) with assent from the child when developmentally appropriate (National Institutes of Health, 2016).

Children in foster care do not have a traditional parent serving as a guardian to promote and protect their welfare and interests and provide informed consent. Instead, foster youth have a variety of adults who serve in different roles: the biological parent(s) may retain the right to see the child and participate in medical decision making, the foster caregiver oversees the child's day-to-day activities and has an obligation to meet the child's daily needs, the caseworker is the temporary legal custodian and oversees the child's healthcare decisions, the guardian ad litem (GAL) and court appointed special advocate (CASA) serve as the legal representatives and advocate for the child's interests, and the judge or magistrate is the final decision-maker regarding the child's stay in foster care. It is frequently unclear who can and should provide informed consent for foster youth to participate in research. Requiring multiple individuals to consent may be logistically burdensome.

Additionally, institutional review boards (IRBs) sometimes consider youth in foster care vulnerable to coercion or undue influence and require extra protections with respect to informed consent and assent. While the Office for Human Research Protections (OHRP) provides guidance on the protection of foster children in research and obtaining informed consent, it has not provided guidance to clarify who among a number of eligible individuals acting on behalf of the child as custodian or in loco parentis should provide consent for children in foster care.

The objective of this study was to identify the informed consent requirements used in published minimal risk research involving foster youth to better understand what approaches investigators and institutional review boards (IRBs) have considered acceptable and to make recommendations for future consent requirements.

Methods

A systematic review of the literature was conducted to characterize the informed consent requirements in published minimal risk research involving youth in foster care. Studies were included if they were conducted in the United States; included current, as opposed to former, foster youth; were minimal risk; peer reviewed, and published in the English language. Eligibility was limited to studies conducted in the United States because child welfare practices vary by country. To maximize the number of studies included in the review, the search was not limited to specific years.

A search of PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), PsychINFO, Embase, Education Resources Information Center (ERIC), Scopus, and Evidence-Based Medicine Reviews (EBMR) was completed on June 2, 2015. With support from a medical librarian, search strategies were developed that varied by database. For example, the PubMed query utilized terms for foster care, informed consent, children, and English (see Supplemental Material). Additional studies were identified through the personal knowledge of investigators and from references in published papers. Articles were screened through review of the titles and abstracts and then through the analysis of the full text. Two individuals conducted the review and discrepancies were resolved by a third reviewer.

Reviewers then evaluated articles meeting the inclusion criteria to determine whether a waiver of consent was granted or informed consent was required. If informed consent was required, the reviewers identified which types of individuals were required to provide consent and/or assent. Data extraction was done independently by 3 reviewers and discrepancies resolved by consensus. In cases where consent procedures were unclear or inadequately described, an investigator attempted to contact the corresponding author for clarification (Figure 1).

Results

The review process identified 1556 unique articles through database searches and other resources; 243 remained after screening of the titles and/or abstracts, and 49 fulfilled the inclusion criteria based on the review of the full text. These 49 articles reflected 33 unique studies. The method of consent was not clear in eight studies. Four of the corresponding authors of the eight studies responded to requests to provide additional information, allowing seven additional articles to be included in this review.

Of the 33 studies, 1 involved a waiver of consent and 32 required informed consent and/or assent (See Supplemental Table 1). The study permitting a waiver was a study to help youth improve their ability to negotiate and cope with changes. Among studies where a waiver was not granted, youth's assent or consent and the consent of an additional 0 to 3 other individuals was required, most frequently (25, 78%) requiring 1 person to consent. The individuals required to consent, in decreasing order of frequency, were case workers (16, 48%), foster caregivers (12, 36%), biological parents (7, 21%), judges (5, 15%), and GALs (2, 6%). Twenty-nine (88%) studies required the youth's assent and 2 (6%) the youth's consent alone (Table 1).

The studies solely requiring the youth's consent enrolled participants greater than or equal to 16 or 17 years old. We identified 14 different combinations of individuals required to consent and/or assent. The most common (9, 28%) was caseworker consent and the youth's assent (Table 2). No clear patterns were present in study content or question and consent procedures across studies.

Discussion

Our literature review revealed significant variation in the approach to consent and assent for foster youth's participation in minimal risk research. Studies varied significantly in the types and number of individuals required to consent and/or assent.

This variation is likely to contribute to the limited research on foster youth. Without clear consensus and guidelines, investigators may be less likely to pursue studies of foster youth, IRBs may be less likely to approve applications or require impractical protections, and journal editors may be less likely to publish studies. In turn, limited research may have a negative impact on youth in foster care by contributing to an absence of evidence-based interventions tailored to the unique challenges presented by foster care, such as placement instability. It is therefore imperative to develop clear informed consent guidelines that adequately protect foster youth without creating burdens that exclude them from the benefits

of research. This is consistent with the Revised 2016 Council of International Organizations of Medical Sciences International Ethical Guidelines, calling for inclusion of children and persons incapable of giving consent in research investigations, with appropriate safeguards in place (van Delden & van der Graaf, 2017).

To the degree that they are able to assent, youth's assent should be required. There is no reason to believe that youth in foster care are less capable to assent.

A number of criteria can be used to evaluate potential candidates to consent for foster youth to participate in minimal risk research. Individuals should have legal authority to consent. In theory, legal authority should be coincident with moral standing, but this is not always the case in practice. The decision whether or not to enroll the child should be based on the child's best interest: "acting so as to promote maximally the good of the individual" (Buchanan & Brock, 1989). While minimal risk research does not have the prospect of direct medical benefit, it may have the prospect of indirect medical, psychological, or pedagogical benefit (Ross, 1998). Knowledge of the child is needed to individualize decisions about whether participation involves risk. For example, while a venous blood draw is generally considered minimal risk, some children have an excessive fear of needles and the risk designation could be higher when that is the case. The decision maker should also not have a significant conflict of interest that would impair his/her decision making. Given the value of research and the potential indirect benefits to participants, logistical considerations also have a legitimate, albeit secondary, role.

Potential candidates to provide consent include biological parents, foster caregivers, case workers and directors of the child welfare agencies, GAL or CASA, and judges.

While the child's biological parents have had many of their parental rights suspended when the child enters foster care, they typically retain medical decision-making authority. While some biological parents have their child's best interests at heart, others have been charged or convicted of abuse. They may have spent limited time with their child recently and may not be aware of their child's current interests. They may also have conflict of interests impairing their decision making. Parents, for example may refuse to give informed consent out of frustration with their child being in foster care. Finally, from a practical standpoint, they may be difficult to contact.

Foster caregivers hold no legal rights over the child. Depending on the duration of the placement, they may not know the child well enough to determine what is in the particular child's best interest. However, in many cases, foster caregivers facilitate the child's participation in a study, e.g., they bring the child to study visits. Their understanding and participation may be important to the study's success. Participation may conflict with the parents' and other children's needs. Lack of consideration of these needs is a limitation of the best interest standard, and these needs are not generally considered a conflict of interest.

Child Welfare (the county or the state) actually holds custody of the child in foster care and as custodian, appear to have the strongest legal argument to give consent. Determining which individual within the child welfare system, if any, should give consent is, however,

difficult. Caseworkers have varying knowledge about individual children and their best interests and typically do not have the authority to make decisions regarding non-routine medical treatment. Caseworkers also carry heavy caseloads and, therefore, it may be difficult to reach them, and they may be reluctant to accept additional responsibilities. The director of the child welfare agency typically has the most authority for decision-making but has the least information about the individual foster child's preferences to consider best interest.

GALs, typically attorneys or social workers, and CASAs, typically volunteers, are specifically appointed by the juvenile court to identify and represent the best interests of the child while in foster care. Variable backgrounds, training, and workloads, however, result in wide discrepancies in level of knowledge about a specific child. An assumption cannot be made that anyone in a GAL or CASA role is adequately informed to represent the child's best interests for research participation.

A legal argument can also be made for juvenile court judges or magistrates giving consent. They have few if any conflicts of interest. They therefore may be more objective and also have experience evaluating children's best interests in other contexts, e.g., divorce proceedings. They, however, often do not know individual children well enough to analyze risks and benefits to them to assess best interest. They can also be difficult to access and may be reluctant to expand their responsibilities.

Unfortunately, no single individual typically fulfills all the criteria which would be desired for consent in research for youth in foster care. The case worker in a well-functioning child welfare system may come the closest. Alternatively, including all the individuals involved in a child's life to fulfill all of the legal obligations and ensure the involvement of representatives who best know the individual child is appealing but logistically impractical. It would be difficult to convene deliberations and to address unresolved conflicts. Finally, individualized determination of the relevant parties to consent for each youth is not practical for investigators.

This study demonstrates that there is no widely accepted practice for informed consent and assent for youth in foster care; this variability likely reflects the complicated nature of the lives of children in state or county custody. To advance the discussion we offer the following recommendations:

1. Participation in minimal risk research should be offered to all youth in protective custody (e.g. foster care), when they are otherwise eligible, as research is essential to improving evidence-based care to improve outcomes for these youth.
2. Consent for minimal risk research studies should be sought from a legal representative AND a best interest representative who has knowledge of the child and his/her particular interests, for all youth in foster care.
    a. The legal representative could be a child welfare caseworker, the director of child welfare, or a juvenile court judge.
    b. The best interest representative could be a biological parent, a foster caregiver, a child welfare case worker, or a GAL/CASA.

c. At times, a legal representative may also serve as a best interest representative, e.g., a case worker who has worked with a child for multiple years through many placements may have the best working knowledge of the child's current welfare and interests.

3. Assent should be required from youth in foster care for minimal risk research as it is for other youth.

While this approach will continue to have practical limitations, such as disagreements between the representatives when two are identified, it at least allows an opportunity for a consistent, ethically justifiable approach towards consent for youth in foster care for minimal risk research. Also, as the reported literature review demonstrates that historically over 20% of studies utilized 3 or more individuals to consent, this is anticipated to be a decrease in burden for research investigators and thereby increase participation. The standardization is an improvement over the current system and allows for evaluation in the future for modification of recommendations.

The study has a number of limitations. As with all systematic literature reviews, relevant articles may not have been identified or may have been inappropriately excluded. There is a risk that unpublished studies used other consent requirements. Other limitations include inadequate descriptions of the consent process in published manuscripts and the potential that investigators' misinterpreted the consent process described in published manuscripts.

CONCLUSIONS

Significant variation exists in informed consent practices for minimal risk research involving youth in foster care. Published studies have required the consent of varying numbers and types of individuals. A consistent approach that recognizes the need for both legal validity and individualized assessment of interests may support investigators, IRB members, and journal editors and facilitate research and improve foster youth health outcomes.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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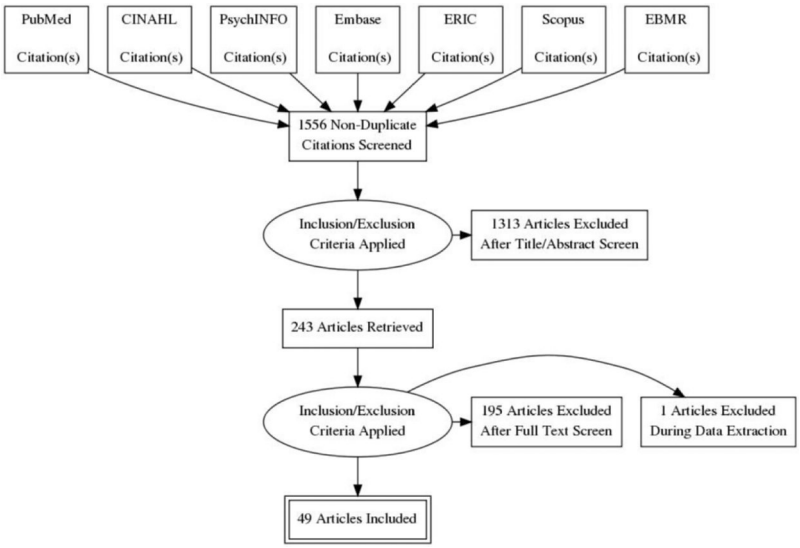

Figure 1.
Literature review inclusion

Table 1:

Summary of consent approaches

Content Process	# Studies	# Publications
Caregiver consent, youth assent	5	9
Biological parent consent, youth assert	4	6
Biological parent and caseworker consent, child assent	2	2
Caseworker consent, youth assent	9	17
Caseworker and GAL consent, youth assent	1	1
Caseworker, GAL, and caregiver consent, youth assent	1	1
Judge consent, youth assent	2	2
Judge and caseworker consent, child assent	1	1
Judge of caseworker consent, caregiver consent, youth assent	1	1
Judge and caseworker and caregiver consent, youth assent	1	3
Caregiver consent only	2	2
Biological parent consent only	1	1
Child consent only	2	2
Waiver of consent and assent	1	1

Table 2:

Summary of consent approaches

Biological Parent	Foster Caregiver	Caseworker	GAL	Judge	Youth	Number of Studies
	X				X	5
X					X	4
x		X			X	2
		X			X	9
		X	X		X	1
	X	X	X		X	1
				X	X	2
		X		X	X	1
	X	X		X	X	1*
	X	X		X	X	1
	X					2
X						1
					X	2
						1**

*This study required judge OR caseworker consent in addition to caregiver consent and youth assent

**This study had a waiver of consent and assent