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Medically Complex Children in Foster Care: Do Research "Protections" Make This "Vulnerable Population" More Vulnerable?

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ABSTRACT

Children in foster care are considered a "vulnerable population" in clinical care and research, with good reason. These children face multiple medical, psychological, and social risks that obligate the child welfare and healthcare systems to protect them from further harms. An unintended consequence of the "vulnerable population" designation for children in foster care is that it may impose barriers on tracking and studying their health that creates gaps in knowledge that are key to their receipt of medical care and good outcomes. These gaps in knowledge have implications for justice, beneficence, and maleficence and serve to undermine "protection" of this population. Here we review the challenges of research regarding children in foster care, particularly medically complex children, and offer specific recommendations to include children in foster care in medical research.

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INTRODUCTION

Children in foster care are considered a "vulnerable population" in clinical care and research, with good reason. These children face multiple medical, psychological, and social risks that obligate the child welfare and healthcare systems to protect them from further harms. An unintended consequence of the "vulnerable population" designation for children in foster care is that it may impose barriers on tracking and studying their health that creates gaps in knowledge that are key to their receipt of medical care and good outcomes. This is a particularly important issue for those children in foster care who have serious and chronic health problems.

While the intention of foster care is to improve the well-being of children at risk, current restrictions placed on the conduct of research with this population undermine our ability to assess, refine, and improve foster care. These gaps in knowledge have implications for justice, beneficence, and maleficence and serve to undermine "protection" of this population. Here we review the challenges of research regarding children in foster care, particularly children who have complex medical needs, and of-

fer recommendations to include children in foster care in medical research.

CASE

"Bridget" is one year old and has a history of extreme prematurity, severe intracranial hemorrhage, developmental delay, chronic lung disease, and dependence on a tracheostomy and feeding tube. She is currently admitted to the hospital for pneumonia.

The medical team discovers that Bridget has missed many doctor visits and has had no weight gain over the last three months. They question her parents' ability to care for such a medically complex child. Child welfare is contacted due to concern regarding medical neglect. They begin to investigate whether Bridget can safely go home with her parents or whether she requires an out-of-home placement such as in foster care.

One morning on rounds, the attending physician says to the team, "It's clear that Bridget's parents are not adequately caring for her medical needs. I'm sure she will do better if we place her with a medical foster care family." A pediatric resident on the team replies, "I searched the literature regarding medical outcomes for children placed in medical foster care, but I found almost no relevant studies. How do we know if foster care will improve Bridget's health outcomes?"

VULNERABLE POPULATIONS IN PEDIATRIC RESEARCH

In the United States, regulations regarding research in children have evolved since the 1970s, when *The Belmont Report* highlighted the tension between two ethical imperatives: that children not be unfairly excluded from benefits of research, and that children are protected from the risks of research.[1] In the 1980s, "Subpart D" of the requirements for the "Protection of Human Subjects" outlined in the U.S. *Code of Federal Regulations* permitted research with children that involved no more than minimal risk.[2] These regulations permit the inclusion of children in research that presents greater risk if the research potentially offers the child a direct benefit or provides vital information about the child's medical condition. "Subpart D" also requires, in most cases, that parents or legal guardians provide permission for the child to be involved in research and, when reasonable, that the child provides assent. These added research protections for children reflect their designation as members of a "vulnerable population," a status conferred to them based on concerns that children could be misled or mistreated in research.[3]

Children in foster care are often considered to be particularly vulnerable, which reflects a history of research abuse in the U.S. in orphanages and concerns that populations in institutions may be oversampled in research because they may be readily available to researchers. For example, allegations that foster children in New York City were inappropriately enrolled in clinical drug trials during the early years of the HIV/AIDS epidemic were highly publicized and led the public and patient advocacy groups to question whether foster children should be allowed to participate in clinical trials.[4] While these allegations were determined to be largely unfounded, they elevated concerns regarding participation in research by children in foster care.[5]

MEDICALLY COMPLEX CHILDREN IN FOSTER CARE

Restrictive application of these research protections has created barriers to understanding the role of foster care on health outcomes. On any given day in the U.S., nearly 440,000 children are in foster care.[6] The majority of these children have been exposed to abuse or neglect and have high rates of physical, developmental, and emotional health problems.[7] An estimated 10 percent of children in foster care are considered to be medically fragile and have medical problems that are complex.[8] Medically complex children in foster care are a uniquely vulnerable population due to their combination of significant medical and social risks, a combination that has been reported to increase the odds of poor health outcomes and high rates of utilization of healthcare services compared to medical risk alone.[9] These children often require intensive daily care due to multiple medications, dependence on technology (for example, feeding tubes, ventilators), and frequent doctor visits and hospitalizations. Once medically complex children enter state custody, they may be placed in a medical foster home with foster parents who receive specialized medical training, or in a group home or institution.

While the goal of foster care is to secure the well-being of at-risk children like Bridget in the case above, it is unknown how health outcomes for children in foster care compare to children with similar medical problems who are not in foster care. Following the outcomes of those with the greatest medical need is critically important to improving care and directing resources.

BARRIERS TO HEALTH OUTCOMES RESEARCH FOR CHILDREN IN FOSTER CARE

There are several key barriers that limit our understanding of how medically complex children do in foster care and how foster care placement impacts their health status. Here we review three essential barriers to research regarding medically complex children in foster care.

Limited Existing Databases

The Children's Bureau within the U.S. Department of Health and Human Services supports state and tribal child welfare agencies in the development of data reporting systems,[10] but encourages local agencies to "build information systems that meet their unique business needs."[11] So while each state agency maintains a data reporting system, much variability exists, and reports regarding health indicators are typically limited in scope and specificity. As such, available databases lack the variables necessary to study health outcomes for medically complex children in foster care.[12]

"Vulnerable" Status Triggers Multi-Layered Review Processes

In addition to federally mandated reviews of research involving children by IRBs (institutional review boards), research involving foster children in the U.S. is commonly subject to additional review by state agencies. In some states, the district circuit court may even have to approve a research study involving children in foster care.[13] Such state agencies are rarely equipped efficiently facilitate research review processes.[14]

While U.S. federal regulations for human subjects protections only require that additional protections be applied to selected studies involving children in foster care (that is, those studies that pose greater than minimal risk without direct benefit), agencies often interpret that these additional requirements should be extended to all research involving children in foster care.[15] Those human subject protections posed as considerations and not imperatives may be over-interpreted by the IRBs or state agencies responsible for research review as formal "requirements." This restrictive application of regulations may impede important minimal risk research, for example, a survey study, by requiring arduous and time-consuming reviews.

Challenges to Obtaining Consent

Identifying who is legally permitted to provide research consent for a child within the foster care system is also challenging. Often times that person is the biological parent or a child welfare administrator, neither of whom may be actively involved with the child's care or who may be inaccessible. The barriers to obtaining consent can result in the exclusion of these children from research participation. Additional provisions in "Subpart D" of the requirements for the "Protection of Human Subjects" permit waivers of parental permission for neglected or abused children under certain conditions,[16] although state agency requirements may prohibit that waiver for children in foster care. As IRB review is generally dependent on securing any other applicable approvals required by federal, state, or local law, an IRB would defer to the state agency requirements, and parental permission may be required.

RECOMMENDATIONS

Change is needed to support high quality research in this area. Without this change, we cannot know whether medical foster care is the best placement option for children like Bridget whose biological parents cannot meet their healthcare needs. Here we highlight initial strategies to accomplish this goal by focusing efforts on projects involving minimal risk, such as data collection and review.

Linked Child Welfare and Health Systems Databases

First, we need to expand child welfare databases to capture nuanced health information for children in foster care.[17] The specific variables (for example. *ICD* codes,[18] medications, hospitalizations, *et cetera*) that track outcomes for other children with complex medical needs should also be available for this same patient population who happens to be in foster care. In addition, consistently including "foster child status" in the medical problem list within electronic medical records would permit retrospective and prospective tracking of health outcomes for quality improvement and secondary analysis research.

Make "Vulnerable" Status Protections Meaningful and Not Prohibitive

"Vulnerable" status should not be an all-encompassing black box that prevents meaningful research due to excessive logistical and regulatory hurdles. Rather, being a child in foster care should trigger reasonable but achievable oversight policies and protections. A collaborative research approval process for studies of foster child health could incorporate hospital IRBs and child welfare research per-

sonnel. This joint perspective on research protections could prevent duplication of efforts and contradictory requirements.

Alternative Consent Strategies

Because locating the person currently allowed to provide research consent for a child in foster care can present a barrier to participation in research, a broad research consent from biological parents at the time a child enters the foster care system would allow for the collection of research data. There are already models in place for this: biological parents often sign a broad medical consent allowing a child welfare agency or foster parents to make routine medical decisions for children[19] (for example, vaccinations, bloodwork, scheduling doctor appointments, *et cetera*). A similar consent could enable decision making for a child's participation in medical research that involves benefit and minimal risk to the child.

CONCLUSION

Making a Vulnerable Population More Vulnerable

Health outcomes for medically complex children in foster care are now invisible. This undermines any effort to improve the quality of care we provide to children and families in the child welfare system, raising the possibility that our application of research protections is actually making this population more vulnerable.

For the case above involving Bridget, we have limited data to help us answer the question of whether foster care will improve her health outcomes. She is a child with significant medical complexity, who requires intensive daily care. It is not currently possible to answer the question of whether her growth, her dependence on medical technology, or her neurologic development are likely to be better if she is with her parents or with a medical foster family. Due to lack of available research, the medical team must make a decision that is not informed by evidence or data. Essentially, it is a "flip of a coin." While multiple strategies will be required to track, assess, and optimize outcomes for children like Bridget, targeted healthcare research is a fundamental component.

BLINDING

Some details of this case have been altered to protect the identities of those involved.

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NOTES

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