

# Practices to Enhance the Diversity of Pediatric Participants Consented into Orthopaedic Research

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## Abstract:

This quality improvement initiative describes challenges to recruiting racially, ethnically, and linguistically diverse infants into a pediatric orthopaedic multicenter research study. The orthopaedic research principal investigator consulted subject-matter experts in pediatric health equity, who provided analyses of baseline research protocols and consulted on improvements to recruitment and consent practices and processes. We describe the subject-matter expert consultation process and the recommendations for changing the research practices that led to increased study enrollment and participation of racially, ethnically, and linguistically diverse pediatric patients. Strategies include equitable remuneration for study participation, flexible study protocols, and visible diversity in patient study recruitment and information materials.

## Introduction

The World Medical Association and National Institutes of Health have both released guidelines on the ethical and scientific importance of including women and minorities in research.<sup>1,2</sup> In pediatrics, children from lower socioeconomic statuses and from racially/ethnically diverse backgrounds are less likely to enroll in randomized controlled trials (RCTs)<sup>3</sup> and more likely to be excluded from multicenter birth cohort studies.<sup>4</sup> Previous studies have described mistrust of the medical system<sup>5</sup> as a barrier to consenting and enrolling racially diverse participants into research. Other studies have described structural barriers to research participation such as parental work schedules or lack of transportation.<sup>4</sup> Lack of diversity in pediatric research participants can limit the generalizability of study findings or potentially exacerbate health inequities. It is imperative to increase recruitment and retention of children from

racially/ethnically diverse, low-income and limited-English proficiency backgrounds in research.

Our institution is currently participating in a multicenter pediatric orthopaedic study designed to determine if magnetic resonance (MR) imaging obtained in the first 16 weeks of life could determine long-term prognosis for infants with brachial plexus birth injury (BPBI). Early in the study, we noticed high rates of decline among all eligible patients and recognized that racially, ethnically, and linguistically diverse patients had different reasons for declining than patients who were nondiverse. This issue was noted at only one of the three participating study sites. Our institution was interested in improving enrollment of patients from diverse backgrounds by developing strategies to ameliorate barriers to participation.

Though the epidemiological research is limited, it is estimated that between 40–50% of infants with BPBI are from racially/ethnically diverse backgrounds,<sup>6–8</sup> a breakdown that may not mirror the greater United States (U.S.) population, as the most recent Census data estimates the U.S. population to be over 60% White, non-Hispanic/Latino/Latinx.<sup>9</sup> This may be indicative of BPBI disproportionately affecting newborns from racially/ethnically diverse backgrounds, making it even more essential that research participants are representative of the patient population impacted by the condition.

The study's principal investigator (PI) consulted subject-matter experts in pediatric health equity through our hospital's Office of Health Equity and Inclusion. The objective of this quality improvement (QI) initiative is to describe the subject-matter expert consultation process and the implementation of the recommendations into the research practices and processes that led to increased study enrollment and participation of racially, ethnically, and linguistically diverse patients.

## Methods

The PI and Clinical Research Coordinator (CRC) of this study met with the faculty and staff of the hospital's Office of Health Equity and Inclusion in 2018. At the time that subject-matter experts in pediatric health equity were consulted, study recruitment was 18 months into a planned 42-month enrollment period. Because the identified challenges in recruitment were unique to this single site, the QI initiative was only undertaken at this hospital.

Initial consultation with these health equity experts offered analysis of baseline recruitment practices and barriers to enrollment. The numbers of patients approached versus consented/not consented were compared between White and racially, ethnically, and linguistically diverse infants to determine baseline rates of consent across racially, ethnically, and linguistically

diverse groups. A patient was considered to be racially, ethnically, or linguistically diverse if they identified as any race other than White or unknown, identified as Hispanic/Latino/Latinx, or spoke a primary language other than English.

Patient-reported reasons for declining participation were captured on baseline case report forms, qualitatively analyzed, and thematically coded through an inductive and iterative coding process. Text was coded manually by a member of the research team and was reviewed by a second member of the research team to confirm agreement.

The QI intervention included having the pediatric health equity experts review the existing research protocol, direct observation of the CRC during a recruitment visit, and subsequent recommendations for protocol and recruitment material modifications. Literature on recruiting racially, ethnically, and linguistically diverse patients into pediatric research was provided by subject-matter experts to the orthopaedic research team.

For the remainder of the study enrollment period (24 months), the rates of consent into the study across racially, ethnically, and linguistically diverse groups were compared to assess how the modified recruitment practices affected enrollment. No other changes to the recruitment or consent practices were made during the enrollment period aside from those described below, and a single CRC recruited all participants with the exception of one patient. All eligible infants were seen in the outpatient orthopaedic specialty clinic and either approached by the CRC prior to their visit by phone or at the end of a routine clinical exam. Hospital-certified interpreters were used for any patient whose family spoke a primary language other than English.

This QI/PI report follows the guidelines set forth by the Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0).<sup>10</sup>

**Table 1. Pre- and Post-Intervention Rates of Study Enrollment**

	Baseline enrollment <sup>a</sup> % (n)	Post-Intervention enrollment <sup>b</sup> % (n)
Racial/ethnic/linguistic diverse	54% (7/13)	68% (15/22)
White/unknown	35% (6/17)	71% (5/7)

<sup>a</sup>Baseline enrollment occurred between May 2017 and December 2018.

<sup>b</sup>Post-intervention enrollment occurred between January 2019 and December 2020.

## Results

### *Baseline and Post-Intervention Recruitment*

Before the intervention, 54% (7/13) of diverse patients agreed to the study, afterwards 68% (15/22) agreed to the study (Table 1). Similarly, nondiverse patient recruitment improved as well, from 35% (6/17) to 71% (5/7).

### *Reasons for Patient Decline*

The themes that emerged from qualitative analysis of the data can be seen in Table 2. Differences in reasons for decline between racially, ethnically, and linguistically diverse patients and nondiverse patients were identified. A high number of racially, ethnically, and linguistically diverse patients expressed not wanting to participate in research in general, while nondiverse families were more likely to cite scheduling difficulties.

### *Baseline Recruitment Observation*

The baseline recruitment script advised patients about the purpose of the study, the eligibility criteria, the study participation remuneration, the MR imaging modality, and MR imaging timeframe. The CRC would accompany physicians during the visit to confirm that infants met study inclusion criteria. After physicians left the exam room, the CRC would explain the study, confirm eligibility, review confidentiality, answer all questions, and review and obtain informed consent.

When our Health Equity and Inclusion expert directly observed our study recruitment practices, several barriers to research participation were identified, summarized in Figure 1.

**Table 2. Reasons for Patients Declining Study Enrollment**

Reason for decline	Racial/ethnic/linguistic diverse (n)	White/unknown (n)
Lack of transportation	1	0
Scheduling difficulty	2	6
Did not want to participate in research	5	1
Did not want child to have an MR	3	0
Not continuing care at hospital	0	2
Burden of care	0	1
Lack of remuneration	1	0
No reason given	0	4

The total number of codes exceeds the number of patients who declined (n = 24) as patients could receive more than one code.

Some identified barriers related to the study materials and recruitment script while others were logistical challenges of study participation. Due to the specialized BPBI care provided at the quaternary care center, many of the families approached for the study lived a far distance from the hospital and were unable to return for a study visit. There was inflexibility with appointment times for the research MR imaging which also posed challenges for working parents, for families with limited childcare or transportation, and for those residing far from the hospital. Finally, unintended disparities in remuneration were identified as a possible barrier to study participation for patients with public insurance.

#### *Recommended Modifications to Study Protocol*

Using a health equity QI framework, subject-matter experts assessed that the baseline recruitment practices were not maximized to encourage participation from racially, ethnically, and linguistically diverse families. Protocol edits to the recruitment script, recruitment materials, and remuneration were recommended. An amendment to the hospital Institutional Review Board was submitted and approved for the incorporation of these recommendations.

#### *Modifications to Recruitment Script*

Modifications to the recruitment script were made to increase trust and rapport between the CRC and eligible participants, to provide greater transparency around the importance of inclusive recruitment of racially, ethnically, and linguistically diverse patients, and to enhance caregiver understanding of the study. Additional information about MR imaging safety and the study's noninvasive nature was added. The recruitment script was modified to use simple (rather than medically complex) language, which has been shown to be best for a linguistically diverse population.<sup>11,12</sup> Additional individual coaching was provided to the CRC around building rapport and trust with patients/families through nonverbal communication skills, including eye contact, smiling, and sitting whenever possible, as opposed to standing. Physical appearance was also addressed, which included dressing in business casual clothing as opposed

#### **Figure 1. Barriers to Study Participation Identified During Baseline Recruitment Observation**

- Complex medical jargon in study materials and recruitment script
- Lack of representation of diverse infants in study materials; study materials only available in English
- Distance from hospital, as the quaternary academic health center attracted patients from far away for the specialized BPBI care
- Short timeframe for the MR imaging due to
  - 1) the age of infants at study recruitment,
  - 2) limited timeframe for the imaging (before 16 weeks of life)
  - 3) inflexible appointment times for the research MR imaging examination
- Disparities in study participation remuneration for publicly insured versus privately insured patients

to business formal clothing and sitting or standing without a clipboard in hand.

#### *Modifications to Study Materials*

Recruitment materials were amended to increase the visibility of diverse infants in the study brochure (Figure 2). Additional information about the MR imaging examination was included to increase exposure to and familiarity with the noninvasive imaging examination. Study materials, including the consent form and brochure, were translated into Spanish. The text of study recruitment materials was edited to more simple language to be inclusive of varying health literacy and linguistic levels.

#### *Modifications to Remuneration*

Prior to the QI consultation, enrolled patients were provided with a parking voucher for the day of their MR imaging appointment, and patients' standard-of-care physical therapy (PT) and occupational therapy (OT) visits were financially covered for the duration of their participation (until 30 months of age).

Changes to study remuneration were made for more equitable travel reimbursement. At baseline, families who drove to the hospital were provided with parking reimbursement, but those families who utilized public transportation or transportation through public insurance were not reimbursed. A change was made to provide families with a single cash payment to compensate for the cost of transportation to the MR imaging appointment. The maximum cost of utilizing city public transportation was calculated to help inform the amount of transportation remuneration.

It was noted that for those patients with public insurance, the coverage of PT and OT services presented less of an incentive, as those benefits are generally covered by public insurance. It was suggested that a monetary incentive be given to study participants instead, but hospital guidelines from the study's lead site prohibited use of such incentives. Therefore, no changes to PT or OT coverage were made.

**Discussion**

This QI consultation with pediatric health equity subject-matter experts led to changes in a pediatric-orthopaedic-research recruitment protocol. This subsequently increased the diversity of consented research participants and increased study enrollment overall. Changes to the research protocol utilized best practices related to improving recruitment and retention of racially, ethnically, and linguistically diverse and low-income children in research.

While race/ethnicity does not equal socioeconomic status, some of the interventions made, such as remuneration and better explanations of MR imaging

**Figure 2. Study Materials Modifications**

### A. Baseline



**NAPTME Research Study**  
Non-anesthetized Plexus Technique for Infant (Brachial Plexus Birth Injury) MRI Evaluation

**About Magnetic Resonance Imaging (MRI)**  
MRI uses a large magnet, radio waves, and a computer to produce three-dimensional images of the brain. MRIs do not have radiation like x-rays and computerized tomography (CT) scans.

**What is brachial plexus birth injury?**  
The brachial plexus is a group of nerves that branch from the head to the neck, through the shoulder area and down to the arm and hand. During childbirth, a baby's neck and head area can be stretched or pulled. This usually happens when the baby's head goes in one direction and the shoulder goes in another direction. This stretch can damage the brachial plexus and make it hard (or impossible) for the baby to move their arm.

Nerves between the neck and shoulder are stretched, compressed or torn during birth.



**Who is conducting this research?**  
NAPTME is a multi-center study being conducted at Boston Children's Hospital, Shriners' Hospitals for Children in Sacramento, and Gillette Children's Specialty Healthcare in Minneapolis.

**How are babies selected for the NAPTME study?**  
Babies diagnosed with brachial plexus birth injury between the age of one month and four months may be selected to participate in this study.

**What will I need to do to participate?**  
When you come in for your first visit at Boston Children's Hospital, a member of our research staff will talk to you about this study and ask if you would like to participate. If you do agree to participate, you will be scheduled for an MRI scan either on the day of your appointment or at your convenience. As part of your child's routine care, your child will have three scans with about one year of age, depending on your child's recovery. We will continue to monitor your baby throughout this process.

**Non-Sedated MRI Scans for Infants**

- Avoiding the use of anesthesia not only makes the scan more comfortable for the parent and the patient's family, it is the safer option.
- This will be a sedation-free no-contrast scan lasting about 1 hour.
- After to this appointment, we will bring you to a quiet room where you and your baby can get settled. We will provide you with enough time to feed your baby and get him or her ready for the scan.

By participating in this study, you are helping us better understand the complexity of brachial plexus injuries in infants, and for that, we thank you!



### B. After Consultation



**NAPTME Research Study**  
Non-Anesthetized Plexus Technique for Infant (Brachial Plexus Birth Injury) MRI Evaluation

**About the NAPTME Research Study**  
Currently, there is no good test that shows us a baby's brachial plexus birth injury (BPBI) after they are born. We are doing this study to see if a short MRI scan can be used, without using anesthesia or medicine to put your baby to sleep, to see if an MRI can tell us more about their injury and how to treat it. We hope this will help us give better advice about how to treat your baby's BPBI in the future. A research coordinator will be at your clinic visit to talk about the study with you, and see you if you would like to take part in the study.

**What is brachial plexus birth injury?**  
The brachial plexus is a group of nerves that go from the head to the neck, through the shoulder and down to the arm and hand. During childbirth, a baby's neck and head can be pulled. This usually happens when the baby's head and shoulder go in different directions. This can hurt the nerves and make it hard for the baby to move their arm.

Nerves between the neck and shoulder are stretched, compressed or torn during birth.



**About the MRI**  
MRI uses a large magnet to create images of the body. MRIs do not have radiation like x-rays, making them safe for babies. Because we do not use anesthesia or medicine to put your baby to sleep, this also makes it safer. Instead of using anesthesia we help your baby go to sleep naturally on their own. Before your appointment, we will bring you to a quiet room where you can feed your baby and help them go to sleep.

**Who is doing this research?**  
There are three hospitals involved in NAPTME, including Boston Children's Hospital, Shriners' Hospitals for Children in Sacramento, and Gillette Children's Specialty Healthcare in Minneapolis.

**How are babies chosen for the NAPTME study?**  
Babies who have a BPBI between one month and four months old can take part in this study.

**Benefits and risks to being in the study**

- If you decide to be in the study, we will pay for your therapy visits that happen during visits with your doctor. We will also pay for getting to the hospital for the MRI.
- Because we do not use any radiation, anesthesia, contrast, or medicine, this study has little risk. MRIs are shown to be safe for babies.

By being in this study, you are helping us better understand BPBI in babies, and for that, we thank you!



This study is paid for by the Shriners Hospitals for Children.

technical details, likely helped increase enrollment across all demographic groups. This underscores that thoughtful, ethical enrollment of research subjects ensures research is inclusive of the patient population impacted by BPBI.

This consultation had important and positive impacts beyond the study discussed here. After consulting with the Office of Health Equity and Inclusion faculty and staff experts, the lessons learned from the consultation process were provided to other PIs in the orthopaedic department and strategies were included in ongoing and newly developed prospective studies within the

department. For instance, it was recommended that the department move away from parking vouchers in favor of cash payments and to ensure that images and text in recruitment materials are racially, ethnically, and linguistically inclusive.

Research practices to enhance the diversity of study participants should be considered for all aspects of study recruitment and retention. Firstly, study protocols must be flexible with amendments to recruitment practices as needed throughout the enrollment period,<sup>13</sup> as researchers should note any themes in barriers to participation when recruiting.<sup>14</sup> Recruitment protocols can be refined to address the documented participation barriers.

Several studies have noted the importance of maximizing incentives for marginalized groups, including those from racially, ethnically, and linguistically diverse and low-income backgrounds.<sup>15,16</sup> Incentives could include providing additional remuneration for patients and families facing financial barriers to research participation (such as no paid time off from work to take a child to a research imaging appointment). Maximizing incentives requires addressing disparities in the incentive process as was noted in our QI initiative and intervention.

During the recruitment encounter, research teams should promote trust and altruism<sup>15</sup> and reinforce the importance of the study.<sup>16</sup> Some researchers even suggest when approaching patients from racially, ethnically, and linguistically diverse backgrounds, to acknowledge possible mistrust of the medical system because of past ethically unjustified research studies involving diverse individuals and communities<sup>13</sup> as well as widely understood and well documented instances of disparities in our current healthcare system.<sup>17</sup> Examples of former unethically justified studies of diverse individuals include the Tuskegee Study of Untreated Syphilis<sup>14</sup> and the scientific mistreatment of Henrietta Lacks, whose tissue was used for scientific research without her consent.<sup>18</sup> Strategies to help promote trust

and feelings of safety include describing the study's proactive strategies to protect participants' privacy, confidentiality, and safety and to explain any potential risks of participation<sup>10</sup>. It is also important to remind marginalized or diverse groups that research participation is voluntary and optional.<sup>15</sup> This would help to further reinforce trust that the research team has the patients' best interests in mind.

Attention should be paid to the informed consent process. Study materials should consider participants' linguistic competencies<sup>16</sup> and should be clearly written at a level that is accessible to varying health literacy levels. Some have even suggested using visuals or whiteboards to explain the consent process.<sup>16</sup>

More practical research recruitment and retention strategies include collecting comprehensive contact information for patients and families<sup>13,16</sup> and facilitating participation in research activities through in-kind supports such as transportation, childcare, and flexible scheduling.<sup>10,12,16</sup> These strategies focus on reducing physical barriers to research participation, such as difficulty traveling to the research location or poor retention due to loss of contact information.

The findings from this intervention may not be generalizable to studies of older children in which assent is required or to higher-level research such as a RCT or an interventional trial. The methods of assessing any disparities in study recruitment and seeking help to address enrollment gaps, however, would still be generalizable.

## Conclusions

In our pediatric academic medical center's experience, using flexible study protocols, addressing equity in remuneration, amending written study materials, and fostering a trusting rapport with patients/families were important research recruitment practices and processes that increased diverse patient recruitment. By consulting experts in pediatric health equity, our orthopaedic research team analyzed barriers to research participation

for racially, ethnically, and linguistically diverse and low-income children and implemented changes to the study protocol. This led to improved diversity in the study sample. This QI initiative and its implementation have implications for pediatric orthopaedic research more broadly. We believe these findings can be extended to other populations or conditions to support recruitment methods to promote diversity in research subjects which will in turn help to promote health equity.

### Additional Links

- Boston Children's Hospital Declaration on Equity, Diversity and Inclusivity:  
<http://www.childrenshospital.org/-/media/About-Us/DeclarationEquityDiversityInclusivity.ashx?la=en&hash=6E9FA68AD76A150B087D66F4685BC5C4B92D8B8A>
- Boston Children's Hospital Patient Education on MR Imaging:  
<http://www.childrenshospital.org/conditions-and-treatments/treatments/mri>
- OpenPediatics Module Addressing Cultural Diversity in Anesthesia Consent:  
<https://learn.openpediatrics.org/learn/course/3261/addressing-cultural-diversity-in-anesthesia-consent>

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