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Racial and Ethnic Disparities in Parental Refusal of Consent in a Large, Multisite Pediatric Critical Care Clinical Trial

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Objective To evaluate whether race or ethnicity was independently associated with parental refusal of consent for their child’s participation in a multisite pediatric critical care clinical trial.

Study design We performed a secondary analyses of data from Randomized Evaluation of Sedation Titration for Respiratory Failure (RESTORE), a 31-center cluster randomized trial of sedation management in critically ill children with acute respiratory failure supported on mechanical ventilation. Multivariable logistic regression modeling estimated associations between patient race and ethnicity and parental refusal of study consent.

Result Among the 3438 children meeting enrollment criteria and approached for consent, 2954 had documented race/ethnicity of non-Hispanic White (White), non-Hispanic Black (Black), or Hispanic of any race. Inability to approach for consent was more common for parents of Black (19.5%) compared with White (11.7%) or Hispanic children (13.2%). Among those offered consent, parents of Black (29.5%) and Hispanic children (25.9%) more frequently refused consent than parents of White children (18.2%, \( P < .0167 \) for each). Compared with parents of White children, parents of Black (OR 2.15, 95% CI 1.56-2.95, \( P < .001 \)) and Hispanic (OR 1.44, 95% CI 1.10-1.88, \( P = .0167 \)) children were more likely to refuse consent. Parents of children offered participation in the intervention arm were more likely to refuse consent than parents in the control arm (OR 2.15, 95% CI 1.37-3.36, \( P < .001 \)).

Conclusions Parents of Black and Hispanic children were less likely to be approached for, and more frequently declined consent for, their child’s participation in a multisite critical care clinical trial. Ameliorating this racial disparity may improve the validity and generalizability of study findings. (J Pediatr 2017;121:278-285.)

Trial registration ClinicalTrials.gov: NCT00814099.

The external validity of any clinical research study requires the participation of representative groups of subjects. Perhaps nowhere is this more important than in randomized controlled clinical trials (RCTs) where we draw conclusions about the safety and efficacy of new therapies. Both the Food and Drug Administration and National Institutes of Health require investigators to include predicted enrollment tables across race and ethnicity in their grant applications.1,2 This requirement provides investigators the opportunity to design enrollment schemes to ensure equity and/or provide a scientific rationale justifying an anticipated imbalance.

There are both lingering concerns and contradictory data regarding the ability of RCTs conducted in the US to recruit equitable numbers of diverse racial and ethnic groups, particularly Blacks. A landmark systematic review of studies related to research consent revealed that Blacks were generally as willing as any others to take part in RCTs, that remarkably few studies reported their consent rates by race and ethnicity and that the heterogeneity in how consent rates were reported precluded comparisons across studies.3 On the other hand, there are studies that document racial and ethnic disparities in health research participation4-7 and a recent systematic review of barriers and facilitators to minority participation in research identified mistrust, stigma, and competing demands as common barriers.8

Unfortunately, there is a paucity of pediatric data on research consent and enrollment and even fewer studies examining this issue in critically ill children. In the previously noted landmark systematic review of research participation by minorities,3 only 2 of the 17 trials included in the review were relevant to pediatrics.9,10 Here, we address this gap by analyzing enrollment in the

<table>
<thead>
<tr>
<th>ICUs</th>
<th>Intensive care units</th>
<th>RCTs</th>
<th>Randomized controlled clinical trials</th>
<th>RESTORE</th>
<th>Randomized Evaluation of Sedation Titration for Respiratory Failure</th>
</tr>
</thead>
</table>

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*List of members of the RESTORE Study is available at www.jpeds.com (Appendix).

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Randomized Evaluation of Sedation Titration for Respiratory Failure (RESTORE) study. Our primary aim was to determine whether race and ethnicity affected the parental consent rates in a pediatric critical care clinical trial.

Methods

We performed a secondary analysis of existing data from RESTORE, a cluster randomized clinical trial of children under 18 years of age with serious respiratory illness requiring mechanical ventilation (ClinicalTrials.gov: NCT00814099). The purpose of this more than minimal risk trial was to determine the safety and efficacy of a nurse-directed, goal-driven sedation algorithm. The primary study was approved by the Institutional Review Board at each of the 31 collaborating sites across the US. Pediatric intensive care units (ICUs), rather than individual subjects, were randomized to study protocolized sedation management (intervention group) or to usual unit-based sedation management (control group). Therefore, all parents approached for consent knew the treatment allocation of their child. The primary study and results have been described elsewhere. Here we focus on the methods relevant to this secondary analysis.

RESTORE enrolled children more than 42 weeks postconceptional age and less than 18 years old who were intubated and mechanically ventilated for acute lung disease. Excluded were children whose length of mechanical ventilation was thought to be unaffected by sedation management; specifically, children with cyanotic heart disease, congenital diaphragmatic hernia, primary pulmonary hypertension, a critical airway, an obstruction of the lower airway, chronic-assisted ventilation, neuromuscular respiratory failure, spinal cord injury, or pain managed by patient-controlled analgesia. Also excluded were children in whom care was considered futile as evidenced by the presence of a “do not resuscitate” order.

At the start of the trial, the lead investigators at each enrolling site received training on best practices in obtaining informed consent using the RESTORE study’s practice guideline. This training tool described the ethical and administrative requirements for informed consent and the study procedures for doing so. Because all eligible patients were intubated and sedated, assent for those over 8 years of age could only be sought after endotracheal extubation and after 72 hours after the last sedative dose. Therefore, this report focuses on parental decision making regarding their child’s participation in this research.

RESTORE’s best practices consent guideline recommended that parents be introduced to study personnel by a treating physician, the informed consent discussions by study personnel be family-centered, and the discussions include careful attention to the distress experienced by parents of critically ill children. Consent discussions were to include thoughtful, open-ended and nondirective questions (eg, “what more would you like to know about this study?”). Consent needed to be obtained within 24 hours of a child meeting eligibility criteria and was typically obtained 7 days per week during the day or evening hours. If the parent was not onsite in the pediatric ICU, the enrollment window could be extended to 48 hours or further with the permission of the clinical coordinating center. Provisions were made for obtaining consent by judicially approved guardians whenever possible. In instances where no parent or guardian was present, procedures did include telephone conversations, especially during the H1N1 influenza epidemic when parent visitation was limited in several centers in symptomatic parents. In these cases, the study was presented to the parent on the telephone and the executed consent was returned by fax or signed remotely using DocuSign (San Francisco, California).

Interpretation services were used in recruiting, interacting with and obtaining consent from a parent whose preferred language was not English. However, use of non-English consent required approval by the local institutional review board of a professionally translated and certified informed consent documents, thereby limiting the ability to recruit parents speaking languages other than the dominant non-English local language, typically Spanish.

Because this was a cluster randomized trial, parents were consenting for their child to receive either algorithm-based sedation management (intervention) or to continued usual sedation management (control) that only involved data extraction from the medical record. There were no special procedures or guidelines for recruitment of particular racial or ethnic groups, nor was the race/ethnicity of those obtaining consent matched to the race/ethnicity of the parent.

Quality monitoring throughout the trial included tracking site-specific consent rates. These data were reviewed during separate intervention and control site conference calls and during yearly site-specific dashboard calls. Discussion of opportunities to improve consent rates was a standing agenda item on study conference calls and included site-to-site sharing of expertise.

For this analysis, we included all patients eligible to participate in the study. All data were extracted as directed by standardized study protocols from medical records review. Data elements included the clinical site, study arm, child’s race, ethnicity (Hispanic vs non-Hispanic), sex, age, and primary reason the patient required endotracheal intubation. Identification of race and ethnicity was based on information provided in the medical record, using site-specific methods or the mother’s race/ethnicity into 3 main groups: Hispanic, non-Hispanic, or unknown. Ethnicities noted as unknown were treated as non-Hispanic. This allowed us to combine race and ethnicity into 3 main groups: Non-Hispanic White, Non-Hispanic Black, and Hispanic of any race. All race and ethnicities other than these 3 groups were excluded from the analysis because of insufficient numbers to adequately analyze these groups.

Statistical Analyses

The primary aim of the study was to compare refusal rates across race/ethnicity groups. We also compared rates for being unable to approach for consent to the families, refusal rates by treatment group, and baseline characteristics of subjects...
across groups. Race/ethnicity groups were compared using logistic or multinomial logistic regression for binary or nominal variables, controlling for pediatric ICU as a cluster variable using generalized estimated equations under the working independence assumption. Using a Bonferroni correction to account for multiple pairwise comparisons, P values of <.0167 were considered to indicate statistically significant differences across groups.

A multivariable logistic regression model was built using race/ethnicity group, sex, age group, and treatment group to predict refusal of consent controlling for pediatric ICU as a cluster variable. Interactions between treatment group and race/ethnicity group, sex, and age group were considered. All data analyses were performed using SAS v 9.4 (SAS Institute, Cary, North Carolina).

Results

As shown in Table I, 1716 non-Hispanic White children, 886 non-Hispanic Black children, and 836 Hispanic children of any race were eligible for study participation, which was conducted between June 2009 and December 2013. In addition to parent refusal of consent, reasons for eligible but not enrolled subjects included parent/guardian unavailability, unclear guardianship issues, and/or language barriers that could not be rectified within the enrollment window. Parents of non-Hispanic Black children (19.5%) were more frequently not offered consent compared with parents of either non-Hispanic White (11.7%) or Hispanic (13.2%) pediatric patients. Overall, just under one-quarter of parents (674/2954, 22.8%) declined to participate in this RCT. Refusal of consent was significantly more common among parents of non-Hispanic Black (29.5%) and Hispanic (25.9%) than among non-Hispanic White (18.2%) children, as also shown in Table I. Among intervention sites, refusal of consent was significantly more common among parents of non-Hispanic Black (43.1%) than among non-Hispanic White (22.9%) and Hispanic (28.5%) children. Among control sites, trends were similar but did not reach statistical significance at the P value equal to .0167 level after adjusting for multiple comparisons, with refusal of consent more common among parents of non-Hispanic Black (21.2%, P = .02) and Hispanic (20.4%, P = .04) than among non-Hispanic White (12.6%) children. In addition, parents of non-Hispanic White and non-Hispanic Black children invited to participate in the intervention group were significantly more likely to refuse participation than those invited to participate in the control group.

Table II characterizes the 2954 non-Hispanic White, non-Hispanic Black and Hispanic children of any race approached for consent for participation in this cluster randomized trial. Hispanic children were younger and more likely to be male, and there were differences in primary reason for intubation across race and ethnic groups.

Multivariable generalized linear mixed models were used to predict consent refusal while adjusting for clustering within participating pediatric ICUs (Table III). After controlling for covariates (sex, age group, and treatment group), parents of non-Hispanic Black (OR 2.15, 95% CI 1.56-2.95, P < .001) and Hispanic children of any race (OR 1.44, 95% CI 1.10-1.88, P = .01) were significantly more likely than parents of non-Hispanic White to refuse consent. Non-Hispanic Black parents were also significantly more likely to refuse consent than Hispanic parents of any race (OR 1.50, 95% CI 1.13-1.98, P = .005). Parents were significantly less likely to consent when invited to participate in the intervention arm of the study (OR 2.15, 95% CI 1.37-3.36, P < .001). No statistically significant interactions were observed, including interactions between treatment group and racial/ethnic groups.

Discussion

Parents of Black and Hispanic children were less likely to be approached and more frequently declined consent for their child’s participation in a multisite pediatric critical care clinical trial. Further, consent refusal was more frequently observed in parents offered participation in the intervention group. In considering these results, it is important to consider the characteristics of the trial that may have influenced parental decision making. Importantly, this cluster randomized trial required enrollment shortly after endotracheal intubation when

Table I. Consent decision stratified by race/ethnicity group

<table>
<thead>
<tr>
<th>Race/Ethnicity Group</th>
<th>Non-Hispanic White</th>
<th>Non-Hispanic Black</th>
<th>Hispanic of any race</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligible subjects, n</td>
<td>1716</td>
<td>886</td>
<td>836</td>
</tr>
<tr>
<td>Unable to offer consent, n (%)**</td>
<td>201 (11.7)</td>
<td>173 (19.5)</td>
<td>110 (13.2)</td>
</tr>
<tr>
<td>Parent/guardian physically unavailable</td>
<td>82 (40.8)</td>
<td>94 (54.3)</td>
<td>50 (45.5)</td>
</tr>
<tr>
<td>Guardianship issues</td>
<td>39 (19.4)</td>
<td>38 (22.0)</td>
<td>13 (11.8)</td>
</tr>
<tr>
<td>Language issues</td>
<td>24 (11.9)</td>
<td>12 (6.9)</td>
<td>19 (17.3)</td>
</tr>
<tr>
<td>Other*</td>
<td>56 (27.9)</td>
<td>29 (16.8)</td>
<td>28 (25.5)</td>
</tr>
<tr>
<td>Refused consent, n/total (%)**</td>
<td>276/1515 (18.2)</td>
<td>210/713 (29.5)</td>
<td>188/726 (25.9)</td>
</tr>
<tr>
<td>Refused consent by treatment group, n/total (%)**</td>
<td>87/689 (12.6)</td>
<td>94/444 (21.2)</td>
<td>48/235 (20.4)</td>
</tr>
<tr>
<td>Control</td>
<td>189/826 (22.9)</td>
<td>116/269 (43.1)</td>
<td>140/491 (28.5)</td>
</tr>
<tr>
<td>Intervention**</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\* P < .0167, non-Hispanic Whites vs non-Hispanic Blacks.
\*\* P < .0167, non-Hispanic Blacks vs Hispanics of any race.
\* Other: for example, parent emotionally unavailable, training issue, system issue.
\*\* P < .0167, non-Hispanic Whites vs Hispanics of any race.
\*\* P < .0167, control vs intervention.
On the other hand, the intervention itself consisted of bedside nurses using a standardized protocol to optimize sedation management and potentially shorten the duration of mechanical ventilation. It did not, therefore, require exposure to novel and still unproven pharmacologic or mechanical interventions. Nor did it require additional laboratory testing or sample collection. To minimize bias in study enrollment, standardized training and best practices were provided for the study personnel who met with parents to describe the study, the treatment to be received by their child, risks and potential benefits, and request their consent for participation.

Perhaps because of these factors, the RESTORE refusal rate is low compared with other similar pediatric research clinical trials. For example, the RESTORE refusal rate of 23% is better than observed in a trial of pulse oximetry monitoring for bronchiolitis (31%) and markedly better than obtained in a nontherapeutic pediatric ICU cohort study of adrenal insufficiency (58%).

However, this low RESTORE refusal rate did not prevent disparities in participation by minority children. Our results demonstrate that there are 2 time points that contribute to lower enrollment of non-White children: the availability of parents for participation in consent procedures and the consent process itself. Disparities at either time point can contribute to differential recruitment and participation in RCTs, potentially compromising the generalizability of study results and not affording children of all races the potential to benefit from research. Although RESTORE was not designed to identify and/or ameliorate specific barriers to parental participation in the consent process, our finding that more minority parents were not available to participate in consent procedures is consistent with the systematic review of barriers to research participation by minorities identifying competing demands as a common barrier across multiple minority groups.

Equitable participation in research remains an important priority for research sponsors such as the Food and Drug Administration and National Institutes of Health. This requires recruiting, enrolling, and obtaining data from individuals who resemble the population of patients in which the results will be applied. Unfortunately, although published reports routinely describe the recruited sample with respect to their sociodemographic characteristics such as race and ethnicity, few studies specifically describe consent rates in racial and ethnic subgroups. Disparities in research participation may compromise study findings. However, the lack of consistently available information documenting such disparities, if any, certainly compromises our ability to monitor, analyze and address this issue. We strongly recommend that journal editors consider implementing standards that would make data regarding research consent and participation in racial and ethnic subgroups routinely available.

Because this was a secondary analysis, certain information was unavailable. For example, information regarding past participation in research, parental experience with the consent process, or their reasons for declining participation was not collected. Furthermore, some information that would be potentially important to consider, such as the educational or socioeconomic status of families being recruited into the study, was not collected. It is also important to realize that participant race and ethnicity is not self-described but rather extracted from the electronic health record by research staff using a standardized, study protocol-defined process. This may have resulted in some degree of misclassification that would not, however, have been influenced by study personnel or study procedures. Similarly, we are unable to match the race or

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### Table II. Baseline characteristics of patients offered consent stratified by race/ethnicity group

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Non-Hispanic White (n = 1515)</th>
<th>Non-Hispanic Black (n = 713)</th>
<th>Hispanic of any race (n = 726)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex, n (%)</td>
<td>805 (53.1)</td>
<td>393 (55.1)</td>
<td>428 (59.0)</td>
</tr>
<tr>
<td>Age (y), n (%)†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than 2 y</td>
<td>714 (47.1)</td>
<td>360 (50.5)</td>
<td>461 (63.5)</td>
</tr>
<tr>
<td>2-6 y</td>
<td>257 (17.0)</td>
<td>145 (20.3)</td>
<td>114 (15.7)</td>
</tr>
<tr>
<td>More than 6 y</td>
<td>544 (35.9)</td>
<td>208 (29.2)</td>
<td>151 (20.8)</td>
</tr>
<tr>
<td>Primary reason for intubation, n (%)§,†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pneumonia</td>
<td>557 (36.8)</td>
<td>205 (28.8)</td>
<td>226 (31.1)</td>
</tr>
<tr>
<td>Bronchiolitis</td>
<td>407 (26.8)</td>
<td>134 (18.8)</td>
<td>262 (36.1)</td>
</tr>
<tr>
<td>Acute respiratory failure related to sepsis</td>
<td>216 (14.3)</td>
<td>96 (13.5)</td>
<td>80 (11.0)</td>
</tr>
<tr>
<td>Asthma or reactive airway disease</td>
<td>80 (5.3)</td>
<td>125 (17.5)</td>
<td>40 (5.5)</td>
</tr>
<tr>
<td>Aspiration pneumonia</td>
<td>94 (6.2)</td>
<td>48 (6.7)</td>
<td>46 (6.3)</td>
</tr>
<tr>
<td>Other*</td>
<td>161 (10.6)</td>
<td>105 (14.7)</td>
<td>72 (9.9)</td>
</tr>
</tbody>
</table>

*Non-Hispanic Black (vs Hispanic of any race) yields OR (95% CI) = 1.50 (1.13-1.98), P = .005.

---

### Table III. Predictors of consent refusal decision among those offered consent

<table>
<thead>
<tr>
<th>Predictor</th>
<th>OR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Hispanic Black (vs Non-Hispanic White)*</td>
<td>2.15 (1.56-2.95)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Hispanic of any race (vs Non-Hispanic White)</td>
<td>1.44 (1.10-1.88)</td>
<td>.01</td>
</tr>
<tr>
<td>Male (vs female)</td>
<td>1.00 (0.82-1.21)</td>
<td>.97</td>
</tr>
<tr>
<td>2-6 y (vs less than 2 y)</td>
<td>1.26 (0.98-1.61)</td>
<td>.07</td>
</tr>
<tr>
<td>More than 6 y (vs less than 2 y)</td>
<td>0.96 (0.74-1.23)</td>
<td>.72</td>
</tr>
<tr>
<td>Intervention (vs control)</td>
<td>2.15 (1.37-3.36)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

*Non-Hispanic Black (vs Hispanic of any race) yields OR (95% CI) = 2.06 (1.56-2.95), P = <.001.
ethnicity of study staff who participated in the consent process with the race and ethnicity of parents or guardians with whom they were discussing potential study participation. Studies specifically designed to experimentally define optimal consent procedures should certainly investigate the contribution of such concordance.

These results document significant differences in study participation related to patient race and ethnicity and, therefore, raise potential questions about the generalizability of study findings. These data contribute to our evolving understanding of racial and ethnic disparities in health and health research. Our results provide a starting place for future work to better understand and ameliorate disparities in pediatric research participation particularly that conducted in critically ill children.

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