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Barriers to Enrollment in a Pediatric Critical Care Biorepository

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Abstract

Background: Individuals of minority race/ethnicity have lower rates of participation in genomic research. This study evaluated sociodemographic characteristics associated with decisions to enroll in a pediatric critical care biorepository.

Methods: Parents of children admitted to the PICU between November 2014 and May 2017 were offered to enroll their child in a biorepository using a single page opt-in consent. Missed enrollment was assessed by failure to complete the form or declining consent on the form. We conducted a retrospective chart review for sociodemographic and clinical information. Bivariate and multivariable regression analyses were performed.

Results: In 4055 encounters, representing 2910 patients with complete data, 1480 (50%) completed the consent form and 1223 (83%) enrolled. We found higher odds of incomplete consent for non-English speaking parents (OR = 2.1, $p < 0.0001$) and parents of children of all races except non-Hispanic White (OR = 1.27–1.99, $p < 0.0001$). We found higher odds of declined consent in patients with Medicaid (OR = 1.67, $p = 0.003$) and parents of children of all races except non-Hispanic White (OR = 1.32–2.9, $p < 0.0001$).

Conclusion: Inability to enroll patients in a critical care biorepository may be associated with several sociodemographic factors at various points in recruitment/enrollment.

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CONTRIBUTIONS

Erin Paquette participated in study conceptualization, design, data collection, analysis, manuscript preparation and revision.
Avani Shukla participated in data collection, analysis, critical manuscript review and revision.
Tracie Smith participated in study design, data analysis, manuscript preparation and revision.
Tricia Prendergast participated in data collection, analysis, critical manuscript review and revision.
Susan Duyar participated in data analysis and critical manuscript review and revision.
Karen Rychlik participated in study design, data analysis and critical manuscript review and revision.
Matthew Davis participated in study conceptualization, design, data analysis, critical manuscript review and revision.

DISCLOSURES

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Keywords

population study

INTRODUCTION:

The *All of Us* Research Program, launched in 2016, is a national effort to bring precision medicine to all diseases by enrolling a diverse cohort of one million or more individuals to advance health through research.[1] Key to success of the program, and genomic research generally, is the ability to enroll diverse participants with respect to their lifestyle, environment and biology.[1] Historically, genomic research has failed to capture diversity. Between 2009 and 2016, Popejoy and Fullerton noted the failure of genomic research to significantly increase inclusion of minority populations in research.[2]

Genomic research may be particularly important in critically ill patients as genetic variation in susceptibility to illness and response to therapy are important targets for sepsis and other critical illness.[3,4] Genomic research in children also raises a host of ethical challenges, particularly in a critical care setting.[5,6] In the critical care setting, enrollment in research generally is challenging owing to the vulnerability and acuity of illness and the often time-sensitive nature of research enrollment.[7–11] Natale et al. demonstrated that, in this setting as well, minority populations are less likely to be enrolled in research.[12] The objective of this study was to evaluate sociodemographic characteristics associated with decisions to enroll a child in a pediatric critical care biorepository.

Specifically, we were interested in examining how minority populations would respond to requests to participate in a biorepository for their critically ill child. We hypothesized that, as previously reported in general populations, there would be low enrollment of minority populations. However, we were also interested in examining how other sociodemographic factors not commonly reported with respect to participation in genomic research, and other clinical factors, relevant to an ICU admission might impact participation.

METHODS:

Distribution of Biorepository Consent Forms

All parents of children admitted to the Pediatric Intensive Care Unit (PICU) between November 2014 and May 2017 were presented with the opportunity to enroll their child in a PICU biorepository. Enrollment occurred via a single page opt-in consent form. The opt in consent requested that parents indicate their willingness to have their child's residual blood from clinical draws, excess urine or respiratory samples routinely collected as a part of clinical care and usually discarded, instead retained in a biorepository. No additional sample collection was performed.

Forms were at a tenth grade reading level after multiple revisions with parent and expert input. They were available in both English and Spanish and were distributed at PICU admission by PICU administrative staff. Parents were instructed to complete the form and return it to administrative staff once completed. Unit clerks received training from study staff

regarding the basics of biorepositories as well as specific workflow for the study. Forms were initially included as a part of the welcome packet, specifically introduced to the parent via the unit clerk with a request to complete. Unit clerks were then instructed to check for a completed form when a parent subsequently came in to the PICU, requiring a stop at the unit clerk desk. Unit clerks would remind parents to complete the form if it was incomplete and were instructed to mark the form declined to complete if the parent did not complete it. Unit clerks were given a sheet of frequently asked questions to provide introductory information in response to parent questions, but were instructed to contact the study team to speak with any parent who had additional questions. Although there was no direct contact made by the study team at the time of form distribution, a study team member was always available to answer any questions or concerns that could not be addressed by administrative staff. Study team members were very rarely contacted for questions.

We evaluated characteristics associated with a missed opportunity for enrollment (missed enrollment) into the biorepository due to (1) failure to return a completed consent form (incomplete consent) or (2) declined consent on the completed form (declined consent). All study activities, including the use of the modified single page opt-in consent, and review of demographic data associated with enrollment, were approved by the Institutional Review Board at the Ann & Robert H. Lurie Children's Hospital (IRB#2015–15998). Alteration of consent was approved for use of the 2-line opt in consent form for the biorepository. A waiver of consent was granted for the data included in this report.

Retrospective Evaluation of Factors Associated with Missed Enrollment

We conducted a retrospective chart review for all patients admitted over the study period. For patients with multiple encounters, forms were distributed at each encounter. For the retrospective chart review, data from each encounter was collected to evaluate associations between encounter level data and decisions regarding biorepository participation. We collected sociodemographic information including race/ethnicity, insurance status, primary language, patient age, and zip code. Zip codes were then used to estimate annual household median income and to extract Child Opportunity Index, another marker of socioeconomic status.[13] Additionally, we collected data about family experience with the PICU including whether the patient had prior PICU admissions and their length of stay. Finally, we assessed admission level factors including reason for admission, comorbidities defined as any other system involvement beyond the organ system involved in the reason for admission, illness severity as measured by the use of invasive PICU interventions such as mechanical ventilation and, vasopressors, dialysis, and extracorporeal membrane oxygenation support. Retrospective data was collected via a combination of data extraction and manual chart review. For data elements that required identification on manual chart review, two raters (AS, SD) evaluated all charts (50% reviewed by each rater) after an initial review of 10 charts by both raters to ensure consistency. A third rater (TP) performed a random review of 10% of all records, demonstrating 99% agreement between raters.

Analysis

We conducted bivariate analyses to assess associations between potential sociodemographic, PICU experience, and admission level factors and (1) completion of a biorepository consent

and (2) consent or declination of participation on completed consent forms. We used chi-squared tests to evaluate associations between categorical predictor variables and co-primary outcomes: (1) completion of consent form (incomplete/complete) and (2) Response on consent form (enrolled/declined). All factors that were evaluated on bivariate analyses were subsequently assessed by multivariable generalized linear mixed models, clustered by encounters within patients. The initial model was evaluated for collinearity and confounding. After removing Child Opportunity Index level, which was collinear with income, factors in the initial model that were nonsignificant were sequentially removed to arrive at the final model. We analyzed factors that were stable over admissions at the patient level and factors that were variable by admission such as reason for admission, illness severity, prior PICU experience at the admission encounter level. For patient-level factors, we utilized the most recent response for the patient to the opt-in consent form. A small number of patient forms had changed responses over multiple admissions that did not yield any statistically significant trends and are not reported here. Sample characteristics and all associations are reported at the patient level except for association with admission-level factors, which are reported at the encounter level as described above.

RESULTS

Sample Characteristics

Over the three-year study period, there were 4055 PICU encounters, representing 2978 unique patients. Of these 2978 unique patients, 2910 had complete data for analysis, 1480 (50.8%) completed the biorepository consent form and 1223 (83%) agreed to enroll in the biorepository. Of the 4055 encounters, 627 indicated to use a response on a prior form and are not included in the encounter level analysis as they did not complete a new form based on the current encounter, leaving 3428 encounters for analysis.

Sample characteristics are presented in Table 1. The majority of the sample that was eligible for participation in the biorepository was White, non-Hispanic with Medicaid insurance status, English-speaking, and lived in zip codes corresponding to annual household income levels below the median income level for Chicago. The median length of stay for those who completed a consent form and enrolled was 6 days (IQR 3, 11). Most had only a single PICU admission. Reasons for admission to the PICU were varied, with the majority of the population admitted for respiratory illness (n = 1370, 46%), post-operative monitoring (n = 536, 18%), neurologic disease (n = 357, 12%), or shock (n = 208, 7%).

Factors Associated with Missed Enrollment Due to Failure to Complete the Consent Form

We first evaluated factors related to missed enrollment due to failure to return a completed biobank consent form (incomplete consent). All sociodemographic, PICU experience and patient admission characteristics were evaluated as potential predictors of completing the consent. Results from bivariate analyses that remained significant on multivariate regression are presented in Table 2.

On bivariate analysis, we found several demographic factors associated with incomplete consents. Individuals with Medicaid insurance status, those who lived in zip codes

corresponding to lower than the median income for Chicago or of low or very low Child Opportunity Index level were all more likely to have incomplete consents. Similarly, we found that individuals of African American, Hispanic, Asian, or Other race/ethnicity and those who spoke Spanish or another non-English language were also more likely to be missed due to incomplete consents. Finally, individuals of age above the median were more likely to have incomplete consents. In generalized linear mixed models (GLMM) adjusting for all predictors, primary language and race/ethnicity remained significant predictors of incomplete consent.

Several clinical factors were also associated with incomplete consents. Individuals requiring invasive PICU interventions were less likely to be missed due to incomplete consents. Specifically, lower rates of incomplete consent were observed in those requiring the following invasive PICU interventions: an endotracheal tube, respiratory support, dialysis, vasoactive support, cardiopulmonary resuscitation (CPR) and extracorporeal membrane oxygenation (ECMO). Individuals who were admitted for post-operative monitoring were less likely to have incomplete consents compared to those admitted for all other reasons. Similarly, individuals whose length of stay (LOS) was longer (>7 days) had lower rates of incomplete consent, while those whose length of stay was shorter (1–2 days) had higher rates of incomplete consent compared to lengths of stay 3–7 days. On multivariable logistic regression, use of certain invasive PICU interventions (ECMO, intubation, and respiratory support), reason for admission and length of stay remained significant positive predictors of completion of the consent.

Factors Associated with Declined consent on a Completed Consent Form

We next evaluated factors related to missed enrollment due to declined consent on a completed consent form. Again, all sociodemographic, PICU experience, and patient admission characteristics were evaluated as potential predictors of declined consent. Results of bivariate analyses that remained significant on GLMM are presented in Table 3.

On bivariate analysis, several demographic factors were associated with whether or not enrollment was declined. Individuals of Medicaid insurance status, those of any non-White race/ethnicity, those living in zip codes corresponding to less than the median income for Chicago or areas of low or very low Child Opportunity Index level, and those below the median age were more likely to decline consent. In multivariable models, only race/ethnicity and insurance status remained significant demographic predictors of declined consent.

Clinical characteristics were variably associated with rates of declined consent. Parents of children requiring respiratory support were more likely to decline consent, while parents of children requiring dialysis and parents of children admitted for oncologic, cardiac and liver disease were less likely to decline consent. On multivariable logistic regression, only need for dialysis remained a significant clinical predictor of declined consent.

DISCUSSION

We found that there were missed opportunities for enrollment into a pediatric critical care biorepository at distinct points in the recruitment and enrollment process, associated with

multiple sociodemographic factors. Further, we found that such factors across multiple domains were associated with likelihood of parents both completing consent forms and declining consent for participation in the biorepository.

Figure 1 outlines a conceptual model for recruitment and enrollment into a research study. From the framing of the research question through the decision to participate, multiple factors can influence the composition of the study population. Some of the factors relevant at the time of the research approach include trust and motivators or barriers to participate. Additionally, factors related to the research, including interaction with the study team, possible study team bias, study risk level, and compensation for participation may play a role in decisions about participation at this time point. In our study, individuals with incomplete consents may have had challenges with the research approach. These groups may have had incomplete consents due to not receiving the form, or may have received the form and not completed it, which cannot be fully distinguished in this study. Unit clerks were instructed to document incomplete consents “declined to complete” when they identified this situation. We expected that if individuals did not want to complete the form, we would have had a higher number of forms returned that were documented “declined to complete.” As we did not have a high number of “declined to complete” forms, it is possible that at least some of the incomplete consents were due to not having received the form from the unit secretary. Since our study demonstrated possible differences in who was approached (received a form), our findings support future investigators working to overcome barriers that could exist at the time of the approach as described above. For example, future investigators may consider interventions to improve trust at the moment of the first interaction with the study team. Additionally, study teams may consider training on identifying and attempting to mitigate biases that may lead to differentially approaching certain groups.

As discussed above, failure to complete the consent form may reflect lack of receipt of the form (i.e., failure to approach the family). Natale et al. have previously reported that diverse groups may be less likely to be approached for research; our findings may be consistent with this report, which may reflect institutional bias or racism.[12] An incomplete consent form, however, could also reflect the family being unwilling to complete the form due to inability to read the form, unwillingness to participate, feeling overwhelmed related to their child’s clinical condition, or forgetting to return the form. Our results suggest that primary language and race/ethnicity were important sociodemographic characteristics related to completion of the consent form. We were expecting to find that parents who did not speak English or Spanish would be more likely to have incomplete consents as the consent forms were only available in these languages. However, we also found that individuals who spoke Spanish as a primary language were also less likely to return completed forms, despite forms being available in the Spanish language. Our finding that individuals of Hispanic background also had higher rates of declined consent suggests that unwillingness to participate may have been a driver of failure to complete the consent form. We also found that individuals of Hispanic race/ethnicity were, independent of language, less likely to return a completed consent form. This could reflect fewer interactions with these families or any of the other above reasons for not returning a consent form.

Several clinical characteristics were also related to missed enrollment due to an incomplete consent. Parents of patients who had a longer length of stay or who required invasive PICU interventions including ECMO, intubation, and respiratory support were less likely to be missed for enrollment due to an incomplete consent. The need for invasive interventions and the longer length of stay might have afforded more opportunities for interaction with these families, leading to higher rates of completed consent forms. Patient acuity at the time of PICU admission may have also played a role in completion of the consent form. Patients who were admitted for post-operative monitoring had lower rates of missed enrollment due to incomplete consent when compared to those whose admission reason was missing/unknown. A patient admitted for expected post-operative monitoring may have been lower acuity, with anticipated admission and lower stress on the part of the parents/family. In contrast, patients of high acuity or unexpected sudden admission may not have had an admission diagnosis immediately recorded. Parental stress may also have been higher for these patients, which may have led them to forget to complete the form or be unwilling to participate. Future study teams conducting biorepository research in the critical care setting should consider alternative/delayed timing for obtaining consent from families of patients with high acuity.

Declined consent was also related to factors across the multiple domains studied. Among sociodemographic factors, race/ethnicity and insurance status were significantly related to willingness to participate. Higher declined consent rates among those of non-White race/ethnicity is consistent with previous reports of lower participation in research by diverse groups, and may relate to low levels of trust with health institutions or factors related to the interaction between the potential participant and study representatives.[14,15] The potential for unconscious bias or racism is an underexplored factor in recruitment and retention of participants for research. Parents were also more likely to decline consent when their children were of Medicaid insurance status, which likely reflects lower agreement to participate by individuals of lower socioeconomic status. Other socioeconomic status factors were significant on bivariate analysis (lower than median income by ZIP code and Child Opportunity Index), although these were not independently significant on multivariable regression. Lower participation rates in this group again might reflect interaction level factors, need for trust building, or promoting better understanding of research/research literacy. Lower health literacy has generally been reported in individuals of lower SES and institutions have a responsibility to convey research information in a manner that facilitates understanding.[16] In general, individuals requiring more invasive PICU interventions were more likely to complete the consent; however, agreement to enroll in the biorepository was not higher for other levels of intensive care support.

Many of our findings merit additional study. In general, we suspect that receipt and completion of the consent form was influenced by availability of parents/legal guardians at the bedside. For individuals with longer lengths of stay or requiring PICU interventions, parents/legal guardians were likely more available and able to complete the form. Conversely, those who were potentially less able to be at the hospital (e.g. those with lower median income) may have been less available to approach with the consent form. Delivery of the consent form to all eligible individuals is the first step in possibly expanding the pool of participants agreeing to engagement in the biorepository. To optimize goals

of precision medicine efforts that may result from use of biorepository samples, more research is warranted to assess reasons why certain groups are less available to approach in order to deliver the form. Historically, factors related to potential participants characteristics have been the focus of lower enrollment. However, in our study, other factors that were significantly related to completing a consent form or declining participation (e.g. language, race, and reason for admission to the PICU) may be more specific to the research interaction itself. Health literacy level utilized by study teams, ability to provide consent forms at accessible levels, and communication between study representatives and parents who may have different backgrounds and different responses to coping with their child's critical illness are all relevant factors to consder. This suggests a role for understanding and addressing barriers to consent, particularly from members of diverse and underrepresented groups, with a particular focus on interventions that study teams in positions of power relative to potential participants may be able to implement. These findings support future study teams increasing interaction with potential participants in order to build trust and to assess understanding in real time. Finally, we found that individuals with greater research experience (e.g. oncology patients) may be more likely to participate in research. This may suggest a role for increasing familiarity and understanding of research as a way to improve participation, particularly for groups who are underrepresented in research. For example, future study teams may consider developing a brief primer on research to orient potential participants and their family to what the purpose of research is, prior to requesting consent for biorepository participation.

Our combined findings suggest, most importantly, that traditional approaches to decreased enrollment, which conceptualize barriers stemming from characteristics or practices of potential participants, may be misguided. Conceptualizing barriers as narrowly applicable to potential participants does not place enough importance on the role of study teams and research infrastructures to address possible study team bias and/or racism, as well as the importance of the study team's interaction with the potential participant as a means to address barriers to enrollment. This is an important area for future study and development of interventions.

Several important limitations of our study must be noted. First, this was a single center study, which may limit its generalizability. Second, as this study was retrospective, we were unable to track reasons for missing consents. For individuals who did not return a consent, we do not know whether they received a form or not. For those who received the form and did not return it, we do not know the reason why the form was not returned. The tenth grade reading level of the form may have been a barrier to completion for some who received the form. Finally, we did not track reasons for declined consent. Future studies would benefit from collecting additional clinical data, including mode of admission to the PICU and additional parental demographics, including age, parent race/ethnicity, and education level.

These limitations notwithstanding, our findings suggest multiple areas for future study and potential for improvement in study enrollment by underrepresented groups. Systematic collection of sociodemographic characteristics beyond race and ethnicity may illuminate opportunities for improving enrollment into precision medicine based studies, particularly in

high-acuity settings where the potential life-saving impact of cutting-edge research may be greatest.

CONCLUSION

Enrollment into biorepository research may be affected by factors leading up to consent, which are different from factors that impact willingness to consent. Additional study into barriers at both stages is warranted to improve participation by diverse groups in biorepository based research in an increasingly precision medicine-focused health care environment.

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PATIENT CONSENT

This study was granted a waiver of informed consent.

DATA AVAILABILITY:

Data can be obtained by contacting the corresponding author.

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Impact:

- Individuals of minority race/ethnicity are less likely to enroll in genomic research and in critical care research.
- This study evaluated sociodemographic characteristics associated with decisions to enroll a child in a pediatric critical care biorepository.
- Sociodemographic factors including race/ethnicity, primary language, and insurance status and patient clinical characteristics are associated with differential enrollment into a pediatric critical care biorepository.
- More research is needed to understand how study team-participant interactions may play a role in differential enrollment.
- Barriers to enrollment occur both at the time of approaching and consenting for enrollment.

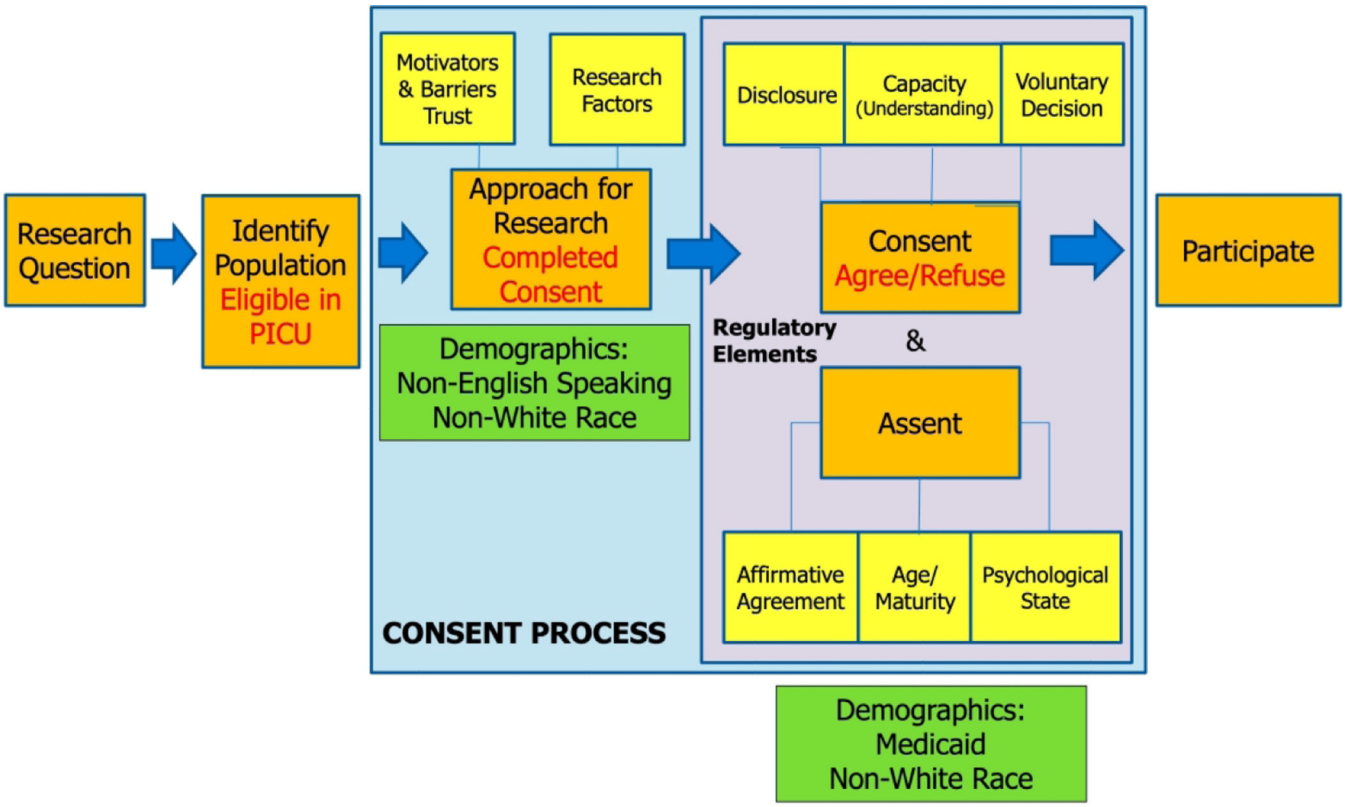

Figure 1. Conceptual Model for Research Enrollment

Decisions to participate in research reflect multiple stages, during which various factors may influence enrollment. Sociodemographic factors were relevant to who was approached, with higher odds of failure to approach non-English speaking and non-White participants, as well as who gave consent, with higher odds of declined consent among non-White and Medicaid participants.

Table 1.

Study Sample Characteristics

		Number	%
Patient Level Data (n=2910)			
RACE/ETHNICITY	White	1057	36.3
	African American	626	21.5
	Latinx	935	32.1
	Asian	134	4.6
	Other	154	5.4
AGE	<= 10	2107	72.4
	>= 11	803	27.6
SEX	Female	1269	43.6
	Male	1641	56.4
INSURANCE	Medicaid	1581	54.3
LANGUAGE	English	2466	84.7
	Spanish	352	12.1
	Other	92	3.2
ANNUAL HOUSEHOLD INCOME	Below Chicago Median	1072	36.8
Number of PICU Admissions During Study Period	1	2381	82
	2	333	11
	3	92	3
	4	104	4
COMORBIDITIES	Yes	1323	45.5
	Encounter Level Data (n=3428)		
PICU EXPERIENCE			
Length of Stay	1–2 days	550	16.0
	3–7 days	1700	49.6
	>7 days	1178	34.4
PICU Interventions	Yes	2101	61.3

		Number	%
Patient Level Data (n=2910)			
REASON FOR ADMISSION	Post-operative	610	17.8
	Medical/Not post-op	2717	79.3
	Missing	101	2.9

Table 2.

Factors Associated with Incomplete Consent/Missed Approach

	Bivariate				Initial Model Multivariable Regression					Final Model Multivariable Regression				
		Missed Approach	Approached	p value	Beta Estimate	SE	OR*	95% CI+	p value	Beta estimate	SE	OR*	95% CI+	p value
Race/Ethnicity				<0.001					0.0004					<0.0001
	White	592 (49)	618 (51)		REF					REF				
	African American	430 (58)	305 (42)		0.31	.11	1.36	1.09–1.7		0.38	0.1	1.47	1.22–1.77	
	Hispanic	678 (60)	444 (40)		0.17	0.11	1.18	0.96–1.46		0.21	0.1	1.24	1.03–1.50	
	Asian	101 (65)	54 (35)		0.53	0.19	1.71	1.18–2.46		0.55	0.18	1.74	1.21–2.50	
	Other	140 (68)	66 (32)		0.61	0.17	1.86	1.33–2.58		0.66	0.17	1.93	1.39–2.67	
Age	<=10	1389 (56)	1096 (44.1)	0.088	REF				0.11	X	X	X	X	X
	>=11	552 (58.5)	391 (41.5)		0.13	0.08	1.14	0.97–1.33						
Language				<0.001					<0.0001					<0.0001
	English	1547 (54)	1327 (46)		REF					REF				
	Spanish	313 (71)	131 (29)		0.69	0.13	1.99	1.54–2.58		0.74	0.13	2.09	1.62–2.69	
	Other	81 (74)	29 (26)		0.74	0.23	2.09	1.33–3.29		0.74	0.23	2.10	1.34–3.31	
PICU Interventions				<0.001					0.01					0.019
	Yes	1133 (54)	968 (46)		REF					REF				
	No	808 (61)	519 (39)		0.2	0.08	0.82	0.70–0.96		−0.18	0.08	0.83	0.71–0.97	
Reason for Admission				<0.001					<0.0001					<0.0001
	Post-op	288 (47)	322 (53)		−0.47	0.10	0.63	0.52–0.76		−0.45	0.1	0.64	0.52–0.77	
	Other Not Post-Op	1567 (58)	1150 (42)		REF					REF				
	Missing	86 (85)	15 (15)		1.6	0.29	4.95	2.81–8.70		1.56	0.29	4.76	2.72–8.4	8.33

	Bivariate				Initial Model Multivariable Regression					Final Model Multivariable Regression				
		Missed Approach	Approached	p value	Beta Estimate	SE	OR*	95% CI+	p value	Beta estimate	SE	OR*	95% CI+	p value
Length of Stay				0.002					<0.0001					<0.0001
	1–2 days	332 (60.4)	218 (39.6)		0.24	0.11	1.27	1.03–1.56		0.24	0.11	1.27	1.03–1.56	
	3–7 days	990 (58.2)	710 (41.8)		REF					REF				
	>7 days	619 (52.5)	559 (47.5)		−0.25	0.08	0.78	0.66–0.92		−0.24	0.1	0.79	0.67–0.93	
Insurance Status				<0.001					0.362	X	X	X	X	X
	Not Medicaid	804 (52)	737 (48)		REF									
	Medicaid	1137 (60)	750 (40)		0.07	0.09	1.08	0.91–1.28						
Income				<0.001					0.328	X	X	XX	X	X
	Below Chicago Median	781 (61)	508 (39)		0.08	0.08	1.09	0.92–1.28						
	@ or above Median	1160 (54)	979 (46)		REF									
Child Opportunity Index				0.068	X	X	X	X	X	X	X	X	X	X
	Very High	323 (54)	280 (46)											
	High	291 (54)	253 (46)											
	Moderate	341 (57)	263 (43)											
	Low	368 (58)	265 (42)											
	Very Low	419 (61)	269 (39)											
Comorbidities				0.679					0.151	X	X	X	X	X
	Yes	970 (57)	754 (43)		0.11	0.07	1.11	0.96–1.28						
	No	971 (56)	733 (44)		REF									

*OR = odds ratio;

+= Confidence Interval

Table 3.

Factors Associated with Consent Refusal

	Bivariate				**Initial Model Multivariable Regression**					**Final Model Multivariable Regression**				
		Declined	**Enrolled**	**P value**	**Beta estimate**	**SE**	**OR***	**95CI+**	**p value**	**Beta estimate**	**SE**	**OR***	**95% CI+**	**p value**
Race/Ethnicity				<0.001					<0.0001					<0.0001
	White	61 (10)	557 (90)		REF					REF				
	African American	91 (30)	214 (70)		0.99	0.23	2.69			1.03	0.21	2.80	1.84–4.26	
	Hispanic	90 (20)	354 (80)		0.52	0.22				0.52	0.21	1.68	1.12–2.52	
	Asian	16 (30)	38 (70)		1.23	0.34				1.24	0.33	3.46	1.81–6.64	
	Other	10 (15)	56 (85)		0.23	0.38				0.27	0.38	1.31	0.62–2.74	
Age				0.007					0.037					0.037
	<=10	215 (20)	881 (80)		REF					REF				
	>=11	53 (14)	338 (86)		−0.36	0.17	0.70	0.49–0.98		−0.35	0.17	0.71	0.51–0.99	
Language				0.275					0.57	X	X	X	X	X
	English	233 (18)	1094 (82)		REF									
	Spanish	27 (21)	104 (79)		−0.04	0.26	0.96	0.58–1.61						
	Other	8 (28)	21 (72)		0.48	0.46	1.61	0.66–3.94						
PICU Interventions				0.944					0.783	X	X	X	X	X
	Yes	174 (18)	794 (82)		0.04	0.16	1.05	0.76–1.43						
	No	94 (18)	425 (82)		REF									
Reason for Admission				0.194					0.246	X	X	X	X	X
	Post-Op	47 (15)	275 (85)		0.16	0.68	1.18	0.31–4.43						
	Other Not Post-Op	218 (19)	932 (81)		REF									
	Missing	3 (20)	12 (80)		−0.32	0.19	0.73	0.49–1.06						
Length of Stay				0.15					0.172	X	X	X	X	X
	1–2 days	33 (15)	185 (85)		−036	0.23	0.70	0.45–1.09						
	3–7 days	142 (20)	568 (80)		REF									
	>7 days	93 (17)	466 (83)		−0.23	0.16	0.79	0.58–1.09						
Insurance Status				<0.001					0.011					0.025

	Bivariate				Initial Model Multivariable Regression					Final Model Multivariable Regression				
		Declined	Enrolled	P value	Beta estimate	SE	OR*	95CI+	p value	Beta estimate	SE	OR*	95% CI+	p value
	Medicaid	183 (24)	567 (76)		0.46	0.18	1.58	1.11–2.25		0.49	0.18	1.64	1.17–2.32	
	Not Medicaid	85 (11)	652 (89)		REF					REF				
Income				<0.001					0.312	X	X	X	X	X
	Below Chicago median	125 (25)	383 (75)		REF									
	@ or above median	143 (15)	836 (85)		0.16	0.16	1.17	0.86–1.6						
Child Opportunity Index				0.010	X	X	X	X	X	X	X	X	X	X
	Very High	42 (15)	238 (85)											
	High	36 (14)	217 (86)											
	Moderate	46 (17)	217 (83)											
	Low	49 (19)	216 (81)											
	Very Low	69 (26)	200 (74)											
Comorbidities				0.84					0.261	X	X	X	X	X
	Yes	134 (18)	620 (82)		0.16	0.15	1.18	0.89–1.57						
	No	134 (18)	599 (82)		REF									

*OR = odds ratio;

+= Confidence Interval