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Socioeconomic Status and the Likelihood of Antibiotic Treatment for Signs and Symptoms of Pulmonary Exacerbation in Children with Cystic Fibrosis

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On behalf of the Investigators and Coordinators of the Epidemiologic Study of Cystic Fibrosis*

Abstract

Objective—To test the hypothesis that antibiotic treatment for pulmonary exacerbations might be influenced by socioeconomic status (SES) in patients withcystic fibrosis (CF)

*List of Investigators and Coordintors of the Epidemiologic Study of Cystic Fibrosis available at www.jpeds.com(Appendix).

Study design—Weused data on 9895 patients age ≤18 years from the Epidemiologic Study of CF.After establishing an individual baseline of clinical signs and symptoms, we determined whether antibiotics were prescribed when new signs/symptoms suggested a pulmonary exacerbation, adjusting for sex, presence of *Pseudomonas aeruginosa*, the number of new signs/symptoms, and baseline disease severity.

Results—Over a 12-month period, 20.0% of patients age <6 years, 33.8% of patients 6-12 years of age, and 41.4% of patients age 13-18 years were treated with any (oral, intravenous, or inhaled) antibiotics; the percentage receiving intravenous antibiotics was 7.3%, 15.2%, and 20.9%, respectively. SES had little impact on treatment for pulmonary exacerbation with any antibiotics, but intravenous antibiotics were prescribed more frequently for patients with lower SES.

Conclusions—SES-related disparities in CF health outcomes do not appear to be explained by differential treatment of pulmonary exacerbations.

Keywords

Outcome assessment (health care); social class; delivery of healthcare

Socioeconomic status (SES) is a strong predictor of outcomes in patients with cystic fibrosis (CF).[1,2] Although barriers in access to quality care is an important cause of SES-related disparities in many patient populations,[3] previous analyses have failed to show any apparent SES-related difference in clinic visits or the prescription of chronic therapies at CF care centers.[1,4] Pulmonary exacerbations are an important contributor to the deterioration in lung function seen in patients with CF.[5] Substantial inconsistencies in the prescription of antibiotics in response to signs and symptoms of a pulmonary exacerbation have been documented,[6] and, as might be expected, treatment has a clear impact on short-term clinical status, although the effect on long-term outcomes is more difficult to demonstrate.[7] Nonetheless, an analysis ofsite-specific variations in practice patterns found that CF care sites whose patients have the best lung function prescribe intravenous (IV) antibiotics more frequently than sites whose patients have lower average forced expiratory volume in 1 second (FEV_1).[8] This analysis sought to determine whether variability in antibiotic treatment of the clinical characteristics of acute pulmonary exacerbations might be related to SES and thus provide an explanation for SES-related disparities in outcomes. We were also interested in determining whether practice patterns might be associated in different ways with several alternative markers of SES.[9-14]

METHODS

This study was a longitudinal analysis that included patients ≤18 years of age who were enrolled in the Epidemiologic Study of Cystic Fibrosis (ESCF) between 2000 and 2005. The design and implementation of the ESCF have been previously described.[15] The ESCF was a multicenter longitudinal cohort study initiated in 1994 to collect data on care practices and outcomes of patients with CF in the United States and Canada. Several additional variables (including those relevant to SES and the treatment of pulmonary exacerbations using nonquinolone oral antibiotics) were added in 2003.Data on patient demographics, pulmonary function, morphometric characteristics, and therapies were collected at each

clinic encounter. Pulmonary function test results were reported as measured values and converted to percent predicted using reference equations from Wang et al[16] for females through age 15 years and males through age 17 years, and Hankinson et al[17] at older ages. Therapies monitored in ESCF include IV, inhaled, and oral antibiotics, as well as a variety of chronic medications.[4] Therapies are recorded as those prescribed by the provider; there is no mechanism for documenting patient adherence to prescribed therapies. The study was approved by the Copernicus Group institutional review board (IRB; tracking number OVA1-03-008) or local IRBs, and participants or their guardians provided informed consent.

Diagnosis and Treatment of Pulmonary Exacerbations

The treatment of pulmonary exacerbation is a cornerstone of therapy for CF, but the definition of these exacerbations is controversial,[18] which contributes to the lack of standardization of their treatment. Rabin et al[6] used ESCF data to characterize signs and symptoms most likely to lead to treatment of a pulmonary exacerbation, and we adopted that approach for this analysis. In the ESCF case report forms, clinicians recorded cough and sputum (none, occasional, or daily), crackles and hemoptysis (present or absent), weight, and FEV_1 (in patients old enough to perform acceptable measurements).[15] Using the approach of Rabin et al we characterized patients over a 12-month baseline period based upon their best reported findings of signs and symptoms and then evaluated the data from each patient during the next 6 months (the study period) for reports of changes from this baseline. The baseline period began on the later of January 1, 2000 or the date of enrollment. For patients age <6 years, each clinic visit during the study period was evaluated for the presence of new crackles, increased cough or sputum, and a relative decline of more than 45% in the weight-for-age percentile at any visit during the study period compared with the best weight-for-age percentile in the baseline period. For patients 6 years or older, clinic visits during the study period were evaluated for new crackles, increased cough, hemoptysis, and a relative decline of more than 10% in FEV_1% predicted compared with the best FEV_1 recorded during the baseline period. Visits of interest were categorized according to the presence of 0, 1, 2, 3, or 4 new clinical characteristics at any visit during the study period. If individuals had more than 1 visit during the study period, the first visit with the maximal number of observed characteristics was defined as their study visit. If patients had none of the characteristics, their last visit in the study period was used as their study visit. Only 1 clinic visit per patient was evaluated. Treatment of a pulmonary exacerbation was defined by a report that antibiotic treatment was prescribed between 7 days before and 28 days following the study visit.

Criteria for Risk and Severity Classification

Patients were categorized as having *Pseudomonas aeruginosa* if the organismwas detected in a respiratory tract culture (throat culture, sputum culture, or bronchoalveolar lavage) obtained at any time in the year prior to and during the baseline period.

Disease severity was categorized in the following ways: (1) Children <6 years old were assigned to a severity group according to their best weight-for-age percentile in the baseline period (0 to <5, 5 to <10, 10 to <25, 25 to <50, 50 to 100); and (2) Children 6 to ≤18 years

old were assigned to a severity group according to their best stable FEV_1 % predicted value in the baseline period (<40, 40 to <70, 70 to <100, ≥100).

SES Variables

We evaluated SES using 3 indicators: (1) Medicaid or state health insurance coverage (MA) — categorized as a dichotomous yes/no variable, independent of whether the patient held any other form of health insurance; (2) Median household income by zip code of residence (MIZ)— categorized into 4 groups: <$40,000; $40,000 to <$50,000; $50,000 to <$60,000; ≥ $60,000, basedon linking ESCF zip code data to the year 2000 US Census report on median annual income of each zip code; and (3) Maternal educational attainment (MEA)— categorized as either less than high school graduate or high school graduate or more.

Data collected over the period prior to 2003 was used to establish baseline signs and symptoms and disease severity; this was merged with data regarding SES and oral antibiotic usage which was collected beginning in 2003.

Statistical Analysis

P values for differences in demographic, SES, andclinical, variables by age group (Table I) are based on the t-test statistic for linear variables (age, FEV_1 % predicted, and weight-for-age percentile), the chi-square test statistic for non-ordered categorical variables (sex, ethnicity/race, wheezing, crackles, *P.aeruginosa* positive, MEA and MA) except for hemoptysis, which was based on the Fisher exact test, and the Mantel-Haenszel test for ordered categorical variables (cough, sputum and MIZ). The relationships between categorical dependent variables and SES were initially evaluated using chi-square tests.A generalized linear model was developed (assuming a binomial probability distribution with the logit link function) to estimate the percentage of patients treated with antibiotics across SES categories, adjusting for sex, the presence of *P. aeruginosa* during the baseline period, the number of new clinical characteristics noted at the visit, and baseline disease severity, as previous reports have indicated that these are potential confounders of the relationship between treatment and SES[1,7]. Separate models were run for use of any antibiotics and for just IV antibiotics for each of the SES indicators. Patients missing data on SES data or other covariates included in the model were excluded from the analysis. *P* values reported for the models are based on the Wald test statistic.

RESULTS

A total of 9895 patients were eligible for inclusion in the analysis. Table I shows the demographic characteristics (age, sex, ethnicity/race), baseline clinical characteristics (FEV_1; weight for age; presence of cough, sputum, wheezing, crackles, hemoptysis, and airway *P. aeruginosa*) of the patients by age group, and the distribution of the SES measures by age group. The amount of data for MA and MIZ was fairly complete (missing data in less than 5% and 9% of patients, respectively), but data on MEA was missing in about 64% of patients.

Table II shows the distribution of the number of new clinical characteristics that were recorded at visits included in this analysis and the percentage that were treated with

antibiotics. As has been previously published,[6,7] the number of new characteristics imperfectly predicts treatment because a small number of patients with no new characteristics are reported to have received antibiotics and a substantial number of patients with even 4 new characteristics were not reported to have been prescribed antibiotics.

SES and the Likelihood of Treatment for Apparent Exacerbation

As shown in Table III, SES appears to have little impact on the percentage of patients treated for pulmonary exacerbation with any antibiotic (oral, IV, or inhaled) when adjusting for baseline age, sex, baseline *P. aeruginosa* status, and baseline disease severity.On the other hand, there appears to be a pattern of more frequent use of IV antibiotics in patients with lower SES (Table IV). This is clearly the case when MA status is used as a marker of SES, but is also seen for younger patients under 6 years of age whose mothers did not graduate from high school. The exception to these general observations is in adolescents living in the zip code with the lowest median household income; they receive less frequent therapy in response to new signs and symptoms of pulmonary exacerbation whether the focus is limited to IV antibiotics ($P<.001$ for <$40K vs. $40-50K; $P = .021$ for <40K vs. $60K+) or more broadly, to any antibiotic therapy ($P =.001$ for <$40K vs. $40-50K) (data not shown).

DISCUSSION

SES is a strong predictor of disease severity in CF.[1,2] Although significant inconsistencies exist in the treatment of pulmonary exacerbations across the CF population, this analysis of ESCF data suggests that SES as indicated by MEA or MIZ was not consistently associated with the likelihood of treatment for a pulmonary exacerbation. On the other hand, MA recipients were more likely than non-MA recipients to receive IV antibiotic treatment if they exhibited new signs or symptoms suggestive of a pulmonary exacerbation, as were children <6 years of age whose mothers were non–high school graduates. The interesting exception to this seems to be that adolescents from zip codes with the lowest median household income appeared to be treated less frequently. This finding is consistent with previous reports that Medicaid patients have more frequent hospitalizations for IV antibiotics.[1,4,19]

Thus, previously reported disparities in CF outcomes that have been associated with SES[1,2,4] do not appear to be related to differential treatment of pulmonary exacerbations. Although low income adolescents living in low income zip codes appear to receive less treatment, SES-related disparities are present from early childhood and do not increase significantly with age,[1,2] so the impact of this solitary exception to the general trend is uncertain. Our findings in CF contrastwith findings in other chronic diseases, such as asthma[3] for which access to quality care is an important contributor to SES-related disparities, but they are in accord with our previous work showing no compelling differences in healthcare utilization or the prescription of chronic therapies by SES status except for an increase in the MA population.[1,4,19] Other mechanisms are probably of greater importance in the CF population.For example, disease self-management (involving both patient and family) is likely an important determinant of long-term outcomes for chronic illnesses such as CF and appears to be associated with SES.[20,21] Health behaviors, such as

cigarette smoking, also are clearly linked to SES[22] and environmental tobacco smoke exposure is a likely a contributing factor to SES disparities in CF.[23] Other potential risk factors include exposure to psychological stress and environmental pollutants.[24]

SES is a broad sociological concept with different attributes and no single ideal measure.[9, 25] Income is an intuitively obvious measure of SES and is a good measure of material resources, but it is potentially confounded by age, education, family size, regional cost of living, and whether it is generated by one or more family members.[9] We do not have direct information on family income in the ESCF database, but used US Census data to link to median family income by zip code. This approach introduces the usual imprecision of an ecological measure,[26] which typically tends to weaken statistical associations.[27] In our analysis, there was no suggestion of any trend associating treatment with MIZ, so this variableof SES does not seem to be relevant to treatment of pulmonary exacerbations in CF. Educational attainment is a more stable characteristic than income and may best reflect disease self-management skills.[21] Unfortunately, we have information on maternal educational attainment on only one-third of our patients, reducing power, and it is not possible to ascertain how biased our sample is. State insurance (Medicaid) eligibility is closely tied to family income and is readily ascertained, making it a simple measure to use. Eligibility is variably determined by individual states, making it problematic for use in comparing outcomes across centers, but of greater concern when used as a national measure is the fact that medical expenses are considered in determining eligibility.[28] Thus, sicker patients are more likely to be MA eligible at any given income level. The fact that MA was associated with greater likelihood of receiving treatment for a pulmonary exacerbation suggests that finances could play a role in prescribing patterns for patients with low SES.

Although patient symptoms and treatment were tracked longitudinally over a short period of time, our analysis of the association between SES and disease status and treatment was effectively a cross-sectional one, so certain caveats must be stated regarding conclusions based upon the associations we have found. The direction and causality of the relationship between SES and disease severity cannot be derived from our cross-sectional study, but its findings are congruent with those of previously reported longitudinal analyses. Similarly, we cannot conclude that SES status preceded the differences (or similarities) that we found in treatment without performing a longer-term longitudinal cohort study, but both conclusions are extremely likely. Causality is more difficult to demonstrate with observational studies in general, and cross-sectional studies in particular.[27]

In conclusion, we have found no evidence that SES-related disparities in CF outcome are due to discrepancies in prescribed care, either in this study of treatment of pulmonary exacerbations or our previous evaluations of the use of chronic therapies and outpatient monitoring.[4] In fact, MA coverage is associated with increased treatment. Future investigations should focus on the possible impact of environmental exposures and differences in disease self-management by patient and family; insights into these mechanisms should not only help to improve outcomes for lower SES groups, but also for the entire CF population, much of which shares at least some of the adverse exposures of patients withlow SES.[29]

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Abbreviations

CF	cystic fibrosis
ESCF	Epidemiologic Study of Cystic Fibrosis
FEV_1	forced expiratory volume in 1 second
MA	Medicaid or state insurance
MEA	maternal educational attainment
MIZ	median household income by zipcode
SES	socioeconomic status

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Table 1

Demographic, SES and Baseline Clinical Measures by Age Group

	Age Group <6	Age Group 6-12	Age Group 13-18	Group Statistical Difference (P<.05)
N, total	4806	2600	2489	
Demographic characteristics				
Age, mean ± SD	2.43 ± 1.86	9.48 ± 2.04	15.70 ± 1.70	all
Sex, n (%)				NS
Male	2435 (50.7%)	1334 (51.3%)	1309 (52.6%)	
Female	2371 (49.3%)	1266 (48.7%)	1180 (47.4%)	
Ethnicity/race, n (%)				all
Non-Hispanic White	4021 (83.7%)	2315 (89.0%)	2294 (92.2%)	
Non-Hispanic Black	161 (3.3%)	88 (3.4%)	73 (2.9%)	
Hispanic	403 (8.4%)	131 (5.0%)	100 (4.0%)	
Other	198 (4.1%)	64 (2.5%)	21 (0.8%)	
Unknown	23 (0.5%)	2 (0.1%)	1 (<0.1%)	
SES measures:				
MEA, n (%)				Age <6 vs. others
Less than high school grad	185 (3.8%)	71 (2.7%)	59 (2.4%)	
High school grad or higher	1606 (33.4%)	949 (36.5%)	701 (28.2%)	
Unknown †	3015 (62.7%)	1580 (60.8%)	1729 (69.5%)	
MIZ, n (%)				NS
<$40,000	985 (20.5%)	486 (18.7%)	497 (20.0%)	
$40K to <$50k	1250 (26.0%)	749 (28.8%)	628 (25.2%)	
$50k to <$60K	842 (17.5%)	446 (17.2%)	464 (18.6%)	
≥$60K	1323 (27.5%)	750 (28.8%)	714 (28.7%)	
Unknown †	406 (8.4%)	169 (6.5%)	186 (7.5%)	
MA n (%)				
Medicaid	2259 (47.0%)	1048 (40.3%)	942 (37.8%)	Age <6 vs. others
Other	2393 (49.8%)	1450 (55.8%)	1437 (57.7%)	
Unknown †	154 (3.2%)	102 (3.9%)	110 (4.4%)	
Baseline Clinical Measures				
FEV_1 % predicted, mean ± SD	NA	94.4 ± 19.5	82.9 ± 21.8	all
Weight-for-age percentile, mean ± SD	44.0 ± 29.5	38.7 ± 28.2	38.3 ± 28.2	Age <6 vs. others
Cough n (%)				all
None	3289 (68.5%)	971 (37.4%)	599 (24.1%)	
Occasionally	1277 (26.6%)	1197 (46.1%)	1099 (44.2%)	
Daily	236 (4.9%)	431 (16.6%)	788 (31.7%)	
Sputum n (%)				all
None	4514 (94.1)	1836 (70.7%)	1264 (50.8%)	

	Age Group <6	Age Group 6-12	Age Group 13-18	Group Statistical Difference (P<.05)
Occasionally	244 (5.1%)	590 (22.7%)	784 (31.5%)	
Daily	40 (0.8%)	171 (6.6%)	438 (17.6%)	
Wheezing n (%)	12 (0.2%)	5 (0.2%)	22 (0.9%)	Age 13-18 vs. others
Crackles n (%)	26 (0.5%)	63 (2.4%)	153 (6.1%)	all
Hemoptysis n (%)	0 (0.0%)	1 (<0.1%)	11 (0.4%)	Age 13-18 vs. others
P. aeruginosa positive, n (%)	1428 (33.5%)	1336 (51.4%)	1560 (70.1%)	all

†Unknown is not included in p-value comparisons

Table 2

Number of New Clinical Characteristics by Age Group and Percentage Treated with Antibiotic Therapy

	Age Group <6 years			Age Group 6-12 years			Age Group 13-18 years		
	N	**% Any ABX**	**% IV ABX**	**N**	**% Any ABX**	**% IV ABX**	**N**	**% Any ABX**	**% IV ABX**
Number of new Clinical Characteristics present									
None	989	4.7	0.6	500	9.4	2.4	498	12.4	3.2
1	1598	13.4	2.6	1043	24.5	7.6	949	35.2	13.5
2	1487	24.6	7.4	780	48.6	23.5	690	53.0	28.0
3	622	43.1	23.3	272	71.3	43.4	328	75.3	50.9
4	110	61.8	41.8	5	80.0	60.0	24	91.7	66.7
Total	**4806**	**20.0**	**7.3**	**2600**	**33.8**	**15.2**	**2489**	**41.4**	**20.9**

Table 3

Crude and Adjusted Percentage of Patents Treated With Any (IV, Inhaled, PO) Antibiotics

SES Measure	Age Group: <6					Age Group: 6-12					Age Group: 13-18				
	N	Percentage Treated	Adjusted Percentage Treated	95% CI	*P* value	N	Percentage Treated	Adjusted Percentage Treated	95% CI	*P* value	N	Percentage Treated	Adjusted Percentage Treated	95% CI	*P* value
Maternal Educational Attainment	**n = 1568**				**.38**	**n = 1016**[§]				**.50**	**n = 677**				**.59**
Less than high school grad	162	27.2	18.1	(12.7-25.2)		70	40.0	42.7	(30.4-56.0)		54	37.0	39.1	(25.0-55.2)	
High school grad or higher	1406	19.6	15.6	(12.8-18.8)		946	33.9	38.3	(33.6-43.1)		623	43.0	43.4	(36.3-50.8)	
Median Family Income by Zip code	**n = 3886**				**.62**	**n = 2431**				**.53**	**n = 2064**				**.017**
<$40K	863	23.2	19.1	(16.3-22.2)		486	33.1	42.1	(33.5-51.3)		444	37.4	34.5	(28.9-40.6)	
$40K to <$50K	1104	20.2	17.5	(15.1-20.3)		749	34.2	46.6	(37.9-55.5)		564	47.0	45.6	(39.8-51.5)	
$50K to <$60K	749	20.0	16.6	(13.9-19.8)		446	34.8	45.0	(35.7-54.6)		413	42.9	40.9	(34.6-47.4)	
$60K+	1170	18.9	17.5	(15.0-20.4)		750	32.0	46.9	(38.1,56.0)		643	43.2	40.2	(34.8-45.8)	
State Insurance Status	**n = 4088**				**.31**	**n = 2498**				**.16**	**n = 2120**				**.12**
Medicaid	1988	22.8	18.0	(16.0-20.2)		1048	38.1	47.2	(39.7-54.9)		854	48.7	42.8	(37.8-47.9)	
Other Insurance	2100	18.1	16.8	(14.7-19.0)		1450	30.9	43.9	(36.4-51.7)		1266	38.9	38.9	(34.4-43.6)	

[§]Patients comprising the lowest severity category in this age group were excluded from the model because they all received antibiotic therapy, resulting in nonestimable values for all other predictors.

Table 4

Crude and Adjusted Percentage of Patients Treated With IV Antibiotics

SES Measure	Age Group: <6					Age Group: 6-12					Age Group: 13-18				
	N	Percentage Treated	Adjusted Percentage Treated	95% CI	*P* value	N	Percentage Treated	Adjusted Percentage Treated	95% CI	*P* value	N	Percentage Treated	Adjusted Percentage Treated	95% CI	*P* value
Maternal Educational Attainment	**n = 1290**[§]				**.021**	**n = 1020**				**.81**	**n = 677**				**.84**
Less than high school grad	137	18.3	11.1	(6.7-17.5)		71	18.3	15.8	(7.2-31.1)		54	20.4	15.7	(7.5-30.0)	
High school grad or higher	1153	7.8	6.1	(4.5-8.3)		949	14.1	13.8	(7.6-23.7)		623	20.1	15.3	(10.2-22.2)	
Median Family Income by Zip code	**n = 3886**				**.66**	**n = 2431**				**.37**	**n = 2064**				**.003**
<$40K	863	9.2	4.3	(3.0-6.2)		486	16.9	15.8	(11.2-21.8)		444	17.1	13.8	(10.3-18.1)	
$40K to <$50K	1104	7.5	4.0	(2.8-5.7)		749	16.8	18.1	(13.1-24.4)		564	26.2	23.1	(18.5-28.4)	
$50K to <$60K	749	7.1	3.6	(2.4-5.3)		446	16.4	15.9	(11.0-22.4)		413	20.6	17.1	(13.0-22.3)	
$60K+	1170	5.9	3.6	(2.4-5.2)		750	12.1	14.3	(10-19.8)		643	23.0	19.2	(5.2-23.8)	
State Insurance Status	**n = 4088**				**<.001**	**n = 2498**				**.002**	**n = 2120**				**.003**
Medicaid	1988	10.1	4.9	(3.7-6.6)		1048	19.9	18.9	(14.4-24.4)		854	28.8	22.6	(18.6-27.1)	
Other Insurance	2100	5.2	3.2	(2.3-4.4)		1450	12.3	13.7	(10.1-18.3)		1266	18.3	17.1	(14.0-20.7)	

[§]Patients comprising the lowest severity category in this age group were excluded from the model because none received IV antibiotic therapy, resulting in non-estimable values for all other predictors.