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Maternal Area of Residence and Outcomes for Mother-Infant Dyads with Perinatal Opioid Exposure

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Abstract

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Objective: Determine the relationship between maternal Social Deprivation Index (SDI), a composite measure of area level deprivation, and maternal characteristics and infant outcomes for mother-infant dyads with perinatal opioid exposure.

Study Design: Post hoc secondary analysis of 1298 mother-infant dyads in the ESC-NOW study, a multicenter, stepped-wedge cluster-randomized controlled trial (2020–2022) conducted at 26 US study hospitals. The 2016 American Community Survey was used to develop SDI scores based on the maternal zip code of residence at the time of delivery. Outcomes evaluated included receipt of pharmacologic treatment for NOWS (PT), receipt of breastmilk during hospital stay, direct breastfeeding at discharge, discharge disposition, and length of stay for infants who received PT (LOS).

Results: The median SDI score was 62 on a scale of 100. The high SDI group, with a score above the SDI median and more social deprivation, was less likely to receive adequate prenatal care or medication for opioid use disorder and more likely to be Black and/or Hispanic. The mean proportion of infants in the high SDI group were 6.2 percentage points (RR 0.89, 95%CI 0.80,0.98) less likely to receive breastmilk during the newborn hospitalization and 7.3 percentage points (RR 0.91, 95%CI 0.87,0.96) less likely to be discharged home with a biological parent. There was no difference between the high and low SDI groups in receipt of PT, direct breastfeeding at discharge, or LOS.

Conclusion: Mothers from high SDI communities with opioid exposure during pregnancy were less likely to receive the established standard of care and more likely to be Black and/or Hispanic. Infants born to these mothers were less likely to receive breastmilk and/or to be discharged home with a biological parent. Targeting interventions to mitigate the impact of social deprivation in high SDI communities may improve outcomes for opioid-exposed infants and their mothers.

Keywords

Social Deprivation; Neonatal Abstinence Syndrome; Opioid; Perinatal Care; Neonatal Opioid Withdrawal Syndrome; Residence Characteristics; Sociodemographic Factors

Background:

The interplay between social factors and health outcomes is increasingly recognized as a critical part of quality health care. Beyond individual social factors, health outcomes may be impacted by the level of resources and/or social support in the area where one lives.^{1–3} The protective effect of community social support on health outcomes is particularly important for vulnerable populations including the mother-infant dyad affected by perinatal substance use.^{4,5}

Perinatal opioid exposure affects mother-infant dyads of all socioeconomic statuses, though there are strong associations with poverty, Medicaid enrollment, and low educational attainment.^{6–10} Infants born to mothers who use opioids during pregnancy may experience neonatal opioid withdrawal syndrome (NOWS). On a county level, NOWS is more common in counties with designated mental health shortage areas, high unemployment rates, and higher infant foster care entry rates.^{11,12} Substance use, poverty, social deprivation, and

stigma often coincide. Many mothers with substance use disorder during pregnancy report stigma as a significant barrier to care.^{13–22}

The Eat, Sleep, Console (ESC) approach is a family-centered model of care increasingly used to care for infants with NOWS. When compared to usual care with the Finnegan tool, the ESC care approach has been shown to reduce the initiation of pharmacologic treatment and the length of hospital stay for these infants.²³ The ESC care approach emphasizes parental engagement including non-pharmacologic care practices such as rooming in, breastfeeding, skin-to-skin care, and parental presence. Parent-focused interventions such as these may be more difficult for a parent who has limited social support, difficulties with transportation, tenuous employment, and/or unstable housing. Few studies have evaluated the relationship between social factors and the severity of NOWS during the infant hospitalization and findings from these studies vary.^{24,25} Further research is needed to elucidate the associations between social factors, including both social deprivation and support, and infant outcomes.

The Social Deprivation Index (SDI) is a composite area level measure of social deprivation that was developed with the goal of evaluating the relationship between area level disadvantage and health outcomes.²⁶ The SDI is associated with a variety of health-related outcomes including cancer, infection, mental health, and other chronic health conditions.^{27–32} The relationship between SDI and medication for opioid use disorder (MOUD) and NOWS has not been assessed to date. This study aims to evaluate the association between maternal SDI at the time of delivery and maternal characteristics and infant outcomes for mother-infant dyads with perinatal opioid exposure.

Methods:

Data Sources

This is a post hoc secondary analysis of mother-infant dyads enrolled in the Eat, Sleep, Console for Neonatal Opioid Withdrawal (ESC-NOW) stepped-wedge cluster-randomized controlled trial. This trial compared the Eat, Sleep, Console care approach to usual care with the Finnegan tool for infants who were at least 36 weeks' gestation at birth, had evidence of antenatal opioid exposure, and were being assessed at a study hospital for NOWS severity. The study was conducted between September, 2020 and March, 2022 in 26 US hospitals across 18 states as a collaboration between the Environmental Influences on Child Health Outcomes (ECHO) Institutional Development Award (IDeA) States Pediatric Clinical Trials Network (ISPCTN) and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development's Neonatal Research Network (NRN). The primary analysis of ESC-NOW was published and the protocol may be found online.²³

Participants

All ESC-NOW study participants for whom SDI scores could be calculated were included in this analysis. SDI scores were assigned as per the American Community Survey data using 5 year estimates (2012–2016) by zip code.²⁶ The SDI is derived from 7 factors on the American Community Survey: percent of the population with household income

less than 100% of the federal poverty level, percent of the population 25 years or more with less than 12 years of education, percent non-employed for population 16–64 years, percent households living in renter occupied housing units, percent households living in crowded housing units, percent single parent families with descendants <18 years, and percent households with no vehicle. SDI scores ranged from 1 (representing low social deprivation) to 100 (representing high social deprivation). This index was selected because it was developed to evaluate the relationship between area level disadvantage and health outcomes. Similar to other studies of SDI, the study cohort was divided into a low social deprivation group with an SDI score at or below the median for the cohort and a high social deprivation group with an SDI score above the median^{27,33}.

Select components of the SDI were evaluated as independent variables: percent of the population with household income less than 100% of the federal poverty level, percent single parent families with descendants <18 years, and percent households with no vehicle. These components were selected due to their potential to negatively affect mothers' ability to actively participate in the care of their infants. Correlations between the individual components were tested, and the associations between each component and the outcomes were evaluated.

Maternal characteristics and infant outcomes were compared between the low social deprivation group and the high social deprivation group. Maternal characteristics included: race/ethnicity, adequate prenatal care (defined as at least 3 visits with the first visit before the start of the third trimester), MOUD, polysubstance use, marital status, and type of insurance coverage.

Outcomes

Binary infant outcomes evaluated at hospital discharge included: receipt of pharmacologic treatment for NOWS, receipt of any maternal breastmilk during hospital stay, direct breastfeeding at discharge, and discharge home with a biological parent. Length of hospital stay (LOS) was a continuous infant outcome evaluated at hospital discharge in the subset of infants who received pharmacologic treatment - the subset of infants with NOWS who tend to have longer and more variable hospital duration.³⁴

Statistical Analyses

Data were summarized as means and standard deviations for continuous variables and counts with percentages for categorical variables. A significance threshold of 2-sided $P < 0.05$ was used for all analyses without correction for multiple comparisons. All regression models accounted for the stepped-wedge design, with intervention and period as fixed effects and site-specific random intercepts, along with the strata indicator (proportion of infants treated pharmacologically at each site prior to trial initiation according to lowest third, middle third, and highest third). Additional analyses were conducted with further adjustments for key baseline maternal and infant characteristics, including maternal race/ethnicity, MOUD, adequate prenatal care (at least 3 visits with the first visit before the start of the third trimester) and polysubstance exposure. The effects of the NOWS care approach

on outcomes across social deprivation group categories were assessed through analysis of the interaction between the intervention and SDI group category.

For binary outcomes, mixed-effect Poisson regression with robust error variance were used and reported as relative risk with 95% confidence intervals. For LOS in pharmacologically treated infants, generalized linear mixed models with negative binomial distribution and log-link was used, reporting incidence rate ratio. All analyses were conducted using SAS version 9.4 (SAS Institute Inc.) and Stata/BE version 18.0 (StataCorp).

Results:

Of the 1305 mother-infant dyads enrolled in the primary study, 1298 (99%) were included in this secondary analysis. Seven were excluded due to missing SDI scores. The median SDI score for the study cohort was 62 on a scale from 1 (low social deprivation) to 100 (high social deprivation), which reflected more social deprivation in our study population than the general United States population (median of 37 for all zip codes).²⁶ Using the median SDI of 62, the study cohort was divided into a low social deprivation group (SDI score ≤ 62 , n=657) and a high social deprivation group (SDI score > 62 , n=641, Figure 1).

Maternal Characteristics:

Women in the high social deprivation group were less likely to receive adequate prenatal care (60% vs 68%) or MOUD (73% vs 78%) when compared to the low SDI group. Mothers in the high SDI group were more likely to be Black (21% vs 6%) or Hispanic (13% vs 9%) (Table 1). Non-Hispanic Black mothers represented 13% of the total study population, 79% of them were in the high SDI group. Similarly, Hispanic mothers represented 11% of the study population with 60% of them in the high SDI group. The high SDI group was also more likely to be single (89% vs 80%) and enrolled in public insurance (93% vs 84%) compared to the low SDI group. There was no substantial difference in polysubstance exposure between SDI groups. Differences in race/ethnicity, adequate prenatal care, MOUD, and polysubstance exposure were accounted for in the adjusted models for infant outcomes.

Infant Outcomes:

For all outcomes, the effects of the NOWS care approach (ESC vs usual care) between the SDI groups (high vs low social deprivation) were examined by analyzing the interaction between the intervention and SDI group. These interactions were not statistically significant. Therefore, models excluded the interaction items and reported the estimated effects on SDI groups.

In the high SDI group, the proportion of infants who received any maternal breastmilk during the hospital stay was 6.2 percentage points (95%CI: 0.8%,11.5%) less than in the low SDI group (47.7% vs 53.9%; RR 0.89 (95%CI: 0.80,0.98); P=0.023) (Table 2). The proportion of infants in the high SDI group discharged home with a biological parent was 7.3 percentage points (95%CI: 3.1%,11.5%) less than those in the low SDI group (76.9% vs 84.2%; RR 0.91 (95%CI: 0.87,0.96); P=0.001). There was no difference in receipt of pharmacologic treatment for NOWS (RR 1.16, 95%CI: 0.99,1.38), LOS for

pharmacologically treated infants (IRR 0.96, 95%CI: 0.88,1.05), or direct breastfeeding at discharge (RR 0.87, 95%CI: 0.74,1.02) between groups.

Select SDI components that may impact the ability of mothers to be present in the hospital were evaluated as independent variables (Table 3). The proportion of infants discharged home with a biological parent was 5.9 percentage points (95%CI: 2.1%,9.7%) less if mothers lived in regions where more than the median proportion of the population had a household income less than 100% of the federal poverty level (77.7% vs 83.5%; RR 0.93 (95%CI: 0.89,0.98); $P=.003$); 7.1 percentage points (95%CI: 3.4%,10.8%) less if mothers lived in regions where more than the median population had single parent families with descendants <18 years (77.1% vs 84.2%; RR 0.92 (95%CI: 0.87,0.96); $P<.001$); and 7.5 percentage points (95%CI: 3.6%,11.3%) less if mothers lived in regions where more than the median proportion of households had no vehicle (76.8% vs 84.3%; RR 0.91 (95%CI: 0.87,0.96); $P<.001$). The proportion of infants who received any maternal breastmilk during the newborn hospital stay was 6.8 percentage points (95%CI: 2.4%,11.3%) less if their mothers lived in regions where more than the median proportion of households had no vehicle (47.5% vs 54.3%; RR 0.87 (95%CI: 0.80,0.95); $P=.002$). There was no substantial difference in the proportion of infants who received any maternal breastmilk during the newborn hospital stay between groups based on regional poverty level or single parent families.

Discussion:

In this secondary analysis of infants enrolled in the ESC-NOW randomized controlled trial and their mothers, there were notable differences in maternal characteristics and infant outcomes between low and high SDI groups based on the SDI of the mother's area of residence. Deviation from the standard of care during pregnancy for women with opioid exposure, which includes regular prenatal care and engagement with MOUD, was more common in the high SDI group. Women in this group were less likely to receive adequate prenatal care and MOUD during pregnancy. In addition, women in the high SDI group were more likely to be Black and/or Hispanic. When controlling for these baseline differences in maternal characteristics, a smaller proportion of infants in the high SDI group received maternal breastmilk during the newborn hospital stay and/or were discharged home with a biologic parent when compared to the low SDI group.

The differences in maternal characteristics and infant outcomes noted in this study mirror known associations. Numerous studies highlight the negative effect of social barriers on access to MOUD or type of MOUD^{35–37} and lower socioeconomic status is a predictor of inadequate prenatal care.³⁸ Black and Hispanic populations are more likely to live below the poverty level and are more often tested for substance use than white families.^{39–45} Families living in poverty, in particular Black families, are also more likely to have child welfare involvement.^{41,46} These factors may have contributed to the lower-proportion of infants discharged home with a biological parent in the high SDI group. Both indices of neighborhood disadvantage and race/ethnicity are associated with differences in any breastmilk exposure and continued exclusive breastmilk feeding rates.⁴⁷ Our findings align

with this published literature and contribute a novel association between the SDI score and characteristics and outcomes for mother-infant dyads affected by perinatal opioid exposure.

Our study did not find an association between SDI and receipt of pharmacologic treatment for NOWS or LOS in pharmacologically treated infants. This differs from existing literature showing higher levels of poverty in a mother's community, as represented by the Area Deprivation Index, to be associated with excess length of stay for infants with NOWS²⁴ and maternal food insecurity to be associated with receipt of pharmacologic treatment for infants with NOWS.²⁵ These were comparatively small studies performed at single centers utilizing varied metrics of social deprivation. Further study is needed to better understand the association between metrics of social deprivation and receipt of pharmacologic treatment or LOS for infants with NOWS.

Gaining insight into the complex relationship between social factors and health outcomes is an important first step in designing and testing interventions related to social supports to improve health outcomes.^{48,49} Identifying that high SDI mothers are at increased risk of not receiving adequate prenatal care and/or MOUD and their infants are at an increased risk of not receiving breastmilk and discharging home with a non-biological caregiver provide valuable future intervention targets.

Potential targeted strategies to support mothers and families in areas of high social deprivation include programs that provide culturally-sensitive, trauma-informed, relationship-based, patient- and family-focused care in a supportive multi-disciplinary and integrated manner, and do so in high risk communities.⁵⁰ Such programs aim to reduce the effects of compounded stigma and bias related to social deprivation and perinatal substance use as well as implicit bias in system policies and barriers to accessing quality resources. In recent years, there has been an increase in the development of integrated and/or co-located perinatal substance use disorder programs that bring together obstetric care with treatment of substance use disorders and co-occurring mental health conditions as well as care coordination for health-related social needs. Such programs have the potential to reduce barriers to recommended prenatal and substance use care by providing a centralized trauma-informed, stigma-free care environment with care coordination to reduce barriers such as time and transportation limitations to attending appointments at multiple sites. Integrated care models are associated with improved obstetric outcomes and lower rates of positive maternal toxicology testing at the time of delivery.^{51–53} Similarly, co-locating pediatric care with the mother's treatment program and/or developing specialty pediatric medical homes for families with perinatal opioid exposure offers an opportunity to provide coordinated trauma-informed care that supports and strengthens parenting and connects families to needed community resources, both of which can potentially mitigate the need for child welfare involvement.⁵⁴ Thoughtful placement of such programs in high SDI locations and consideration for ways to increase access to transportation, telehealth, and other virtual supports (e.g., parenting, lactation, and substance use peer support) are additional interventions that should be considered.

There are a number of parenting interventions which focus on quality of parent-child relationship, emotional regulation and caregiver responsiveness that may promote

family well-being and mitigate increased risks related to high SDI. These interventions include: BRIGHT (Building Resilience through Intervention: Growing Healthier Together), Mothering from the Inside Out, and Circle of Security among others.^{55–58} These approaches align well with the trauma-informed and family-centered model of ESC and may provide mothers with ongoing support in a continuum of care. Early identification of families in prenatal and substance use treatments living in areas with high SDI may offer an opportunity for care systems to connect families with parenting resources and education that enable families to stay together or support reunification. Use of formal interdisciplinary-developed “Plans of Safe Care” to support families may be an effective tool for this coordinated education and support.^{52,59,60}

Finally, integration of peer counselors into breastfeeding education and lactation support in high SDI communities may help to improve breastfeeding rates.^{61–65} In addition to reducing barriers for lactation support, ensuring hospital policies reflect the current standard of care for lactation support in the setting of substance exposure may help address barriers to breastfeeding.⁶⁶

While the large sample size and prospectively collected data from this multicenter cohort are clear strengths of this study, there are several limitations. 1) a regional measure of social deprivation may speak to community level resources in a way that individual metrics do not, yet it could also over- or under-estimate an individual’s social deprivation,⁶⁷ 2) as a post hoc secondary analysis, this analysis was limited to the data collected for the primary study and did not include detailed individual information about social deprivation, and 3) the SDI is a composite measure that combines information about different types of social deprivation into one score; it is possible that additional component level information could identify aspects of social deprivation that impact particular outcomes more than others and that updates in SDI may have occurred between 2012–2016 and our study period 2020–2022.

In combination, our study findings highlight the need to further investigate social factors in order to improve care for opioid-exposed dyads. While ongoing support is critical for all families impacted by opioid exposure, this study suggests that those residing in areas with high SDI are particularly vulnerable and consideration should be paid to this when planning for program implementation. When developed, such programs deserve further study to ensure they are reaching families at high risk and improving access to care.

Conclusion:

Mother-infant dyads in the ESC-NOW trial who resided in communities with higher levels of social deprivation differed in maternal characteristics and infant outcomes from those who resided in communities with less social deprivation. Mothers in these more vulnerable communities were less likely to receive established standards of care and more often Black and/or Hispanic, while their infants had comparatively poorer outcomes. Targeting interventions to mitigate the impact of social deprivation may help to improve pregnancy and neonatal outcomes in this population.

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Key Points:

- Living in an area with high social deprivation was associated with differences in health outcomes
 - Mothers were more likely to be Black and/or Hispanic
 - Mothers were less likely to receive the standard of care during pregnancy
 - Infants were less likely to receive breastmilk and/or be discharged home with a biological parent
- Interventions designed to address community social deprivation may improve outcomes

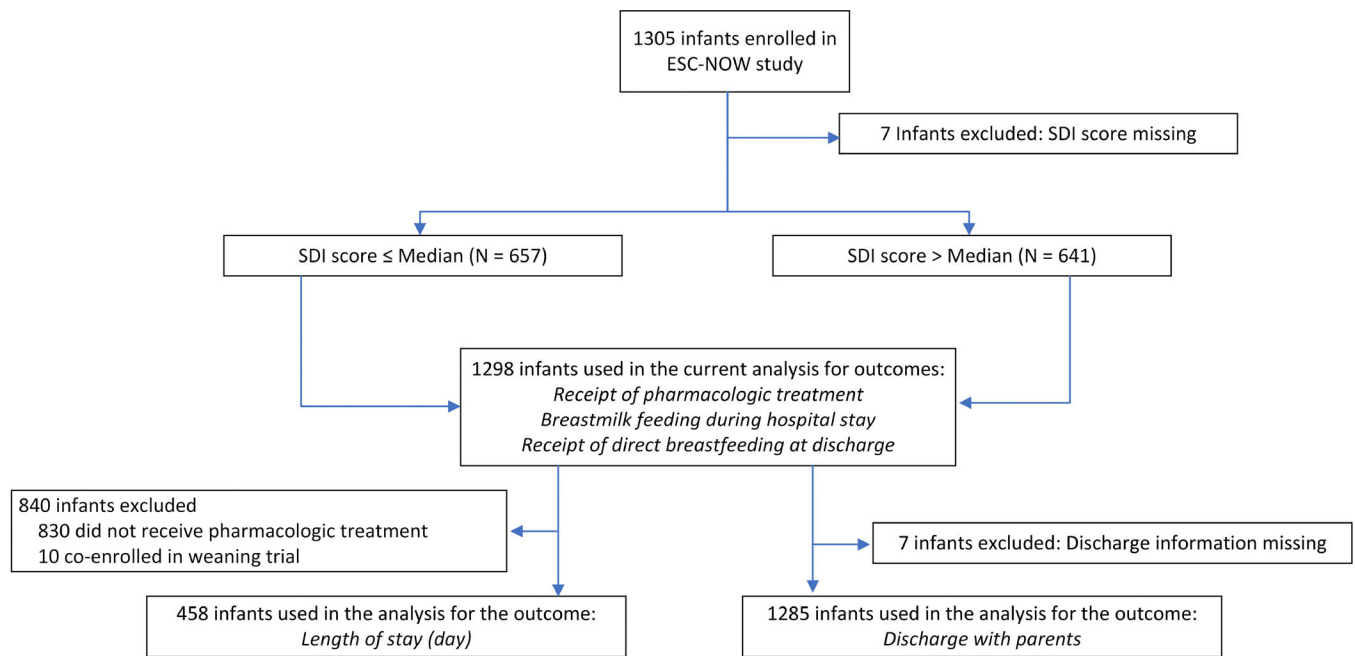


Figure 1:
Analytic sample based on ESC-NOW study cohort

Table 1.

Characteristics of mothers and infants by dichotomized SDI score (SDI score $\leq$ Median ^a vs SDI score $>$ Median)

	Low: SDI score $\leq$ Median (N = 657)	High: SDI score $>$ Median (N = 641)
Treatment Arms - no./total no. (%)		
Usual Care	342/657 (52)	353/641 (55)
Eat, Sleep, Console	315/657 (48)	288/641 (45)
Maternal Characteristics - no./total no. (%)		
Race/Ethnicity ^{b,c}		
Non-Hispanic white	523/642 (81)	381/631 (60)
Non-Hispanic Black	36/642 (6)	133/631 (21)
Hispanic	56/642 (9)	83/631 (13)
Other ^d	27/642 (4)	34/631 (5)
Missing	15	10
Adequate Prenatal Care ^e		
Yes	430/637 (68)	378/631 (60)
No	207/637 (32)	253/631 (40)
Missing	20	10
Medication for Opioid Use Disorder ^e		
Yes	500/639 (78)	458/624 (73)
No	139/639 (22)	166/624 (27)
Missing	18	17
Polysubstance Exposure ^f		
Yes	372/657 (57)	386/641 (60)
No	285/657 (43)	255/641 (40)
Marital Status ^e		
Married	126 (20)	71/629 (11)
Single	512 (80)	558/629 (89)
Missing	19	12
Insurance ^g		
Public Insurance ^e	549/657 (84)	598/641 (93)
Private Insurance ^e	85/657 (13)	29/641 (5)
Self-pay/uninsured	13/657 (2)	16/641 (2)
Unknown Insurance	19/657 (3)	10/641 (2)

^aMedian Social Deprivation Index (SDI) score for the study cohort is 62 out of 100. The high SDI group has more community social deprivation (a score above the SDI median). The low SDI group has less community social deprivation (a score at or below the SDI median).

^bRace and ethnicity were obtained from the electronic medical record.

^cChi-square test, $p < 0.05$

^dOther: American Indian or Alaska Native, Native Hawaiian or other Pacific Islander, Asian, and more than one race.

^eAdequate prenatal care: ≥ 3 visits and prenatal care prior to the initiation of the third trimester.

^fPolysubstance exposure: exposure to opioids in addition to any of the following: amphetamines, barbiturates, benzodiazepines, kratom, cocaine, gabapentin, marijuana, methamphetamines, phencyclidine, and selective serotonin reuptake inhibitors.

^gInsurance categories are not mutually exclusive.

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Table 2.
Outcome measures by dichotomized SDI score (SDI score ≤ Median ^a vs SDI score > Median)

Outcomes	Models ^b Adjusted by study design		Models ^c Adjusted by study design and characteristics			
	Estimated Means		Estimated Means		Absolute Difference (95% CI)	Estimated Effect (95% CI)
	Low: SDI score ≤ Median	High: SDI score > Median	Low: SDI score ≤ Median	High: SDI score > Median		
Percent of receipt of pharmacologic therapy (N = 1298)	32.9 (26.6, 39.3)	36.0 (30.1, 41.9)	32.0 (26.1, 37.8)	37.2 (32.4, 42.0)	5.3 (-0.3, 10.8)	1.16 ^d (0.99, 1.38)
Percent of breastmilk feeding during hospital stay (N = 1298)	53.9 (49.1, 58.6)	45.5 (42.1, 48.9)	53.9 (49.2, 58.6)	47.7 (43.9, 51.6)	6.2 (0.8, 11.5)	0.89 ^d (0.80, 0.98)
Percent of receipt of direct breastfeeding at discharge (N = 1298)	28.7 (23.6, 33.7)	22.9 (18.0, 27.8)	27.3 (23.1, 31.6)	23.7 (18.6, 28.7)	3.7 (-0.2, 7.5)	0.87 ^d (0.74, 1.02)
Percent of discharge with parents (N = 1285)	83.2 (80.4, 86.0)	76.3 (72.4, 80.3)	84.2 (81.9, 86.6)	76.9 (73.5, 80.3)	7.3 (3.1, 11.5)	0.91 ^d (0.87, 0.96)
Length of stay (day) for infants who received pharmacologic treatment (N = 458)	20.4 (18.3, 22.5)	19.8 (17.8, 21.8)	20.9 (18.7, 23.2)	20.2 (18.1, 22.3)	0.7 (-1.1, 2.6)	0.96 ^e (0.88, 1.05)

^aMedian Social Deprivation Index (SDI) score for the study cohort is 62 out of 100. The high SDI group has more community social deprivation (a score above the SDI median). The low SDI group has less community social deprivation (a score at or below the SDI median).

^bAdjusted for the trial design – with intervention (usual care vs. ESC) and period as fixed effect, and a site-specific random intercept to account for the clustering of infants within sites, and a randomization strata indicator.

^cAdjusted for the trial design (listed above) and baseline characteristics including maternal ethnicity/race, medication for opioid use disorder, adequate prenatal care and poly exposure.

^dReported as relative risk (RR) based on mixed effect Poisson regression model with robust error variance.

^eReported as incidence rate ratio (IRR) based on a generalized linear mixed model (GLMM) with negative binomial distribution.

Table 3.
Outcome measures for select area level SDI components dichotomized (component percent $\leq$ Median vs component percent $>$ Median)

Outcomes	Models ^a Adjusted by study design		Models ^b Adjusted by study design and characteristics			
	Estimated Means		Estimated Means		Absolute Difference (95% CI)	Estimated Effect (95% CI)
	Low: component % ≤ Median	High: component % > Median	Low: component % ≤ Median	High: component % > Median		
Percent of the population with household income less than 100% of the federal poverty level						
Percent of receipt of pharmacologic therapy (N = 1298)	33.4 (27.0, 39.8)	35.4 (29.3, 41.5)	32.5 (26.7, 38.3)	36.6 (31.3, 41.8)	4.1 (−2.1, 10.2)	1.13 <i>c</i> (0.94, 1.35)
Percent of breastmilk feeding during hospital stay (N = 1298)	52.7 (47.5, 58.0)	46.7 (43.0, 50.5)	53.0 (48.1, 57.9)	48.7 (45.1, 52.3)	4.3 (−0.9, 9.5)	0.92 <i>c</i> (0.83, 1.02)
Percent of receipt of direct breastfeeding at discharge (N = 1298)	27.9 (23.2, 32.6)	23.7 (18.5, 28.9)	26.7 (22.6, 30.7)	24.5 (19.3, 29.6)	2.2 (−1.5, 5.9)	0.92 <i>c</i> (0.79, 1.07)
Percent of discharge with parents (N = 1285)	82.8 (79.9, 85.7)	76.7 (73.1, 80.4)	83.5 (81.3, 85.8)	77.7 (74.4, 80.9)	5.9 (2.1, 9.7)	0.93 <i>c</i> (0.89, 0.98)
Length of stay (day) for infants who received pharmacologic treatment (N = 458)	20.6 (18.4, 22.7)	19.7 (17.7, 21.7)	21.0 (18.8, 23.3)	20.1 (18.0, 22.2)	0.9 (−0.9, 2.8)	0.96 <i>d</i> (0.87, 1.05)
Percent of the population single parent families with descendants <18 years						
Percent of receipt of pharmacologic therapy (N = 1298)	34.3 (28.7, 40.0)	34.5 (28.7, 40.4)	33.8 (28.2, 39.4)	35.3 (30.6, 40.1)	1.5 (−3.4, 6.4)	1.05 <i>c</i> (0.91, 1.21)
Percent of breastmilk feeding during hospital stay (N = 1298)	53.5 (48.8, 58.2)	46.1 (42.0, 50.1)	53.9 (49.2, 58.6)	48.0 (43.7, 52.3)	5.9 (0.0, 11.8)	0.89 <i>c</i> (0.79, 1.00)
Percent of receipt of direct breastfeeding at discharge (N = 1298)	27.7 (23.0, 32.3)	23.9 (18.4, 29.4)	26.2 (21.5, 30.8)	25.1 (20.0, 30.3)	1.0 (−3.9, 6.0)	0.96 <i>c</i> (0.79, 1.17)
Percent of discharge with parents (N = 1285)	83.4 (81.1, 85.8)	76.2 (72.8, 79.6)	84.2 (81.9, 86.6)	77.1 (74.1, 80.1)	7.1 (3.4, 10.8)	0.92 <i>c</i> (0.87, 0.96)
Length of stay (day) for infants who received pharmacologic treatment (N = 458)	20.3 (18.2, 22.4)	19.9 (17.8, 21.9)	20.9 (18.6, 23.2)	20.2 (18.1, 22.4)	0.7 (−1.2, 2.5)	0.97 <i>d</i> (0.88, 1.06)
Percent of households with no vehicle						
Percent of receipt of pharmacologic therapy (N = 1298)	32.2 (25.3, 39.1)	36.5 (31.4, 41.6)	31.5 (24.9, 38.1)	37.5 (33.5, 41.5)	6.0 (0.4, 11.6)	1.19 <i>c</i> (1.00, 1.42)
Percent of breastmilk feeding during hospital stay (N = 1298)	53.5 (49.5, 57.4)	46.1 (42.7, 49.4)	54.3 (50.1, 58.5)	47.5 (43.7, 51.2)	6.8 (2.4, 11.3)	0.87 <i>c</i> (0.80, 0.95)

Outcomes	Models ^a Adjusted by study design		Models ^b Adjusted by study design and characteristics			
	Estimated Means		Estimated Means		Absolute Difference (95% CI)	Estimated Effect (95% CI)
	Low: component % ≤ Median	High: component % > Median	Low: component % ≤ Median	High: component % > Median		
Percent of receipt of direct breastfeeding at discharge (N = 1298)	28.3 (23.2, 33.4)	23.7 (18.5, 28.9)	27.3 (22.8, 31.8)	24.0 (18.9, 29.1)	3.3 (−0.9, 7.5)	0.88 ^c (0.74, 1.04)
Percent of discharge with parents (N = 1285)	82.9 (79.9, 85.8)	76.7 (73.5, 79.8)	84.3 (81.5, 87.2)	76.8 (74.2, 79.5)	7.5 (3.6, 11.3)	0.91 ^c (0.87, 0.96)
Length of stay (day) for infants who received pharmacologic treatment (N = 458)	20.5 (18.3, 22.7)	19.9 (17.9, 21.9)	20.9 (18.5, 23.2)	20.3 (18.2, 22.4)	0.6 (−1.3, 2.5)	0.97 ^d (0.89, 1.07)

^a Adjusted for the trial design – with intervention (usual care vs. ESC) and period as fixed effect, and a site-specific random intercept to account for the clustering of infants within sites, and a randomization strata indicator.

^b Adjusted for the trial design (listed above) and baseline characteristics including maternal ethnicity/race, medication for opioid use disorder, adequate prenatal care and poly exposure.

^c Reported as relative risk (RR) based on mixed effect Poisson regression model with robust error variance.

^d Reported as incidence rate ratio (IRR) based on a generalized linear mixed model (GLMM) with negative binomial distribution.