

IN THE SUPREME COURT OF PENNSYLVANIA

NO. 10 MAP 2018

In the Interest of L.J.B., A Minor.
Appeal of: A.A.R., Mother.

BRIEF OF NATIONAL ADVOCATES FOR PREGNANT WOMEN,
COMMUNITY LEGAL SERVICES OF PHILADELPHIA, AND EXPERTS IN
MATERNAL AND CHILD HEALTH, CHILD WELFARE, AND LAW AS
AMICUS CURIAE IN SUPPORT OF APPELLANT

Appeal from the Order of the Superior Court of Pennsylvania entered December 27, 2017 at No. 884 MDA 2017, vacating the Final Order of the Court of Common Pleas of Clinton County, Pennsylvania, Juvenile Division CP-18-DP -9-2017, and Remanding for Further Proceedings.

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STATEMENT OF INTEREST OF AMICI CURIAE

National Advocates for Pregnant Women and Community Legal Services of Philadelphia file this brief on behalf of *amici curiae*, who collectively represent experts in the fields of maternal, fetal, and child health, child welfare, public health, and law, committed to the health and rights of pregnant and parenting women and their children (collectively “*amici*”).¹ *Amici* fully incorporate the legal and constitutional arguments made by the mother in this case, and write separately in an effort to assist the Court by bringing to bear relevant information which militates against the judicial expansion of Pennsylvania’s child abuse law to address pregnancy. *Amici* are concerned that allowing this expansion of the law will undermine public health and the interests of children and families. Applying the child abuse law to actions, decisions, and conditions of pregnant women undermines their human rights and threatens maternal and fetal health by deterring pregnant women from seeking medical care.

No one other than the *amici curiae* or its counsel paid for the preparation of this *amicus curiae* brief or authored this brief, in whole or in part.

STATEMENT OF JURISDICTION

Amici incorporate the Statement of Jurisdiction in Appellant’s Brief.

¹ Further information about each *amici* is included as Appendix A.

ORDER OR OTHER DETERMINATION IN QUESTION

Amici incorporate the statement of the Order or Other Determination in Question in Appellant’s Brief.

STATEMENT OF THE SCOPE AND STANDARD OF REVIEW

Amici incorporate the Statement of the Scope and Standard of Review in Appellant’s Brief.

STATEMENT OF THE QUESTIONS INVOLVED

Amici incorporate the Statement of the Questions involved and Suggested Answers in Appellant’s Brief.

STATEMENT OF THE CASE

Amici incorporate the Statement of the Case in Appellant’s Brief.

SUMMARY OF ARGUMENT

The Superior Court’s expansion of “child abuse” in the Child Protective Services Law (“CPSL”) to include pregnancy needlessly and irrationally expands the reach of the statute, undermining its purpose and violating the Constitutional and human rights of pregnant and parenting people in Pennsylvania. Pennsylvania law, the U.S. Constitution, and international human rights principles all have as their foundation the protection of individuals and the family. 23 Pa.C.S. § 6302;

Pa. Const. §§I; XXVII. U.S. Const. Amdts. V, XIV; Universal Declaration of Human Rights, G.A. Res. 217A (111), UN Doc. A1810 (1948).²

The Superior Court’s expansion of the CPSL’s abuse provisions to include pregnancy or pregnancy outcomes as intentional acts to injure a child is unfounded and undermines these fundamental protections. The lower court’s counter-productive interpretation of Pennsylvania law also inflicts punishment through placement on a child abuse registry. Expanding the CPSL as the Superior Court has done here will also deter women from seeking health care and increase the likelihood of intrusive and stress-inducing surveillance. This Court cannot permit such an interpretation of the law to stand.

² The Universal Declaration of Human Rights, which the U.S. helped develop, established internationally acknowledged principles of human rights. It states at art. 16, “The family is the natural and fundamental group unit of society and is entitled to protection by society and the State.” And at art. 12, “No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence [and] has the right to the protection of the law against such interference or attacks.” *See also*, Amnesty International, *Criminalizing Pregnancy* 46 (2017), <https://www.amnesty.org/download/Documents/AMR5162032017ENGLISH.pdf> (“States have an obligation to respect, protect and fulfill the full range of human rights for all people, including pregnant women. These obligations apply to both states’ law and policy-making, criminal and civil law enforcement and provision of services, including health and social services.”)

ARGUMENT

I. Pennsylvania Law Presently Provides a Comprehensive Structure to Protect Children and Taking the Unprecedented Step of Including Pregnancy as a Basis for Placement on the ChildLine Registry Will Have Grave Consequences for Women, Children, and Families.

A. The Juvenile Act and CPSL offer a robust framework for the protection and safety of infants.

This Court may be concerned about the impact of substance use on a person’s ability to safely parent a young child. However, that is not the issue before this Court. The Commonwealth already maintains a robust statutory scheme to protect the welfare of infants, which would not be enhanced by an expansion of the definition of abuse to include pregnancy. An infant who is identified as “affected” by “illegal substance abuse by the child’s mother,” which includes infants that present with Neonatal Abstinence Syndrome (“NAS”)³, must already be reported by her health care provider to the county Children and Youth Agency (“CYS”). 23 Pa.C.S. § 6386(a). CYS must then assess the family and determine whether child protective services or general protective services are warranted. 23 Pa.C.S. § 6386(b). CYS also must “provide or arrange reasonable services to ensure the child is provided with proper parental care, control and supervision.” 23 Pa.C.S. § 6386(c). Pennsylvania’s law closely follows the requirements of the Child Abuse Prevention and Treatment Act and its amendments, key federal law in

³ See II(B). *infra* for definition and explanation of NAS.

this field. Child Abuse Prevention and Treatment Act, 42 U.S.C.A. §§5101-5108 (2016).

If an infant is found to be in danger and needs to be removed from her mother's care, the Juvenile Act authorizes the court to issue an order of protective custody. 42 Pa.C.S. § 6324. The court may further adjudicate such a child dependent and maintains broad authority to issue any dispositional order best suited to the welfare of the child. 42 Pa.C.S. § 6341; 42 Pa.C.S. § 6351. CYS may even seek to permanently sever the parent-child relationship through the termination of parental rights. 23 Pa.C.S. § 2511. Importantly, a finding of child abuse is a not prerequisite for any of these interventions, however, it does result in the parent's name being placed on ChildLine, a statewide registry of child abuse, that may remain for the rest of the parent's life. *ChildLine and Abuse Registry*, Penn. Dept. of Human Services, (last visited Apr. 26, 2018), <http://www.dhs.pa.gov/provider/childwelfareservices/childlineandabuseregistry/>.

B. Expanding the CPSL to permit a finding of child abuse based on pregnancy will cause severe and counterproductive economic consequences to women, children, and communities.

The Superior Court's expansion of the law to permit a finding of child abuse based on an infant being prenatally exposed to a substance will do little to further the welfare of the child, but will instead serve as punishment that erects intractable barriers to recovery and stability for a family. This is because the employment

consequences of being placed on the ChildLine registry are broad and largely irreversible, leading to a lifetime of stigma and severely curtailed employment opportunities in fields that have traditionally served as pathways out of poverty for women.

Job applicants must submit a child abuse clearance when they apply for a wide variety of positions, most often held by low-income women. This includes work as a daycare provider; teacher; school lunch aide; bus driver; crossing guard; school janitor; counselor; caregiver; librarian; pastor; clerk at a children's store; athletic coach; many health care providers; camp counselor; lifeguard; or as an employee at *any* "program, activity or service" placing her in direct contact with children. 23 Pa.C.S. § 6344.⁴ She would also be prohibited from working for a home health care agency, or providing in home personal care or respite care. 28 Pa. Code § 611.53(b). And yet, unlike forms of abuse that may warrant exclusion from certain jobs (for example pedophiles being prevented from working in schools), being pregnant and having used a substance is not, predictive of, or correlated with a lifetime inability to perform these jobs or to care for children.⁵ Indeed, there is no

⁴ Although a founded child abuse report within the past 5 years is an absolute bar to employment in these positions, in practice any indicated or founded child abuse report potentially remains on the ChildLine Registry indefinitely and may serve as a *de facto* bar to employment.

⁵ Janet Dolgin, *The Law's Response to Parental Alcohol and "Crack" Abuse*, 56 Brook. L. Rev. 1213, 1224 (1991) ("In general, there has been little research on the effects of illegal substance abuse on the children of users . . . there is [also] disagreement among researchers about the extent to which drug use correlates with neglect . . . [one study found] neither drug use nor addiction, per se, produces [child] neglect.") See also Susan C. Boyd, *Mothers and Illicit Drugs:*

bar to *any* employer making employment contingent upon a child abuse clearance, and in practice a growing number of employers, including nursing homes and elder care facilities, choose to do so, further limiting the economic opportunities for low-income mothers.

i. The proposed expansion of the CPSL will exacerbate child poverty.

In Pennsylvania, 35.8% of single mothers live in poverty, *Poverty in Pennsylvania*, National Women’s Law Center, (last visited Apr. 19, 2018), <https://nwlc.org/state/pennsylvania/>. Nearly 1 in 5 children live in poverty. *Children in Poverty*, Kids Count Data Center, (last visited Apr. 19, 2018), <https://datacenter.kidscount.org/data/tables/43-children-in-poverty-100-percent-poverty?loc=1&loct=2#detailed/2/40/false/870,573,869,36,868/any/321,322>. The caregiving jobs proscribed by the CPSL are *precisely* the jobs that serve as pathways out of poverty and toward economic stability for mothers:

Low-income women cluster in caregiving and customer service work. Nationally, 20.51% of the female workforce is employed in retail, while 46.64% of the female workforce is employed in service and caregiving fields... [which] are high growth fields in which there are jobs available. For example, home health care is the largest industry in Pennsylvania--a state with one of the highest elderly populations in the country. As the baby boomers continue to age, the demand for health care workers will only increase, making it an essential field for low-income workers.

Transcending the Myth 60 (1999) (listing studies demonstrating that women who use illicit drugs can be adequate parents), attached as Appendix B.1; Margaret H. Kearny et al., *Mothering on Crack Cocaine A Grounded Theory Analysis*, 38 Soc. Sci. & Medic. 351, 355 (1994); Brenda D. Smith & Mark F. Testa, *The Risk of Subsequent Maltreatment Allegations in Families with Substance-Exposed Infants*, 26 Child Abuse and Neglect 97 (2002), attached as Appendix B.2.

Jesse Krohn & Jamie Gullen, *Mothers in the Margins: Addressing the Consequences of Criminal Records for Young Mothers of Color*, 46 U. Balt. L. Rev. 237, 245–46 (2017). See also *Labor Force Statistics from the Current Population Survey*, Bureau of Labor Statistics, (last modified Jan. 18, 2018), <http://www.bls.gov/cps/cpsaat11.htm>, (reporting that 93.7% of people employed as childcare workers and 88.6% of people employed in the nursing, psychiatric, and home health aide professions are women).

The burden of lack of access to meaningful employment falls not only on mothers, but on their children, because “when women are shut out of the workforce, children are far more likely to live in poverty.” Krohn *supra* at 251. The lifelong effects of child poverty cannot be overstated. Childhood poverty can significantly hinder a child’s educational prospects, and is a widely-recognized risk factor for a host of chronic health issues. David Wood, *Effect of Child and Family Poverty on Child Health in the United States*, 112 J. Am. Acad. of Pediatrics 707, 707-711 (2003). Notably, children who grow up in poverty are more likely to remain impoverished as adults, and are less likely to attain stable employment themselves, creating an intergenerational cycle of poverty. Caroline Ratcliffe & Signe-Mary McKernan, *Child Poverty and Its Lasting Consequence* 1-15 (The Urban Institute 2012),

<https://www.urban.org/sites/default/files/publication/32756/412659-Child-Poverty-and-Its-Lasting-Consequence.PDF>.

ii. A child abuse finding may have lifetime consequences for mothers and their families.

The economic and other consequences of a child abuse finding may be lifelong and virtually irreversible. When a child abuse report is indicated, meaning that CY S has made a determination that substantial evidence of abuse exists, 23 Pa.C.S. § 6303, the report generally remains on the registry “indefinitely.” 23 Pa.C.S. § 6338(c). An alleged perpetrator may request a hearing to review the accuracy of the finding, if she does so within 90 days. 23 Pa.C.S. § 6341(a). The CPSL also permits the Secretary of the Pennsylvania Department of Human Services to review a finding of child abuse, and the Secretary may expunge an indicated report for “good cause,” which may include evidence that the perpetrator in an indicated report of abuse “no longer represents a risk of child abuse.” *Id.* Such relief lies solely in the discretion of the Secretary, and may not be granted until years or even decades after the initial finding. In practice, the consequences of most indicated reports may last a lifetime. The CPSL also allows for expungement in other very limited circumstances. *See* 23 Pa. C.S. §6338(b), (c), 23 Pa. C.S. §6338.1.

Even the narrow relief available for indicated reports is completely unavailable to those with founded reports. A founded report exists any time there has been a judicial adjudication of child abuse, including, as in the instant case, in the context of a dependency proceeding. 23 Pa.C.S. § 6303. A mother with a founded report may not seek relief from the Secretary at all unless she can establish that the judicial adjudication has been reversed or vacated. 23 Pa.C.S. § 6341(c.1). There exists no opportunity for a mother with a founded report to establish, in any forum or tribunal, that she has rehabilitated or “no longer represents a risk of child abuse.” 23 Pa.C.S. § 6341(a).

This means under the Superior Court’s interpretation, a mother who at age 20 gives birth to a substance exposed infant and is subject to a founded report may remain on the child abuse registry for life. She will experience deep stigma and face crippling employment consequences at age 30, 40, 50, and beyond, regardless of whether she had a substance use disorder at all, or abstains from all drug use, maintains stability, or contributes to the care of her family and community. If so, she will be foreclosed from many jobs that could offer stability and meaningful paths out of poverty. Decades later, she could be prohibited from volunteering in her grandchild’s school. If she is needed as a kinship provider or adoption resource for a family member, she will likely be denied. Worse, her child and any children she has had previously or will have in the future, will be vulnerable to the effects

of these consequences. The consequences created by the Superior Court's expansion of the CPSL's reach are destabilizing to children and families; they are not protective and should not stand.

II. Judicial Expansion of Pennsylvania's Child Abuse Law to Include Pregnancy and Childbirth is an Unsound and Unsupported Policy.

A myriad of factors can influence pregnancy and pregnancy outcomes. As one court noted, every aspect of a pregnant woman's experience "shapes the prenatal environment which forms the world for the developing fetus" *Stallman v. Youngquist*, 531 N.E.2d 355, 360 (Ill. 1988). The numerous factors and interactions that can contribute to particular birth outcomes make attempts to expand child abuse law to include pregnancy illogical as well as punitive.

A. Birth outcomes are not "injuries" supporting a finding of child abuse.

"A range of biological, social, environmental, and physical factors have been linked to maternal, infant, and child health outcomes." Office of Disease Prevention & Health Promotion, *Maternal, Infant, and Child Health – Life Stages & Determinants*, U.S. Dep't of Health & Human Serv., (last updated Apr. 26, 2018), <https://www.healthypeople.gov/2020/leading-health-indicators/2020-lhi-topics/Maternal-Infant-and-Child-Health/determinants>. As the U.S. Department of Health and Human Services has found, "[t]hese include race and ethnicity, age, and socioeconomic factors, such as income level, educational attainment, medical insurance coverage, access to medical care, pre pregnancy health, and general

health status.” *Id.* These are not things the CPSL should be expanded to address in its effort to prevent abuse and protect abused children from further injury.

Certainly, the CPSL is not meant to include knowingly or recklessly being poor; older; or stressed, even though each of these are likely to affect child health outcomes.⁶ Yet the Superior Court’s expansion of the CPSL, which by rationale is not limited to NAS, carries a very real risk that mothers could be punished for a wide variety of birth outcomes not within their control.

Medical science has great difficulty separating factors and determining a single cause of a pregnancy outcome, even when the outcome is a perinatal loss.⁷ “[S]ocial characteristics of a community . . . hold important implications for pregnancy outcomes . . . the physical and social environments within which individuals function need to be safe, clean, affordable, socially supportive and adequately resourced in order to maximize every woman’s potential to deliver a full-term and healthy infant.” Am. Public Health Ass’n, Policy No. 20062, *Reducing Racial/Ethnic and Socioeconomic Disparities in Preterm and Low Birthweight Births* (Nov. 8, 2006); *see also* Simone C. Gray, et al., *Assessing the*

⁶ See Sarah Richardson, *Don’t blame the mothers*, 512 *Nature* 131 (2014), <https://www.nature.com/news/society-don-t-blame-the-mothers-1.15693>.

⁷ More than 20% of pregnancies end in miscarriage or stillbirth. Ruth C. Fretts, *Etiology and Prevention of Stillbirth*, 193 *Am. J. Obstetrics & Gynecology* 1923, 1924 (2005), attached as Appendix B.3; Raj Rai et al., *Recurrent Miscarriage*, 368 *Lancet*. 601, 602 (2006). *See also* Donald J. Dudley et al., *A New System for Determining the Causes of Stillbirth*, 116 *Obstetrics & Gynecology* 254, 258 (2010)(noting that identifying a single cause of a stillbirth is extremely difficult, as fetal demise can be very complex, and often results from the cumulative effect of several risk factors.)

impact of race, social factors and air pollution on birth outcomes: a population-based study, Environmental Health, Jan. 29, 2014 at 1 (finding that exposure to pollution, individual and neighborhood socioeconomic status, race, and education all impacted birth outcomes). Moreover, research fails to support the assumptions the Superior Court’s conclusion rests on, among these, that prenatal exposure to *illegal* substances is *uniquely* dangerous, and that a newborn’s health depends solely or even primarily on the pregnant woman. See *Social Determinants of Health*, World Health Organization (2017), http://www.who.int/social_determinants/sdh_definition/en/ (“social determinants of health are the conditions in which people are born, grow, live, work and age.”); Kim Krisberg, *Shift Toward Social Determinants Transforming Public Health Works: Targeting Causes of Health Disparities*, The Nation’s Health, July 2016 (“at least 50% of health outcomes are due to the social determinants . . .”).

B. Child welfare interventions must be evidence-based and in the best interest of the child.

It is in a newborn’s best interest not to have the parent-child bond disrupted. The expansion of the law would subject families to arbitrary interference with that bond in violation of the Commonwealth’s obligation to protect the family unit.⁸

Prenatal exposure alone to any particular substance also does not constitute an

⁸ 23 Pa.C.S. § 6302; International Covenant on Civil and Political Rights, art. 17, Dec 16, 1966, S. Treaty Doc. No. 95-20 I.L.M. 368 (1967), 999 U.N.T.S. 171. “No one shall be subjected to arbitrary or unlawful interference with his . . . family” (signed and ratified by the United States creating obligations on the federal and state governments to comply with its provisions.).

intentionally inflicted bodily injury necessitating a punitive governmental response against the parent.⁹

Most risks identified as possible outcomes of prenatal exposure to drugs are temporary and treatable, including withdrawal symptoms experienced by some newborns exposed to opioids, called Neonatal Abstinence Syndrome (“NAS”) Substance Abuse & Mental Health Services Administration (SAMHSA), U.S. Department of Health & Human Services, Pub. No. [SMA] 14-4124, *Methadone Treatment for Pregnant Women* (2014).¹⁰ While NAS is understandably concerning, there is no evidence to indicate that with effective modern treatment, NAS itself is life threatening or results in permanent harm. For infants with symptoms of NAS-whether from exposure to prescribed opioids or not, there are safe, effective, and evidence-based protocols to treat such symptoms. American College of Obstetricians and Gynecologists (“ACOG”), Comm. on Obstetric Practice, American Society of Addiction Medicine, Comm. Op. No. 711 (Aug. 2017).

Furthermore, skin-to-skin contact, breastfeeding, and caring for mother/baby in the same room (“rooming in”) is the medically recommended response and can significantly reduce the hospital stay of a newborn diagnosed with NAS and cut the

⁹ Lauren M. Jansson et al., *The Opioid Exposed Newborn: Assessment and Pharmacologic Management*, 5 J. Opioid Mgmt. 47 (2009).

¹⁰ See also, Walter K. Kraft & John N. van den Anker, *Pharmacologic Management of the Opioid Neonatal Abstinence Syndrome*, 59 Ped. Clinics of N. Am. 1147 (2012).

need for medication in half.¹¹ This underscores what we know about this period in human development where close attachment provides physiologic stability and the building blocks for continued development.¹² Understanding attachment is now widely regarded as a best-practice in child welfare. N.C. Div. of Soc. Serv., *Attachment and Welfare Practices*, Children's Service's Practice Notes, July 2014, http://www.practicenotes.org/v19n3/CSPN_v19n3.pdf. In this delicate period CYS involvement should be cautious, and when necessary focused on child welfare interventions, other than an abuse determination, recognizing the unique characteristics of the postpartum period and the importance of attachment for both mother and baby.

Medical conditions of newborns should be treated by the healthcare system, not through a child abuse proceeding and placement on the ChildLine Registry. There is no evidence suggesting that mothers who have used a controlled substance are more likely to prey on or pose a risk of abuse to children – a central purpose of the Registry. *See supra* note 5. On the other hand, there is evidence that supporting a close, uninterrupted connection between a newborn and caregiver immediately after birth, including breastfeeding, protects against child abuse, and will respect

¹¹ Matthew Grossman, *An Initiative to Improve the Quality of Care of Infants With Neonatal Abstinence Syndrome* Pediatrics May 2017 at e20163360, attached as Appendix B.4; Kathryn MacMillan et al., *Association of Rooming-in with Outcomes with Neonatal Abstinence Syndrome: A systematic review and meta-analysis*, 172 JAMA Pediatrics 345 (2018), attached as Appendix B.5.

¹² *See Jorge Cesar Martinez, International Perspectives*, NeoReviews, Feb.2007, <http://neoreviews.aappublications.org/content/8/2/e55>.

the basic human rights of the child's parent. Lane Strathearn et al., *Does Breastfeeding Protect Against Abuse and Neglect? A 15 Year Cohort Study*, 123 Pediatrics 483 (2009). The system imposed by the Superior Court is contrary to evidence-based care and will undermine Pennsylvania's child protective goals.

C. The judicial expansion of the CPSL to pregnancy will allow for any act or condition, legal or illegal, of pregnant women to be investigated as a potential form of child abuse.

The Superior Court's decision in this matter suggests the expansion of Pennsylvania's child abuse law would be limited to cases in which a woman has "recklessly" consumed illicit substances while pregnant. Nothing in the very broadly worded decision, however, limits the use of the statute in such a manner. The Superior Court's decision opens the door to a dramatic and legislatively unauthorized expansion of the Commonwealth's power to investigate and intrude upon the rights of pregnant women. As discussed above, many factors impact pregnancy and pregnancy outcomes, as sister jurisdictions have already concluded. *See, e.g., Stallman v. Youngquist*, 531 N.E.2d 355, 360 (Ill. 1988) (refusing to recognize a tort of prenatal negligence); *In re Valerie D.*, 613 A.2d 748, 765 (Conn. 1992) (refusing to apply termination of parental rights statute to mother's cocaine use while pregnant, explaining that using the law this way would have "sweeping consequences" for other conduct during pregnancy).

As Judge Strassburger noted in his concurring opinion below, using this law to prosecute pregnant women “opens the door to interpretations of the statute that intrude upon a woman's private decision-making as to what is best for herself and her child.” He went on to list the many decisions that may or may not impact a pregnancy, including whether to:

engage in physical activity. . . eat a turkey sandwich, soft cheese, or sushi? . . . drink an occasional glass of wine? What about a daily cup of coffee? . . . continue . . . medication even though there is a potential risk to the child? . . . travel to countries where the Zika virus is present?

In the Interest of L.B., a Minor, 177 A.3d 308, 314-315 (Pa. Super. Ct. 2017). He inquired whether a pregnant woman “is a child abuser if her partner kicks or punches her in her abdomen during her pregnancy and she does not leave the relationship because she fears for her own life?” *Id.* Under the lower court’s interpretation, a “woman must act at least recklessly for her decision to constitute child abuse, [but] reasonable people may differ as to the proper standard of conduct” *id.*, especially when it comes to pregnancy.

Applying the abuse law to pregnancy “is quite broad indeed” and can lead to invasive, stressful investigations into every woman’s pregnancy and every aspect of her life, improperly infringing on personal privacy, freedom of decision-making, and undermining public health. *Id.* Judge Strassburger’s concerns regarding jurisdiction over pregnant women’s choices are well founded. *See, e.g., New Jersey Div. of Youth and Family Serv. v. L.V.*, 889 A.2d 1153 (Sup. Ct. N.J. Chanc. Div.

2005) (child neglect petition based on mother's alleged refusal during pregnancy to take medications to reduce the risk of transmitting HIV); *New Jersey Division of Youth and Family Serv. v. V.M. & B.G.*, 974 A.2d 448 (Sup. Ct. NJ 2009) (addressed child neglect petition based in part on mother's refusal to consent to c-section). Wisconsin, for example, has gone so far as to permit involuntary detention and forced treatment of pregnant women accused of any amount of past or current substance use for the stated purpose of protecting the fetus. *Loertscher v. Anderson*, 259 F. Supp. 3d 902 (W. D. Wis. 2017) (striking down "unborn child abuse" law as void for vagueness in violation of due process; law remains in effect pending appeal); *see also* Report of the U.N. Working Group on Arbitrary Detention on its visit to the United States of America, U.N. Doc A/HRC/36/37/Add.2, at 15-16 (2017), <http://undocs.org/A/HRC/36/37/ADD.2> (Wisconsin law is a "deprivation of liberty" that "is gendered and discriminatory in its reach and application, as pregnancy, combined with the presumption of drug use is the determining factor for involuntary treatment.") These cases all demonstrate an attempt to treat pregnancy as a basis for a finding of child abuse, neglect, or maltreatment. This is not and cannot be the law in Pennsylvania, and this Court should reject this harmful expansion of the law.

The judicial expansion here is particularly troubling because it increases the potential for the discriminatory use of the child abuse law against poor parents and

parents of color. Research reveals a disturbing prevalence of race and class disproportionality with respect to when and how alleged child abuse claims are reported to and handled by child welfare authorities. As the National Council of Juvenile and Family Court Judges has noted, “Research has demonstrated that minority children and families experience disparate decision-making in the investigation, substantiation, removal, placement in foster care, and final permanency determinations.” Nat’l Council of Juvenile & Family Court Judges, *Enhanced Resource Guidelines: Improving Court Practice in Child Abuse and Neglect Cases* 66 (2016), <http://www.ncjfcj.org/sites/default/files/%20NCJFCJ%20Enhanced%20Resource%20Guidelines%2005-2016.pdf>. “In 2013, African American children comprised only 13.9% of the overall population of children in the United States but represented nearly double that percent in foster care at 26%.” Tanya Cooper, *Racial Bias in American Foster Care: The National Debate*, 97 *Marquette L. Rev.* 215, 224 (2013).¹³

Specifically, when looking at substance exposed newborns, one study explained that infants born to Black mothers were more likely than those born to white mothers to have been screened for illicit drugs, leading researchers to

¹³ See also Khiara Bridges, *The Poverty of Privacy Rights* 114-125 (2017) (A national study showed “Two thirds of all cases of maltreatment identified by the study involved families with income below \$15,000” Further, “[R]esearch . . . revealed that doctors are more likely to diagnose physical injuries among poor families as “abuse” and to diagnose them as “accidents” among affluent families.”)

conclude that “providers seemed to have used race as a factor in deciding whether to screen an infant for maternal illicit drug use.” Emma Ketteringham et al., *Healthy Mothers, Healthy Babies*, 20 CUNY L. Rev. 77, fn. 53 (2016), referencing Marc A. Ellsworth et al., *Infant Race Affects Application of Clinical Guidelines When Screening for Drugs of Abuse in Newborns*, 125 Pediatrics 1379 (2010).¹⁴ This is despite the fact that drug use by Black and white women occurs at approximately the same rate. U.S. Dept. of Health & Human Services, *Results from the 2013 National Survey on Drug Use and Health Summary of National Findings* (2014),

<https://www.samhsa.gov/data/sites/default/files/NSDUHresultsPDFWHTML2013/Web/NSDUHresults2013.pdf>.

Thus, the harmful effects of the judicial expansion of this law are overwhelmingly likely to disproportionately burden low-income women and women of color.

III. Expanding the Child Abuse Law is Harmful to the Health and Human Rights of Families in Pennsylvania.

Over the course of nearly three decades, nearly every leading medical and public health organization has concluded that responding to issues of pregnancy and substance use through a punitive legal system is wrong. It is “damaging to

¹⁴ Attached as Appendix B.6. See also Sarah CM Roberts et al., *Does adopting a prenatal substance use protocol reduce racial disparities in CPS reporting related to maternal drug use?* 35 Journal of Perinatology 146 (2015).

public health and human rights.” Amnesty International *supra* at 50. As a United Nations Working Group has found, “the use in some countries of . . . punitive rather than educative measures to prevent injury to the fetus as a result of drug or alcohol consumption by addicted pregnant women is another manifestation of gender discrimination.” Rep. of the Working Group on the issue of discrimination against women in law and practice, UN Doc. A/HRC/32/44 10 (2016),

http://www.ohchr.org/Documents/Issues/Women/WG/A_HRC_32_44_WithFootnotes.doc. The UN Special Rapporteur on extreme poverty and human rights also

critiqued the U.S.’s "confused and counter-productive drug policies" finding them to be "highly punitive regimes directed against pregnant women, rather than trying to provide sympathetic treatment and to maximize the well-being of the fetus.”

Philip Alston (United Nations Special Rapporteur on extreme poverty and human rights), Statement on Visit to the USA (2017),

<http://www.ohchr.org/en/NewsEvents/Pages/DisplayNews.aspx?NewsID=22533&LangID=E>.

In Pennsylvania, substance use among pregnant women is generally treated as a matter of public health – not a basis for punishment. In 2012, Pennsylvania established a separate Department of Drug and Alcohol Programs. “This change reflects a strong commitment by the Commonwealth to provide education, intervention and treatment programs to reduce the drug and alcohol abuse and

dependency for all Pennsylvanians.” *About DDAP*, Pa. Dep’t of Drugs and Alcohol Programs (last visited Apr. 26, 2018), <http://www.ddap.pa.gov/Pages/About.aspx>. In fact, the Commonwealth issued Guidelines specifically to address opioid use disorders among pregnant women, and recommends the use of methadone and buprenorphine, medication assisted treatments. Commonwealth of Pennsylvania, *Prescribing Guidelines for Pennsylvania: Use of Addiction Treatment Medications in the Treatment of Pregnant Patients with Opioid Use Disorder* (2016), <http://www.dos.pa.gov/ProfessionalLicensing/BoardsCommissions/Documents/Prescribing%20Guidelines%20Pregnant%20Patients.pdf>. This Court must respect the Commonwealth’s commitment to public health and reject the Superior Court’s attempt to address pregnancy and substance use as a form of child abuse rather than a public health issue.

As explained above, the Juvenile Act and the CPSL already offer a legal framework for the protection of infants that an additional finding of child abuse does not further. In addition to the overwhelming consensus among medical groups that such approaches actually undermine maternal, fetal, and child health¹⁵ – the Pennsylvania legislature has specifically refused to enact such an expansion of the definition of child abuse. S. 275, 2011 (Pa. 2011) (introduced amendment of child abuse definition to include a child who at birth tested positive for certain

¹⁵ See *infra* III.

substances; the bill was not passed),

<http://www.legis.state.pa.us/cfdocs/billinfo/billinfo.cfm?year=2011&ind=0&body=S&type=B&bn=753>.

A. Expansion of the child abuse law to pregnancy will deter women from seeking health care.

Researchers and courts long ago determined that punishing women for being pregnant and using certain drugs is harmful, because fear of prosecution can trigger an avoidance of healthcare. Sarah C.M. Roberts and Amani Nuru-Jeter, *Women's perspectives on screening for alcohol and drug use in prenatal care*, 20 *Women's Health Issues* 193 (2010). Involvement of the child welfare system is often perceived by pregnant women as punishment. In the context of criminal prosecutions, the U.S. Supreme Court has observed, there is "near consensus in the medical community" that addressing problems of drug use and pregnancy through the criminal justice system will "harm, rather than advance, the cause of prenatal health." *Ferguson v. City of Charleston*, 532 U.S. 67, 84 n.23 (2001) (noting the *amicus* submissions of numerous leading medical and public health organizations concluding that searching pregnant women for evidence of drug use and facilitating their arrest will harm prenatal health by discouraging women from seeking prenatal care.) In child protective proceedings, civil courts have recognized that a newborn's prenatal exposure to a particular substance alone is

not indicative of “harm” so as to be the sole basis for a legal finding against the parent.¹⁶

Eminent medical organizations, including the American Medical Association, have uniformly condemned punitive approaches to substance use during pregnancy. Am. Med. Ass’n, Policy Statement H420.962, *Perinatal Addiction-Issues in Care and Prevention* (2017) (“Transplacental drug transfer should not be subject to criminal sanctions or civil liability . . . In particular, support is crucial for establishing and making broadly available specialized treatment programs for drug-addicted pregnant women wherever possible. . .”). The American Academy of Pediatrics and American College of Obstetricians and Gynecologists, among others, have also condemned this approach as dangerous to both women and children. Am. Acad. Of Pediatrics Comm. on Substance Use and Prevention, *A Public Health Response to Opioid Use in Pregnancy*, 139 *Pediatrics* 3 (2017) (“The existing literature supports the position that punitive approaches to substance use in pregnancy are ineffective and may have detrimental effects on

¹⁶ See, e.g., Cal. Penal Code § 11165.13 (“For purposes of this article, a positive toxicology screen at the time of the delivery of an infant is not in and of itself a sufficient basis for reporting child abuse or neglect”); *In re Dante M.*, 87 N.Y.2d 73, 79 (N.Y. 1995) (“a positive toxicology for a controlled substance generally does not in and of itself prove that a child has been physically, mentally or emotionally impaired, or is in imminent danger of being impaired.”); *N. J. Div. of Child Prot. & Permanency v. Y.N.*, 220 N.J. 165 (N.J. 2014) (court held the fact that newborn experienced neonatal abstinence syndrome as a result of mother’s participation in a medically prescribed treatment program while pregnant was insufficient to establish child neglect or abuse.)

both maternal and child health.”); Am. Coll. of Obstetricians & Gynecologists Comm. on Ethics, Committee Opinion No. 473, *Substance Abuse Reporting and Pregnancy: The Role of the Obstetrician-Gynecologist* (2011, reaffirmed 2014) (“Seeking obstetric–gynecologic care should not expose a woman to criminal or civil penalties, such as incarceration, involuntary commitment, loss of custody of her children, or loss of housing.”)

Research confirms that threats of punishment undermine rather than advance state interests in encouraging healthy pregnancies and improved birth outcomes. Studies have found that fetal health can only “be legitimately pursued and achieved through maternal protection, in the form that nonpunitive therapeutic interventions afford. Results from this study confirm that mothers themselves also have the child’s welfare as their priority concern.” Martha Jessup et al., *Extrinsic Barriers to Substance Abuse Treatment Among Pregnant Drug Dependent Women*, 33 J. Drug Issues 285, 299 (2003); *see also* Nancy Poole & Barbara Isaac, *Apprehensions – Barriers to Treatment for Substance-Using Mothers* 12 (British Columbia Centre of Excellence for Women's Health 2001) (62% of the study’s participants identified fear of losing their children as a barrier to treatment); Sarah Roberts & Cheri Pies, *Complex Calculations: How Drug Use During Pregnancy Becomes a Barrier to Prenatal Care*, 15 Maternal and Child Health J. 333, 338 (2011) (study showed that “most women feared that attending prenatal care while

using drugs would lead to CPS reports and losing their children”); Seema Mohapatra, *Unshackling Addiction: A Public Health Approach to Drug Use During Pregnancy*, 26 Wis. J.L. Gender & Soc'y 241, 245 (2011).

As explained above, both substance use and substance use disorders are treated as a matter of public health in Pennsylvania, for everyone including pregnant women. This Court should not allow an interpretation of the law that would raise Constitutional concerns regarding equal protection, that undermines the Commonwealth’s commitment to the health of its residents, and that could serve as a deterrent for pregnant women to receive healthcare.

B. Women who seek healthcare will be deterred from sharing information with physicians if such disclosures can be the basis of a child abuse finding.

The appropriate role for a physician is as “counselor and medical advisor.” Am. Med. Ass’n, Board of Trustees, *Legal Interventions During Pregnancy: Court-Ordered Medical Treatments and Legal Penalties for Potentially Harmful Behavior by Pregnant Women*, 264 JAMA 2663, 2666 (1990).¹⁷ A relationship of trust is critical for effective medical care because the promise of confidentiality encourages patients to disclose sensitive subjects to a physician. *The AMA Code of Medical Ethics’ Opinions on Confidentiality of Patient Information*, 14 American Medical Ass’n J. of Ethics 715 (2012) (“The patient should feel free to make a full

¹⁷ Attached as Appendix B.7.

disclosure of information to the physician in order that the physician may most effectively provide needed services.”) Transforming pregnancy outcomes into the basis for child abuse findings, conscripts health care providers by compelling them to collect evidence from, report on, and testify against their own patients. As the U.S. Supreme Court has recognized, a “confidential relationship” is a necessary precondition for “successful [professional] treatment.” *Jaffee v. Redmond*, 518 U.S. 1, 10 (1997). “Patients who fear sensitive information may be disclosed to others will be inhibited from honest reporting to their physicians.” Am. Coll. Of Obstetrics & Gynecology Comm. on Ethics, Opinion No. 663, *Alcohol Abuse and Other Substance Abuse Disorders: Ethical Issues in Obstetric and Gynecological Practice* (2015).

As explained above, healthcare providers in Pennsylvania are required to report “to the appropriate county agency” instances of children who are “affected” by the mother’s “substance abuse.” 23 Pa. C.S.A. § 6386. However, that report is for the purpose “mandating the agency to conduct an assessment . . . to . . . ensure the child's safety, and provide services to the family as needed.”¹⁸ *In the Interest of L.B., a Minor*, 177 A.3d 308, at 313. The Superior Court’s ruling is improperly transforming that report into an accusation that a pregnant woman intentionally injured a child, equating pregnancy and the use of an illegal substance with an

¹⁸ Changes made in response to CAPTA’s 2006 amendments.

inflicted injury. This ruling only serves the punitive purpose of placing a new mother on the Commonwealth's registry of child abuse, potentially for the rest of her life.

Because the threat of such a punitive outcome can discourage pregnant women from honest communication with their doctors or from treatment altogether, reinterpreting laws to use in the context of pregnancy will tragically undermine the Commonwealth's commitment to its residents' health.

C. Expansion of the child abuse law infringes upon the reproductive autonomy and bodily integrity of women in Pennsylvania.

A legal regime that threatens civil prosecution and a lifetime on a registry of child abusers in the event of a positive toxicology result for controlled substances, creates an extraordinary risk to women who carry their pregnancies to term. Some women who cannot overcome a substance dependency on pregnancy's timetable may feel it necessary to eliminate the risk of legal consequences by deliberately terminating an otherwise wanted pregnancy. *See Cleveland Board of Education v. LaFleur*, 414 U.S. 632, 640 (1974) ("there is a right 'to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child.") J. Flavin, *A Glass Half Full? Harm Reduction Among Pregnant Women Who Use Cocaine*, 32 J. Drug Issues 973, 985 tbl.2 (2002) (one study reported two-thirds of the women surveyed who reported using cocaine while pregnant also considered having an abortion); Interim report of

the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, U.N. General Assembly, 66th Sess., 3 August 2011, UN Doc. A/66/254 (such policies can “violate the right to health by infringing human dignity by restricting the freedoms to which individuals are entitled under the right to health, particularly in respect to decision-making and bodily integrity”).¹⁹

Inducing women to terminate otherwise wanted pregnancies is manifestly inimical to the purposes the CPSL is intended to serve, and another harmful effect of the Superior Court’s expansion of the child abuse law.

CONCLUSION

For the foregoing reasons, *amici curiae* respectfully request this Court to reverse the Superior Court’s decision in this matter and reject the judicial expansion of Pennsylvania’s child abuse law to address pregnancy.

¹⁹ In the context of criminal cases, courts have noted how fear of prosecution may impact a woman’s decision to have an abortion. *See State v. Greywind*, No. CR-92-447 (N.D. Cass County Ct. Apr. 10, 1992) (criminal defendant in North Dakota sought an abortion to avoid prosecution for reckless endangerment of a fetus); Motion to Dismiss With Prejudice, *State v. Greywind*, No. CR-92-447 (N.D. Cass County Ct. Apr. 10, 1992)(after the defendant terminated her pregnancy, the prosecutor sought dismissal of the case stating that the “legal issues presented are no longer ripe for litigation.”), attached as Appendix B.8; *see also Whitner v. South Carolina*, 492 S.E. 2d 777, 787 (SC 1997) (*J. Moore dissenting*); Heather Sprintz, *The Criminalization of Perinatal Aids Transmission*, 3 Health Matrix: J. L. Med. 495, 525 (1993) (criminal prosecution of pregnant women’s drug use “implicitly advocates abortion rather than childbirth, to avoid the risk of prosecution.”)

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CERTIFICATE OF COMPLIANCE

The foregoing brief complies with the word count limitation of all relevant Pennsylvania Rules of Appellate Procedure, including Rule 2135. This brief contains 6970 words. In preparing this certificate, the word count feature of Microsoft Word was relied upon.

Dated: May 3, 2018

/s/Kathleen Creamer
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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that on this 3rd day of May, 2018, a true and correct copy of the foregoing Brief for Appellants was served in compliance with Pa.R.A.P.121.

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Kathleen Creamer

Appendix A: Descriptions of Individual Amici

Amicus curiae **The Allegheny County Bar Foundation Juvenile Court Project** (“JCP”) has been representing indigent parents in dependency proceedings, termination of parental rights cases and ChildLine Appeals in Allegheny County for over thirty years and has represented thousands of clients. The JCP’s mission is to ensure that impoverished and underprivileged parents within Allegheny County receive fundamental fairness within the Juvenile, Orphans’, Administrative Law and Appellate Courts concerning their dependency, termination of parental rights and ChildLine Appeal cases. Fundamental fairness includes not only due process and equal treatment under the law but also statutory interpretation analysis that executes only the legislative purpose of the act.

Amicus curiae **The Allentown Women's Center** (“AWC”) has been providing sexual and reproductive healthcare in Pennsylvania's Lehigh Valley since 1978. AWC provides abortion care to 23 weeks of pregnancy, medical and surgical gynecology, professional counseling and therapy services, and has a robust practice providing hormone therapy and transition support to hundreds of individuals who identify as transgender and gender non-binary. AWC is a training site in abortion care and trans-health for nursing and medical students, OB/GYN and family practice residents, and other graduate students.

Amicus curiae **American Academy of Addiction Psychiatry** (“AAAP”) is an international professional membership organization made up of practicing psychiatrists, university faculty, medical students and other related health professionals. Founded in 1985, it currently represents approximately 2,000 members in the United States and around the world. AAAP is devoted to promoting access to evidence-based practices, supporting the development and dissemination of new information in the field of addictions, and encouraging research on the etiology, prevention, identification, and treatment of addictions. AAAP opposes the prosecution of pregnant women based on the belief that the disclosure of personal drug use to law enforcement for use in criminal prosecutions will undermine prenatal care, discourage many women from seeking substance use treatment, and damage the medical provider-patient relationship that is founded on principles of confidentiality.

Amicus curiae **American College of Obstetricians and Gynecologists** (“ACOG”) is a national non-profit educational and professional organization that works to promote the advancement of women’s health through continuing medical education, practice, research, and advocacy. ACOG is the leading organization of

women's health care providers, with more than 58,000 members, including more than 2,000 obstetrician-gynecologists in Pennsylvania.

ACOG is dedicated to continuously improving all aspects of healthcare for women, establishing and maintaining the highest possible standards for education and clinical practice, promoting high ethical standards, publishing evidence-based practice guidelines, encouraging contributions to medical and scientific literature, and increasing awareness among its members and the public about the changing issues facing women's healthcare.

ACOG supports evidence-based strategies to address the needs of women with addictions, including the development of safe, affordable, available, efficacious, and comprehensive alcohol and drug treatment services for all women, especially pregnant women, and their families. ACOG opposes the use of the legal system to address and penalize perinatal alcohol and substance use. Although legal action against women who use drugs and alcohol while pregnant may have the intent to produce healthy birth outcomes, negative results, including discouraging and deterring women from obtaining obstetric and gynecologic care, are frequently cited. Seeking obstetric-gynecologic care during pregnancy should not expose a woman to legal consequences. For this reason, among others, ACOG urges that the Pennsylvania law be struck down.

Amicus curiae **The American Medical Association** ("AMA") is the largest professional association of physicians, residents and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all US physicians, residents and medical students are represented in the AMA's policy making process. The AMA was founded in 1847 to promote the science and art of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in every medical specialty area and in every state, including Pennsylvania. The AMA joins this brief on its own behalf and as a representative of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center is a coalition among the AMA and the medical societies of each state, plus the District of Columbia, whose purpose is to represent the viewpoint of organized medicine in the courts.

Amicus curiae **The American Medical Student Association** ("AMSA") is the oldest and largest independent association of physicians-in-training in the United States. Founded in 1950, AMSA is a student-governed, non-profit organization committed to representing the concerns of physicians-in-training. For more than 60

years, AMSA has represented the voice of physicians-in-training in their efforts to best serve the public. There are four aspirations on which AMSA members focus their activism: advocating for quality, affordable health care for all, global health equality, enriching medicine through diversity, and professional integrity, development and student well-being. To that end, AMSA believes that drug abuse and addiction are not primarily criminal problems, but are health problems with socioeconomic and legal implications, and as such, should be dealt with by health professionals. There are many alternatives to problematic substance use; complete abstinence from substance use is one, but not the only, solution. AMSA supports harm-reduction-based interventions, including medication assisted treatment (MAT) for opioid use disorder during pregnancy, as proven and effective methods of promoting health and reducing harm among substance users who may not be ready to stop using entirely. However, incarceration has not been shown to reduce rates of addiction. AMSA strongly supports a shift of emphasis of drug policy away from overly harsh, punitive policies that inevitably tend to disproportionately affect people of color and poor people, particularly during pregnancy. AMSA therefore discourages a criminal justice response and opposes any actions by the Justice Department and law enforcement that fail to deal with drug abuse and addiction as health problems.

Amicus curiae **American Medical Women's Association** (“AMWA”) is a national, non-profit organization of over 10,000 women physicians and physicians-in-training representing every medical specialty. Founded in 1915, AMWA is dedicated to promoting women in medicine and advocating for improved women's health policy. AMWA strongly supports treatment and rehabilitation of women who use alcohol or drugs during pregnancy, and opposes the arrest, jailing and/or prosecution of pregnant women as a method of preventing or punishing chemical dependency during pregnancy. AMWA encourages all pregnant women to seek prenatal care and believes that breaching the medical confidentiality of these women or otherwise hindering their ability to establish a relationship of trust with their treatment providers will deter women, especially those that may be at high risk for adverse pregnancy outcomes, from receiving prenatal care.

Amicus curiae **American Society of Addiction Medicine** (“ASAM”) is a nationwide organization of more than 5,000 of the nation's foremost physicians and allied health professionals specializing in prevention and treatment of addiction. ASAM believes that the proper, most effective solution to the problem of substance use disorder during pregnancy lies in medical prevention, i.e. education, early intervention, treatment, and research on chemically-dependent pregnant women. ASAM further believes that state and local governments should avoid any

measures defining alcohol or other drug use during pregnancy as a crime and should avoid prosecution, jail, or other punitive measures as a substitute for providing effective health services.

Amicus curiae **The Association of Reproductive Health Professionals** (“ARHP”) is a national nonprofit, interdisciplinary health care association for clinicians and advocates in the reproductive and sexual health care field. Founded in 1963 and comprised of physicians, nurse practitioners, physician assistants, pharmacists, certified nurse midwives, researchers, educators, and other allied professionals, ARHP is an important source of sexual and reproductive health education and information for health care professionals, patients, legislators, industry representatives, and the public at large. With regard to *In the Interest of: L.B., a Minor Appeal of: CCCYS*, in the Superior Court of Pennsylvania, ARHP is concerned that if this ruling were allowed to become law, it would pose serious general public health risks, including stigmatizing mothers and deterring them from pursuing needed substance abuse treatment and care. For these reasons, ARHP supports this amicus brief.

Amicus curiae the **Black Women’s Health Imperative** (“BWHI”) has been the only national organization dedicated solely to improving the health and wellness of our nation’s 21 million Black women and girls - physically, emotionally and financially for more than 30 years. BWHI advances and promotes Black women’s health in three ways: evidence-based programs and initiatives; policy and advocacy; and research translation. As part of their advocacy for the health of Black women and their families, BWHI seeks to ensure Black women’s reproductive autonomy is protected. The criminalization and prosecution of pregnant people disproportionately affect low income women and Black women. BWHI works to improve the health of Black women and girls through a reproductive justice lens, which includes pushing back on policies and laws that function to interfere with their reproductive health.

Amicus curiae **Center for Gender and Justice** (“CGJ”) seeks to develop gender-responsive policies and practices for women and girls who are under criminal justice supervision. The Center is committed to research and to the implementation of policies and programs that will encourage positive outcomes for this underserved population.

Amicus curiae **The Center for Reproductive Rights** (the “Center”) is a global nonprofit organization incorporated and headquartered in New York that uses the power of law to advance reproductive rights as fundamental human rights around

the world. The Center has undertaken a variety of initiatives, both in the U.S. and around the globe, to ensure that women do not lose their core rights to autonomy, dignity, or equality when they become pregnant. As part of its work to ensure legal guarantees to the full range of reproductive rights, the Center works to promote and ensure non-discriminatory access to safe and respectful maternal health care. The Center has advocated against the shackling of women in prison during childbirth in the U.S., and challenged the detention of postpartum women for failure to pay medical bills in Kenya. To carry out its work, the Center promotes the domestic and international application of international human rights instruments and consideration of related precedent in comparative law.

Amicus curiae **Community Legal Services of Philadelphia** (“CLS”) is a non-profit organization that provides free legal assistance to low-income individuals on a broad range of civil matters, including public benefits, landlord/tenant, utilities, mortgage foreclosure, employment and other areas of great need in Philadelphia. While the Employment Unit handles a significant amount of more traditional employment law matters, the largest need for CLS’ clients is addressing barriers to employment, such as criminal records and child abuse reports. Over the past five years, CLS’ office has handled hundreds of abuse expungement cases. The Family Advocacy Unit (FAU) is a unit within CLS which provides high quality representation to hundreds of parents each year in Philadelphia dependency and termination of parental rights proceedings. As part of its mission, the FAU works to ensure that low-income vulnerable families involved with the child welfare system receive the due process to which they are entitled and have meaningful access to justice in these extremely important proceedings. In addition to individual client representation, the FAU engages in policy advocacy and continuing legal education at both a statewide and local level to improve outcomes for children and families.

Amicus curiae **Delaware County Women’s Center** (“DCWC”) is a state licensed private doctor’s office that has a professional medical team specializing in medication abortion services up to 10 weeks of pregnancy. DCWC provides compassionate abortion care and reproductive health services, inspired by DCWC’s belief in the autonomy of the individual, and DCWC’s commitment to strengthening communities and building a better future. DCWC believes that threatening policies against substance-using women will discourage them from seeking medical care or treatment during their pregnancy for fear of facing legal penalization. No one should have to sacrifice their health in order to avoid punitive action.

Amicus curiae **Facing Addiction with NCADD** (The National Council on Alcoholism and Drug Dependence, Inc. has merged with Facing Addiction). The organization, with its Network of Affiliates, is dedicated to turning the tide on America's addiction epidemic through education, information and advocacy. The Network of Affiliates provides prevention, education, information, referral, advocacy, and hope in the fight against the chronic diseases of alcoholism and other drug addictions. For nearly 75 years, they have provided confidential assessment and referral services for persons addicted to alcohol and other drugs and their families. In 1990, the NCADD Board of Directors adopted a policy statement on 'Women, Alcohol, Other Drugs, and Pregnancy' recommending that 'states should avoid measures which would define alcohol and other drug use during pregnancy as prenatal child abuse and should avoid prosecutions, jailing, or other punitive measures which would serve to discourage women from seeking health care services.

Amicus curiae **Harm Reduction Coalition** ("HRC") is a national advocacy and capacity-building organization that promotes the health and dignity of individuals and communities impacted by drug use. HRC was founded in 1993 and incorporated in 1994 by a working group consisting of syringe exchange providers, advocates, and drug users. Today, HRC is a diverse network of community-based organizations, service providers, researchers, policy-makers, academics, and activists challenging the persistent stigma placed on people who use drugs, and advocating for sensible policy reform. HRC advances policies and programs that help people address the adverse effects of the "War on Drugs" and drug use including overdose, HIV, Hepatitis C, addiction, and incarceration. HRC recognizes that the structures of social inequality impact the lives and options of affected communities. Since its inception in 1994, HRC has advanced harm reduction philosophy, practice, and public policy by prioritizing areas where structural inequalities and social injustice magnify drug related harm.

Amicus curiae **Harm Reduction International** is a leading non-governmental organization working to promote and expand support for harm reduction. Harm Reduction International works to reduce the negative health, social and human rights impacts of drug use and drug policy by promoting evidence-based public health policies and practices, and human rights based approaches to drug policy. Harm Reduction International is an NGO in Special Consultative Status with the Economic and Social Council of the United Nations.

Amicus curiae the **Health Federation of Philadelphia** has a mission to expand access to comprehensive, coordinated and culturally responsive health and social

services for underserved populations in the Greater Philadelphia region. Health Federation of Philadelphia advocates for policies that reduce stigma and increase engagement in care for vulnerable adults, children and families and opposes policies that erect barriers to treatment and support.

Amicus curiae **Institute for Health and Recovery** ("IHR") is a statewide service, research, policy and program development agency. IHR's mission to develop a comprehensive continuum of care for individuals, youth and families affected by alcohol, tobacco and other drug use, mental health problems and violence/trauma. IHR focuses on the development of collaborative models of service delivery and the integration of gender-specific, trauma-informed and relational/cultural models of prevention, intervention and treatment. IHR serves individual women and men, and families, with a continuing emphasis on serving pregnant and parenting women and their children, and on fostering family-centered, strength-based and multiculturally competent approaches. IHR members know firsthand the fears pregnant substance-abusing women have regarding prosecution, causing them to be reluctant to seek prenatal care and substance abuse treatment.

Amicus curiae **Legal Action Center** ("LAC") is a national, non-profit law and policy organization, with offices in New York and Washington, D.C., that fights discrimination against and promotes the privacy rights of individuals with criminal records, substance use disorders, and/or HIV/AIDS. LAC's work includes extensive policy advocacy to expand prevention and treatment opportunities for people with or at risk for substance use disorders and to oppose legislation and other measures that employ a punitive, rather than public health approach, to addiction. LAC has also represented individuals and substance use disorder treatment programs who face discrimination based on inaccurate stereotypes about the disease of addiction. The question posed in this case is of vital concern to LAC's constituency across the country.

Amicus curiae **Legal Voice** is a non-profit public interest organization that works in the Pacific Northwest to advance the legal rights of women through public impact litigation, legislation, and legal rights education. Since its founding in 1978 (as the Northwest Women's Law Center), Legal Voice has been dedicated to protecting and expanding women's legal rights. Toward that end, Legal Voice has advocated for legislation protecting pregnant persons' rights, including their rights to be free from shackling if they are incarcerated and pregnant or in labor. In addition, Legal Voice has participated as counsel and as amicus curiae in the Pacific Northwest and across the country in numerous cases involving the rights of pregnant and birthing women. Legal Voice opposes, and has successfully

challenged, prosecutions of women for their pregnancy outcomes and works to end punitive measures that undermine the humanity and legal rights of all pregnant women.

Amicus curiae **Maternity Care Coalition** (“MCC”), since 1980, has assisted more than 100,000 families throughout Southeastern Pennsylvania, focusing particularly on neighborhoods with high rates of poverty, infant mortality, health disparities, and changing immigration patterns. MCC knows a family’s needs change as they go through the pregnancy and their child’s first years and MCC offers a range of services and programs for every step along the way including helping families dealing with substance use disorder and child abuse. MCC works with families on the frontline starting with MCC’s home visiting programs that help parents with programs which strengthens families, promotes positive parenting practices and encourages early learning. Evidenced based parenting skills are taught that help reduce child abuse and neglect. In addition MCC has programs working with high risk women suffering from behavioral health issues including substance use disorder. MCC works with babies diagnosed with neonatal abstinence syndrome providing home visiting support, which is part of the plan of safe care for the baby. MCC engages in advocacy supporting regional and state efforts addressing the opioid epidemic.

Amicus curiae **National Advocates for Pregnant Women** (“NAPW”) is a non-profit organization that advocates for the rights, health, and dignity of all women, focusing particularly on pregnant and parenting women, and those who are most likely to be targeted for state control and punishment. Through litigation, representation of leading medical and public health organizations and experts as amicus, and through organizing and public education, NAPW works to ensure that women do not lose their constitutional, civil, and human rights as a result of pregnancy. The organization also conducts research and has published a peer-reviewed study on prosecutions of and forced medical interventions on pregnant women. NAPW believes that health and welfare problems experienced by women during pregnancy should be addressed as health issues, not as crimes, and promotes policies that actually protect maternal, fetal, and child health.

Amicus curiae **National Alliance of Medication Assisted Recovery** (“NAMA Recovery”) is an organization composed of Medication Assisted treatment (i.e. methadone and buprenorphine) patients and healthcare professionals who support quality opiate agonist treatment. NAMA Recovery has thousands of members worldwide with a network of chapters in the United States and international affiliated organizations. The primary objective of NAMA Recovery is to advocate

for the patient in treatment by destigmatizing and empowering MAT patients. The goals of NAMA Recovery include eliminating discrimination against MAT patients, including pregnant and parenting women; creating a more positive image of MAT; helping to preserve patients' dignity and rights and making treatment available on demand to every person who needs it. First and foremost, NAMA Recovery confronts the negative stereotypes that impact the self esteem and worth of many medication-assisted treatment patients with a powerful affirmation of pride and unity.

Amicus curiae **National Association of Neonatal Nurses** (“NANN”) is a community of registered nursing professionals at all stages of their careers who care for newborn infants born with a variety of health challenges, including prematurity, birth defects, infection, cardiac malformations, and surgical problems. For more than 30 years, NANN has supported its members and advanced the profession by providing opportunities for members to influence care for neonates and their families, collaborate with leaders and peers in their field, and gain knowledge to improve their daily practice.

Amicus curiae **The National Association of Perinatal Social Workers** (“NAPSW”) was incorporated in 1980 for the purpose of promoting, expanding, and enhancing the role of social work in perinatal health care. The NAPSW helps individuals, families, and communities respond to psychosocial issues that emerge during the period from pre-pregnancy through an infant's first year of life.

Amicus curiae **National Coalition for Child Protection Reform** (“NCCPR”) is an organization of professionals from the fields of law, psychology, social work, and journalism who are dedicated to improving child welfare systems through public education and advocacy. NCCPR is a tax-exempt non-profit organization founded at a 1991 conference at Harvard Law School. NCCPR is incorporated in Massachusetts and headquartered in Alexandria, Virginia. Further information about the organization is available on its website, www.nccpr.org

Amicus curiae **The National Women’s Health Network** (“NWHN”) was founded in Washington, DC, in 1975 to improve the health of all women by developing and promoting a critical analysis of women’s health issues. NWHN works to defend women’s sexual and reproductive health and autonomy against threats that seek to undermine women's ability to make the best decisions regarding their own health.

Amicus curiae **New Voices for Reproductive Justice** (“NVRJ”) is a Human Rights and Reproductive Justice advocacy organization with a mission to build a

social change movement dedicated to the full health and well-being of Black women, femmes, and girls in Pennsylvania and Ohio. Since 2004, the organization has served over 75,000 women of color and LGBTQIA+ people of color, through community organizing, grassroots activism, civic engagement, youth mentorship, leadership development, culture change, public policy advocacy and political education. New Voices defines Reproductive Justice as the human right of all people to have full agency over their bodies, gender identity and expression, sexuality, work, reproduction and the ability to form families. New Voices stands in staunch opposition to laws that criminalize birth outcomes and pregnant women who have used substances during pregnancy. Such laws create fear of criminalization that could deter mothers who may be struggling with addiction from seeking care, and are likely to unequally harm women of color and poor women. Women of color face disproportionately high rates of pregnancy-related maternal deaths and infant mortality for a number of reasons, including the pervasive effects of institutional racism, stress, and barriers to comprehensive reproductive healthcare. New Voices firmly believes that, rather than criminalizing mothers, lawmakers should pass laws that increase access to a full range of pregnancy related and substance treatment care.

Amicus curiae the **Pennsylvania Chapter, American Academy of Pediatrics** (“The PA Chapter”) is a state level organization of approximately 2200 pediatricians who are dedicated to promoting the health and well being of children. The PA Chapter accomplishes its mission through advocacy, education, quality improvement and practice support. In carrying out this mission, The PA Chapter collaborates with any entities that touch the lives of children, including families, communities, media, public officials, insurers and other advocacy groups. The PA Chapter is in favor of any initiative that supports families of working women.

Amicus curiae **Pennsylvania Coalition Against Domestic Violence** (“PCADV”) is a private nonprofit organization working at the state and national levels to eliminate domestic violence, secure justice for victims, enhance safety for families and communities, and create lasting systems and social change. PCADV was established in 1976 as the nation’s first domestic violence coalition, and is now comprised of 60 funded community-based domestic violence programs across Pennsylvania, providing a range of life-saving services, including shelters, hotlines, counseling programs, safe home networks, medical advocacy projects, transitional housing and civil legal services for victims of abuse and their children. Current PCADV initiatives provide training and support to further advocacy on behalf of victims of domestic violence and their children.

Amicus curiae the **Pennsylvania Medical Society** (“the Medical Society”) is a Pennsylvania non-profit corporation that represents physicians of all specialties and is the Commonwealth’s largest physician organization. The Medical Society regularly participates as *amicus curiae* in cases raising important health care issues, including issues that have the potential to adversely affect the quality of medical care. Through these efforts, PAMED advocates for the interpretation of laws that are in the best interest of Pennsylvania’s citizens. Accordingly, the Medical Society’s overriding concern in this case is an interpretation of the Child Protective Services law that promotes that health and safety of the mother and child.

Amicus curiae **Pennsylvania Society of Addiction Medicine** (“PSAM”), is the Pennsylvania branch of ASAM, representing physicians specializing in the care and treatment of addicted individuals. PSAM’s mission is to educate fellow clinicians and the public at large, to advocate for patients to have access to treatment without discrimination, and to combat stigma against addicted persons. PSAM’s parent organization ASAM (American Society of Addiction Medicine) has authored a public policy statement on “Substance Use, Misuse, and Use Disorders During and Following Pregnancy, with an Emphasis on Opioids.”

Amicus curiae the **Philadelphia Department of Public Health** has a mission to protect and promote the health of all Philadelphians and to provide a safety net for the most vulnerable.

Amicus curiae **Physicians for Reproductive Health** (“PRH”) is a doctor-led nonprofit that seeks to assure meaningful access to comprehensive reproductive health services, including contraception and abortion, as part of mainstream medical care. Founded in 1992, the organization currently has over 6,000 members across the country, including over 3,000 physicians who practice in a range of fields: obstetrics and gynecology, pediatrics, family medicine, emergency medicine, cardiology, public health, neurology, radiology, osteopathic medicine, and more. These members, many of whom provide abortion care, include faculty and department heads at academic medical centers and top hospitals.

Amicus curiae **Philadelphia Women’s Center** (“PWC”) has been continually meeting the needs of women and families by providing professional, confidential and compassionate abortion care since 1972. Philadelphia Women’s Center (PWC) provides compassionate abortion care and reproductive health services, inspired by PWC’s belief in the autonomy of the individual, and PWC’s commitment to strengthening communities and building a better future. PWC believes that

threatening policies against substance-using women will discourage them from seeking medical care or treatment during their pregnancy for fear of facing legal penalization. No one should have to sacrifice their health in order to avoid punitive action.

Amicus curiae **Project RESPECT** (Recovery, Empowerment, Social Services, Education, Community and Treatment) Addiction Recovery in Pregnancy at Boston Medical Center is a comprehensive, multidisciplinary team treating pregnant women with Substance Abuse Disorders in the Greater Boston Area. Dr. Kelley Saia, an Assistant Professor of Obstetrics and Gynecology at Boston University Medical School, is the director of the program. Project RESPECT has been helping and treating pregnant women for several decades; Dr. Saia has been the director since 2006. Project RESPECT cares for and treats more than 125 mother/baby pairs per year, managing their medical, obstetric and psychiatric health. Project RESPECT provides opioid maintenance therapy, including methadone and buprenorphine. As one of the largest addiction treatment and obstetrics clinics in the country, Project RESPECT strongly objects to the appellee's position in this case. Opioid maintenance therapy during pregnancy is the American College of Obstetrics and Gynecology's recommended treatment for women with opioid addiction during pregnancy. Comprehensive care for women with substance abuse disorders, specifically opioid addiction, which includes methadone or buprenorphine, has been shown to reduce preterm delivery, NICU admissions, and low birth weight, not to mention the harm reduction of morbidity for the mother.

Amicus curiae **SisterReach**, founded October 2011, is a Memphis, TN based grassroots 501c3 non-profit supporting the reproductive autonomy of women and teens of color, poor and rural women, LGBT+ and gender non-conforming people and their families through the framework of Reproductive Justice. SisterReach's mission is to empower its base to lead healthy lives, raise healthy families and live in healthy communities. SisterReach provides comprehensive reproductive and sexual health education to marginalized women, teens and gender non-conforming people, and advocate on the local, state and national levels for public policies which support the reproductive health and rights of all women and youth.

Amicus curiae **SisterSong: Women of Color Reproductive Justice Collective** ("SisterSong") is a national organization of Indigenous women and women of color and allied organizations and individuals working for Reproductive Justice. Its core principles are threefold: it believes that every woman has the human right to choose if and when she will have a baby and the conditions under which she will

give birth; the human right to decide if she will not have a baby and her options for preventing or ending a pregnancy; and the human right to parent the children she already has with the necessary social supports to do so. Through advocacy, mentoring, and support, SisterSong raises the voices of women of color impacted by human rights violations on the national, state, and local levels.

Individual Experts

*Institutional affiliations designated with * are provided for identification purposes only.*

Amicus curiae **Kara R. Finck, JD***, is a Practice Professor of Law at University of Pennsylvania Law School and the Director of the Interdisciplinary Child Advocacy Clinic. In her clinic, she focuses on the civil legal needs of children and families through a holistic, interdisciplinary model of representation. Professor Finck previously served as the Managing Director of the Family Defense Practice at The Bronx Defenders where she oversaw the first institutional representation program for parents accused of abuse or neglect in Bronx Family Court. There she created a groundbreaking model for holistic representation of parents involved in the child welfare system. As a lecturer, she has presented both nationally and internationally on issues including child welfare, parents' rights, child advocacy and interdisciplinary collaboration. She co-authored "Social Work Practice and the Law" (Springer Publishing, 2011) and has written on child welfare theory and practice in various law journals.

Amicus curiae **Sarah Katz, JD*** is an Associate Clinical Professor of Law at the Temple University Beasley School of Law. In that capacity she directs the Family Law Litigation Clinic of the Temple Legal Aid Office, which provides free legal services to low-income residents of Philadelphia in a variety of family law matters. An expert in family law and child protection, a practicing attorney for 15 years, and a clinical law professor, Ms. Katz is deeply concerned about the dampening effect the law at issue in this matter (and similar laws) will have on low income women, and particularly low income women of color.

Amicus curiae **Dorothy E. Roberts, JD***, is the fourteenth Penn Integrates Knowledge Professor, George A. Weiss University Professor, and the inaugural Raymond Pace and Sadie Tanner Mossell Alexander Professor of Civil Rights at University of Pennsylvania, where she holds appointments in the Law School and Departments of Africana Studies and Sociology. An internationally recognized scholar, public intellectual, and social justice advocate, she has written and lectured extensively on the interplay of gender, race, and class in legal issues and

has been a leader in transforming public thinking and policy on reproductive health, child welfare, and bioethics. Professor Roberts is the author of the award-winning books *Killing the Black Body: Race, Reproduction, and the Meaning of Liberty* (Random House/Pantheon, 1997) and *Shattered Bonds: The Color of Child Welfare* (Basic Books/Civitas, 2002), as well as co-editor of six books on constitutional law and gender. She has also published more than eighty articles and essays in books and scholarly journals, including Harvard Law Review, Yale Law Journal, and Stanford Law Review. Her latest book, *Fatal Intervention: How Science, Politics, and Big Business Re-create Race in the Twenty-First Century*, was published by the New Press in July 2011. Among her many public interest positions, Roberts is the chair of the Board of Directors of the Black Women's Health Imperative.

APPENDIX B.1

SUSAN C. BOYD

Mothers and Illicit Drugs:
Transcending the Myths

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aration as a result of incarceration or child apprehension, they are further stigmatized by society through social ostracism and harsh sentencing (Carlen, 1976, 1983; Daly, 1987; Eaton, 1983, 1985; Masson, 1992).

Women who use illicit drugs are considered to be unfit mothers, out of control, and a danger to their children (Paltrow, 1992; Rosenbaum et al., 1990; Taylor, 1993). However, a comparable set of characteristics concerning fathers who use illicit drugs is lacking in drug literature. Although most research on illicit drug use centres on the male user, his parenting qualities and responsibility to his family are rarely addressed. Rather, the male user has often been described as the 'man about town' (Preble & Casey, 1969), and little was known about his family relations until Hanson, Beschner, Walters, and Bovelie (1985) studied male heroin users in the United States. Outside of the area of monetary support, little attention has been given to the family responsibilities of male illicit drug users. This reflects Western ideological assumptions about men, as opposed to ideological assumptions concerning women.

In contrast, research on women who use illicit drugs overwhelmingly explores, and often centres on, the women's lack of parenting abilities, and failure to be responsible for children and the household (see Chasnoff, 1989; Dembo et al., 1990; Densen-Gerber & Rohrs, 1973; Howard, Beckwith, Rodning, & Kropenske, 1989; Jaudes, Ekwo, & Voorhis, 1995; Julien, 1992; Kantor, 1978; Murphy et al., 1991; Peak & Papa, 1993; Robins & Mills, 1993; Steinberg, 1994; Weston, Ivins, Zuckerman, Jones, & Lopez, 1989).

However, as noted earlier, on reviewing the literature on mothers who use illicit drugs, it becomes apparent that qualitative research with in-depth interviews (see Colten, 1980, 1982; Dreher, Nugent, & Hudgins, 1994; Jackson & Berry, 1994; Kearney, Murphy, & Rosenbaum, 1994; Leeders, 1992; Rosenbaum, 1981; Rosenbaum et al., 1990; Sterk-Elifson, 1996; Taylor, 1993) demonstrate that these mothers can be adequate parents and view mothering as their central role.

For many women, pregnancy is an event that significantly changes their status in society (Kitzinger, 1992; Oakley, 1992; Rothman, 1989). Women who are identified as illicit drug users during pregnancy are closely monitored by medical and social services professionals, who assess, and eventually determine, maternal health and parental fitness.

In the course of the research, it became apparent that the women interviewed perceived themselves as different from male drug users who are parents, because of their role as mothers. The full responsibility of caring for their children shaped their drug use, both positively and nega-

APPENDIX B.2



Pergamon

Child Abuse
& Neglect

Child Abuse & Neglect 26 (2002) 97–114

Spotlight on practice

The risk of subsequent maltreatment allegations in families with substance-exposed infants☆,☆☆

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Abstract

Objective: This study seeks to: (1) assess the relationship between identified prenatal substance use and the risk of subsequent maltreatment allegations among families involved with child protective services; and (2) compare the types of safety threats encountered by children whose parents had substance-exposed infant (SEI) allegations to the types of safety threats faced by children whose parents had other types of allegations.

Method: Survey data from a probability sample of parents were linked to state administrative data over a 33-month time frame. Cox regression models were conducted to assess the relative risk of subsequent allegations associated with parents whose child welfare case opened following an SEI allegation (the SEI group) compared to parents whose case opened following other types of allegations.

Results: The likelihood of subsequent allegations is greater among parents in the SEI group. However, the increased risk stems almost entirely from subsequent SEI-related allegations. Parents in the SEI group are not more likely to incur other types of allegations such as physical abuse or lack of supervision.

Conclusions: An increased risk of subsequent maltreatment has been used to justify opening child protective cases on the basis of an SEI allegation alone. By looking closely at the types of subsequent

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allegations as well as the incidence of subsequent allegations, this research helps to clarify the maltreatment risks associated with SEI cases. © 2002 Elsevier Science Ltd. All rights reserved.

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Introduction

One of the legacies of the cocaine epidemic of the late 1980s and early 1990s is the large number of families who became involved with child protective services as a result of drug enforcement and surveillance policies. Child protective services have been concerned about parental substance use for decades, but with the cocaine epidemic came a new concern: prenatal drug exposure. In response to alarms sounded by medical researchers suggesting that a generation of “cocaine-damaged” infants faced an uncertain future of developmental and behavioral problems, some states moved to mandate the reporting of infant substance exposure to child protective authorities. In addition, fearful of the risks prenatal drug use posed to subsequent child safety and well-being, caseworkers and judges escalated the removal of children from drug-using parents on allegations of “inadequate supervision,” “environmental neglect,” or “risk of harm.”

After a decade, opinions on how best to fashion a child protective response to the problem of prenatal substance use have diverged (see Barth, 2001; Ondersma, Simpson, Brestan, & Ward, 2000). On the one hand, in light of follow-up research that shows the developmental consequences of prenatal drug exposure to be less dire than originally feared (Lester, Freier, & LaGrasse, 1995; LaGrasse, Seifer, & Lester, 1999; Mayes, Granger, Bornstein, & Zuckerman, 1992; Slutsker, 1992), hospitals are reconsidering the advisability of testing newborns for substance exposure. Some court jurisdictions are treating prenatal substance exposure as a public health matter and invoking child protective authority only if there is a finding of direct harm to a child. On the other hand, public intolerance for maternal substance use continues. In South Carolina, women who use substances during pregnancy can be prosecuted in criminal court; Wisconsin passed a “Cocaine Mom Bill” enabling the state to mandate substance abuse treatment for pregnant women; and Illinois has a law stipulating that a second substance-exposed infant (SEI) finding shall constitute sufficient evidence to initiate termination of parental rights.

As child welfare administrators and practitioners struggle to form appropriate policy and practice responses to families with substance-exposed infants, researchers have attempted to answer a fundamental question: To what extent does prenatal substance use place children at risk of subsequent abuse or neglect? Generally, evidence points to an association between parental substance use and intervention by child protective services (Children’s Bureau, US Department of Health and Human Services, 1997; Curtis & McCollough, 1993; Magura & Laudet, 1996). And researchers have identified an association between parental substance use and subsequent maltreatment as measured by child protective services reports (Jaudes, Ekwo, & Van Voorhis, 1995; Wolock & Magura, 1996) and incidents of maltreatment found in medical records (Wasserman & Leventhal, 1993). Still, such studies fall short of demonstrating that substance use, per se, increases threats to child safety. Case-control studies that

compare samples of identified substance users in the child welfare system to matched samples from the general population cannot control adequately for the myriad of social, environmental, and other factors that confound the association between parental substance use, threats to child safety, and involvement with child protective services. Differences attributed to substance use might be because of other factors that affect detection or identification of substance use or affect the likelihood of child welfare involvement (see Franck, 1996).

For several reasons there is a distinction between substance-exposed infants identified by the child welfare system and all infants exposed to substances. First, research has identified race and class bias in hospital policy and practice regarding tests for infant substance exposure (Chasnoff, Landress, & Barrett, 1990). Some hospitals have a policy to test every newborn; others test only “high-risk” cases. Second, despite evidence of the deleterious effects of fetal exposure to alcohol, infants are tested for exposure to illicit substances, not for exposure to alcohol. Finally, tests identify substance use in the past several days only; an infant might be exposed to substances at various points during a pregnancy and still test negative at birth.

The distinction between prenatal substance exposure and identified prenatal substance exposure has two implications for studies seeking to assess the subsequent maltreatment risks associated with prenatal substance exposure. First, to avoid the spurious attribution of safety risks to substance exposure when such risks stem from factors associated with child welfare involvement, studies should make comparisons among families already involved with the child welfare system. For example, safety risks among families with substance-exposed infant allegations should be compared to safety risks among families with other types of maltreatment allegations. Second, if researchers cannot isolate the effects of prenatal substance exposure from the effects of *identified* prenatal substance exposure, studies should clearly specify that their findings apply to identified prenatal substance exposure.

Some researchers have conducted bivariate analyses to assess risks associated with identified prenatal substance use among families involved with child protective services. One study found that infants with verified substance exposure had more caregiving needs than infants with suspected substance exposure (McNichol, 1999). Another study found that families with SEI allegations have higher subsequent maltreatment rates than families with other types of allegations (Goerge & Harden, 1993). Such findings suggest that, even among families involved with child protective services, children in families with identified prenatal substance use face greater subsequent maltreatment risks than children with other types of allegations. Such findings provide justification for opening child protective cases on the basis of prenatal substance use alone. The important implications of such findings warrant investigation using multivariate survival analysis methods.

The purposes of this study are to: (1) assess the relationship between identified prenatal substance use and the risk of subsequent maltreatment allegations among families involved with child protective services; and (2) compare the types of safety threats encountered by children whose parents had SEI allegations to the types of safety threats faced by children whose parents had other types of allegations. A clearer understanding of these relationships can help child welfare agencies develop family-centered protective interventions that better

balance the severity of risks posed by prenatal substance use against the harms of parent-infant separation and out-of-home placement.

The study addresses the following questions:

1. Are child welfare cases that open because of an SEI allegation at greater risk of subsequent abuse or neglect allegations than cases that open for other reasons?
2. Is giving birth to a substance-exposed infant after a child welfare case opens a predictor of subsequent abuse or neglect allegations?
3. What types of subsequent abuse and neglect allegations are parents with prior SEI allegations likely to incur?

Illinois provides a rich source of data for addressing these research questions. In Illinois, unlike many states, evidence of fetal substance exposure constitutes *prima facie* evidence of child neglect, and infant substance exposure is identified as a particular type of child protective services allegation: a substance-exposed infant, or SEI, allegation. The parents of all infants testing positive for illicit drugs are charged with neglect and have a child welfare case opened. Thus, all infants identified as being exposed to illicit drugs can be followed longitudinally with state administrative data.

Methods

Data source

This study is part of a larger study conducted by the Illinois Department of Children and Family Services (DCFS) using state administrative data and survey data. The survey data were collected from a probability sample of parents who had an open DCFS case in June 1995. To assure adequate representation of families with SEI allegations, the sample was stratified so that half of the sample members had an indicated SEI allegation that preceded their case opening. The sample was also stratified by whether or not a parent had an intact case (no children in state custody) or a placement case (at least one child in state custody). Also, selection chances were weighted by the inverse of the case duration. This step increased the selection chances of shorter-term cases and generated a sample which is more representative of all families who become involved with child welfare services rather than a sample which only represents families with open cases at a point in time (see Wulczyn, 1996), but this step does not rule out the possibility that our sample over-represents long-term cases. Social work students conducted in-home interviews with the sample members during the spring and summer of 1996. The survey data were linked with state administrative records on child maltreatment reports from June 1995 through March 1998. We refer to this 33-month time period as the study's "observation window."

The survey response rate, shown in Table 1, was 55%. While this response rate is only minimally adequate, we have the advantage of having state administrative data from the entire sample. Thus, we can compare respondents to nonrespondents in areas included in the administrative data to better understand how the respondents might differ from the nonrespondents. The respondents are like the nonrespondents in virtually all demographic and

Table 1
Survey response rate

	SEI	Non-SEI	Total
Placement	83 of 161 (52%)	92 of 158 (58%)	175 of 319 (55%)
Intact	59 of 96 (61%)	43 of 93 (46%)	102 of 189 (54%)
Total	142 of 257 (55%)	135 of 251 (54%)	277 of 508 (55%)

child welfare characteristics compared (age, number of children, race, length of case opening, SEI group status, having a subsequent allegation by March 1998, having a closed case by March 1998, and, among placement cases, having a return home goal). One possible difference exists among sample members with a child in placement. A slightly higher percentage of placement respondents than placement nonrespondents had a return home goal (50% vs. 42%). This difference is not statistically significant ($p = .16$), and it is unlikely to have major implications for this study, but it will be considered in our interpretation of the study findings.

Definition of variables

Dependent variables. There are two dependent variables in this study. Both are hazard rates (defined below) for substantiated subsequent maltreatment allegations. The first is the hazard rate for any substantiated subsequent maltreatment allegation during the 33-month observation window; the second is the hazard rate for a substantiated non-SEI-related subsequent maltreatment allegation during the observation window. The study focuses only on substantiated allegations. (Substantiated allegations are less than perfect indicators of maltreatment. The distinction should be considered when interpreting the study findings.) The presence of subsequent allegations is indicated in the administrative data; substantiation status and type of allegation are determined by child protective services (CPS) investigators.

In Illinois, an SEI allegation is a particular type of allegation, like physical abuse, lack of supervision, and so forth. However, very rarely does a parent receive only an SEI allegation. Rather, when an investigator assigns an SEI allegation, he or she often assigns a “risk of harm” allegation at the same time. For many investigators, by definition, a substance-exposed infant is at risk of harm. Thus, the two allegations go hand in hand. The second dependent variable, therefore, indicates subsequent allegations that are neither SEI allegations nor risk of harm allegations accompanying an SEI allegation.

Independent variables. The SEI group designation refers to respondents whose child welfare case opened within 30 days of receiving an SEI allegation. In such cases, we say the case opened because of an SEI allegation. This status is distinct from receiving a new SEI allegation during the observation window. Eighty-nine percent of new SEI allegations were against members of the SEI group, and 11% were against respondents whose child welfare cases opened following allegations other than SEI (the non-SEI group). Conversely, 22% of the members of the SEI group received a new SEI allegation, and 3% of the non-SEI group received a new SEI allegation during the observation window. The “birth” designation comes

from the survey data. Respondents were asked the birth dates of all their children. Respondents having a child with a birth date between June 1995 and March 1998 are included in the new birth category. New births were further categorized by whether they were an SEI or clean birth. If a respondent received an SEI allegation (determined from the administrative data) within 30 days of a new birth, the birth is classified as an SEI birth; other births are classified as clean births. Respondents classified as “intact” had no children placed out of the home at the time of the sample selection.

The models also contain several control variables that constitute key risk or protective factors for families involved with child protective services: having a family income below the poverty line, living in a public housing high-rise, attending work or school, and living with another adult. Variable definitions are included in Appendix A.

Cox regression

Multivariate models were analyzed using Cox regression—a type of hazards analysis. With hazards analysis, the dependent variable is an unobserved variable, commonly called a hazard rate or hazard function. The hazard rate is the probability at each point in time (such as each day) of an event occurring given that it has not yet occurred (Allison, 1984). This technique offers some advantages over logistic regression, for example, in which the dependent variable is simply an indicator of whether or not an event occurred. First, the models account for the existence of right-censored cases, or cases in which a subsequent allegation has not yet occurred but may occur later. Second, this technique enables us to account for the time-varying impact of independent variables. The effect of a new birth on a subsequent allegation, for example, may vary depending on how closely in time the birth and the allegation are related. Our models account for a new birth on the day it occurs. Finally, the Cox regression models enable us to account for the changing status of being “at risk” of a subsequent allegation. Many parents experience periods of time during the observation window when their risk of receiving a subsequent allegation is markedly reduced, if not eliminated, because their children have been placed in state custody. With hazards analysis, we can specify precisely, at every point in time, whether a parent has custody of at least one child. As individuals gain and lose custody of children or give birth, they move in and out of the set of individuals who are at risk of receiving a subsequent allegation. A parent is included in the “risk set” when she has custody of at least one child.

Findings

Descriptive data

Demographic information. Demographic information about the survey respondents is shown in Table 2. Summary statistics are shown for all respondents and disaggregated by SEI group status. The respondents’ ages ranged from 17 years to 52 years; the average age was 32 years. The number of children ranged from 1 to 13; the average number and the median were both 4. About half of the respondents had completed high school; about one third were currently

Table 2
Descriptive statistics by SEI group and total

Characteristic	SEI group (<i>n</i> = 142)	Non-SEI group (<i>n</i> = 135)	<i>p</i>	Total (<i>n</i> = 277)
	<i>Mean</i>	<i>Mean</i>		<i>Mean</i>
Age	31	33	.01	32
Number of children	4.4	3.9	.06	4
Personal income last month	572	686	.07	\$ 627
Household income last month	1004	1149	.21	\$ 1075
	Percent	Percent		Percent
Live with another adult	58%	54%	.54	56%
Completed high school	45%	54%	.13	51%
Currently work or attend school	20%	36%	.003	32%
Receive work income	17%	27%	.03	24%
HH income below poverty	80%	66%	.007	70%
Live in public housing	15%	5%	.005	8%
Race				
African American	88%	79%	.05	83%
White	8%	10%	.58	9%
Mexican/Puerto Rican	4%	10%	.07	8%
SEI group (Initial SEI alleg.)	(all)	(none)		51%
Intact group	42%	32%	.09	37%
New birth	42%	27%	.01	35%
SEI birth	22%	3%	<.001	13%
Clean birth	29%	27%	.47	28%
Any subsequent allegation	35%	13%	<.001	24%
SEI subseq. alleg	22%	3%	<.001	13%
Non-SEI subseq. alleg	15%	10%	.27	13%

either working or attending school; 24% received some personal income from work. Seventy percent of the respondents had household incomes below the federal poverty line. The racial composition of the respondent group reflects the racial composition of parents involved with child protective services in Cook County: 83% of the respondents were African American, 9% White, and 8% of Hispanic (mostly Mexican or Puerto Rican) decent.

Independent variables. Table 2 also contains descriptive statistics for the covariates included in the analysis. Fifty-one percent of the respondents were in the SEI group. Thirty-seven percent of the respondents had an intact family case. Thirty-five percent of the respondents had a new birth during the 33-month observation window; 13% had a new birth which received an SEI allegation; 28% had a “clean birth” or a new birth that was not identified as substance exposed. (The sum of the SEI and clean births does not equal the overall new birth figure because some respondents had two births: one substance exposed and one not.)

Subsequent allegations. There were 220 subsequent allegations during the observation window occurring in 84 separate events and involving 67 (24%) of the 277 survey respondents. During the observation window, an individual parent could have more than one event leading

Table 3
Distribution of subsequent allegations by type

Subsequent allegation type	All subsequent allegations			Most serious subsequent allegation against each mother		
	Total	SEI group	Non-SEI group	Total	SEI group	Non-SEI group
Physical abuse	1%	0	5%	4%	0	17%
Substance use	19%	23%	8%	52%	63%	22%
Lack of supervision	22%	19%	30%	25%	18%	44%
Environmental neglect	18%	11%	34%	4%	2%	11%
Medical neglect	4%	4%	3%	2%	2%	0
Risk of harm	36%	43%	20%	12%	14%	6%
Total	100%	100%	100%	100%	100%	100%
	(<i>n</i> = 220)	(<i>n</i> = 159)	(<i>n</i> = 61)	(<i>n</i> = 67)	(<i>n</i> = 49)	(<i>n</i> = 18)

to an allegation and, especially with multiple children, more than one allegation stemming from each event. For example, one event resulting in both an “inadequate supervision” and a “risk of harm” allegation against four children would result in eight allegations against a parent. An allegation event typically results in multiple allegations. However, most parents having an allegation event during the observation window had just one event. Our analysis focuses on the first allegation event.

Subsequent allegations by SEI group status

A bivariate comparison of subsequent allegation status by SEI group status (shown in Table 2) indicates that 35% of parents in the SEI group had a subsequent allegation compared to 13% of parents in the non-SEI group. This statistically significant difference ($p < .001$) is consistent with the findings reported in other research (Goerge & Harden, 1993): parents in the SEI group were more likely than parents in the non-SEI group to incur a subsequent maltreatment allegation.

Types of subsequent allegations

To better understand the greater risk of incurring a subsequent allegation associated with the SEI group, we first looked at types of subsequent allegations. Table 3 shows the distribution of subsequent allegations by type of allegation. Few of the subsequent allegations were allegations of physical abuse: less than 6% of the subsequent allegations in the non-SEI group and none in the SEI group. The most common type of subsequent allegation in the non-SEI group was environmental neglect; the most common type of subsequent allegation involving members of the SEI group was risk of harm. There were no subsequent allegations of sexual abuse or death.

To facilitate a comparison of the types of allegations incurred by each parent, the allegation types were ranked according to severity. (We used our subjective notions of severity as the ranking criteria. Clearly, the severity of maltreatment incidents cannot be definitively determined by the type of allegation. The ranking shown in Table 3 provides

Table 4
Subsequent allegations by birth, child and SEI status

Percent having any type of subsequent allegation					
	SEI		Non-SEI		<i>p</i>
	percent	(<i>n</i>)	percent	(<i>n</i>)	
No new birth	6%	(16)	0	(21)	.33
No other children at home	6%	(16)	0	(21)	.33
Other children at home	12%	(66)	12%	(77)	.94
New birth					
No other children at home	85%	(27)	40%	(10)	.025
Other children at home	52%	(33)	19%	(27)	.008
Total	35%	(142)	13%	(135)	<.001
Percent having a non-SEI-related subsequent allegation					
	SEI		Non-SEI		<i>p</i>
	percent	(<i>n</i>)	percent	(<i>n</i>)	
No new birth					
No other children at home	6%	(16)	0	(21)	.33
Other children at home	12%	(66)	12%	(77)	.94
New birth					
No other children at home	22%	(27)	20%	(10)	.89
Other children at home	18%	(33)	11%	(27)	.45
Total	15%	(142)	10%	(135)	.27

only an indication of severity.) Table 3 indicates the allegation types ranked from most severe to least severe. For almost two-thirds of the parents in the SEI group with subsequent allegations, the most severe subsequent allegation was another SEI allegation; for 18%, lack of supervision was the most serious subsequent allegation; and for 14%, the most serious subsequent allegation was risk of harm. For most parents in the non-SEI group, the most severe type of subsequent allegation was lack of supervision.

Thus, rather than physical harm or lack of supervision, SEI allegations constitute the most serious type of subsequent allegation against most members of the SEI group. This finding raises two questions: (1) Because SEI allegations, by definition, accompany births, to what extent are subsequent allegations associated with subsequent births? (2) Are members of the SEI group simply at greater risk of subsequent SEI allegations or are they at greater risk of other types of allegations as well?

Subsequent allegations by birth, child, and SEI group status

Table 4 again shows the subsequent allegation rate by SEI group status. The top half of the table shows the percentage of parents having any type of subsequent allegation during the observation window; the bottom half shows the percentage having a subsequent allegation which was not SEI-related (neither an SEI allegation nor a risk of harm allegation accompanying an SEI allegation). Because investigators tend to assign risk of harm allegations when they assign SEI allegations, the risk of harm allegations accompanying SEI allegations may

Table 5
Cox regression models: any subsequent allegation

Variable	Model 1			Model 2		
	Coeff.	SE	Relative Risk [Exp (B)]	Coeff.	SE	Relative Risk [Exp (B)]
SEI group status	.87***	.28	2.39	.45	.30	1.57
Intact family	-.33	.26	.72	-.09	.28	.91
Birth	2.79***	.28	16.25	2.74***	.28	15.54
Live with adult				-.92**	.29	.40
Poverty				-.17	.39	.85
Public high rise				.75*	.31	2.12
Work or school vs. White				-.99*	.50	.37
Black				.05	.55	1.05
Hisp				-.21	.81	.81
*** $p < .001$	Model 1 Log Likelihood -270.63			Model 2 Log Likelihood -259.96		
** $p < .01$	Global Chi-Square 180.40, $p < .001$			Global Chi-Square 205.74, $p < .001$		
* $p < .05$						

contribute to the increased likelihood of subsequent allegations among the SEI group. (Recall that risks of harm allegations are the most common type of subsequent allegation against members of the SEI group, and an SEI allegation is the most serious subsequent allegation for almost two thirds of this group.) Table 4 also compares parents with other children at home (besides a newborn) to parents with no other children at home. We included this comparison to assess the safety of children living with parents, either as part of wholly intact families or as part of families in which the custody of siblings is split between a parent and the state.

Table 4 shows that among parents who had no new births during the observation window, there was little difference between the SEI and non-SEI groups in the subsequent allegation rate. This was true whether or not other children besides a newborn were living with the parents and when comparing all allegations or only non-SEI allegations. Thus, in the absence of a subsequent birth, the SEI allegation does not increase the likelihood of incurring a subsequent maltreatment allegation. Among parents who had a new birth, however, when comparing allegations of any type, the subsequent allegation rate among parents in the SEI group was more than twice as high as the subsequent allegation rate among parents in the non-SEI group. This was true whether or not other children were living with the parents. Thus, if another child is born, the SEI allegation is associated with an increased likelihood of incurring a subsequent maltreatment allegation. However, when only non-SEI-related allegations are considered, the allegation rate difference, based on SEI group status, vanishes almost entirely. The table figures suggest that the higher subsequent allegation rate among parents in the SEI group stems primarily from the birth of subsequently indicated substance-exposed infants.

Multivariate findings—Cox Regression Models

The multivariate hazards results, shown in Tables 5 and 6, affirm the relationships shown

Table 6
Cox regression models: Non-SEI-related subsequent allegation

Variable	Model 1			Model 2			Model 3		
	Coeff.	SE	Relative Risk [Exp (B)]	Coeff.	SE	Relative Risk [Exp (B)]	Coeff.	SE	Relative Risk [Exp (B)]
SEI group status	.10	.33	1.11	.27	.33	1.31	-.02	.36	.98
Intact family	-.17	.32	.85	-.20	.32	.82	.06	.39	1.06
Birth	1.41***	.33	4.08						
SEI birth				.61	.46	1.83	.36	.48	1.43
Clean birth				1.91***	.32	6.75	1.91***	.34	6.72
Live with adult							-.59	.38	.55
Poverty							-.26	.44	.77
Public high rise							1.08**	.38	2.93
Work or school vs. White							-.60	.52	.55
Black							-.32	.64	.72
Hisp							.05	.85	1.06

*** $p < .001$ Model 1 Log Likelihood -203.89 Model 2 Log Likelihood -196.67 Model 3 Log Likelihood -190.64
** $p < .01$ Global Chi Square 22.50, $p < .001$ Global Chi Square 45.91, $p < .001$ Global Chi Square 60.84, $p < .001$
* $p < .05$

in Table 4. Tables 5 and 6 include the coefficient and standard error for each independent variable as well as the exponentiated coefficient, which is also called the risk ratio (Allison, 1984), or relative risk. Table 5 shows the relative risk of having a subsequent allegation of any type. Model 1 indicates that, controlling for new births and intact family status, members of the SEI group are almost two times (95%) more likely than members of the non-SEI group to incur a subsequent allegation. In addition, parents who had a new birth in the observation window are more than 12 times more likely than those without a new birth to incur a subsequent allegation.

To what extent is the SEI group's higher subsequent allegation rate a consequence of prenatal drug use, per se, as opposed to other risk factors associated with the SEI group? Table 5, Model 2 indicates that once additional risk factors are taken into account, the increased risk associated with the SEI group diminishes considerably. The model indicates that members of the SEI group are still about 43% more likely than members of the non-SEI group to incur a subsequent allegation, but the difference is not statistically significant. Moreover, the model indicates that living with another adult and, perhaps, attending work or school decrease the likelihood of incurring a subsequent allegation. Having a new birth still substantially increases the likelihood of incurring a subsequent allegation. This model shows how the SEI group's higher subsequent allegation rate may be, in part, explained by risk factors associated with the SEI group.

Table 6 restricts the analysis to the relative risk of incurring a non-SEI-related subsequent allegation. Model 1 shows that members of the SEI group are only slightly (23%) more likely than members of the non-SEI group to have a non-SEI-related subsequent allegation. This small difference is not statistically significant. Thus, again, parents in the SEI group are more likely than parents whose cases opened following other types of allegations to incur a

subsequent allegation when allegation type is not taken into account. But the group difference is largely explained by the SEI group's greater likelihood of having subsequent births and incurring SEI-related allegations. The SEI group is not more likely than the non-SEI group to incur non-SEI-related subsequent allegations.

In addition to the subsequent allegation risk associated with the SEI group, we also assessed the subsequent allegation risk associated with new SEI allegations (those occurring during the observation window). As shown in Table 6, Model 2, parents who gave birth to a new substance-exposed infant during the observation window were more than two times (155%) more likely than parents who had no new births to also receive a non-SEI-related subsequent allegation. However, parents who gave birth and did not receive an SEI allegation (a clean birth) were over four times more likely than parents with no births to receive a non-SEI-related subsequent allegation.

Why should clean births be associated with subsequent allegations? Clearly all births create the opportunity for subsequent allegations. If a parent's other children are in state custody, a new birth places the parent back in the "risk set" for incurring a subsequent allegation. As shown in Table 4, subsequent allegation rates tend to be higher among parents with a new birth than among parents with no new birth. However, among parents with other children at home, a new birth seems to increase the subsequent allegation rate only for members of the SEI group. New births among custodial parents in the non-SEI group were not clearly associated with subsequent allegations. Might the higher coefficient for new "clean" births be reflecting other risk factors that put children, especially those from the SEI group, at risk?

Table 6, Model 3, tests whether the effect of having a clean birth fades after controlling for other risk factors, especially factors that distinguish the SEI from the non-SEI group. The model indicates that living with another adult decreases the likelihood of incurring a non-SEI-related subsequent allegation, while staying in a public housing high rise increases the likelihood of incurring a non-SEI-related subsequent allegation. However, the model indicates that once other risk factors are considered, clean births are still highly associated with non-SEI-related subsequent allegations. Perhaps once a parent is involved with child protective services, any new babies born to her are considered to be at "risk of harm," perhaps for good reason or perhaps because of stigma and risk aversion. When a child welfare agency indicates a subsequent birth for substance exposure, it establishes a basis for continued protective services involvement. But if a new baby born to a previously SEI-indicated parent tests clean, the child welfare agency may seek other reasons to maintain heightened surveillance of the family. Either actual harm or risk aversion could explain the higher allegation rate associated with clean births.

Other indications of risk associated with an SEI allegation

The administrative data analysis suggests that the greater likelihood of subsequent allegations among members of the SEI group stems from the much greater tendency for members of this group to have subsequent SEI allegations. We looked to the survey data for other indications of increased risk associated with the SEI group. The survey included a composite scale designed to assess risks to child safety. The scale assessed parent charac-

Table 7
T-tests of the difference between the SEI and Non-SEI groups in parent risk factors

Characteristic	Group	Mean Score	<i>SD</i>	<i>t</i>	<i>p</i>
Authoritarianism	SEI	2.46	.54	-.096	.92
	Non-SEI	2.47	.64		
Unrealistic expectations	SEI	2.99	.59	.019	.98
	Non-SEI	2.99	.58		
Coping difficulties	SEI	2.43	.75	-.092	.93
	Non-SEI	2.44	.84		

teristics in three dimensions believed to be associated with child abuse or neglect potential: authoritarianism, unrealistic expectations, and coping difficulties. As shown in Table 7, a comparison of the SEI group to the non-SEI group in the three dimensions measured by this scale reveals no significant differences between the two groups. These bivariate tests are consistent with the administrative data analysis in suggesting that the risk of subsequent harm is no greater among families with an SEI allegation than it is for families with other types of allegations.

Summary and discussion

Child welfare authorities have two primary reasons to open a child welfare case when an infant tests positive for substance exposure: (1) because the infant has been harmed by the substance exposure, and (2) because the substance exposure constitutes a predictor of future maltreatment. Thoughts about the first reason have become more complex in recent years. Although early research suggested that intrauterine cocaine exposure led to severe and chronic health and developmental problems such as irreparable brain damage and sudden infant death syndrome, follow-up research has tempered these early predictions (see Berger & Waldfogel, 2000; LaGasse, Seifer, & Lester, 1999; Mayes et al., 1992; Slutsker, 1992). In early research, conditions associated with drug use such as poverty, poor nutrition, and inadequate prenatal care were not accounted for sufficiently, nor had the effects of legal substances such as alcohol, tobacco, and environmental toxins been isolated adequately from the effects of illicit drugs. More recent research suggests, first, that the effects of cocaine exposure, per se, are limited and, second, that the near-term effects of fetal cocaine exposure can be mitigated by the caregiving environment (Lester, Freir, & LaGasse, 1995).

Focusing on the second reason to open a child welfare case when an infant tests positive for substance exposure, this study addressed the question: Among families involved with child protective services, to what extent does identified prenatal substance exposure increase the risk of future maltreatment allegations? Because Illinois authorities open a child welfare case with every confirmed instance of infant substance exposure, we had the opportunity to track the subsequent maltreatment allegations associated with every confirmed substance-exposed infant among our respondents. Our analysis is consistent with other research (Goerge & Harden, 1993) in finding that parents whose child welfare cases opened because

of an SEI allegation are more likely than parents whose cases opened for other reasons to incur subsequent maltreatment allegations. However, the analysis suggests that the greater likelihood of subsequent allegations among members of the SEI group is largely attributable to subsequent births and accompanying SEI-related allegations. Thus, among open child welfare cases, an SEI allegation may predict subsequent prenatal drug use, but it does not predict other types of maltreatment allegations.

These results do not suggest that there are no risks associated with identified prenatal substance exposure. For one thing, as evidenced by subsequent SEI allegations, the findings indicate that identified prenatal substance exposure is associated with ongoing substance use. For a portion of these families, substance abuse continues despite CPS involvement. In addition, and importantly, the “comparison group” for the families with SEI allegations is comprised of families with other types of maltreatment allegations. We find that, aside from subsequent SEI allegations, the subsequent allegation risks for these two groups are similar, as are their ratings in a measure of parenting beliefs and attitudes.

Still, in clarifying the subsequent maltreatment risks associated with prior SEI allegations, these findings might offer guidance to policymakers and practitioners. These results suggest that concerns about SEI allegations might be balanced with concerns about other risks facing substance-exposed and nonexposed children. The results suggest that child welfare authorities might pursue the same family-centered interventions with families having SEI allegations that are pursued with families having other types of allegations. For example, instead of conditioning reunification upon a parent’s completing drug treatment and remaining drug-free—an endeavor which could easily surpass Adoption and Safe Families Act timeframes—authorities might consider reunification with monitoring after sobriety is attained and a parent successfully engages in out-patient treatment. Delaying reunification not only weakens parent-child bonds, but may also exacerbate, in unintended ways, substance use and other problems related to future births. In addition, because much of the subsequent allegation risk appears related to later births, service plans ought to offer parents with SEI allegations genuine opportunities to obtain family planning services.

Potential limitations

Some issues should be considered when interpreting the study findings. First, the SEI group status is based on identified substance use. It is not a precise indication of prenatal drug use, and it is not generally assigned for prenatal alcohol use. Perhaps sharper distinctions between the SEI and non-SEI groups would emerge if a more precise indicator of prenatal substance use were used. Then again, perhaps being identified as a prenatal substance user versus not being identified indicates a more meaningful distinction for assessing subsequent maltreatment risk than a precise distinction between substance users and nonusers. In any event, the primary purpose of this study was to better understand the risks associated with the SEI allegation. Second, the findings may reflect omitted variable bias. Certainly, the models do not include many factors that may be associated both with having an SEI allegation and the likelihood of subsequent maltreatment. For example, the higher birth rate among the SEI group is largely unexplained. Third, the discovery that respondents were more likely to have a return home goal than nonrespondents suggests that our respondent group may have made

more progress toward reunification than Cook County child welfare clients as a whole and, consequently, may be less likely to incur subsequent allegations. This possibility would have important implications if the study sought to assess the absolute maltreatment risk associated with SEI allegations rather than the relative risk associated with SEI versus other types of allegations. Given the study objectives, we would be most concerned about response bias in which SEI group respondents differed from SEI group nonrespondents. No such differences were detected. Moreover, the fact that this study used a probability sample and has the capacity to assess response bias provides it with an advantage over much of the existing research in this area.

Finally, one might hypothesize that having a child welfare case, in itself, increases the likelihood of receiving a subsequent maltreatment allegation because of added surveillance. On the other hand, one might hypothesize that having a child welfare case, in itself, decreases the likelihood of receiving a subsequent maltreatment allegation because of extra support services, controls, and monitoring. But the study was designed to assess the relative risk of subsequent maltreatment among parents having an open child welfare case, not the absolute maltreatment risk associated with SEI allegations. If we assume that the effect of having a child welfare case is likely to be similar for all cases, regardless of what types of allegations led to the case opening, then the present study is well designed to test the relative risk of subsequent maltreatment associated with SEI allegations compared to the risks associated with other types of allegations. If, however, the effect of having a child welfare case differs for parents with SEI allegations compared to parents with other types of allegations, the difference could have important implications for the study results. For example, if having an SEI allegation exposed parents to additional surveillance or additional risk aversion on the part of decision-makers, such differences could, in turn, affect the likelihood of receiving a subsequent allegation. Such possibilities should be explored in future research.

Conclusions

Three primary lessons emerge from this study. First, efforts to understand the child safety risks associated with SEI allegations should specify whether the “maltreatment” identified in subsequent allegations is SEI-related or not. If infant substance exposure is defined as maltreatment then justified as such because recipients of SEI allegations show an increased likelihood of subsequent incidents of maltreatment, we risk perpetuating a tautology if subsequent incidents tend to be incidents of infant substance exposure. Efforts to assess the risks associated with open child welfare cases should look beyond the status of having subsequent allegations to the types of subsequent allegations and the circumstances surrounding them. Second, we need to look more closely at other risk factors associated with SEI allegations and parental substance use. We often focus on SEI status or substance use, *per se*, when associated factors may be a more appropriate point of intervention. For example, in this study, living with another adult emerges as a potential protective factor against subsequent allegations. Finally, we need to look at the phenomenon of subsequent births among women involved with child protective services. This study suggests that, among parents with child welfare cases, a substantial portion of subsequent allegations are

related to subsequent births. We are left to wonder whether the association between subsequent allegations and new births indicates harm to newborn children or represents the risk aversion of CPS investigators when parents already involved with child protective services have a new child. All three-study lessons point to the need for better measures of the child safety threats associated with parental substance use. The study findings not only have implications for understanding the relationship between parental substance use and child maltreatment, but they highlight the need to more precisely describe subsequent allegations if they are to be used as indicators of child maltreatment.

Acknowledgments

The authors thank Mark Courtney, Anne E. Fortune, Bonnie E. Carlson, and Jill Doner Kagle for helpful comments.

Appendix A. Variable Definitions

-Living with another adult	A respondent is coded as living with another adult if she included persons over age 18 among the list of current members of her household.
-Poverty status	A respondent is coded as having a household income below poverty if the reported last month's income is below the federal poverty threshold for her household size.
-Public high rise	A respondent receives this classification if she stayed in a public housing high rise at the time of the survey. This variable is an indicator of place, rather than financing. Survey respondents staying in publicly-funded housing that was not in a high-rise complex would be coded no on this variable.
-High school education	A respondent is coded as having a high school education if she reported completing 12 grades of school or receiving a GED.
-Race/Ethnicity	The respondent classification of her own race and/or ethnicity.
-Parenting risk factors	A composite index including items from the Child Abuse Prevention Inventory (CAPI)(Milner, Gold, & Ayoub 1984), the Adult-Adolescent Parenting Inventory (AAPPI)(Bavolek, 1989), and the Michigan Screening Profile of Parenting (MSPP)(Schneider, 1982). A higher score indicates a greater degree of risk.
-authoritarianism;	
-unrealistic expectations;	
-coping difficulties.	

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Résumé

Objectif: Cette étude a pour but de (1) évaluer la relation entre l'usage avant la naissance de drogues identifiées et le risque d'allégations ultérieures de mauvais traitements dans des familles suivies par des services de protection de l'enfance; et (2) de comparer les types de risques concernant la sécurité

des enfants dont les parents ont fait l'objet d'allégations d'exposer leur jeune enfant aux drogues (SEI) avec les types de risques menaçant les enfants dont les parents ont fait l'objet d'autres allégations.

Méthode: Les données d'une enquête provenant d'un échantillon probabiliste de parents ont été reliées aux données administratives d'un Etat pour une période de 33 mois. Les modèles de la régression de Cox ont été utilisés pour évaluer le risque relatif d'allégations ultérieures associées concernant des parents pour l'enfant de qui un dossier d'assistance avait été ouvert après une allégation SEI (groupe SEI) comparativement avec des parents dont le dossier avait été ouvert pour d'autres types d'allégations.

Résultats: Le risque d'allégations ultérieures est plus grand chez les parents dans le groupe SEI. Toutefois l'augmentation du risque est limitée presque entièrement aux allégations ultérieures liées au SEI. Les parents du groupe SEI ne sont pas plus susceptibles d'encourir d'autres types d'allégations comme des mauvais traitements physiques ou un manque de supervision.

Conclusions: Un risque augmenté de mauvais traitements ultérieurs a été observé et justifie d'ouvrir un dossier de protection de l'enfance sur la base d'une seule allégation SEI. En regardant de près les types d'allégations ultérieures tout comme l'incidence des allégations ultérieures, cette recherche aide à clarifier les risques de mauvais traitements associés aux cas de SEI (exposition d'un jeune enfant aux drogues).

Resumen

Objetivo: El estudio tiene como objetivos (1) evaluar la relación entre el consumo de drogas durante el embarazo y el riesgo de acusaciones posteriores de maltrato entre familias implicadas en los servicios de protección infantil y (2) comparar los tipos de amenazas a la seguridad ocurridas en niños/as cuyos padres/madres fueron acusados de consumo de drogas durante el embarazo con las amenazas a la seguridad ocurridas en niños/as cuyos padres/madres fueron objeto de otros tipos de acusaciones.

Método: Los datos de una encuesta obtenidos de una muestra probabilística de padres/madres se unieron con los datos administrativos estatales a lo largo de un periodo de 33 meses. Se llevaron a cabo modelos de regresión de Cox para evaluar si existe un mayor riesgo relativo de acusaciones posteriores en padres/madres cuyo expediente de protección fue abierto tras una acusación de consumo de drogas durante el embarazo, que en padres/madres cuyo expediente se abrió tras otro tipo de acusaciones.

Resultados: La probabilidad de que se produzcan acusaciones posteriores de maltrato fue mayor en el grupo de padres/madres que habían consumido drogas durante el embarazo. Sin embargo, la mayor parte de estas acusaciones estaban relacionadas con la exposición del niño/a a las drogas. Los padres/madres de este grupo no eran más propensos que el resto a ser acusados de otros tipos de maltrato tales como maltrato físico o falta de supervisión.

Conclusiones: El hecho de que el consumo de drogas durante el embarazo esté asociado a un riesgo elevado de un maltrato posterior, ha sido utilizado como justificación para la apertura de un expediente de protección. Observando detalladamente tanto los tipos de acusaciones posteriores como la incidencia de dichas acusaciones, esta investigación ayuda a clarificar el riesgo de maltrato en casos de abuso de drogas durante el embarazo.

APPENDIX B.3



REVIEW ARTICLE

Etiology and prevention of stillbirth

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KEY WORDS

Stillbirth
Fetal death
Prevention
Risk factors

Objective: This is a systematic review of the literature on the causes of stillbirth and clinical opinion regarding strategies for its prevention.

Study design: We reviewed the causes of stillbirth by performing a Medline search limited to articles in English published in core clinical journals from January 1, 1995, to January 1, 2005. Articles before this date were included if they added historical information relevant to the topic. A total of 1445 articles obtained, 113 were the basis of this review and chosen based on the criterion that stillbirth or fetal death was central to the article.

Results: Fifteen risk factors for stillbirths were identified and the prevalence of these conditions and associated risks are presented. The most prevalent risk factors for stillbirth are prepregnancy obesity, socioeconomic factors, and advanced maternal age. Biologic markers associated with increased stillbirth risk are also reviewed, and strategies for its prevention identified.

Conclusion: Identification of risk factors for stillbirth assists the clinician in performing a risk assessment for each patient. Unexplained stillbirths and stillbirths related to growth restriction are the 2 categories of death that contribute the most to late fetal losses. Late pregnancy is associated with an increasing risk of stillbirth, and clinicians should have a low threshold to evaluate fetal growth. The value of antepartum testing is related to the underlying risk of stillbirth and, although the strategy of antepartum testing in patients with increased risk will decrease the risk of late fetal loss, it is of necessity associated with higher intervention rates.

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Methods

A Medline search was used with the MeSh terms “etiology,” “causality,” “pregnancy outcome,” “fetal death,” “stillbirth,” as was limited to human subjects, English articles with abstracts in core clinical journals from January 1, 1995, to January 1, 2005, identified 1445 papers. Articles were chosen if they had sufficient statistical power to address the risk factor of interest and

were performed in developed countries. A total of 113 were identified with this search and an additional 9 were cited for their historical information.

Scope of the problem

Although stillbirth is infrequent, it occurs 10 times more often than sudden infant death.¹ In the United States, stillbirth accounts for a large proportion of all perinatal losses, although its causes remain incompletely understood. In developing nations, preterm births and stillbirths are grossly underreported, thus making international comparisons difficult. Even in developed nations, there is considerable variability in the threshold

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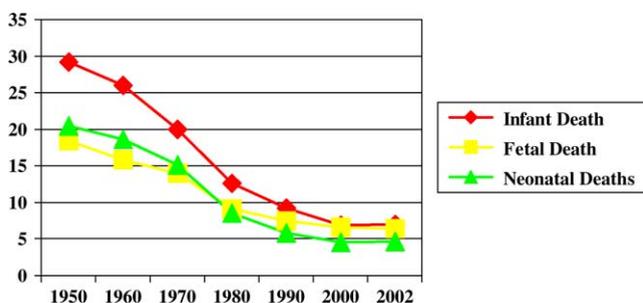


Figure 1 Infant death rates, fetal death rates, and neonatal death rates.⁶

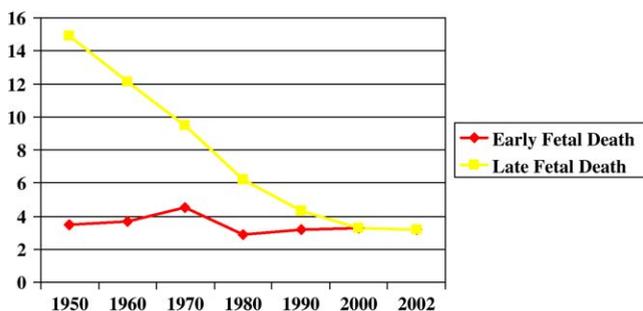


Figure 2 Early (20-28 weeks of gestation) and late (29+ weeks of gestation) fetal deaths.⁶

for reporting stillbirth. These include differences in either the length of gestation or the birth weight.²⁻⁴ The World Health Organization (WHO) classification of stillbirth is defined as fetal loss in pregnancies beyond 20 weeks of gestation, or, if the gestational age is not known, a birth weight of 500 g or more, which corresponds to 22 weeks of gestation in a normally developing fetus.⁵

In the United States during 2002, there were approximately 26,000 stillbirths, a rate of 6.4/1,000 total births. There also were about 28,000 infant deaths (equaling a rate of 7.0/1,000 live births), and 19,000 neonatal deaths (4.7/1,000 live births).⁶ Black women have more than twice the rate of stillbirth of white women and, although some of this increased risk can be attributed both to access to, and quality of, medical care, other factors probably play a role as well.⁶⁻⁸ Within the United States, there is no national program of review for these losses. Death certificates are filled out by the delivering clinician typically before autopsy and other data relevant to the stillbirth evaluation are available. Also, there is no international consensus on the classification of perinatal loss.

Since the 1950s, there has been a decline in rate of stillbirth, but it has not declined to the same extent as the neonatal death rate (Figure 1). Indeed, recent data from the United Kingdom show that there has been a slight increase in the stillbirth rate, related perhaps to the growing number of pregnancies in older women, as well as to increased numbers of multiple pregnancies,

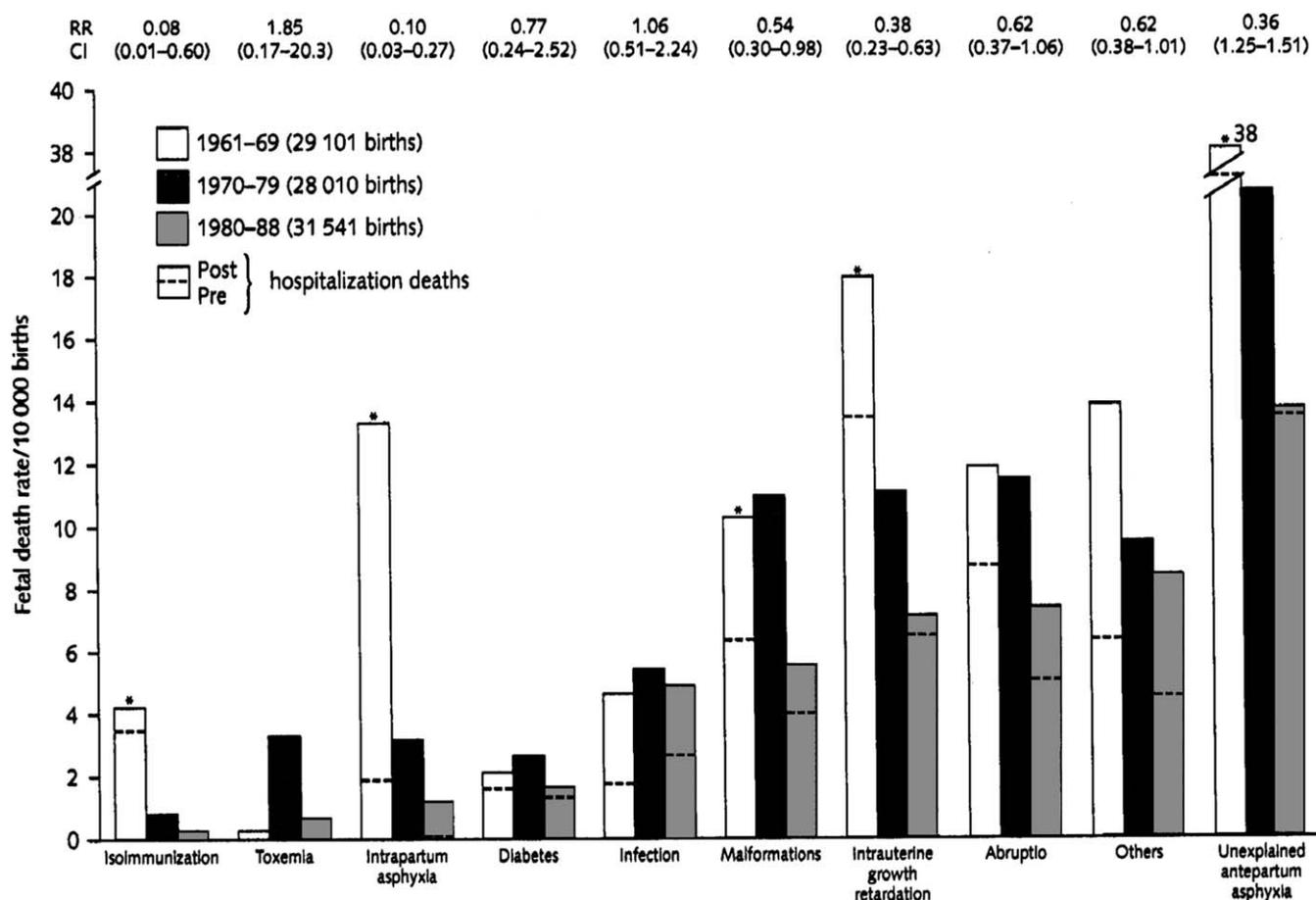
due in large part to an increase in assisted reproduction techniques.⁹

In large databases, fetal death is stratified by gestational age into early losses (ie, 20-28 weeks) and late fetal death (29 weeks or more; Figure 2).⁶ Presumably, this approach was used initially to divide those pregnancies that might be salvageable (ie, late losses), from very early term losses, the majority of which would not be salvageable. Recent advances in neonatal care make this distinction somewhat arbitrary, but the causes of fetal death do vary according to gestational age.¹⁰ The prevention of early fetal losses, in which a large proportion is related to infection, has been the most difficult to impact to date.¹⁰ Ideally, of course, stillbirths deserve the same systematic evaluation as sudden infant deaths. If an obvious cause of death is not found, then by exclusion the stillbirth is usually considered “unexplained.” Only when fetal deaths are reported according to the specific causes of fetal demise can appropriate strategies be designed to reduce these losses.

Causes of stillbirth

One of the largest and most comprehensive analyses of the causes of fetal death has been compiled and reported with the use of a Canadian database maintained at McGill University.¹⁰ This analysis evaluated 709 stillbirths among 88,651 births with a 97% autopsy rate. This study was able to track changes in the specific causes of stillbirth over 3 decades (Figure 3). Since the 1960s, when the database was created, the greatest reductions in stillbirth occurred when strategies were developed to intervene in specific causes of fetal demise. Since the introduction of Rh immune prophylaxis, for example, there has been a 95% reduction in stillbirths because of Rh isoimmunization. Stillbirths during labor (intrapartum asphyxia) also decreased by 95% after the introduction of intrapartum monitoring (Figure 3). Currently, these causes of stillbirth account for less than 1 fetal death per 10,000 births. Higher rates of intrapartum asphyxia in fetuses weighing more than 2.5 kg suggests deficiencies in obstetric quality of care.^{11,12} Interestingly, in the McGill experience throughout the 30-year study period, there was a low rate of stillbirths among women who had preeclampsia or diabetes (ie, less than 2/10,000), due in large part to aggressive management of these conditions.

Among other causes of stillbirth, the small-for-gestational-age (SGA) (ie, <2.4th percentile) fetus had an incidence of stillbirth of 46.8 per 1000, whereas the appropriate-for-gestational-age fetus had a rate of 4.0 per 1000 (odds ratio [OR] = 11.8; 95% CI 8.1-17.1).¹⁰ The identification and appropriate management of the growth-restricted fetus remains a significant opportunity for stillbirth prevention. Indeed, although 25% of



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Figure 3 *P < .5 for 1961-1969 compared with 1980-1988 rates. Reprinted from Fretts RC, Boyd ME, Usher RH, Usher HA. The changing pattern of fetal death 1961-1986. *Obstet Gynecol* 1992;79:37.

stillbirths that occurred in women carrying a SGA fetus had known risk factors such as maternal hypertension, most pregnancies that ended in stillbirth in nonanomalous growth-restricted fetuses had not been identified as having a problem with fetal growth.

Between 24 and 27 weeks of gestation, the most common causes of stillbirth were related to infection (19%), abruption (14%), or significant lethal anomalies (14%), and 21% were "unexplained." As noted previously, stillbirths related to infection occur most frequently in fetuses weighing less than 1000 g. The stillbirth rates due to infection, like that of preterm birth, have been quite resistant to change despite the availability and wide use of antibiotics.¹⁰ The risk of a fetal death due to abruption has actually decreased modestly over several decades, although it also remains a significant cause of perinatal morbidity and mortality.

Unexplained stillbirth

After 28 weeks of gestation, the most common category of a stillbirth is that of "unexplained," followed by

deaths related to fetal malnutrition, and abruption (Table I.) The proportion of fetal deaths that have no known cause after complete pathologic evaluation increases as gestational age advances.¹⁰ A fetal death that is unexplained by fetal, placental, maternal, or obstetric factors is the most frequent type of fetal demise, representing between 25% and 60% of all fetal deaths.¹³⁻¹⁷ It is also one of obstetrics' most distressing outcomes, because preventative effective strategies have not yet been identified, in large part because unexplained fetal demise is, by definition, a diagnosis of exclusion and depends on the rigorosity of the stillbirth assessment.¹⁵

In the first comprehensive analysis of a single large database, Yudkin et al¹³ evaluated the timing of fetal demise in 40,635 deliveries in Oxford, England, from 1978 to 1985, in all gestations of 28 weeks or greater. In their examination of 63 unexplained fetal deaths (ie, 43% of all fetal deaths) in this cohort, they found that the risk of unexplained fetal demise more than doubled in pregnancies of greater than 40 weeks of gestation. In the largest study of unexplained stillbirth to date, Huang

Table I Most frequent types of stillbirth according to gestational age

24-27 weeks	28-36 weeks	37+ weeks
Infection (19%)	Unexplained (26%)	Unexplained (40%)
Abruptio placenta (14%)	Fetal malnutrition (19%)	Fetal malnutrition (14%)
Anomalies (14%)	Abruptio placenta (18%)	Abruptio placenta (12%)

Fetal malnutrition was defined as an otherwise unexplained fetus weighing less than the 2.4%, anomalies were only considered a cause of death if they were potentially lethal. The unexplained stillbirth was diagnosed when other causes of death were eliminated with the use of a comprehensive evaluation that included autopsy in 97% of cases. Adapted from Fretts et al¹⁰ and Fretts and Usher.²⁰

et al¹⁴ described a number of apparent risk factors for unexplained stillbirth in a cohort of women from 1978 to 1996. These risk factors included advanced maternal age (ie, 40 years or older, OR = 3.7, 95% CI 1.3-10.6), low educational attainment (OR = 2.5, 95% CI 1.1-5.5), alterations in fetal growth (ie, between the 2.4-10.0 percentile OR = 2.8, 95% CI 1.5-5.2), infants larger than the 87th percentile (OR = 2.4, 95% CI 1.3-4.4), primiparity (OR = 1.9, 95% CI 1.1-3.1), parity 3 or greater (OR = 2.4, 95% CI 1.0-5.7), and the presence of cord loops (OR = 1.7, 95% CI 1.0-2.97).

Froen et al,¹⁵ using a large data set from Norway, reported findings similar to those of Huang et al,¹⁴ although with slightly higher risk estimates for advanced maternal age (ie, 35 years or older, OR = 5.1, 95% CI 1.3-19.7), low educational attainment (OR = 3.7, 95% CI 1.5-9.8), prepregnancy obesity, and a body mass index (BMI) of greater than 25 (OR = 2.4, 95% CI 1.1-5.3). Smoking is also associated with the unexplained growth-restricted stillbirth,^{18,19} but appeared not to be associated with stillbirths among appropriate-for-gestational age fetuses.¹⁴ With respect to the timing of unexplained fetal deaths, these studies and others have consistently shown increased losses late in pregnancy, with the rate rising significantly after 37 to 39 weeks of gestation.¹³⁻¹⁵ In addition, Fretts and Usher,¹⁰ using the McGill Obstetrical Neonatal Database, found that this increase was more pronounced in older women (Figure 4).²⁰

Common risk factors for stillbirth

Race and socioeconomic factors

Nationally, black women consistently have had approximately twice the risk of stillbirth of white women, although typically these rates are not adjusted for differences in obstetric and socioeconomic factors. In Massachusetts in 2002, for example, the household income for black families was significantly lower than

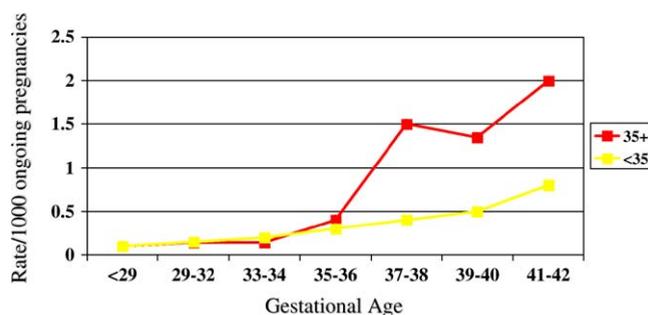


Figure 4 Reprinted with permission. Fretts RC, Usher RH. Fetal death in women in the older reproductive age group. *Contemporary Reviews in Obstetrics and Gynecology* 1997;9:173-9.

that of white families, and black women are less likely to receive adequate prenatal care, less likely to have completed a high school education, and more likely to have received publicly funded prenatal care.²¹ Black mothers who have had a stillbirth were also less likely than white mothers to have sought obstetric care in the first 3 months of pregnancy.²²

Even when evaluating only women who had received adequate prenatal care, Vintzileos et al⁷ found that, in the United States, black women still had twice the risk of stillbirth when compared with white women. The excess of stillbirth was attributed to higher rates of diabetes, hypertension, placental abruption, and premature rupture of membranes.⁷ Given that black women are a relatively high-risk group for stillbirth, increasing access to prenatal care, and the identification and management of those medical and socioeconomic risk factors that contribute to stillbirth obviously will be important.

Advanced maternal age

Advanced maternal age remains an independent risk factor for stillbirth, even after accounting for medical conditions that are more likely to occur in older women, such as multiple gestation, hypertension, diabetes, previous abortion, and abruptio placenta, all of which are associated with higher rates of stillbirth. Older women are also more likely to have preterm births, and growth-restricted infants.²⁶⁻²⁹ Historically, women 35 years or older also have had an increased risk of stillbirth related anomalies.²⁰ Nevertheless, with the introduction of prenatal diagnostic testing and the availability of elective abortion, where these services are available, there has been a significant reduction in this cause of perinatal demise.³⁰ Indeed, longitudinal databases that track anomalies show a transfer of fetal deaths from after 20 weeks to elective terminations before 20 weeks.³¹ After the introduction of routine prenatal diagnosis in the McGill population, for example, women 35 years or older had fewer stillbirths related to lethal anomalies, declining to that observed in younger counterparts. In recent years in this population, the only type of stillbirth

that was statistically more common in older women was the “unexplained” category of fetal demise, and these were likely to occur late in pregnancy.²⁰

Obesity

The prevalence of maternal obesity is increasing steadily and is associated with an increased risk of fetal macrosomia and perinatal mortality.³²⁻³⁶ The reasons for this association are speculated to be due to behavioral, socioeconomic, as well as obstetric factors. Obese women are more likely to smoke and to have pregnancies complicated by gestational diabetes and preeclampsia.³⁷ However, even when controlling for these factors, an elevated BMI remains a significant risk factor for stillbirth,^{33,36} and the association appears to increase as the gestation advances. A number of mechanisms for the increased risk seen in obese women have been postulated. Thinner women may be better able to perceive decreased fetal movements. Maternal obesity is also associated with hyperlipidemia,³⁸ which may contribute to increased endothelial dysfunction, platelet aggregation, as well as to clinically significant atherosclerosis. Sleep studies of pregnant women have shown that obese women spend more time snoring (32% vs 1%; $P < .001$), have more apnea-hypoxia events (1.7 vs 0.2/h; $P < .05$), and have more episodes of oxygen desaturation (5.3 vs 0.3/h; $P < .005$) than nonobese pregnant women.³⁹ Snoring has also been associated with pregnancy-induced hypertension and fetal growth restriction.⁴⁰ Indeed, in addition to advanced maternal age and low socioeconomic status, as discussed previously, the most prevalent risk factor for stillbirth is prepregnancy obesity.

Thrombophilias

Our understanding of the relationship between inherited abnormalities of blood clotting and stillbirth is seriously deficient, in that there have been no large population-based studies that have evaluated this association.⁴¹⁻⁴⁴ The relationship between late fetal death and thrombophilia is more consistent than with early fetal losses,⁴⁵ although the odds ratio ranges from as low as 1.8 to estimates as high as 12.^{46,47-50} A meta-analysis of smaller studies suggested that the presence of thrombophilias does increase the risk of stillbirth (OR = 3.6; 95% CI 1.4-9.4), with the analysis of specific defects limited by power.⁴¹ Martinelli et al⁵¹ found the prevalence of mutations either in factor V or prothrombin to be 16% in those pregnancies that ended in an unexplained loss, compared with 6% of normal pregnancies,⁵¹ although the value of placental disease to discriminate unexplained losses with and without a diagnosis of thrombophilia is in question. The authors found that 24% of the placentas were normal, whereas the remaining 76% showed intravascular thrombi, decidual vasculopathy, and ischemic necrosis with villous infarctions.

The placentas were abnormal in 7 of 9 (78%) women with a mutation and in 40 of 53 (75%) stillbirths without a mutation so that the presence of a known mutation did not correlate with a specific placental histologic or biochemical abnormality. In another small study of 22 women with at least 1 unexplained loss, 4 of 9 placentas showed extensive infarcts in women who had documented thrombophilia, whereas none of the 8 without thrombophilia exhibited similar pathologic findings.⁴⁷

Systemic lupus erythematosus

Systemic lupus erythematosus (SLE) complicates less than 1% of pregnancies but the risk of stillbirth in this population is disproportionately high, especially in women with preexisting renal disease.⁵² Hypertension, preeclampsia, and fetal growth restriction are common in these patients.⁵³⁻⁵⁵ Even when pregnancy is conceived during a relatively quiescent period in terms of disease activity, stillbirth can complicate up to 3% to 8% of pregnancies.⁵³⁻⁵⁵ The presence of a lupus anticoagulant has been reported to significantly increase the risk of a fetal loss after 20 weeks of gestation. The optimum management of patients with SLE is uncertain, but the use of heparin and aspirin was associated with an improved outcome in 1 small series.⁴⁵

Medical risk factors

Hypertension and diabetes are 2 of the most common medical conditions to complicate pregnancy (7%-10% and 3%-5%, respectively).^{23,52,56-59} Historically, both of these conditions have been shown to be responsible for a significant proportion of fetal deaths. However, optimal management, including counseling, preconceptional care, and close medical management of these conditions, has been shown to reduce the risk for perinatal death to a level only marginally elevated over that of the general population.⁵⁶ Management of patients remains a challenge, however, because of the increased risks of abruptio placenta, of intrauterine growth restriction, and of superimposed preeclampsia, which often necessitates early delivery.^{57,58,60} Other important medical conditions associated with an increased risk of stillbirth are listed in Table II.⁵²

Infection and immunologic exposure

A significant proportion of perinatal morbidity and mortality is related to infection, which often leads to delivery of a premature liveborn or a stillborn infant. Despite the adoption of a strategy to reduce the risk of perinatal infection caused by group B streptococci, there has been little change in the risk of fetal death caused by infection because most of these deaths occur preterm.^{10,61} Although there are some pathogens that are probable causes of stillbirth, such as parvovirus 19,

Table II Estimates of maternal risk factors and risk of stillbirth

Condition	Prevalence	Estimated rate of stillbirth	OR*
All pregnancies		6.4/1000	1.0
Low-risk pregnancies	80%	4.0-5.5/1000	0.86
Hypertensive disorder			
Chronic hypertension	6%-10%	6-25/1000	1.5-2.7
Pregnancy-induced hypertension			
Mild	5.8%-7.7%	9-51/1000	1.2-4.0
Severe	1.3%-3.3%	12-29/1000	1.8-4.4
Diabetes			
Treated with diet	2.5%-5%	6-10/1000	1.2-2.2
Treated with insulin	2.4%	6-35/1000	1.7-7.0
SLE	< 1%	40-150/1000	6-20
Renal disease	< 1%	15-200/1000	2.2-30
Thyroid disorders	0.2%-2%	12-20/1000	2.2-3.0
Thrombophilia	1%-5%	18-40/1000	2.8-5.0
Cholestasis of pregnancy	< 0.1%	12-30/1000	1.8-4.4
Smoking > 10 cigarettes	10%-20%	10-15/1000	1.7-3.0
Obesity (prepregnancy)			
BMI 25-29.9 kg/m ²	21%	12-15/1000	1.9-2.7
BMI > 30	20%	13-18/1000	2.1-2.8
Low educational attainment (< 12 y vs. 12 y+)	30%	10-13/1000	1.6-2.0
Previous growth-restricted infant (< 10%)	6.7%	12-30/1000	2-4.6
Previous stillbirth	0.5%-1.0%	9-20/1000	1.4-3.2
Multiple gestation	2%-3.5%		
Twins	2.7%	12/1000	1.0-2.8
Triplets	0.14%	34/1000	2.8-3.7
Advanced maternal age (reference < 35 y)			
35-39 y	15%-18%	11-14/1000	1.8-2.2
40y +	2%	11-21/1000	1.8-3.3
Black women compared with white women	15%	12-14/1000	2.0-2.2

* OR of the factor present compared to the risk factor absent. Some estimates of medical conditions and stillbirth risk from Simpson.⁵² Other risk estimates from references 24,25,29,33,34,35,38,55,58,68.

cytomegalovirus, toxoplasmosis, and listeria, there are others that may be associated with an increase in risk, but the evidence for which remains inconclusive. For example, colonization with *Ureaplasma urealyticum*, *Mycoplasma hominis*, and group B streptococci has all been associated with an increased risk of stillbirth,⁶¹ although colonization with these pathogens is also common among healthy women.

In recent reports, Refuerzo et al⁶² and Blackwell et al⁶³ found that women who had had an unexplained stillbirth, without any evidence of obvious infection, had a higher number of “memory T cells” (CD45RO) than “naive T cells” (CD45RA) when compared with live-born controls. Although this finding suggests that, despite the absence of any overt evidence of clinically significant infection, these women had had prior exposure to infectious agents. Froen et al⁶⁴ found, in an epidemiologic study of unexplained stillbirths, that bacteruria or symptomatic urinary tract infections during pregnancy were associated with a *reduced* risk of fetal death, a finding not fully explained by treatment with antibiotics. The role of the immune system has lately become a subject of considerable interest in

perinatal birth injury. There is evidence that elevated inflammatory processes are associated with an increase in the risk of adverse outcomes in the premature neonate.⁶⁵ Infected infants, both premature and term, were shown to exhibit a significant increase in interleukin 6 production, with C-reactive protein (CRP) increasing rapidly at the onset of infection and remaining elevated until the infection was cleared.⁶⁶ Animal data suggest that the combination of subclinical infection and a fetal inflammatory response can both cause abnormalities of gas exchange that result in fetal hypoxia and decreased survival.⁶⁷

Infertility

Because women who choose to delay their childbearing are also more likely to have a history of infertility and to conceive with the aid of reproductive technologies, it is important to evaluate the effect of infertility and infertility treatment on the risk of fetal death. Patients treated with advanced reproductive technologies experience excess perinatal mortality.⁶⁸⁻⁷⁰ Although the frequency of multiple gestations is responsible for a

significant portion of this excess mortality, it also appears that women who undergo either in vitro fertilization (IVF) or ovarian stimulation and have a singleton gestation, also have a statistically increased risk of prematurity, low birth weight, and SGA fetuses.⁷¹⁻⁷⁴ There have been no studies that have evaluated whether infertility itself is associated with an increase in unexplained fetal death. Nevertheless, many physicians who care for infertile patients perceive these pregnancies to be at “high risk” for adverse maternal and fetal outcomes.

Multiple gestations

Over the past 2 decades, the rate of pregnancies with twins has more than doubled, the rate of triplets has increased 6-fold, and the number of quadruplets has increased by 12-fold.⁶⁸⁻⁷⁰ With this increase in the number of multiple gestations, there has been a measurable increase in prenatal mortality and morbidity in industrialized countries. The main reason for this increase is the use of reproductive technologies and the associated increase in maternal age.^{75,76} It has been estimated that a strategy of lowering the transfer rate to 2 embryos during IVF could reduce the perinatal mortality rate by 45% in the case of limiting a triplet to twins, or 74% when limiting the quintuplet pregnancies to twins.⁷⁰ The optimal duration of an otherwise uncomplicated pregnancy is shorter for multiple gestations. Kahn et al⁷⁷ found, for example, that it was safer for a twin pregnancy to be delivered than undelivered at 39 weeks, and for triplets who remain undelivered at 36 weeks, an elective delivery at this time minimized adverse fetal outcomes.

Biologic markers of increased risk of stillbirth

Hemoconcentration

Froen et al⁶⁴ from Norway have demonstrated that women with hemoconcentration, defined as the lowest hemoglobin measured during pregnancy greater than 13.0 g/dL, is associated with a 9-fold increase in the risk of unexplained fetal death. Stephansson et al,⁷⁸ using a Swedish database, found that both an initial elevated hemoglobin and the failure of significant hemodilution over the course of the pregnancy, increased the risk of stillbirth by 2-fold, even when women with preeclampsia and eclampsia were excluded.⁷⁸ Plasma volume expansion and lowered hemoglobin concentration are normal physiologic responses to pregnancy. Plasma volume expansion appears to be important for fetal growth and failure of sufficient hemodilution is associated with an increased risk of stillbirth, even if the fetus is not growth restricted. Stephansson et al⁷⁸ suggest that those

patients with high initial hemoglobin concentrations should be considered at high risk for adverse obstetric outcomes.

Amniotic and serum markers

Pregnancy-associated plasma protein A (PAPP-A) is a maternal serum marker used in combination with other tests to detect an increased risk of chromosomal abnormalities; it also appears to be of help in detecting, in the second trimester, pregnancies that might be at an increased risk for an adverse outcome. Smith et al⁷⁹ assessed adverse perinatal outcomes among the 8839 patients recruited into a multicenter study. Patients with serum markers in the lowest fifth percentile were found to have an increased risk of premature delivery (OR = 2.9, 95% CI 1.6-5.5), preeclampsia (OR = 2.3, 95% CI 1.6-3.3), and stillbirth (OR = 3.6, 95% CI 1.2-11.0).⁷⁹ In growth-restricted fetuses, the maternal serum alpha-fetoprotein was not particularly helpful in identifying pregnancies that would later go on to an adverse perinatal outcome, but a combination of factors, an elevated HCG and a low unconjugated estriol, was 67% sensitive and 70% specific in predicting a composite “adverse perinatal outcome” metric, which included perinatal death and neonatal morbidity.⁸⁰

Amniotic fluid abnormalities also have been found to be associated with fetal demise. Florio et al⁸¹ performed a case control study of women undergoing amniocentesis for routine reasons, in which 12 patients with a stillbirth all had elevated levels of S100B (a marker of brain damage in both adult and pediatric patients, but which is not specific for cerebral damage),⁸² but the 746 healthy controls did not. At least in this dataset, this test was perfect in predicting fetal death, a very rare finding in medicine, although these data will need to be replicated.⁸¹ The mechanisms linking most abnormal maternal serum and amniotic markers with adverse fetal outcomes are not known, but further study is required before recommendations for specific clinical applications can be considered.

Prevention strategies

The data available for cost-effective stillbirth prevention are limited. The remaining aspect of this review represents the author’s opinion based on the limited data available. In the absence of a prior obstetric history, the patient’s risk for stillbirth is related to her underlying health and lifestyle. Globally, one of the largest modifiable risk factors is smoking, as it is obviously tied to the pathophysiology of many diseases. Additional medical risk factors, as discussed previously, significantly impact both maternal and child health as well, and appropriate medical care for these conditions and preconception counseling can have a significant impact

on outcome. The provider should perform a risk assessment for each individual patient and give realistic estimates of anticipated obstetric outcomes. Screening for hypertension and diabetes are essential to prevent poor pregnancy outcomes, but a number of other factors should be included in any risk assessment, including advanced maternal age, prepregnancy obesity, infertility, low educational attainment as a marker of lower socioeconomic status, and black race.^{7,8,25,33} Although the black race may be a proxy for socioeconomic factors, it is helpful to remember that black women 35 years or older have a risk of stillbirth 4 to 5 times higher than the national average and therefore deserve the same vigilance afforded to other groups at high risk for stillbirth.⁶

A moderate proportion of stillbirths related to congenital anomalies could be reduced with preconceptual counseling and testing, adequate prenatal care, and prenatal diagnostic testing, with elective terminations for affected pregnancies.³⁰ During pregnancy, patients with medical conditions need to be closely monitored to optimize their treatment and fitness for pregnancy and ensure fetal well-being.

In terms of reducing potentially preventable stillbirths, the Confidential Inquiry into Stillbirths and Infant Death (CISID) of Northern Ireland found that the failure to adequately diagnose and manage fetal growth restriction was the most common error, followed by failure to recognize additional maternal medical risk factors.⁸³ Given that deaths of intrauterine growth-restricted fetuses represent 1 of the most common types of stillbirths,^{84,85} a significant opportunity remains to improve outcomes. Assessment of fetal growth by ultrasound should be considered in at-risk patients. A customized growth chart more readily identifies the growth-restricted fetus, and reduces "false alarms" in the constitutionally small fetus.⁸⁶ Ideally, serial ultrasound reports should be reported together so that the history of intrauterine growth over time can be more readily appreciated. The threshold to perform an ultrasound in the obese patient should be low because fetal growth is often difficult to estimate clinically.

In women who have had a previous pregnancy, a previous preterm delivery, previous obstetric complication, delivery of a growth-restricted fetus, or a stillborn fetus, these events significantly increase their risk for adverse events in future pregnancies.⁸⁷⁻⁸⁹ There is some evidence, for example, that a previous cesarean section at term might reduce placental function and therefore increase the risk of a late antepartum unexplained stillbirth.⁹⁰ Nevertheless, this association should be confirmed by other groups before it is considered an important risk factor.

Given all of the potential factors that influence the risk of stillbirth, it would be helpful to have an interactive model that would estimate the risk of a fetal

demise in a manner similar to that used by physicians who care for patients with cardiovascular risk factors, who have a wealth of information to estimate the risk of myocardial infarction and death. A risk analysis should guide management policies and provide an evidenced-based approach to alter the threshold at which antepartum testing and early delivery is considered. Until such evidence-based guidelines exist, the obstetric care provider must decide on the appropriate type of vigilance, and decide when expectant care increases the risk to the ongoing pregnancy to a degree that warrants intervention for delivery.^{91,92}

Fortunately, for the majority of obstetric patients who are low risk, the incidence of a late stillbirth is a relatively low (1-2/1000).⁹³ Still, there is a role for vigilance in these pregnancies. In a reanalysis of the results of a fetal movement counting study initially published by Grant et al,⁹⁴ Froen⁹⁵ has appropriately reignited the interest in fetal kick counting. Even low-risk pregnancies with decreased fetal movement are known to have a higher risk of fetal distress in labor, for being growth restricted, and for having an increased frequency of stillbirth.

The risk of stillbirth in late pregnancies has been appreciated by many authors, as discussed previously.⁹⁶⁻¹⁰¹ Antepartum surveillance with judicious delivery of fetuses with poor fetal testing has been shown to improve outcomes in pregnancies with growth-restricted fetuses.¹⁰² Antepartum testing is also widely used in patients perceived to be at increased risk for fetal death, with the use of the testing related to the underlying risk of stillbirth.¹⁰² Randomized control trials of expectant versus induction of the postdates pregnancy are not large enough to detect a difference in the perinatal mortality.¹⁰³ However, in an analysis of the effect of labor induction rates in the 41st week, Sue et al¹⁰⁴ found that in Canada between 1980 and 1995 there was a marked decrease in the number of pregnancies at 41 or more weeks of gestation. The authors correlated the increase in the number of inductions after 41 weeks to a lowering of the stillbirth rate.¹⁰⁴ Fretts et al,⁹³ using the McGill Obstetrical Neonatal Database to obtain risk estimates, performed a decision-analysis of the risks and benefits of antepartum testing late in pregnancy for women 35 years or older. This decision analysis considered only late unexplained stillbirth, but this covers the majority of late stillbirths.⁹³ For the neonate, there is no measurable long-term adverse effect of being born at 36 weeks of gestation or later, so the analysis was begun starting during the 37th week. The major risk of antepartum testing after 36 weeks is induction of labor and its associated downstream effects, such as a potential for an increase in the cesarean delivery rate,¹⁰⁵ and therefore a potential increase the maternal mortality rate. For multiparous patients, induction carries a lower risk, and although induction does probably increase the risk of cesarean delivery, it does so only

Table III Unexplained stillbirth risks and outcomes of weekly antepartum testing initiated at the 37th week of gestation

Outcome*	OR for unexplained stillbirth				
	1.0	2.0	3.0	4.0	5.0
Fetal deaths per 1000 with antepartum testing	0.4	0.8	1.2	1.5	1.9
Fetal deaths averted [†]	1.2	2.4	3.5	4.7	5.9
Tests per pregnancy	3.4	3.4	3.3	3.3	3.3
Tests per fetal death averted	2862	1418	950	711	569
Inductions per fetal death averted	233	116	78	58	47
Cesarean deliveries per fetal death averted	44	22	15	11	9

Assuming base-case test characteristics (70% sensitivity, 90% specificity).

* Outcomes from week 37 of gestation through week 41.

[†] Unexplained fetal deaths averted per 1000 pregnancies compared to no testing.⁹³

marginally.¹⁰⁶ In the initial study by Fretts et al⁹³ on the risks and benefits of antepartum testing late in pregnancy for older women, they constructed a sensitivity analysis that applies to any condition associated with an increased risk of late stillbirth.⁹³ Three strategies were compared: no testing, testing after the 36th week with induction for a positive test, and no testing with induction at 41 weeks. The number of fetal deaths averted and the number of tests, inductions, and additional cesarean deliveries per fetal death averted were calculated assuming antepartum testing to be 70% sensitive and 90% specific. The results for OR 1.0 to 5.0 are presented in **Table III**.

Although a strategy of antepartum testing is predicted to be most successful in reducing the number of unexplained stillbirths, it was also associated with the highest induction rate. For nulliparous women of advanced maternal age, predicted to have an OR of 3.3 over younger women, the number of additional cesarean deliveries performed for unsuccessful inductions was only 14 per fetal death averted. The model also estimated that it would take approximately 863 antepartum tests and 71 additional inductions to prevent 1 unexplained stillbirth. Nevertheless, a strategy of liberal antepartum testing, to identify at-risk pregnancies will also reduce the number of patients undelivered at each gestational age starting at the time that testing is initiated, thereby further reducing the number of pregnancies still at risk of a stillbirth.

Management of stillbirth

The diagnosis of a singleton stillbirth must be confirmed with an ultrasound examination of the fetal heart. Most hospitals have instituted a program to help bereaved parents cope with their loss and follow good practice guidelines, which include the opportunity to see and hold their infant and obtain tokens of remembrance.¹⁰⁷ A worksheet for both parents and providers help to streamline the management of these losses and can facilitate the optimal investigation for determining the cause of death. Delayed delivery after 24 hours of the

diagnosis has been associated with an increased risk of anxiety years after the loss, when compared with women whose labors were induced within 6 hours.¹⁰⁸ The expectant management of a stillbirth therefore should be discouraged, in addition to the fact that delayed delivery is also associated with increased maternal risks of consumptive coagulopathy.^{109,110} The availability of prostaglandins, in particular misoprostol, has made induction of stillbirth safer and more efficient in women without a previous cesarean delivery. For now, oxytocin will remain the main method of induction for women with a previous cesarean delivery.

After delivery, the parents and other family members should have the opportunity to spend as much time as needed with the deceased infant. Even in the scenario of obvious maceration of the infant, after initial anxiety, parents often find something to connect them to the infant. A recent study has questioned whether holding a stillborn child might increase the risk of later anxiety,¹¹¹ this finding has not been duplicated to date.

One important aspect of a woman's care after a stillbirth is an appropriate and comprehensive stillbirth assessment. It is unfortunate that the United States has 1 of the lowest rates of obtaining a comprehensive stillbirth assessment when compared with other developed countries. This may be in part due to an increased level of anxiety over litigation in the United States, but it may also reflect the absence of a nationally coordinated program to evaluate these deaths. Notwithstanding, there are centers within the United States that can serve as role models for a comprehensive approach to stillbirth such those at the University of Southern California and the Wisconsin Stillbirth Service Program.^{112,113} Incerpi et al^{113,114} have demonstrated that, within the context of developing a cost-effective stillbirth assessment program, the single most important test to determine the cause of a stillbirth is the autopsy, followed by an evaluation of the placenta. For some parents, a limited fetal evaluation will be more acceptable than a complete autopsy, and this option should be explored if a complete autopsy is not acceptable.^{115,116} An external

physical examination and radiologic testing performed by the perinatal pathologist, with or without sampling fetal tissues in situ, can provide significant information. Although an autopsy is optimal, a postmortem magnetic resonance image (MRI) can provide useful additional information, although typically MRI staff are not used to receiving these requests.¹¹⁷

A genetic analysis of chromosomes will reveal abnormalities in between 5% and 10% of stillbirths.¹¹³ After a stillbirth, the highest yield for obtaining fluid for cytogenetic analysis will be at the time of amniocentesis at the time of the diagnosis of the stillbirth, but this has not been the usual practice at most centers of care within the United States. If amniotic fluid is unavailable, a sample of fetal blood, skin, or fascia lata will be best sources of tissue for culture. The use of a cytogenetic evaluation decreases with the duration of time that the infant has been dead, so reserving placental tissue for fluorescence in situ hybridization (FISH) in a buffered saline solution is an alternative method of determining whether the infant had a common chromosomal abnormality.^{118,119}

With the use of a protocol of autopsy, evaluation of the cord/placenta and membranes, and laboratory tests of fasting glucose, a Kleihauer-Betke test, urine toxicology and hemoglobin A_{1c} in selected cases, and a thrombophilia workup in normally formed infants, Incerpi et al¹¹³ were able to attribute a primary cause of death in 72% of cases of stillbirth, leaving only 28% as "unexplained." Notably absent in their protocol was the recommendation of obtaining TORCH titers, (ie, cytomegalovirus, toxoplasmosis, herpes simplex virus, and rubella) because these titers, in and of themselves, almost never aid in the diagnosis of a congenital infection in the absence of autopsy and placental findings of infection. Incerpi et al¹²⁰ found no significant association between antinuclear antibodies and stillbirth in the evaluation of 286 unexplained stillbirths. Parvovirus 19 is most commonly associated with a fetal death in the setting of nonimmune hydrops, but parvovirus 19 DNA can also be found in the placenta and fetus even in the nonhydropic infant.^{121,122}

The value of a comprehensive stillbirth assessment cannot be underestimated, because the results are relevant to assess the risk of recurrence, the development of prenatal diagnostic recommendations for subsequent pregnancies. Pauli's group at the Wisconsin Stillbirth Service, a model state-wide program for the prevention of stillbirth, estimated that in 2001, the real cost of a stillbirth assessment was approximately \$1450 US or approximately \$12 per cared-for pregnancy, and influenced subsequent perinatal care in 51% of cases.¹¹² After studying 1631 stillbirths, the most significant consequence of this analysis was the change in the risk estimate of recurrence or stillbirth in 42% of cases. Other consequences were a change in the recommenda-

tions with respect to prenatal diagnosis in 22.2% and preconceptional management in 10.9% of subsequent pregnancies.

Summary

Clinicians need to be able to assess each patient's risk for adverse outcomes, including stillbirth, and to have a low threshold to evaluate fetal growth in at-risk pregnancies. As reviewed previously, late pregnancy is also associated with progressively increasing risk of stillbirth, and although the strategy of antepartum testing in patients with increased risk will decrease the risk of late fetal loss, it is of necessity also associated with higher intervention rates.

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APPENDIX B.4

An Initiative to Improve the Quality of Care of Infants With Neonatal Abstinence Syndrome

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BACKGROUND AND OBJECTIVES: The incidence of neonatal abstinence syndrome (NAS), a constellation of neurologic, gastrointestinal, and musculoskeletal disturbances associated with opioid withdrawal, has increased dramatically and is associated with long hospital stays. At our institution, the average length of stay (ALOS) for infants exposed to methadone in utero was 22.4 days before the start of our project. We aimed to reduce ALOS for infants with NAS by 50%.

METHODS: In 2010, a multidisciplinary team began several plan-do-study-act cycles at Yale New Haven Children's Hospital. Key interventions included standardization of nonpharmacologic care coupled with an empowering message to parents, development of a novel approach to assessment, administration of morphine on an as-needed basis, and transfer of infants directly to the inpatient unit, bypassing the NICU. The outcome measures included ALOS, morphine use, and hospital costs using statistical process control charts.

RESULTS: There were 287 infants in our project, including 55 from the baseline period (January 2008 to February 2010) and 44 from the postimplementation period (May 2015 to June 2016). ALOS decreased from 22.4 to 5.9 days. Proportions of methadone-exposed infants treated with morphine decreased from 98% to 14%; costs decreased from \$44 824 to \$10 289. No infants were readmitted for treatment of NAS and no adverse events were reported.

CONCLUSIONS: Interventions focused on nonpharmacologic therapies and a simplified approach to assessment for infants exposed to methadone in utero led to both substantial and sustained decreases in ALOS, the proportion of infants treated with morphine, and hospital costs with no adverse events.

Infants exposed to opioids in utero may develop neonatal abstinence syndrome (NAS), a constellation of neurologic, gastrointestinal, and musculoskeletal disturbances associated with opioid withdrawal.¹ At our institution, infants exposed to methadone in utero who developed signs of withdrawal were given a

diagnosis of NAS. The number of infants at Yale New Haven Children's Hospital (YNHCH) exposed to methadone in utero increased by 74% from 2003 to 2009, and the average length of stay (ALOS) in 2008 to 2009 was 22.4 days, longer than almost all other primary inpatient diagnoses at our institution. In addition, these

abstract



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Dr Grossman conceptualized and designed the project, drafted the initial manuscript, and coordinated data collection; Drs Berkowitz and Osborn helped design the project, collected data, and critically reviewed the manuscript; Ms Xu and Dr Esserman carried out the statistical analysis and critically reviewed the manuscript; Dr Shapiro helped analyze data and critically reviewed the manuscript; Dr Bizzarro helped design the project and critically reviewed the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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infants were occupying an increasing percentage of NICU beds and had an average cost of hospitalization of \$44 800. From 2003 to 2009 at YNHCH, 98% of infants exposed to methadone in utero were treated with morphine, a higher percentage than in any published report.¹

Previous initiatives at other institutions have successfully reduced ALOS for NAS. Holmes et al² reported a reduction in ALOS from 17 to 12 days after adopting a rooming-in model focused on optimizing nonpharmacologic interventions. Asti et al³⁻⁵ reported a reduction in ALOS in a NICU of 36 to 18 days for infants with NAS after implementing a stringent weaning protocol and standardizing the scoring of the Finnegan Neonatal Abstinence Scoring System (FNASS), a tool that assigns a numerical score to 21 subjective clinical signs of NAS and is commonly used to guide pharmacologic management of NAS.

Despite the wide acceptance of the FNASS, its utility in improving outcomes for infants with NAS has not been formally evaluated.⁶ There is also no evidence that most infants with NAS require management in a NICU.⁶ In fact, the environment in some NICUs may impose barriers to implementing nonpharmacologic interventions, such as rooming-in. We set out to change the paradigm of how we approached the management of infants with NAS. We aimed to decrease our ALOS by 50% by focusing interventions on nonpharmacologic care. We also measured morphine use and hospital costs for infants with NAS born at our institution.

METHODS

Context

From March 2010 to June 2016, we conducted a quality improvement project at YNHCH, an academic medical center with ~4500 births

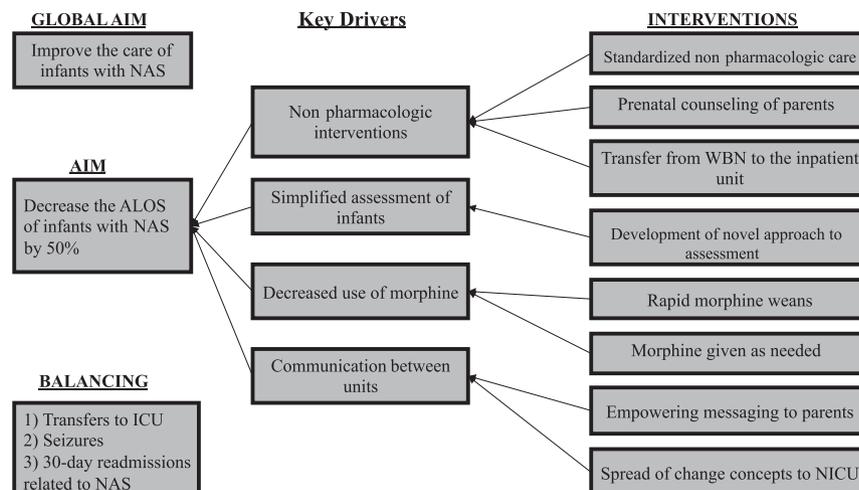


FIGURE 1
Key driver diagram for NAS quality improvement project.

and 850 NICU admissions annually. We applied our interventions to all infants with NAS (infants exposed in utero to opioids who developed signs of withdrawal), but we analyzed only those born at ≥ 35 weeks' gestation whose mothers took methadone daily for at least 1 month before delivery. We considered this population to be the most likely to develop signs of withdrawal.⁶ We excluded infants with significant comorbidities, including sepsis and the need for either surgery or respiratory support (supplemental oxygen, noninvasive ventilation, and/or intubation for ≥ 2 days).

During the preintervention period (January 2008 to February 2010), all infants at risk for NAS were admitted directly to our NICU after birth, where signs of NAS were monitored by using the FNASS. Infants with either 3 FNASS scores ≥ 8 or 2 scores ≥ 12 in a 24-hour period were given morphine (starting at 0.05 mg/kg per dose every 3 hours and adjusted based on subsequent FNASS scores). Infants were initially managed in the NICU and then, at the discretion of the attending neonatologist, were either discharged from the NICU or transferred to the inpatient unit. In either unit, infants were discharged at day 5 of life (if no morphine was

given) or 1 day after morphine was stopped.

Interventions

In 2009, we noted an increase in the number of infants with NAS and formed a multidisciplinary team that included attending physicians, residents, staff nurses, nursing leadership, child life specialists, and social workers to develop interventions aimed at improving care of these infants and reducing ALOS. We identified 4 key drivers of ALOS: nonpharmacologic interventions, simplified assessment of infants, decreased use of morphine, and communication between units (Fig 1). During the next 5 years, using plan-do-study-act cycle methodology, we developed and implemented 8 interventions (listed below their respective key driver) aimed at reducing the ALOS of infants with NAS. The chronology of the interventions is listed in Table 1.

Nonpharmacologic Interventions

Standardized Nonpharmacologic Care on the Inpatient Unit

We standardized 4 nonpharmacologic interventions. (1) Infants were placed in a low-stimulation environment with dimmed lights, muted televisions, and reduced noise. (2) Staff engaged

parents continuously in the care of their infants (volunteers were used if a family member was not available); parents were strongly encouraged to room-in, to feed their infants on demand, and to tend to their infant if crying. (3) Staff were trained to view nonpharmacologic interventions as equivalent to medications; when increased intervention was warranted, the approach was to increase the involvement of the parents before using pharmacologic treatment. Finally, in conjunction with the well-baby nursery (WBN), we encouraged breast-milk feeding of all infants for whom there were no contraindications (ie, illicit drug use or HIV).

Prenatal Counseling of Parents

Several weeks before delivery, our outpatient care coordinator provided parents with informational handouts, told them that they would be expected to stay with their infant throughout the hospitalization, and answered questions.

Empowering Messaging to Parents

On the inpatient unit, we explained that our first-line and most important treatment would center around measures to comfort the infant and that these should be performed by a family member. Parents were told that they were the treatment of their infants and must be present as much as possible. Nurses and physicians focused on supporting and coaching parents on the care of their infants.

Simplified Assessment of Infants

We discontinued use of FNASS scores to guide pharmacologic management on the inpatient unit (FNASS was still used in the WBN and NICU). Instead, we developed and used our own functional assessment focused on 3 simple parameters: the infant's ability to eat, to sleep, and to be consoled. If the infant was able to

TABLE 1 Summary of Interventions

Interventions	Completion Date
Standardized nonpharmacologic care on the inpatient unit	February 2010
Transfer from WBN to the inpatient unit	February 2011
Development of a novel approach to assessment	January 2014
Spread of change concepts to NICU	January 2014
Rapid morphine weans	June 2014
Prenatal counseling of parents	June 2014
Morphine given as needed	May 2015
Empowering messaging to parents	May 2015

breastfeed effectively or to take ≥ 1 oz from a bottle per feed, to sleep undisturbed for ≥ 1 hour, and, if crying, to be consoled within 10 minutes, then morphine was neither started nor increased regardless of other signs of withdrawal. If the infant did not meet these criteria, staff first attempted to maximize nonpharmacologic interventions; if these attempts were unsuccessful, morphine was initiated or increased.

Decreased Use of Morphine

Rapid Morphine Weans

Our previous approach for infants with NAS had been to reduce the initial dose of morphine by not $>10\%$ every 24 to 48 hours. With the increase in nonpharmacologic management, we modified our approach to allow for decreases in the peak dose of morphine by 10% as often as 3 times a day.

Morphine Given as Needed

We noticed that signs of withdrawal were not always consistent throughout the day. In addition, sometimes we were unable to provide optimal nonpharmacologic care, such as when no parent, family member, or volunteer could be present. If maximal nonpharmacologic interventions were unsuccessful, we would give 1 dose of morphine (0.05 mg/kg per dose) and reassess the infant in 3 hours. If the infant was sleeping well, eating well, and consolable within 10 minutes, additional doses of morphine were not administered.

Communication Between Units

Transfer From WBN to the Inpatient Unit

Our level IV NICU housed infants with NAS in rooms with as many as 12 infants. Parents were not able to room-in and the ability to provide a low stimulation environment was extremely limited. We discontinued the practice of directly admitting infants at risk for NAS to the NICU after birth in an effort to keep the mother-infant dyad intact. Instead, these infants were brought to the WBN where FNASS scores were measured. If any score was ≥ 8 , the neonates were preferentially transferred to the inpatient unit where the mothers could room-in. Neonates were admitted to the NICU only if an unforeseen medical problem arose or if there was no bed available on the inpatient unit. On the inpatient unit, nonpharmacologic interventions were initiated as soon as possible for all opioid-exposed infants, whether they had clinical signs of withdrawal or not.

Spread of Change Concepts to NICU

A focused educational session about our new approach to the management of infants with NAS was provided to NICU staff who were encouraged to transfer infants with NAS to the inpatient unit as soon as possible and, ideally, before starting morphine.

Study of the Intervention

We compared demographic features, including rates of polypharmacy (defined as methadone use in addition to mother's use of cocaine,

selective serotonin reuptake inhibitors, benzodiazepines, or opioids other than methadone) and outcomes of infants in the baseline and postimplementation periods. *P* values (2-tailed) are reported from pairwise *t* tests for continuous variables and from either χ^2 tests or Fisher's exact tests (if cell count <5) for categorical variables. Analyses were performed by using SAS version 9.3 (SAS Institute, Inc, Cary, NC).

Measures and Analysis

Our primary outcome measure was ALOS, calculated from date of birth, measured as day of life 0, until date of discharge. Secondary measures included the proportion of infants treated with morphine and the average total cost of hospitalization, including direct and indirect costs. Cost information was obtained from the YNHCH analytics department and adjusted for inflation (2016 dollars).⁷ Process measurements included the proportion of infants who were taking $\geq 50\%$ of their feeds as breast milk at time of discharge and the proportion of infants initially admitted to the NICU for management of NAS. As balancing measures, we tabulated the number of infants transferred to an ICU from the inpatient unit, the number of infants with seizures, and readmissions within 30 days of discharge related to withdrawal. We compared measures after the interventions were fully implemented (May 2015 to June 2016) with the same measures during the baseline period (January 2008 to February 2010). There were no additional hospitalwide interventions to reduce ALOS in newborns ≥ 35 weeks' gestational age during the study period. To ensure completeness of data, records of all patients with administrative codes for NAS (*International Classification of Diseases, Ninth Revision: 779.5 and 760.72; International Classification of Diseases, 10th Revision: P04.49 and*

P96.1) were reviewed for inclusion criteria. We used statistical process control (SPC) charts to evaluate the impact of our interventions. SPC charts were developed by using Microsoft Excel QIMacros. SPC uses statistical methods to analyze common cause variability, to produce control limits to assess the process capability, and to identify special cause variation, or incidences of statistically significant ($P < .01$) variability.⁸

Ethical Considerations

The Yale University Human Investigation Committee determined that this project was exempt from review. No interventions involved comparison of therapies and subjects were not randomized. All charts were accessed by quality team members and no personal health information was shared outside of the organization.

RESULTS

Of the 421 infants ≥ 35 weeks' gestational age diagnosed with NAS from January 2008 to June 2016, 287 met inclusion criteria, including 55 in the baseline period, 188 during the intervention period, and 44 in the postimplementation period. Those excluded included 132 infants not exposed to methadone and 2 infants who had serious comorbid conditions. The characteristics and outcomes of the infants during the different time periods are presented in Table 2. The ALOS decreased from 22.4 days in the preimplementation period (January 2008 to February 2010) to 5.9 days (74% reduction) in the postimplementation period (May 2015 to June 2016) ($P < .001$). Special cause variation (8 consecutive points below the centerline) first occurred in March 2010, after standardization of nonpharmacologic interventions; it next occurred in December 2011, after implementation of direct transfer to the inpatient unit; it next

occurred in January 2014, after implementation of novel approach to assess infants on the inpatient unit and spread of change concepts to the NICU; it next occurred in June 2014, after implementation of prenatal counseling and rapid morphine weaning; and it next occurred in June 2015, after implementation of as-needed morphine dosing and empowering messaging to parents. There was narrowing of the control limits after each special cause variation (Figs 2 and 3).

The proportion of infants treated with morphine decreased from 98% to 14% ($P < .001$) and the average cost of hospitalization decreased from \$44 824 to \$10 289 ($P < .001$). For the infants transferred from the WBN to the inpatient unit without a NICU stay, only 6% (2/35) received treatment with morphine. The proportion of infants that took the majority of their feeds from breast milk increased from 20% to 45% ($P = .01$), and the proportion of infants admitted directly to the NICU decreased from 100% to 20% ($P < .001$).

No patient admitted to the inpatient unit required transfer to an ICU. There were no seizures reported in any patient. There were no readmissions within 30 days of discharge related to signs of withdrawal in either the baseline or the postimplementation periods.

DISCUSSION

The use of quality improvement methodology to improve the care of infants with NAS led to both substantial and sustainable decreases in ALOS, far beyond our goal of a 50% reduction. The use of morphine and the average cost of hospitalizations also were substantially reduced. Our 8 plan-do-study-act cycles led to an improvement in ALOS, well below that reported in any other published studies. There were no statistically significant differences in

the characteristics of infants in our baseline and postimplementation periods, and we are confident that our interventions directly resulted in the changes observed.

One of our study's strengths was the inclusion of all methadone-exposed infants, which allowed us to fully measure the impact of our interventions. Many studies define infants with NAS as only those who receive pharmacologic treatment.⁹⁻¹² However, requiring pharmacologic treatment for a diagnosis of NAS limits the ability to draw conclusions about the efficacy of nonpharmacologic interventions. The use of medication to treat clinical signs should not be the sole factor used to define the syndrome. Although we applied our interventions to all opioid-exposed infants, we focused our evaluation on the subset of opioid-exposed infants most likely to develop withdrawal, regardless of the eventual treatment received. Infants exposed to methadone are more likely to manifest signs of withdrawal than those exposed to short-acting opioids or buprenorphine.^{6,13} By initiating intensive nonpharmacologic interventions for all methadone-exposed infants from the time of birth and before the presentation of clinical signs of withdrawal, we were able to intervene earlier and to prepare parents for their critical role in treatment. We believe this strategy contributed greatly to our success.

Another strength of our project was the development of novel criteria for the clinical assessment of infants with NAS. Criteria for either starting or altering treatment with opioids based on FNASS scores have never been validated.⁶ An FNASS score cannot be obtained without disturbing and unswaddling the baby, which increases the likelihood of high scores in many categories (eg, tremors, tone, and cry). Our approach encouraged providers to focus on a small number of clinically

TABLE 2 Characteristics and Outcomes of the Newborns and Their Mothers

Characteristics of the Newborns	Baseline (N = 55)	Postimplementation (N = 44)	P
Girl, no. (%)	31 (56)	25 (56)	.96
Race, no. (%)			.19
White	45 (85)	42 (95)	
African American	2 (4)	0 (0)	
Hispanic	6 (11)	2 (5)	
Birth weight, kg ^a	3.1 ± 0.6	3.1 ± 0.6	.72
Apgar score at 5 min ^a	8.7 ± 0.8	8.8 ± 0.8	.92
Head circumference, cm ^a	33.1 ± 1.8	32.8 ± 1.4	.44
Characteristics of the mothers			
Polypharmacy, no. (%) ^b	18 (33)	16 (36)	.70
Cesarean delivery, no. (%)	24 (44)	13 (30)	.15
Cigarette smoking, no. (%)	30 (58)	26 (59)	.53
Alcohol, no. (%)	1 (2)	0 (0)	.36
Public insurance, no. (%)	48 (96)	42 (95)	.90
Mother's age, y ^a	27.5 ± 5.8	29.1 ± 5.1	.16
Gestational age, wk ^a	38.9 ± 1.6	38.4 ± 1.4	.09
Methadone dose, mg/d ^a	85.6 ± 34.3	94.5 ± 37.8	.23
Gravida ^a	3.2 ± 1.8	3.2 ± 1.9	.94
Outcomes			
Hospital length of stay, d ^a	22.4 ± 10.8	5.9 ± 1.9	<.001
Treated with morphine, no. (%)	54 (98)	6 (14)	<.001
Cost, US dollars ^{a,c}	44 824 ± 23 726	10 289 ± 5068	<.001
Breast-milk fed at discharge, no. (%)	11 (20)	20 (45)	.01
NICU stay, no. (%) ^d	55 (100)	9 (20)	<.001

In the baseline period, data were unavailable for 5 patients for insurance, 3 patients for cigarette smoking, and 2 patients for ethnicity.

^a Mean ± SD.

^b Methadone use in addition to mother's use of cocaine, selective serotonin reuptake inhibitors, benzodiazepines, or opioids other than methadone (determined either via history and/or urine testing of mother).

^c Adjusted for inflation.

^d Patients with any time spent in the NICU.

relevant factors to assess the need for treatment with morphine. Ideally, all infants should feed well, sleep well, and be easily consoled. We determined that if infants with NAS met these goals, then treatment was successful irrespective of the FNASS score.

When we began our initiative, all infants with NAS were admitted directly to the NICU, an environment that did not permit rooming-in and rarely provided consistent, nonpharmacologic interventions other than swaddling. In this setting, 98% of infants exposed to methadone developed signs of withdrawal severe enough to receive pharmacologic treatment. Our intervention changed the milieu in which these infants were managed from one with limited ability to optimize nonpharmacologic interventions to a low-stimulation environment with an intense focus on the involvement of parents and

continuous assessment of the infant's comfort. In the process, we were able to change a system in which parents were merely allowed to visit their infant to one in which they were empowered to be the most important part of their infant's care. This approach employed the power of the maternal-infant bond to treat NAS.^{14,15} After the implementation of these interventions, the use of morphine to treat NAS decreased to 14%.

In the United States from 2009 to 2012, the ALOS for all infants with NAS was 17 days; infants requiring pharmacologic interventions had an ALOS of 23 days.¹⁶ By changing the paradigm of how infants with NAS are treated and evaluated, we reduced our ALOS to 5.9 days. The potential savings in hospital costs from this approach is considerable. Based on the average cost of a hospital day for an infant with NAS at our institution in 2015 to 2016

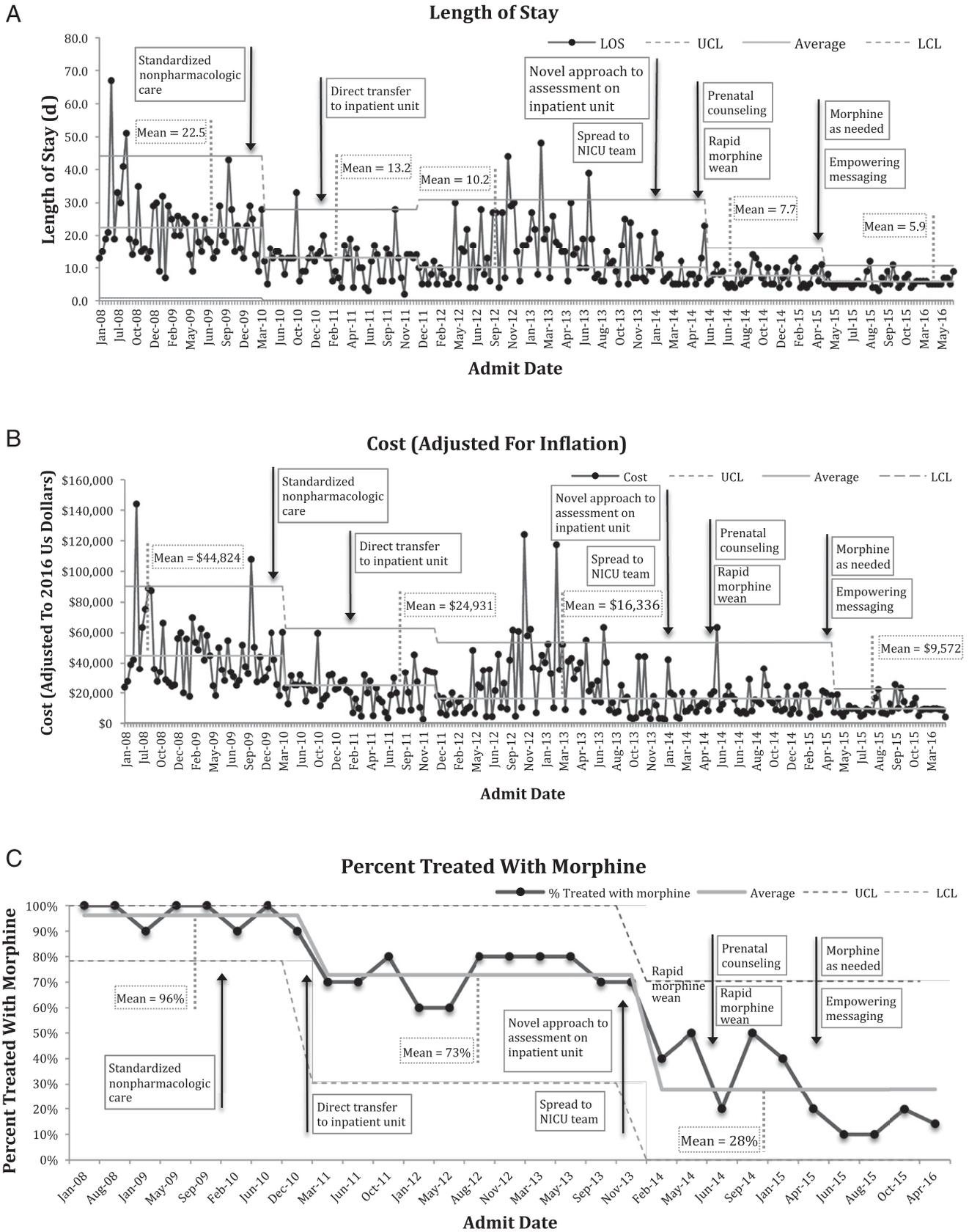


FIGURE 2

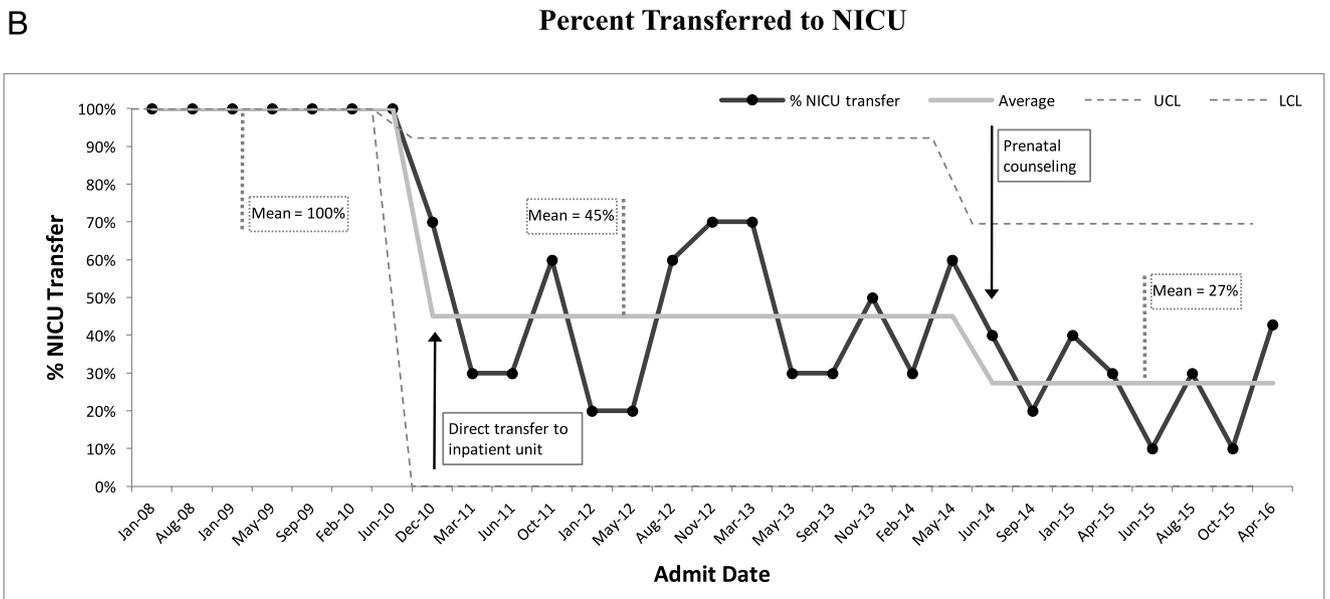
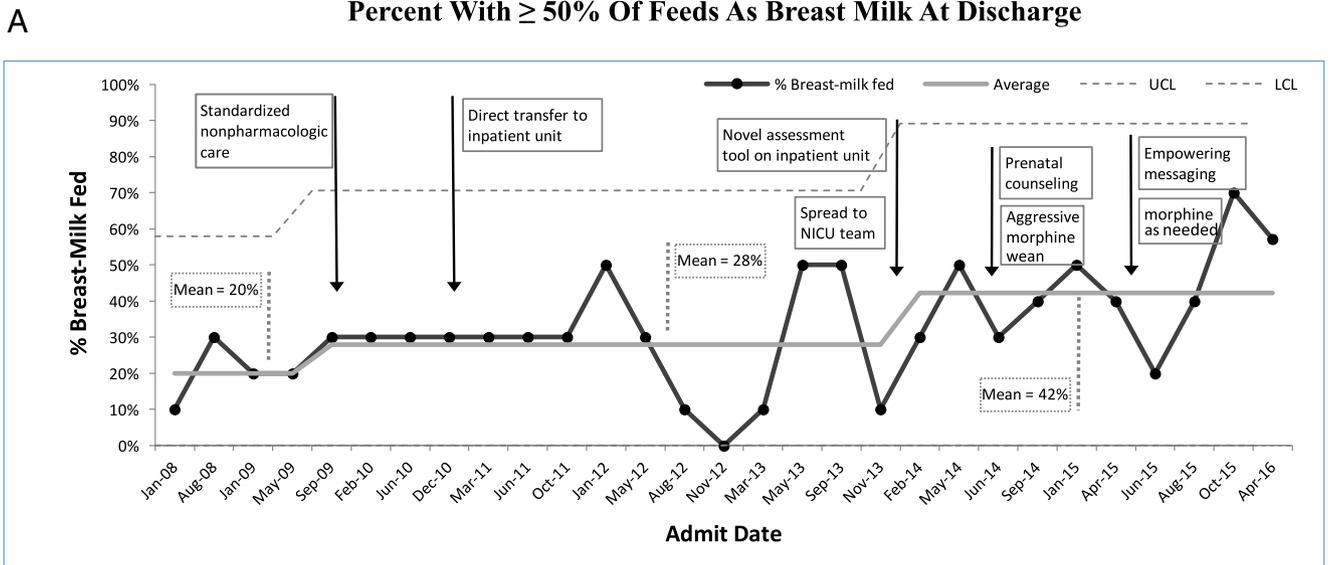


FIGURE 3

A (% breast-milk fed) and B (% transferred to the NICU), SPC p-charts where each point represents 10 infants exposed to methadone prenatally. The centerline for A shifted upward in February 2010 and January 2014. The centerline for B shifted downward in January 2010 and June 2014. LCL, lower control limit; UCL, upper control limit.

(\$1750), we estimate a savings of \$1.52 million in total hospital costs if the ALOS of infants with NAS had remained at baseline level (22.4 days). Applying this approach

nationally could lead to substantial savings.

There are some limitations to our study. Implementation of our intervention bundle evolved over

a 5-year period. Several of our interventions involved changes in the culture of how infants with NAS were managed, a process that takes time to implement, particularly when

FIGURE 2 Continued

A (length of stay) and B (cost), XmR SPCs where each dot represents a patient exposed to methadone prenatally. C (treated with morphine), p-chart where each dot represents 10 patients exposed to methadone prenatally. The centerline for A and B shifted downward (8 consecutive points below the mean) in March 2010, January 2012, and May 2015. The centerline in A also shifted downward in June 2014. The centerline in C shifted in March 2011 and January 2014. LCL, lower control limit; LOS, length of stay; UCL, upper control limit.

existing models of care have been ingrained for many years. During implementation of the intervention bundle, there were changes in both staffing models and hospital policies that may have affected our results. However, the proportional decrease in ALOS for all hospital patients during this period (9%) was far smaller than the proportional decrease in ALOS for infants with NAS (74%). Second, although rooming-in was an important component of the intervention, we do not have an estimate of the amount of time that a parent was with his/her child, so we could not assess whether there was a “dose-response” effect. Lastly, we do not know if any infants were readmitted to a different hospital. However, that is unlikely because most hospitals in the area transfer infants with NAS to YNHCH.

CONCLUSIONS

We demonstrated that supportive, nonpharmacologic interventions combined with assessments that focused on the functional well-being of infants with NAS, rather than on FNASS scores, dramatically and sustainably reduced ALOS below previously published levels. We reduced resource use, including less use of morphine and fewer NICU stays. Additional studies that assess effects on growth, development, and behavioral outcomes are needed as are studies that quantify the effect of the involvement of parents in the care of children with NAS.

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ABBREVIATIONS

ALOS: average length of stay
 FNASS: Finnegan neonatal abstinence scoring system
 NAS: neonatal abstinence syndrome
 SPC: statistical process control
 WBN: well-baby nursery
 YNHCH: Yale New Haven Children’s Hospital

responsibility of the authors and do not necessarily represent the official view of NIH. This project was approved by the Human Investigation Committee of the Yale School of Medicine. Funded by the National Institutes of Health (NIH).

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An Initiative to Improve the Quality of Care of Infants With Neonatal Abstinence Syndrome

Matthew R. Grossman, Adam K. Berkowitz, Rachel R. Osborn, Yaqing Xu, Denise A. Esserman, Eugene D. Shapiro and Matthew J. Bizzarro
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APPENDIX B.5

Association of Rooming-in With Outcomes for Neonatal Abstinence Syndrome

A Systematic Review and Meta-analysis

Kathryn Dee L. MacMillan, MD; Cassandra P. Rendon, BA, BS; Kanak Verma, MPH; Natalie Riblet, MD, MPH; David B. Washer, MBA, MPH; Alison Volpe Holmes, MD, MPH

 Supplemental content

IMPORTANCE Rising incidence of neonatal abstinence syndrome (NAS) is straining perinatal care systems. Newborns with NAS traditionally receive care in neonatal intensive care units (NICUs), but rooming-in with mother and family has been proposed to reduce the use of pharmacotherapy, length of stay (LOS), and cost.

OBJECTIVE To systematically review and meta-analyze if rooming-in is associated with improved outcomes for newborns with NAS.

DATA SOURCES MEDLINE, CINAHL, The Cochrane Library, and clinicaltrials.gov were searched from inception through June 25, 2017.

STUDY SELECTION This investigation included randomized clinical trials, cohort studies, quasi-experimental studies, and before-and-after quality improvement investigations comparing rooming-in vs standard NICU care for newborns with NAS.

DATA EXTRACTION AND SYNTHESIS Two independent investigators reviewed studies for inclusion. A random-effects model was used to pool dichotomous outcomes using risk ratio (RR) and 95% CI. The study evaluated continuous outcomes using weighted mean difference (WMD) and 95% CI.

MAIN OUTCOMES AND MEASURES The primary outcome was newborn treatment with pharmacotherapy. Secondary outcomes included LOS, inpatient cost, and harms from treatment, including in-hospital adverse events and readmission rates.

RESULTS Of 413 publications, 6 studies (n = 549 [number of patients]) met inclusion criteria. In meta-analysis of 6 studies, there was consistent evidence that rooming-in is preferable to NICU care for reducing both the use of pharmacotherapy (RR, 0.37; 95% CI, 0.19-0.71; $I^2 = 85\%$) and LOS (WMD, -10.41 days; 95% CI, -16.84 to -3.98 days; $I^2 = 91\%$). Sensitivity analysis resolved the heterogeneity for the use of pharmacotherapy, significantly favoring rooming-in (RR, 0.32; 95% CI, 0.18-0.57; $I^2 = 13\%$). Three studies reported that inpatient costs were lower with rooming-in; however, significant heterogeneity precluded quantitative analysis. Qualitative analysis favored rooming-in over NICU care for increasing breastfeeding rates and discharge home in familial custody, but few studies reported on these outcomes. Rooming-in was not associated with higher rates of readmission or in-hospital adverse events.

CONCLUSIONS AND RELEVANCE Opioid-exposed newborns rooming-in with mother or other family members appear to be significantly less likely to be treated with pharmacotherapy and have substantial reductions in LOS compared with those cared for in NICUs. Rooming-in should be recommended as a preferred inpatient care model for NAS.

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Neonatal abstinence syndrome (NAS) is a collection of signs and symptoms of newborn opioid withdrawal after intrauterine exposure.¹ Other descriptions of the syndrome include neonatal opioid withdrawal syndrome and neonatal withdrawal syndrome.² Neonatal abstinence syndrome manifests 24 to 96 hours after delivery with increased muscle tone, tremors, sweating, vomiting, diarrhea, and other symptoms. Between 1999 and 2013, the incidence of NAS in the United States increased from 1.5 to 6.0 cases per 1000 births,³ with a mean cost in 2012 of \$93 400 per newborn stay.⁴

While standardized approaches to pharmacologic treatment of NAS improve outcomes, the role of nonpharmacologic or “environmental” interventions in managing NAS is less clear.⁵ Opioid-exposed newborns are typically cared for in neonatal intensive care units (NICUs), and standardized scoring systems, such as the modified Finnegan system, are used to quantify NAS symptoms and to adjust medications used in treatment.⁶ Paradoxically, studies^{6,7} have found that opioid-exposed newborns in NICUs experience more severe withdrawal, longer length of stay (LOS), and increased pharmacotherapy compared with newborns who room in. In rooming-in care, infant and mother remain together 24 hours a day unless separation is indicated for medical reasons or safety concerns.⁸ More maternal time at the infant bedside improves NAS outcomes but is harder to accomplish in a typical NICU.⁹ Neonatal intensive care units may be poor settings for newborns with NAS because of increased sensitivity to high clinical activity levels.¹⁰ In settings where separation from mothers is inherent in a NICU admission, it can interfere with bonding and may contribute to maternal perceptions of guilt and stigma.⁹⁻¹¹ While rooming-in may be effective for NAS, potential risks include unintentional suffocation, falling from an adult bed, or undertreated NAS after hospital discharge.¹⁰⁻¹²

The benefits and harms of rooming-in for NAS have to date only been evaluated by single-center studies. We conducted a systematic review and meta-analysis to evaluate the benefits and harms of rooming-in compared with standard NICU care for management of NAS.

Methods

Review Protocol

We used Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines for reporting of methods and findings (Figure 1).¹³ We included randomized clinical trials, cohort studies, quasi-experimental studies, and before-and-after quality improvement (QI) investigations of rooming-in as an intervention for opioid-exposed newborns. Prenatal opioid exposure comprised maternal use of heroin, prescription opioids, and nonprescription opioids, as well as prescribed or illicit opioid replacement therapy. Polysubstance users were not excluded. We defined rooming-in as infant and mother remaining together 24 hours per day throughout the postpartum hospital stay unless separation was indicated for medical needs other than NAS symptoms. We included studies reporting on other cointerventions, such as increased skin-to-skin contact, swaddling, soothing, and breastfeeding sup-

Key Points

Question Does rooming-in with family reduce the use of medications, length of stay, and costs in the inpatient treatment of neonatal abstinence syndrome?

Findings In this systematic review and meta-analysis of 6 studies comprising 549 patients, rooming-in was associated with a reduction in the need for pharmacologic treatment and a shorter hospital stay when rooming-in was compared with standard neonatal intensive care unit admission for neonatal abstinence syndrome.

Meaning Rooming-in should be considered as the preferred inpatient care model for all opioid-exposed newborns, including those with neonatal abstinence syndrome.

port, because greater parental involvement in infant soothing is the primary plausible mechanism for rooming-in efficacy.^{14,15} We required reporting on at least the primary outcome of interest. Our systematic review protocol and search methods are available in the eMethods in the Supplement.

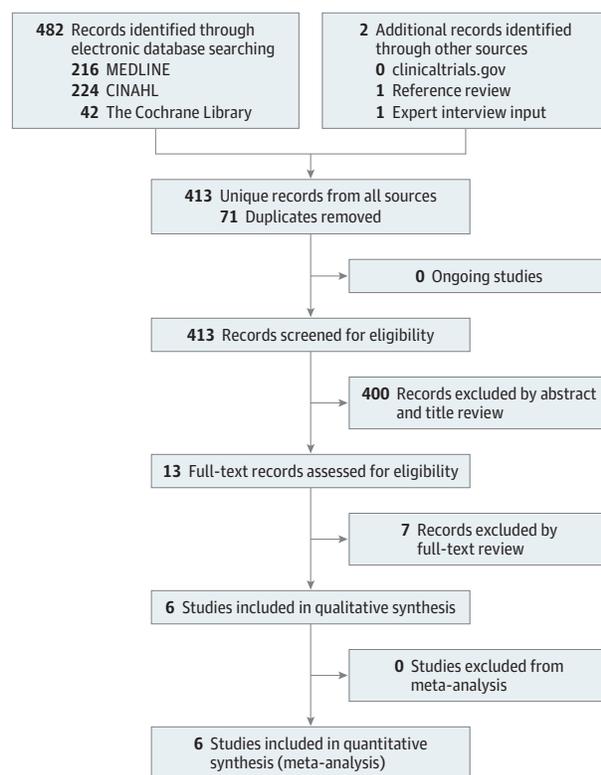
Outcome Measures

The primary outcome was the proportion of infants requiring pharmacologic treatment. Current treatment guidelines call for the use of oral morphine sulfate or methadone hydrochloride to relieve moderate or severe NAS symptoms.⁵ Therefore, the proportion of pharmacologically treated newborns was used as an adequate proxy for those with significant NAS.⁵ As secondary outcomes, we assessed the cumulative dose of opioid medication, duration of opioid treatment course, LOS, total cost of hospitalization, family satisfaction, breastfeeding incidence, and the proportion of infants discharged home in familial custody. To evaluate potential harms of rooming-in, we examined reports of adverse events and readmission rates.¹⁶

Search Strategy, Study Selection, and Data Collection

We searched MEDLINE (1946 to June 25, 2017), CINAHL (1981-2016), and The Cochrane Library using keywords and Medical Subject Headings to generate sets for the themes of NAS and rooming-in. We used the Boolean term “AND” to find intersections. No limits were applied. In addition, we searched clinicaltrials.gov, reviewed references of included studies meeting inclusion criteria, and used the expertise of one of us (A.V.H.) in the field of NAS to identify any unpublished studies not identified by our principal electronic database search strategy. Complete search strategies for each database are included in the eMethods in the Supplement. Two of us (K.D.L.M. and C.P.R.) independently screened titles and abstracts. After the initial screening, these 2 authors independently assessed selected full texts to determine appropriateness for inclusion. They then independently used a standardized, piloted data collection form to extract data on key study components, including methods, participant characteristics, outcomes, and assessment techniques. Two independent reviewers (2 of us, K.V. and D.B.W.) then applied the Risk of Bias in Non-randomised Studies of Interventions (ROBINS-I) tool¹⁷ to each study. Studies were defined as having low risk of bias if

Figure 1. PRISMA Study Selection Flow Diagram



PRISMA indicates Preferred Reporting Items for Systematic Reviews and Meta-analyses.

the 2 independent reviewers rated the study as such across all categories. The results of our quality assessment were incorporated into the described sensitivity analysis. Discrepancies at each stage were resolved by consensus.

Statistical Analysis

To summarize the treatment effect, we measured risk ratio (RR) and 95% CI for dichotomous outcomes and weighted mean difference (WMD) and 95% CI for continuous outcomes. Some secondary outcomes were not amenable to quantitative analysis because either studies measured them in disparate manners that could not be mathematically resolved or too few studies reported on the primary outcome of interest. Therefore, we provided a qualitative summary for this subset of outcomes across studies.

Of the included publications, 3 studies^{7,18,19} provided insufficient data to allow for quantitative analysis. We contacted the respective authors and received responses from 2, allowing us to analyze the need for pharmacotherapy and LOS from these 2 studies.^{18,19} The third study⁷ was included in the systematic review but was excluded from the portion of the analysis associated with the missing data.

We used a software program (RevMan, version 5.3; The Cochrane Collaboration²⁰) to conduct the meta-analysis using a random-effects model by pooling study results for all outcomes to appropriately address expected heterogeneity. In the case of multiple comparison groups, only one group was selected for di-

chotomous variables.⁷ We assessed groupings for the heterogeneity using the I^2 statistic. This statistic evaluates the consistency of the results across studies. A notable advantage of the I^2 statistic is that it does not depend on the number of studies included in the meta-analysis and thus can be used even when the study sample size is small.²¹ We used the conventional threshold of I^2 exceeding 50% to define meaningful heterogeneity. In instances of heterogeneity, we first considered the contribution of study design or methodological flaws. We then performed sensitivity analyses to reanalyze outcomes, including the greatest possible number of homogeneous studies ($I^2 < 50\%$). We performed sensitivity analyses based on each element of the ROBINS-I methodological quality assessment tool on the overall summary estimates, restricting analysis to only those studies deemed to have low risk of bias. We evaluated whether this restricted analysis affected the magnitude, direction, and statistical significance of the overall summary estimate. We also performed additional sensitivity analysis to account for the different types of study designs. First, we limited the summary estimates to the before-and-after studies.^{7,18,19,22,23} Second, we removed the study by Hünseler et al²⁴ owing to high risk of bias in selection of participants (ie, mothers were encouraged to choose the intervention rather than systematically applying rooming-in to the entire population of interest). We then excluded 2 QI studies, by Holmes et al¹⁸ and by Grossman et al,¹⁹ because during the implementation phase of the rooming-in intervention there were concurrent changes in how NAS scores affected the use of pharmacotherapy.

For the outcomes not amenable to quantitative analysis, we provided a qualitative result summary, first assessing which group (rooming-in vs comparison group) was favored for each outcome and then considering potential methodological flaws influencing these results. We generated a summary assessment based on the overall trends in the results and categorized outcomes as favoring rooming-in, the comparison group, or neither group or as unclear. Statistical significance was determined using P values calculated by 2-sided t tests.

Results

The initial search identified 482 potentially eligible studies. After removing duplicates, we screened 413 studies and excluded 400 based on title and abstract. We performed full-text review of 13 publications, and 6 studies^{7,18,19,22-24} ($n = 549$ [number of patients]) met our inclusion criteria (Figure 1 and Table). The included studies were published between 2007 and 2017 and were varied in sample size, geographic location, and clinical setting. In 3 included studies,^{7,19,22} all infants in the comparison group were admitted to the NICU for increased observation. In the remaining 3 studies,^{18,23,24} only infants in the comparison group who needed increased observation or pharmacologic intervention were transferred to NICU-level care. The reasons for exclusion of 7 studies after full-text review included overlapping populations across studies, institutional practices that limited pharmacologic treatment during the initial 36 to 72 hours of life, or insufficient data on rooming-in.

There was strong and robust consistency in the results across included studies (eTable 1 in the Supplement). The most com-

Table. Characteristics of Studies Evaluating the Use of Rooming-in to Reduce the Need for Pharmacotherapy to Treat Neonatal Abstinence Syndrome

Source	Study Design	Total No.	RI, No.	CG, No.	Maternal Age, Mean (SD), y		Gestational Age, Mean (SD), wk		Birth Weight, Mean (SD), g	
					RI	CG	RI	CG	RI	CG
Abrahams et al, ⁷ 2007	Before-and-after assessment, retrospective cohort	106	32	38, ^a 36	29.2	29.8, 26.2	NR	NR	NR	NR
Holmes et al, ¹⁸ 2016	Before-and-after assessment of QI intervention	163	48	61, 54 ^a	NR	NR	39	39	2979	2979
Hünseler et al, ²⁴ 2013	Retrospective cohort	77	24	53	28.8 (5.7)	29.9 (5.8)	38.1 (1.9)	37.9 (2.6)	2720 (570)	2620 (630)
Grossman et al, ¹⁹ 2017	Before-and-after assessment of QI study	99	44	55	29.1 (5.1)	27.5 (5.8)	38.4 (1.4)	38.9 (1.6)	3100 (600)	3100 (600)
McKnight et al, ²² 2016	Before-and-after assessment	44	24	20	30	30	39	40	3261.9 (366.0)	3314.4 (532.3)
Saiki et al, ²³ 2010	Before-and-after assessment	60	18	42	29.5	31	39.5	39.1	2910	2860

Abbreviations: CG, comparison group; NR, not recorded; QI, quality improvement; RI, rooming-in.

^a Comparison group used in meta-analysis of dichotomous variables.

mon methodological concern was risk for confounding. In the 2 QI studies,^{18,19} clinical criteria for pharmacologic management were adjusted during implementation of the rooming-in intervention. Baseline study characteristics for the rooming-in vs control groups were not described in one study.¹⁸ Five studies^{7,19,22-24} provided data to support that there were no statistically significant differences between the rooming-in and comparison groups. Specifically, 4 studies^{7,22-24} reported on maternal type of specific drug abuse, with no statistically significant difference in rates of use between intervention and comparison groups. The use of the different patient samples as controls in the before-and-after studies and the historical controls in QI studies also raised concerns that the reported change in outcomes may have been due to secular trends rather than the rooming-in intervention.^{18,19,22,23} One study⁷ also included an external control group. In all included studies, outcomes were reported based on the initial assignment to intervention or comparison group, which was determined before birth.

Need for Pharmacotherapy

All 6 studies found that rooming-in was associated with a lower proportion of infants requiring pharmacotherapy compared with standard NICU care (RR, 0.37; 95% CI, 0.19-0.71). However, there was significant heterogeneity among the included studies ($I^2 = 85\%$). After removing 3 studies for simultaneously using multiple interventions^{18,19} or for allowing maternal group selection,²⁴ the heterogeneity resolved, and rooming-in continued to be significantly favored (RR, 0.32; 95% CI, 0.18-0.57) ($I^2 = 13\%$) (Figure 2).

In the first sensitivity analysis, we examined the value of using a historical internal control group (vs an external control) for the study by Abrahams et al.⁷ This resulted in an unchanged RR of 0.37. In our second sensitivity analysis, we limited the investigation to 4 before-and-after studies.^{18,19,22,23} This resulted in an RR of 0.28, with significant heterogeneity ($I^2 = 62\%$). In our third sensitivity analysis, we removed the 2 QI studies.^{18,19} This resulted in an RR of 0.35, with an I^2 of 81%. Finally, we removed the QI studies^{18,19} and the study by

Hünseler et al.²⁴ This resulted in an RR of 0.32, with an I^2 of 13%. All sensitivity analyses demonstrated an association between rooming-in as an intervention and limiting pharmacotherapy, with statistically significant RRs between 0.27 and 0.37.

Length of Stay

All 6 studies found that LOS was significantly shorter with rooming-in vs standard NICU care (WMD, -10.41 days; 95% CI, -16.84 to -3.98 days). However, there was again significant heterogeneity among the included studies ($I^2 = 91\%$). After removing 3 studies^{18,19,24} for the same reasons related to study design noted above (see the Need for Pharmacotherapy subsection in this Results section), the heterogeneity resolved, and rooming-in continued to be favored (WMD, -12.84 days; 95% CI, -20.02 to -5.67 days) ($I^2 = 58\%$) (Figure 3).

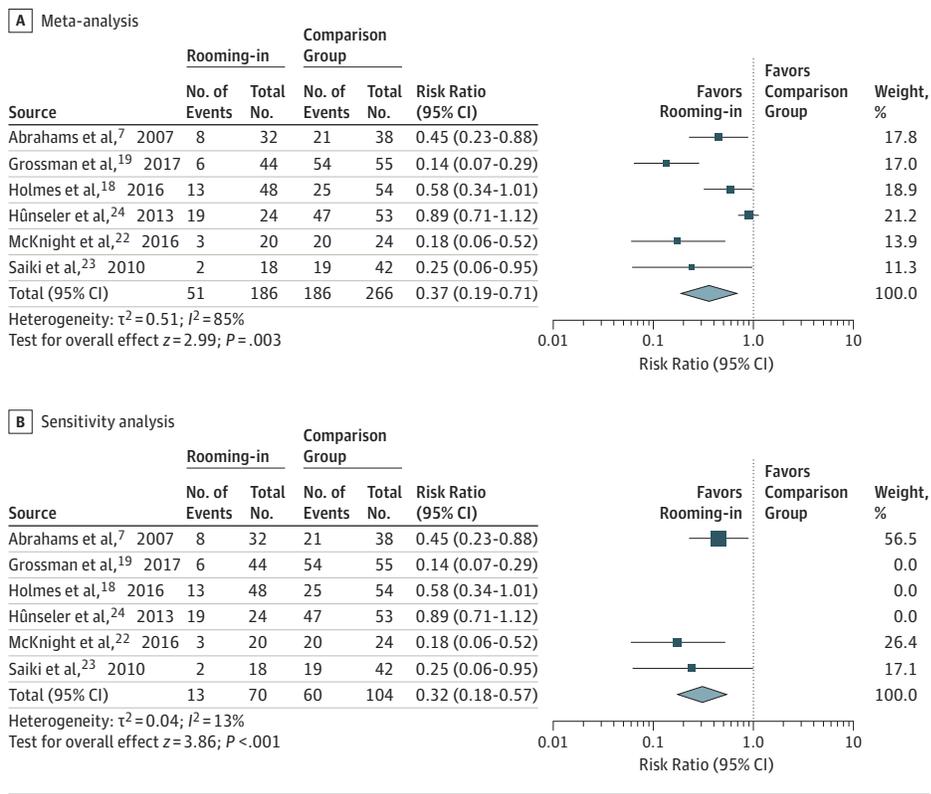
In the first sensitivity analysis on LOS, we examined the value of using the historical internal control group (vs the external control) in the study by Abrahams et al⁷ and found an unchanged LOS (WMD, -10.41 days). In the second sensitivity analysis, we limited our investigation to 4 before-and-after studies.^{18,19,22,23} This resulted in a WMD of -10.84 days, with significant heterogeneity ($I^2 = 95\%$). In the third sensitivity analysis, we removed the 2 QI studies.^{18,19} This resulted in a WMD of -10.86, with significant heterogeneity ($I^2 = 65\%$). Finally, we removed the QI studies^{18,19} and the study by Hünseler et al.²⁴ This resulted in a WMD of -12.84 days, with an I^2 of 58%. All sensitivity analyses demonstrated a strong association between rooming-in as an intervention and shortening LOS by approximately 10 to 12 days.

Sensitivity analyses conducted based on each element of the ROBINS-I methodological quality assessment tool showed no significant association with the need for pharmacotherapy. Similar results were found for length of stay.

Cost

The results of the 3 studies^{18,19,24} reporting inpatient costs in US dollars suggested that rooming-in is associated with

Figure 2. Rooming-in vs Usual Care on the Need for Pharmacotherapy



lower costs (eTable 2 in the Supplement). However, there was significant heterogeneity across studies ($I^2 = 97\%$), which precluded a formal meta-analysis.

Qualitative Analysis

None of the included studies reported any adverse events with rooming-in. Three studies^{7,18,23} reported on readmission rates, with no increase found (eTable 3 in the Supplement). Four studies^{7,19,22,23} reported on breastfeeding, with 2 studies noting an increase in breastfeeding with rooming-in and 2 studies reporting no difference (eTable 4 in the Supplement). Four studies^{7,18,23,24} reported on discharge home with mother or other family member; only one study⁷ showed a larger proportion of rooming-in infants remaining in familial custody. The remaining 3 studies^{18,23,24} all reported high rates of discharge with family, with no statistically significant difference in rates between study groups (eTable 5 in the Supplement).

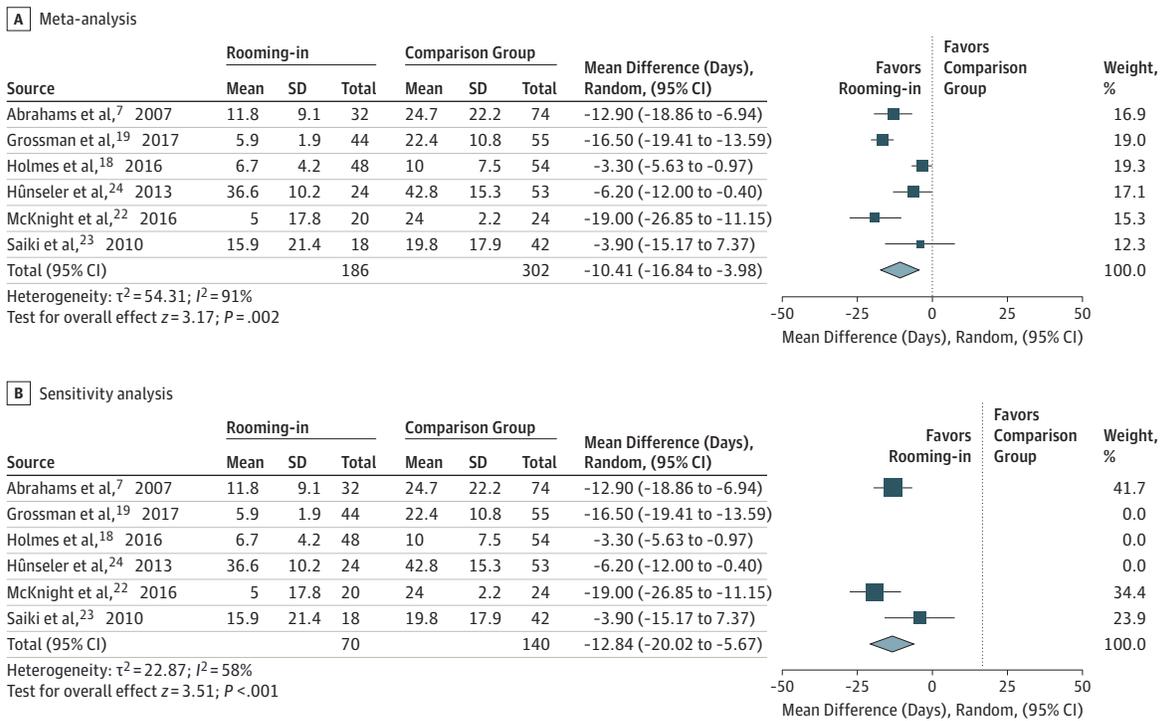
Three studies^{7,23,24} reported on the mean length of opioid medication treatment, all of which identified a decrease in the number of days receiving pharmacotherapy, proportionate to the decrease in LOS seen above (see the Length of Stay subsection herein). Only one study¹⁸ reported on changes in the cumulative dose of opioid medication, and no included studies reported on patient satisfaction. We were unable to conduct a formal assessment for publication bias due to inclusion of only 6 studies in the meta-analysis.²⁵

Discussion

This systematic review and meta-analysis demonstrates that rooming-in is associated with decreased need for pharmacologic treatment of NAS and shorter LOS. The results of several included studies^{18,19,24} suggest that rooming-in is associated with reduced hospital costs, but the significant heterogeneity across studies precluded quantitative analysis. Because of variable reporting, we were unable to draw formal conclusions about the role of rooming-in on other secondary outcomes of interest. The findings of 2 studies^{7,19} suggested that breastfeeding increases with rooming-in. There was no evidence that rooming-in for NAS was associated with a significant increase in hospital readmission. Reporting of adverse events was insufficient to draw any conclusions about an association between rooming-in and these outcomes. Our findings agree with prior review articles^{14,26,27} of nonpharmacologic management of NAS, which also suggested that rooming-in is associated with decreased NAS severity and shorter LOS.

Our systematic review included studies from the United States, Canada, and Europe and covered a range of clinical settings. Therefore, rooming-in could be effective in diverse settings that manage neonates at risk for NAS. Our findings are relevant to current practice because implementing rooming-in for opioid-exposed newborns is straightforward and has clear benefits. It allows for greater parental involvement by in-

Figure 3. Rooming-in vs Usual Care on Length of Stay



A, Meta-analysis, including 6 studies.^{7,18,19,22-24} B, Sensitivity analysis, including only the before-and-after studies that were not quality improvement investigations.

creasing opportunities for families to provide nonpharmacologic treatment and permits more efficient use of institutional resources.

The quality of the included studies was high, and the results were consistent across them. Because most of the studies used a historical cohort, it is important to consider the observed results in light of secular trends. Studies that included a concurrent external control group also favored rooming-in and demonstrated no significant change in the findings. The risk for ascertainment bias in studies was low because the included studies used standardized definitions for rooming-in and the studied outcomes were objective (ie, the proportion treated with medications, LOS, and total cost). However, rooming-in is not an isolated intervention. In the 2 included QI studies,^{18,19} a number of cointerventions occurred during the course of the investigations, including changes to scoring practices that could have explained some of the observed improvement in outcomes. While the results of all included studies could be considered confounded by factors known to lessen NAS symptoms, such as increased skin-to-skin time, more opportunities for breastfeeding, and greater parental involvement and improved soothing techniques, we believe that these covariates are not confounders but rather are mediators that contribute to the benefits of rooming-in.

Strengths and Limitations

This study has a number of strengths, including strict adherence to The Cochrane Library and PRISMA guidelines for systematic review and meta-analysis conduct and reporting. We used a comprehensive search strategy that included multiple electronic da-

tabases and additional techniques to identify unpublished studies. Because rooming-in is a recent intervention for NAS, there is limited available literature. We believe that our search strategy comprehensively synthesized the available data.

First among the limitations of this systematic review and meta-analysis is the likely publication bias favoring rooming-in because it would be unlikely for researchers to publish their results with negative or insignificant findings. This is particularly concerning for QI studies because negative QI interventions are rarely published.^{25,28} We were unable to formally assess publication bias due to analyzing less than 10 studies.²⁵ Second, to comprehensively identify negative or insignificant outcomes, we incorporated all reported outcome measures from each study, regardless of whether the measure was the intervention target. The included studies may have lacked sufficient power to fully evaluate secondary outcomes. Third, there was variable reporting of the secondary outcomes of this systematic review and meta-analysis across the included studies, particularly regarding adverse events and readmission rates. While the included studies^{7,18,23} measuring readmission demonstrated no increase among roomed-in infants, these events are rare, and it is possible that investigations lacked sufficient power to detect potential negative consequences of rooming-in. Fourth, we encountered significant heterogeneity among the included studies for the primary and secondary outcomes. This was anticipated given the varied nature of the study designs and settings and was particularly exacerbated by inclusion of 2 large QI studies^{18,19} that by virtue of their methods incorporated several staged interventions. Reassuringly, when we accounted for these

methodological issues in our sensitivity analysis, we were able to resolve the heterogeneity for our primary outcome, and rooming-in continued to show a statistically significant benefit over standard NICU care. The results of this systematic review and meta-analysis should be interpreted with careful consideration of the validity of the final estimations of intervention effect size.

As rooming-in interventions are implemented across a growing number of institutions, it will be important to monitor for potential adverse events of rooming-in, such as failure to thrive, accidental suffocation, and readmission rates. It will also be necessary to determine an association between rooming-in and breastfeeding and custody arrangements at discharge. While there is emerging evidence to suggest that rooming-in may also be associated with lower hospital costs, future studies should evaluate this in a systematic and standardized manner, allowing for adequate comparison across studies. Fi-

nally, future research should explore the possible long-term implications of rooming-in for infant health and development, strength of the mother-child bond, and potential to mitigate the risk of maternal relapse into active substance abuse.

Conclusions

There is consistent evidence supporting rooming-in as an effective strategy for managing NAS by reducing the need for pharmacotherapy and decreasing LOS. This systematic review and meta-analysis of the current literature demonstrates compelling data for rooming-in as beneficial for newborns with NAS or at risk for NAS. In clinical care settings where it is safe and feasible, we recommend that rooming-in be considered as a preferred management strategy for opioid-exposed newborns and for newborns with NAS.

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Study concept and design: All authors.

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APPENDIX B.6

PEDIATRICS®

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Infant Race Affects Application of Clinical Guidelines When Screening for Drugs of Abuse in Newborns

Marc A. Ellsworth, Timothy P. Stevens and Carl T. D'Angio

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One of the causes of high-risk and premature infant deliveries is maternal abuse of illicit drugs such as cocaine during the prenatal period. Several prenatal factors, such as limited prenatal care and placental abruption, have been associated with a higher likelihood of drug abuse in mothers.¹⁻⁴ Similarly, factors identified during the infant's neonatal period have also been associated with maternal drug abuse.⁵⁻⁸ Because of the reported high incidence of intrauterine cocaine exposure (IUCE) among infants admitted to NICUs^{9,10}, including our own¹¹, our NICU uses specific guidelines for the screening of infant urine for a cocaine metabolite, a finding that suggests cocaine exposure in utero.

Drug screening in newborns entails significant privacy, social, and legal risks for families. In Monroe County, New York, IUCE may be used as grounds for reports to child protective services. Such reports, in the presence of other social risk factors, may result in removal of the child from parental care. In other states, positive results of drug screening have been used as a basis for alerting law-enforcement authorities, which has led to the arrest and imprisonment of mothers of newborns.¹² In Pinellas County, Florida, which requires that findings of illicit drug use during pregnancy be reported to health authorities, discrepancies in reporting of findings that indicate maternal drug use have been described and attributed to the use of race as a factor in determining which mother-infant pairs to screen for illicit drugs. During a 6-month period, the proportion of white women reported for drug use was 1.1%, whereas that for black women was 10.7%. This discrepancy occurred despite similar rates of positive drug-screening results among white and black women (15.4% vs 14.1%) when universal drug screening was performed.¹³

Although screening for in utero drug exposure may serve a legitimate purpose of facilitating identification of high-risk infants, the application of drug screening in a prejudicial manner places an unfair burden on patients subjected to screening by exposing them disproportionately to child-protective and law-enforcement actions. We pursued further research in this area by investigating the screening practices in an institution at which specific screening guidelines were in place. We explored the possibility that drug screening in our NICU might be applied in a manner that considers factors not included in our screening criteria, such as race, to determine whether an infant should be screened. We hypothesized that infants born to black mothers would be more likely than those born to white mothers to be screened for illicit drugs even if they did not meet the criteria for screening that have been specifically delineated at our institution.

METHODS

Population

The University of Rochester Medical Center NICU has ~1100 patient admissions per year. To include a minimum of 2000 mother-infant pairs in our study, we used data for all infants admitted to our NICU during the years 2005 and 2006. Because our institution performs standard maternal data collection on all patients, we were able to include mother-infant data for infants born at our institution (inborn) and for infants born at surrounding hospitals and then transferred to our NICU (outborn).

Data Collection

The protocol for record review was approved by the University of Rochester research subjects review board, which waived the requirement for patient consent. We used our NICU's clinical

database to identify all infants admitted from January 1, 2005, through December 31, 2006. This relational database contained demographic information concerning the mother-infant pair, including delivery statistics (including infant gestational age and weight), pregnancy and delivery complications, neonatal diagnoses, admission and discharge notes, and daily updates of the clinical course.

Maternal medical information was obtained from our clinical obstetrical database. The database contained maternal obstetric and demographic data on all obstetrical patients admitted to our hospital. For inborn patients, socioeconomic and clinical data were collected before delivery. Similar data for mothers of outborn patients were collected when these infants were admitted to our institution. Variables for which data were obtained included maternal race, level of maternal education, insurance status, number of prenatal visits, maternal drug and alcohol use, maternal history of sexually transmitted diseases, and delivery complications. Race information entered into the database was the choice selected by the mother from a menu on a questionnaire administered at the time of her admission to the hospital's obstetrics unit.

Data on newborn and maternal toxicology screening were obtained from the hospital's clinical information system. We examined only screening for cocaine use, because we wanted to eliminate possible false-positive results for opiates and benzodiazepines attributable to maternal medication and because marijuana reporting was not required by child protective services.

Infant urine was screened, and the presence of cocaine was confirmed by identification of the metabolite benzoylecgonine. Benzoylecgonine screening was accomplished by using a cloned enzyme-donor immunoassay

TABLE 1 Demographic Characteristics of the Study Population (N = 2121)

Characteristic	Value
Mean (range) maternal age, y	29.19 (13–51)
Race/ethnicity	
White	1412 (67.2)
Black	412 (19.6)
Hispanic	189 (9.0)
Asian	76 (3.6)
Other	11 (0.5)
Unknown	21 (0.9)
Level of maternal education, n (%)	
Less than high school diploma	319 (17.8)
High school diploma	380 (21.3)
Some college or more	1089 (60.9)
Insurance, n (%)	
Private	1265 (59.7)
Public	693 (32.7)
Self-pay	162 (7.6)
Median household income, n (%)	
<25th percentile ^a	404 (19.2)
25th–50th percentile	473 (22.4)
51st–75th percentile	371 (17.6)
>75th percentile	861 (40.8)
Mean (range) No. of prenatal visits	10.1 (0–36)
Mean (range) gestational age of newborn, wk	35.8 (23.7–42.0)
Mean (range) birth weight of newborn, kg	2.7 (0.4–6.3)
Mother-infant pairs who met drug-screening criteria	565 (26.9)
Newborns screened for drug exposure, n (%)	
Cocaine-positive screen results	13 (8.5 ^b)

^a Data are the median household income of the ZIP code of mother's residence, expressed as percentiles of 2000 census data.

^b Percentage of positive results among those who were screened.

study population, and these mothers were excluded from any analysis that used race as an independent variable. Of the infants evaluated, 153 (7.2%) were screened for exposure to an illicit drug, and test results were positive for 13 (8.5%).

Table 2 lists the individual screening criteria and the number of mother-infant pairs who had documented evidence of meeting each specific criterion. The number of infants whose urine was actually screened for drugs when the criterion was present is also shown. The highest rates of screening were found in infants with maternal drug-use history (47% screened) and

TABLE 2 Presence of Screening Criteria

Factor	No. of Pairs With Documented Evidence	No. (%) Screened
Drug history	148	70 (47.3)
Limited prenatal care	90	35 (38.9)
Sexually transmitted disease(s)	44	11 (25.0)
Placental abruption	104	33 (31.7)
Precipitous labor	57	10 (17.5)
Repeated spontaneous abortions	43	2 (4.7)
Neurologic complications	25	2 (8.0)
Evidence of drug withdrawal	65	14 (21.5)
IUGR ^a	136	15 (11.0)
Urogenital anomalies	35	1 (2.9)

No mother-infant pair had evidence of myocardial infarction, cerebrovascular accidents, severe mood swings, sudden hypertensive episodes (other than preeclampsia), or necrotizing enterocolitis in the first 1 to 2 days after birth.

^a Birth weight at <3rd percentile.

limited prenatal care (39% screened). The presence of factors such as repeated spontaneous abortions in the mother and neurologic complications and urogenital anomalies in the infant rarely resulted in screening of the infant.

We identified 565 mother-infant pairs as having documented evidence of meeting at least 1 screening criterion (Table 3). For those mother-infant pairs that met screening criteria, 117 (20.7%) of the infants were actually screened. Infants born to black mothers were threefold more likely than those born to white mothers to be screened if they met screening criteria. Thirty-four (2.2%) of the mother-

infant pairs who did not have documented evidence of meeting screening criteria were screened. Among pairs that did not meet screening criteria, infants born to black mothers were fourfold more likely to be screened than those born to white mothers.

The results of the multivariate analysis (Table 4) demonstrated several characteristics independently associated with infant drug screening. Among them, race was independently associated with screening of an infant. After we adjusted for other factors, infants born to black or Hispanic mothers were more than twice as likely to be screened for illicit drug use. Other factors independently associated with screening included maternal history of drug use, limited prenatal care, placental abruption, and IUGR. Conversely, as the level of maternal education increased, the likelihood of her infant being screened for drug exposure decreased.

Among our study population, 153 infants were screened for drug exposure, and positive test results indicating exposure to cocaine were found in 13 (8.5%). Among those infants whose urine test results were positive, 7 (12.3% of white infants screened) were white, 3 (4.2%) were black, and 3 (14.3%) were Hispanic (Table 5). Of the 13 infants whose test results were positive, 11 had mothers with a history of drug use. The other 2 positive results were obtained from infants who were

TABLE 3 Drug Screening Among Patients

Race	At Least 1 Screening Criterion Documented		No Documented Screening Criteria	
	Total	No. (%) Screened	Total	No. (%) Screened
White	342	44 (12.9)	1070	13 (1.2)
Black	165	58 (35.1) ^a	247	13 (5.3) ^a
Hispanic	49	14 (28.6) ^a	140	7 (5.0) ^a
Asian	7	1 (14.3)	69	1 (1.4)
Other	2	0 (0.0)	9	0 (0.0)
Total	565	117 (20.7)	1535	34 (2.2)

^a Infants of black or Hispanic mothers were more likely to be screened than those born to white mothers regardless of whether screening criteria were met ($P < .001$ for both comparisons according to χ^2 test).

We found that even the established criteria in our institutional guidelines were not being applied equally in determining which infants were screened. Maternal drug history was the factor most commonly present among infants who were screened. Other factors associated with high rates of screening were limited prenatal care, placental abruption, and IUGR. However, other factors included in screening criteria, such as infant urogenital anomalies, almost never triggered screening.

This study had several limitations. Urine testing was the method used for detecting IUCE in infants at our institution. Meconium testing is a more accurate way to detect cocaine exposure, and some reports have suggested that urine screens may miss up to 40% of positive results.^{11,19} However, unless we assume that in our study meconium testing of infants would have differentially revealed false-negative screens for black patients, the type of testing would not affect our conclusion regarding factors associated with screening.

The use of electronic records and the lack of complete electronic data on some infants may also be considered a weakness of this study. Because we obtained data exclusively by searching electronic records we may have missed screening indications found only in patient data recorded on paper. However, the use of uniform coding

and ability to perform field text searches allowed us to more completely evaluate a larger number of records than if we had reviewed paper charts. Unless incomplete data were distributed unevenly among racial groups, the inclusion of data from this additional source would not have affected our conclusions. Furthermore, the largest disparity in our study was seen with providers who did not screen infants of mother-infant pairs who were documented to have met screening criteria, a finding unaffected by incomplete risk data.

The ultimate goal of screening for IUCE in the newborn is to effectively identify and treat those infants who are at the highest risk for complications. This goal might best be accomplished if only specific risk factors that have been proven to predict both positive screening results and poorer outcomes were applied strictly and universally. Results of some studies have suggested that only a few screening criteria are actually useful in the prediction of poorer neonatal outcomes.^{19,20} Similarly, certain studies have shown that only a few screening criteria are associated with positive drug-screening results.^{15,16,21–23} The 2 most commonly identified criteria that may be useful for predicting both poorer outcomes and positive screens are maternal history of drug use and limited prenatal care.^{16,19,20} Additional research is needed to better identify specific criteria that would help pro-

viders more accurately achieve the aims of neonatal drug screening. This goal might be most effectively accomplished by use of protocols that include consistent screening of infants who meet defined, limited criteria and the use of both urine and meconium testing to detect drug exposure.

CONCLUSIONS

Screening infants for IUCE is an important component of optimal care for at-risk infants. However, we found that at our institution many infants who met specified criteria were not being screened and that differences in screening decisions made by providers were associated with maternal race. Lack of training and inclusion of several largely ignored (and possibly clinically insignificant) criteria in the screening protocol may have contributed to inequitable application of the screening criteria. A more effective screening protocol might contain fewer criteria, with an emphasis on maternal drug history and prenatal care, factors that are associated with high risks of poor neonatal outcomes.

ACKNOWLEDGMENTS

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Infant Race Affects Application of Clinical Guidelines When Screening for Drugs of Abuse in Newborns

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APPENDIX B.7

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Law and Medicine/Board of Trustees Report

Helene M. Cole, MD, *Section Editor*

Legal Interventions During Pregnancy

Court-Ordered Medical Treatments and Legal Penalties for Potentially Harmful Behavior by Pregnant Women

ORDINARILY, the pregnant woman, in consultation with her physician, acts in all reasonable ways to enhance the health of her fetus. Indeed, clinicians are frequently impressed with the amount of personal health risk undertaken and voluntary self-restraint exhibited by the pregnant woman for the sake of her fetus and to help ensure that her child will be as healthy as possible.¹ In a limited number of situations, however, a pregnant woman may reject a medical treatment or procedure that her physician believes would benefit the health of her fetus. For instance, she may refuse to submit to a cesarean section when her physician believes that a cesarean section is in the best interests of the fetus. Or a pregnant woman may behave in ways that are potentially detrimental to fetal well-being, for example, taking illegal drugs while pregnant.

Increasingly, legal interventions are being sought in cases in which the decisions or actions of pregnant women do not accord with medical recommendations that could benefit fetal health. Physicians have sought, and some courts have granted, permission to override refusals of pregnant women to submit to medical procedures. Public officials have tried to impose legal penalties on women whose behavior is not in the best interest of the fetus. This report, which is based on the deliberations of the Committee of Medicolegal Problems, discusses the various legal and policy concerns and makes recommendations regarding legal interventions in pregnancy.

SEEKING COURT ORDERS TO OVERRIDE THE MEDICAL PREFERENCES OF PREGNANT WOMEN Recent Medical Advances Enable Physicians to Address the Health of the Fetus More Directly

Until recently, promoting fetal well-being was generally not a separate endeavor from promoting the health of the pregnant woman. Advances in medicine and surgery, however, have increased the ability of physicians to direct medical procedures specifically at the fetus. Diagnostic tools, such as ultrasonography, amniocentesis, or chorionic villus sampling, can be used to detect fetal abnormalities that, in some cases, may be treated through prenatal therapy or fetal surgery.²

The ability to treat the fetus more directly than in the past has given rise to the question of whether a pregnant woman has a legal obligation to undergo medical treatments that could benefit the fetus. When a pregnant woman refuses

treatment or procedures that could benefit fetal health, a conflict arises between her right to make medical decisions that affect the health of her fetus and herself and the state's desire to intervene on behalf of the fetus.

Questions and concerns over a pregnant woman's legal obligations to accept medical care are exacerbated by the unique physical relationship that exists between a pregnant woman and her fetus. Invariably, one cannot be treated without affecting the other. Performing medical procedures against the pregnant woman's will violates her right to informed consent and her constitutional right to bodily integrity.^{3,4} These rights are among the most basic and are well established in both society and medicine. However, preservation of these rights may come at the risk of preventable fetal impairment or death.

Moral and Legal Responsibilities of the Pregnant Woman Toward Her Fetus

A woman who chooses to carry her pregnancy to term has a moral responsibility to make reasonable efforts toward preserving fetal health. This moral responsibility, however, does not necessarily imply a legal duty to accept medical procedures or treatments in order to benefit the fetus.

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Legal Precedent.—Several courts have considered the issue of legal interventions to impose medical treatments on pregnant women. However, few requests for court-ordered obstetrical interventions have been reviewed by appellate courts. Only two appellate courts have considered a decision to override a pregnant woman's refusal of a blood transfusion. In 1964, the New Jersey Supreme Court ordered a blood transfusion for a pregnant woman who refused the transfusion on religious grounds.⁷ Also in 1964, an appeals court in the District of Columbia ruled that a pregnant woman could be forced to undergo a blood transfusion for the sake of her fetus.⁸ However, both of these cases were decided in the early 1960s, before the current legal emphasis on the integrity of the individual and the right to refuse treatment.

Approximately two dozen courts have been asked to order cesarean sections.⁹ Only two of these cases have reached the appellate level. In one, a trial court judge in the District of Columbia ordered a cesarean section on a woman who was terminally ill.¹⁰ The woman's treatment desires and her competency were major points of controversy in this case. The District of Columbia Court of Appeals, en banc, ruled that the lower court was in error for ordering the cesarean section. The court of appeals ruled that rather than weighing the interests of the state (in protecting the potential life of the fetus) against the interests of the pregnant woman, the lower court should have used "substituted" judgment and proceeded according to what it could best ascertain the pregnant woman's wishes would have been.

In 1981, a trial court in Georgia ordered a cesarean section performed on a woman who had refused the operation for religious reasons. The physician involved diagnosed placenta previa, with a 99% to 100% chance of fetal demise if vaginal delivery occurred.¹¹ The Georgia Supreme Court, with minimal explanation or policy discussion, refused to stay the trial court's order. A few days after the court's denial of a stay, the woman had a safe vaginal delivery.

The remainder of this section of the report provides an analysis of relevant law and policy considerations and recommends guidelines on the extent to which a pregnant woman's moral duties toward the fetus should be legally enforced.

Distinctions Between Moral and Legal Responsibilities.—Society places a positive moral value on aiding those who may need help or be in danger, yet it does not ordinarily impose a legal duty on specific individuals to render that needed assistance.¹² This reluctance to impose a legal duty on the individual is especially strong where rendering aid would pose a risk to the health of the individual or would require an invasion of his or her bodily integrity.^{13,14}

There is also no legal duty for an individual to render aid even if a life would be saved and the assistance rendered would incur minimal risk to the health of the person providing the aid. For example, a person need not donate bone marrow to a cousin who is dying of aplastic anemia.¹⁵

Yet the responsibility of a pregnant woman to her fetus is stronger than that of one individual to another. The duty of a pregnant woman to her fetus is more akin to the obligations of a parent to his or her child. And in fact, a parent's duty to his or her child is enforced with legal sanctions. The parent-child relationship is considered a "special relationship" under "Samaritan" law.¹⁶ Samaritan law, which applies to duties to render aid, provides that those people who have a special relationship to another person, such as innkeeper to guest or

common carrier to passenger, have a legal obligation to come to the aid of that person.¹⁷

Even in cases of special relationships, however, the obligation to render aid is minimal and cannot require the rescuer to endanger him or herself.¹⁸ For example, if a child needed a bone marrow transplant, but the only compatible donor was the child's father, the father would not be legally required to donate his bone marrow to his child.

There are other situations in which a parent's obligation to his or her child is legally enforced. Parents clearly have both a moral and legal duty to provide reasonable medical care for their children. All states legally require parents to provide such care.¹⁹ A pregnant woman who refuses a surgical intervention, treatment, or therapy that might benefit fetal health is, in practical terms, withholding medical care from her fetus. However, in the case of a pregnant woman, in order for her not to withhold medical treatment, she generally must accept a risk to her life or health, as well as bodily invasion of her person. Just as parental legal obligations to provide medical care to children do not include compelled acceptance of risk to life or health, neither should a pregnant woman's obligations to her fetus include the acceptance of such risk.

Current procreative law reflects this principle. Under *Roe v Wade*, the state's interest in potential life becomes compelling at the point of viability.²⁰ It is at that point, therefore, that the state may prevent a woman from having an abortion. Nevertheless, the state may not adopt postviability abortion regulations that trade off risks to the health of the pregnant woman against benefits to the health of her fetus.²¹

In addition, legally enforcing a pregnant woman's moral obligation to the fetus creates a burden or penalty on pregnancy itself.²² The right to bear a child is constitutionally protected.²³ Forcing a pregnant woman to undertake a health risk or to accept an invasive procedure against her will burdens her decision to have a child.²⁴

Even a viable fetus does not generally receive the same legal recognition as a child. Consequently, the legal enforcement of a pregnant woman's moral responsibility to her fetus should not exceed the legal enforcement of a parent's moral duty to his or her child.²⁵ Society does not legally require parents to undergo a risk of life, health, or bodily invasion in order to carry out their moral obligations to provide medical care for their children. Few, if any, medical procedures meant to benefit the fetus would entail no risk to a pregnant woman's health. Thus, while a pregnant woman should be resolutely encouraged to fulfill her moral responsibilities to her fetus, a legal duty to accept medical procedures meant to benefit her fetus generally should not be imposed.

Ethical Obligations of the Physician in Instances of Treatment Refusal

A physician's ethical duty toward the pregnant woman clearly requires the physician to act in the interest of the fetus as well as the woman. Arguably, adherence to a pregnant woman's refusal of treatment that is intended to benefit the fetus would violate that ethical obligation, particularly when the physician believes that the potential benefit to the fetus outweighs the health risk to the mother. While some physicians find adherence to a pregnant woman's wishes morally untenable in situations of fetal endangerment,²⁶ the duty to protect the health of both the pregnant woman and the fetus precludes balancing one against the other. The physician's

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responsibilities in other settings provide a useful analogy, eg, (there is no situation (other than perhaps the case of conjoint twins) when it is appropriate for a physician to impose a medical risk on one patient in order to preserve the health of another. A physician cannot force one patient to donate blood to another patient, even if the donation would save the second patient's life. Similarly, such a balancing should generally not be undertaken in the context of pregnancy.

The doctrine of informed consent also indicates that a pregnant woman's refusal of treatment should not be overridden for the benefit of the fetus. Principles of informed consent require a physician to respect the wishes of a mentally competent adult in situations of medical decision making.¹ These principles recognize that decisions that would result in health risks are properly made only by the individual who must bear the risk.^{1,2} Considerable uncertainty can surround medical evaluations of the risks and benefits of obstetrical interventions.¹⁹⁻²² Through a court-ordered intervention, a physician deprives a pregnant woman of her right to reject personal risk and replaces it with the physician's evaluation of the amount of risk that is properly acceptable.¹ This undermines the very concept of informed consent.

Adverse Consequences of Seeking Court-Ordered Obstetrical Interventions in Instances of Treatment Refusal

There are additional reasons why seeking a court order is not necessarily an appropriate response to a pregnant woman's treatment refusal.

A Court Is an Inappropriate Forum for Resolving Treatment Disputes.—Courts are ill-equipped to resolve conflicts concerning obstetrical interventions. The judicial system ordinarily requires that court decisions be based on careful, focused deliberation and the cautious consideration of all facts and related legal concerns. In addition, there is always an opportunity for review on appeal. Court-ordered obstetrical interventions, on the other hand, are likely to be requested on extremely short notice and require immediate judicial action. A study done of court-ordered obstetrical interventions reported that in 70% of cases in which orders were considered, hospital administrators and attorneys were aware of the situation only a day or less before seeking a court order; 88% of the orders were obtained in less than 6 hours, and in 19%, less than an hour.⁶ It is unlikely that most judges would already be familiar with the policy concerns or relevant legal precedents required to make a carefully considered decision on such short notice.²⁰ Decisions made under these immediate deadlines and intense pressures are likely to be hasty and lack well-reasoned conclusions. In the case of an improperly reached conclusion, there is no meaningful appeal available.²⁰

In addition, such court proceedings may be unfairly weighted against the pregnant woman. A woman in such a situation is probably under considerable psychological stress and may be suffering from substantial physical pain as well. Her ability to articulate her interests may be seriously impaired. It is further unlikely that the woman will be able to find adequate counsel on such short notice, and it is even more unlikely that counsel will have time to prepare properly for the hearing.

When a decision must be rendered almost immediately, there will be little or no time to obtain the full range of medical opinions or facts. The inability of a court to understand the full range of the relevant medical evidence may lead to error with

serious and irreversible consequences.

The Bases for Selecting Cases for a Court Order May Result in the Inconsistent Application of Compelled Treatment.—A physician's decision to pursue a court order reflects his or her personal evaluation of the importance of a pregnant woman's autonomy vis-à-vis the importance of fetal health. Accordingly, whether a woman must undergo judicial review of her decision regarding medical care will vary from physician to physician.

A troubling fact is that court-ordered obstetrical interventions seem to be sought more often in cases where the woman is either a member of a minority group or of a lower economic background. According to an initial study,⁷ in 81% of the instances in which a court-ordered intervention was sought, the woman belonged to a minority group. Every request for a court order involved a woman who had received care at a teaching hospital or who had received public assistance.

Women from lower socioeconomic groups and from differing ethnic backgrounds may have religious and other personal beliefs or circumstances that vary greatly from those of their physicians or the judges who decide their cases.²⁰ A woman's reasons for refusing care may be misunderstood or disregarded by the physician seeking the court-ordered override of her decision or by the judge who decides the case.

Creating Impermissible Legal Obligations for the Physician.—An important consideration for physicians is the extent to which they should encourage or contribute to state or court intervention in the medical decision-making process in general. Physicians have traditionally rejected outside intrusion into the physician-patient relationship. Imposing legal duties to accept medical care on pregnant women may result in concomitant legal duties for the physician. Such duties may require the physician to act as an agent of the state rather than as an independent patient counselor.

Judicial intervention is often sought in part to minimize either physician or hospital liability. However, seeking such interventions could ultimately serve to expand rather than limit liability.¹ The tendency to resort to judicial intervention in cases of treatment refusal may create an obligation for the physician to obtain a court order in any situation in which a pregnant woman's preference does not accord with the physician's evaluation of the fetus' needs. If a pregnant woman's obligations to the fetus become legally enforceable, then it is up to the physician to decide in which situations a woman is shirking her legal obligations by rejecting proposed care. Courts may therefore consider a physician negligent for not seeking a court order in situations where a pregnant woman's decision led to fetal impairment.

Another consideration is the extent to which a physician would be required to participate in the practical aspects of enforcing an override of a pregnant woman's treatment decision.²¹ In one case in which a court granted permission to a hospital to perform an unwanted cesarean section, the pregnant woman left the hospital before delivery.¹ Should a court choose to enforce an override by compelling the woman to accept treatment, severe methods of restraint may be required. A pregnant woman may have to be forcibly restrained to prevent her from leaving the hospital or physical force may have to be used in order to administer a particular medicine to her. Inviting the state to override a pregnant woman's decision legally may also be inviting government-mandated participation by physicians in administering the treatment. The

physician-patient relationship would certainly be damaged by physician participation in the forcible administration of medical care.²⁹

A physician's role is as a medical adviser and counselor. Physicians should not be responsible for policing the decisions that a pregnant woman makes that affect the health of herself and her fetus, nor should they be liable for respecting an informed, competent refusal of medical care. In the interest of preserving fetal health, the physician must ensure that a pregnant woman's decision is a fully informed, competent, and considered decision. A physician should make sure that the pregnant woman understands the nature of the proposed treatment and the implications of treatment and nontreatment for both herself and her fetus. A physician may encourage the pregnant woman to consult other sources, such as family members, health professionals, social welfare workers, or the clergy, to provide her with additional information regarding her decision. When a pregnant woman makes an informed refusal of a procedure meant to benefit fetal health, the physician cannot be held morally responsible for the consequences of the pregnant woman's decision.

Adverse Effects on the Physician-Patient Relationship.—Requests for court intervention may interfere with the physician-patient relationship in other ways. Physician willingness to override a pregnant woman's decision creates an adversarial relationship between physician and patient.³⁰ In a specific case, the damage to the physician-patient relationship may appear to be outweighed in relation to the benefit to the fetus. However, it may also precipitate general distrust of physicians on the part of pregnant women. Once it becomes known a particular physician or physicians in general are willing to override a pregnant woman's preferences, women may withhold information from the physician that they feel might lead the physician to seek judicial intervention. Or they may reject medical or prenatal care altogether,³¹ seriously impairing a physician's ability to treat both the pregnant woman and her fetus. While the health of a few infants may be preserved by overriding a pregnant woman's decision, the health of a great many more may be sacrificed.

Conclusions

The Physician's Professional Duty.—The physician's duty is to ensure that the pregnant woman makes an informed and thoughtful decision, not to dictate the woman's decision.

Physicians Should Not Have a Legal Duty to Seek Court-Ordered Obstetrical Interventions.—There may be no other case where patient rejection of medical advice is as frustrating as when a pregnant woman rejects a procedure designed to benefit her fetus.³² Yet, physicians should refrain from using the courts to impose personal value judgments on a pregnant woman who refuses medical advice meant to benefit her fetus. As a corollary, a physician should not be liable for injuries sustained as a result of honoring a pregnant woman's informed refusal of treatment designed to benefit the fetus.

Justification for Seeking Court-Ordered Interventions May Be Permissible Only in Exceptional Circumstances.—An absolute rule that a pregnant woman has no legal duty to accept any medical treatment that would substantially benefit her fetus would be problematic. For example, a woman conceivably could refuse oral administration of a drug that would cause no ill effects in her own body but would almost certainly prevent a substantial and irreversible injury

to her fetus. Given the current state of medical technology, it is unlikely that such a situation would occur. In addition, as a practical matter, it is unlikely that a woman would refuse treatment in that situation.

If an exceptional circumstance could be found in which a medical treatment poses an insignificant—or no—health risk to the woman, entails a minimal invasion of her bodily integrity, and would clearly prevent substantial and irreversible harm to her fetus, it might be appropriate for a physician to seek judicial intervention. However, the fundamental principle against compelled medical procedures should be a control in all cases that do not present such exceptional circumstances.

RESPONSES TO HARMFUL BEHAVIOR BY THE PREGNANT WOMAN

Alarm at the Rising Percentages of Infants Exposed to Harmful Substances In Utero

Currently, attention is increasingly being drawn to instances where the behavior of pregnant women is potentially harmful to fetal well-being. There has been particularly great concern with the incidence of babies born with cocaine in their systems as a result of cocaine use by pregnant women. Hospitals are reporting an alarming rise in the number of births of these drug-exposed infants.³³ The unprecedented rise in cocaine use among women of childbearing age is primarily due to the current popularity of the use of "crack," a concentrated, inexpensive, and highly addictive form of cocaine. Experts estimate that as many as 11% of pregnant women have used an illegal drug during pregnancy, and of those women, 75% have used cocaine.³⁴ The American Medical Association (AMA) Board of Trustees³⁵ profiled the current problem of substance abuse among pregnant women and discussed the clinical challenges involved in identifying and providing comprehensive treatment for these women.

The alarm with which these figures have been met is not unwarranted. The effects of cocaine use by a pregnant woman on her fetus and subsequently on her infant can be severe. Cocaine can cause in utero strokes, spontaneous abortion, and abruptio placentae.³⁶ It also results in increased infant mortality. On the average, cocaine-exposed babies have lower birth weights, shorter body lengths at birth, and smaller head circumferences than normal infants.³⁷ They also have a higher incidence of physical abnormalities, including deformed kidneys and neural tube defects.³⁸ Cocaine-exposed babies often experience withdrawal symptoms that make them more irritable and resistant to bonding than other babies.³⁹ Researchers believe that cocaine-exposed babies will be more likely to experience learning disabilities.⁴⁰

Although drug and other substance abuse by the pregnant woman attracts intense media attention, there are actually a large variety of behaviors that can adversely affect the fetus. Cigarette smoking by pregnant women results in higher rates of spontaneous abortion, premature birth, increased perinatal mortality, low birth weight, and negative effects on later growth and development in infants.⁴¹ Many prescription or over-the-counter medicines will cross the placenta and affect fetal health.⁴² Exposure to hazardous chemicals heightens the risk for spontaneous abortion, premature birth, stillbirth, low birth weight, and birth defects.⁴³

Special mention should be made of alcohol use. Many studies have confirmed the dangerous effects of alcohol use by

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pregnant women on their infants.³⁴ Babies born with fetal alcohol syndrome suffer from prenatal and postnatal growth retardation; cardiovascular, limb, skull, and facial defects; impaired fine- and gross-motor function; and impaired intellectual function.³⁵ Despite the serious health effects of alcohol consumption, the legal and social acceptance of alcohol make its use particularly difficult to prevent. Further, while excessive alcohol use during pregnancy *certainly* can cause serious fetal harm, no minimum level of alcohol use has yet been established as safe.³⁶ The AMA, former Surgeon General Koop, and a number of other experts have concluded that total abstinence is the only way to ensure no ill effects from alcohol consumption during pregnancy.³⁷

Legal Penalties as a Response to Substance Abuse by Pregnant Women

The rising percentage of babies born with cocaine in their systems has been matched by the rising frustration of the health care and legal communities in finding ways to prevent the problem. A growing number of jurisdictions have tried to impose legal penalties, often criminal sanctions, in an attempt to deter drug use by pregnant women.³⁸ Women have been charged under statutes against child abuse and neglect and the delivery of a controlled substance to a minor,³⁹ or given special penalties for an unrelated conviction because they were pregnant and suspected of cocaine use.⁴⁰ Evidence of drug abuse by pregnant women is being used as grounds for the state's assuming immediate custody of newborns.⁴¹ In addition, other legal interventions, such as civil detention, have been sought in order to monitor or control the behavior of a pregnant woman when her behavior was considered potentially dangerous to her fetus.⁴² For the most part, these attempts to criminalize or legally penalize behavior by pregnant women have been unsuccessful. Several courts have ruled that existing statutes against child abuse and neglect cannot be applied to the fetus.⁴³

Some public officials believe that imposing criminal sanctions will deter substance abuse by pregnant women. However, many health and social welfare experts feel that the problem is more effectively addressed as a health concern rather than as a legal problem.⁴⁴ They further maintain that criminal sanctions will not only fail to deter pregnant women from substance abuse, they will in fact prevent them from seeking prenatal care or medical help for their dependency.

Incarceration or Detention During Pregnancy.—Incarceration or detention might seem to be the most effective means of preventing a specific harmful behavior. Ostensibly, the state could force an incarcerated or detained woman to adopt behavior that would promote the health of her fetus. However, incarcerating pregnant women in order to preserve fetal health may prove counterproductive.

Any attempt at detecting and managing the potentially harmful behavior of pregnant women through legal intervention is likely to require substantial participation on the part of the medical community. For instance, if a pregnant woman's actions are classified as child abuse, legal obligations are created for the physician. All states require physicians to report suspected abuse.⁴⁵ Most, in fact, hold health care personnel liable for failure to report, and some states even maintain liability for failure to diagnose child abuse properly.⁴⁶

It is not unreasonable to assume that at-risk pregnant women would be deterred from seeking contact with those

people or institutions who might take action leading to their incarceration. Pregnant women will be likely to avoid seeking prenatal or other medical care for fear that their physicians' knowledge of substance abuse or other potentially harmful behavior could result in a jail sentence rather than proper medical treatment. This fear is not unfounded; recently, a pregnant woman who sought medical care for injuries received as a result of a spousal beating was reported to the authorities, arrested, and charged with criminal child abuse for drinking during her pregnancy.⁴⁷ The case was subsequently dismissed. In addition, the number of women who are convicted and incarcerated for potentially harmful behavior is likely to be relatively small in comparison with the number of women who would be prompted to avoid medical care altogether. As a result, the potential well-being of many infants may be sacrificed in order to preserve the health of a few.

Imposing criminal or civil sanctions on pregnant women for potentially harmful behavior may also encourage women to seek abortions in order to avoid legal repercussions. In addition, incarceration would be of only limited value since a considerable amount of damage could be done to the fetus before a woman even realized she was pregnant.⁴⁸

Further, while the incarceration of pregnant women would be intended to benefit the fetus, the reality of the environment in which pregnant women would be placed would do little to ensure fetal health. Prisons in general have inadequate health care resources. Moreover, prison health experts warn that prisons are "shockingly deficient" in attending to the health care needs of pregnant women.⁴⁹ Most prisons have inadequate protocol, staff, or training to properly attend to the special needs of pregnant prisoners. The result has been widespread deficiencies in prenatal diet, nutrition, and exercise and seriously inadequate, if any, prenatal care. Pregnant women in jail are routinely subject to conditions that are hazardous to fetal health, such as gross overcrowding,⁵⁰ 24-hour lock-up with no access to exercise or fresh air, exposure to tuberculosis, measles, and hepatitis, and a generally filthy and unsanitary environment. Additionally, it is unclear that incarceration would prevent drug use by pregnant women because drugs are readily available in prison.⁵¹

Legal Penalties Imposed After Birth.—*Criminal Sanctions.*—The most compelling reason that has been proposed for instituting postnatal criminal sanctions in cases of substance abuse by pregnant women is to prevent damage to fetal health. The actual efficacy of criminal sanctions as a method for preventing substance abuse is doubtful, however. Obviously, fetal harm caused by substance abuse is averted only by effecting abstinence from harmful substances by pregnant women. Punishing a person who abuses drugs or alcohol is not generally an effective way of curing their dependency or preventing future abuse. The AMA has stated that "it is clear that addiction is not simply the product of a failure of individual willpower."⁵² Substance abuse is caused by complex hereditary, environmental, and social factors. Individuals who are substance dependent have impaired competence in making decisions about the use of that substance.

Punishing a person for substance abuse is generally ineffective because it ignores the impaired capacity of substance-abusing individuals to make decisions for themselves. In all but a few cases, taking a harmful substance such as cocaine is not meant to harm the fetus but to satisfy an acute psychological and physical need for that particular substance. If a preg-

nant woman suffers from a substance dependency, it is the physical impossibility of avoiding an impact on fetal health that causes severe damage to the fetus, not an intentional or malicious wish to cause harm.

A woman's socioeconomic position may further affect her ability to carry out her moral responsibility to provide reasonable care in preserving fetal health. The women most likely to be prosecuted for exposing their fetuses to harmful substances are those from the lower economic levels.⁶⁴ These women are more likely to lack access to both prenatal care and substance abuse treatment because of financial barriers.⁶⁷ They are often uninsured or underinsured.⁶⁸ Even when Medicaid is available, women may still lack access to medical care because of inadequate system capacity.⁶⁹

Access to care does not guarantee that pregnant women will receive drug treatment; one of the most commonly missed diagnoses in obstetric and pediatric medicine is drug abuse.⁶⁵ Additionally, many prenatal care facilities do not have the capacity to treat substance abuse.

Pregnant substance abusers also tend to have other severe life stresses that may contribute to their substance abuse. An AMA Board of Trustees⁶⁷ report states that female substance abusers tend to have more dysfunction in their families than nonabusers. They have high levels of depression, anxiety, sense of powerlessness, and low levels of self-esteem and self-confidence.⁶⁴ A study done by a center that treats female substance abusers found that 70% of them were sexually abused as children, as compared with 15% of nonsubstance abusers.⁶¹ Eighty-three percent had had a chemically dependent parent, as opposed to 35% of the nonabusers.⁶¹ Seventy percent of female substance abusers report being beaten.⁶⁴ Ten percent of female substance abusers in one study were homeless, while 50% had occasional housing problems.⁶¹

Substance dependence and contributing factors cannot be used as an excuse for disregarding the consequences of dependent behavior on fetal and infant health. However, the magnitude of the problem and the influence of aggravating factors may preclude criminal sanctions from being an effective deterrent. For example, the use of illegal substances already incurs criminal penalties. Pregnant women who use illegal substances are obviously not deterred by existing sanctions; the reasons that prompt them to ignore existing penalties might also prompt disregard for any additional penalties. Furthermore, in ordinary instances, concern for fetal health prompts the great majority of women to refrain from potentially harmful behavior. If that concern, generally a strong impetus for avoiding certain actions, is not sufficient to prevent harmful behavior, then it is questionable that criminal sanctions would provide the additional motivation needed to avoid behaviors that may cause fetal harm.

Civil Liability as a Remedy for Harmful Behavior by Pregnant Women.—Regardless of the inefficiency of criminal sanctions, a woman who uses harmful substances during her pregnancy often gives birth to a child who is either impaired or less healthy than the child would have been had the mother abstained from substance abuse. It is widely accepted that if a person other than the pregnant woman acts in such a way that fetal health, and consequently a child's health, is impaired, then that person can be held civilly liable for the impairment.⁷⁰ While recovery in such situations is meant to compensate the parents of the impaired child, it may also be used to compensate the subsequent child for injuries

resulting from negligent actions during the prenatal period.⁷¹

The consequences of harm may be similar regardless of whether the responsible party is the pregnant woman herself or another person (a third party). Some commentators have stated that to punish third parties but not pregnant women for actions that result in harm to the fetus would be inconsistent.⁷⁰ However, a pregnant woman and her fetus share a physical interdependency that a third-party tort-feasor and the fetus do not. The nature of the relationship between the pregnant woman and her fetus makes problematic tort liability against the mother for prenatal injuries.

Third-party liability protects both the pregnant woman and her fetus from behavior that is normally unacceptable under any circumstances.⁷⁷ For instance, a drunk driver is liable for his or her actions because they are a menace to all, the born and unborn alike. However, every action on the part of a pregnant woman can have substantial impact on fetal health. Maternal liability would severely restrict a pregnant woman's freedom to act in even normally innocuous ways.

Causes of action would arise much more frequently than instances where the mother would actually be at fault. The difficulty in determining the cause of infant impairment could give rise to numerous unfounded claims of maternal liability. Many women who behaved in an acceptable manner during pregnancy would be unfairly subjected to liability proceedings, just as presently many physicians who practice good obstetrical medicine are subjected to unfounded liability claims.

Even if it could be proven that a pregnant woman's behavior caused infant impairment, intense scrutiny of the most intimate details of a pregnant woman's life would be required to evaluate the extent to which she could be held responsible for her actions.⁷⁷ A judicial investigation to determine which action caused the harm and its reasonableness would have to include a determination of whether the harm was caused before or after the woman realized she was pregnant and whether she realized the behavior could affect fetal health. The court would also have to determine whether she could have reasonably prevented the harm or whether the action taken was reasonable in the context of other circumstances. Even the most insignificant decision on the part of the pregnant woman could be subsequently called into question.

The imposition of civil liability on women whose infants are born impaired would pose too great a burden and too great an intrusion into the lives of innocent women to justify it as a remedy to harmful behavior by the pregnant woman.

The Most Effective Method of Preventing Harmful Behavior by Pregnant Women Is Through Treatment and Education

Many health and public welfare officials feel that the most effective way of preventing substance abuse in pregnant women is through education about potential harms and the provision of comprehensive treatment for their abuse.^{63,64} Important methods for preventing or minimizing fetal harm due to substance abuse by pregnant women include identification of women who are at high risk for being substance abusers, early medical and psychotherapeutic intervention in the pregnancies of substance-abusing women, and access to programs that address the full range of social and health care needs associated with substance abuse.⁶¹ The National Association for Perinatal Addiction Education and Research has docu-

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mented the efficacy of programs that follow these methods.¹⁴

In contrast, criminal penalties may exacerbate the harm done to fetal health by deterring pregnant substance abusers from obtaining help or care from either the health or public welfare professions, the very people who are best able to prevent future abuse. The California Medical Association¹⁵ has noted:

While unhealthy behavior cannot be condoned, to bring criminal charges against a pregnant woman for activities which may be harmful to her fetus is inappropriate. Such prosecution is counterproductive to the public interest as it may discourage a woman from seeking prenatal care or dissuade her from providing accurate information to health care providers out of fear of self-incrimination. This failure to seek proper care or to withhold vital information concerning her health could increase the risks to herself and her baby.

Florida's secretary of Health and Rehabilitative Services has also observed that potential prosecution under existing child abuse or drug use statutes already "makes many potential reporters reluctant to identify women as substance abusers."¹⁶

It may seem that a pregnant substance abuser has an obligation to obtain treatment for her dependence. However, obtaining treatment is not currently a practical alternative for pregnant substance abusers. Even the most persistent woman is likely to fail to find a treatment program for her substance dependency. Rehabilitative centers for substance abusers are in short supply.¹⁷ The majority of those facilities that do treat substance abuse refuse to accept pregnant women, in part due to concerns over liability.¹⁸ Of the few centers that do treat pregnant women, most have long waiting lists.

Further, the majority of substance abuse treatment facilities operate on an adult-male centered model.¹⁹ They are not designed to address problems specific to women's psychological or physiological needs. Nor are they equipped to handle other problems that substance-dependent women often have, such as how to arrange day-care for older children or counseling for a woman who is abused by a spouse or partner. It would be an injustice to punish a pregnant woman for not receiving treatment for her substance abuse when treatment is not an available option to her.

Finally, societal efforts to educate pregnant women and provide accessible treatment for those who may be substance abusers promote relationships and attitudes that are beneficial to fetal health in general. Criminal penalties levied against pregnant women for their actions would posit physicians as government agents with enforcement responsibilities rather than as concerned patient advocates.²⁰ Criminal penalties would also emphasize conflict between the pregnant woman and her fetus, which does not encourage a healthy relationship between the pregnant woman and her future child. On the other hand, providing education and treatment emphasizes cooperation and trust between the pregnant woman and her physician and facilitates a more emotionally positive relationship after birth.²¹

State-Assumed Custody of Exposed Infants

Another response to harmful behavior by pregnant women is taking the woman's baby into state custody after birth. Probably the most widely accepted action for preterm substance abuse is state-assumed custody of infants who show signs of prenatal exposure to harmful substances.²² Legal penalties for behavior while pregnant are problematic be-

cause a pregnant woman and her fetus cannot practically be treated as separate entities. Once an infant is born, this is not a consideration. In addition, evidence shows that parental substance abuse and child abuse are highly correlated.²³ Children who have been impaired due to in utero exposure to harmful substances are likely to be especially difficult to care for, requiring above normal parenting skills.^{24,25} Courts have ruled that the potential for abuse implied by substance abuse by a woman while pregnant is adequate justification for allowing the state to assume at least temporary custody of these infants.¹⁴

Ordinarily, the state cannot impose punishment for potential, rather than actual, actions. Presumably, the termination or suspension of parental rights is an exception because it is primarily a protection for the child and not a penalty directed at the parent.²⁶ In the interest of preserving family unity wherever reasonably possible, courts should be careful to ensure that such actions are actually protective of the child.

Consideration of Criminal or Civil Sanctions in Exceptional Cases

Some commentators have argued that legal penalties or state intrusion into the lives of pregnant women are legally justifiable because once a pregnant woman forgoes her right to have an abortion she has a "legal . . . duty to bring the child into the world as healthy as is reasonably possible."²⁷ This duty includes restrictions that "may significantly limit a woman's freedom of action and even lead to forcible bodily intrusion."²⁸ The implication is that once a woman has become pregnant and does not take affirmative steps to terminate her pregnancy, then she has forfeited her constitutional rights to bodily integrity and privacy.

However, this legal argument has been criticized as misplaced.² One commentator notes that such a waiver of constitutional rights never actually takes place because "women do not appear before judges to waive their rights at any time during pregnancy."²⁹ The fact that a woman does not abort her fetus cannot be construed as the willing forfeiture of her constitutional rights. Further, if the decision to have a child automatically precipitates a waiver of constitutional rights, then the state has created a penalty for choosing to bear a child.³ The right to procreate is constitutionally protected and its exercise cannot be penalized.³ In addition, state-imposed penalties upon the decision to bear children would be troubling as a policy matter.

Absolutely prohibiting legal penalties for all potentially harmful actions by a pregnant woman may seem extreme. For instance, if a situation arose in which a woman willingly engaged in an elective behavior that would clearly cause severe and irreparable injury to the future child, it seems incongruous to suggest that society should have no legal recourse for such behavior.

Yet, it is difficult to imagine that such circumstances might occur in significant numbers, if at all. More important, the conscious infliction of certain and severe harm to the fetus would generally pose a serious risk of harm to the pregnant woman as well. Therefore, counseling, psychiatric treatment, or other support services would probably be a more appropriate response than criminal punishment. In addition, it is difficult to imagine a situation in which legal rules would be the best policy choice as legal penalties or liability may be ultimately detrimental, rather than beneficial, to fetal health.

RECOMMENDATIONS

The AMA Board of Trustees recommends adoption of the following statement:

1. Judicial intervention is inappropriate when a woman has made an informed refusal of a medical treatment designed to benefit her fetus.

If an exceptional circumstance could be found in which a medical treatment poses an insignificant or no health risk to the woman, entails a minimal invasion of her bodily integrity, and would clearly prevent substantial and irreversible harm to her fetus, it might be appropriate for a physician to seek judicial intervention. However, the fundamental principle against compelled medical procedures should control in all cases that do not present such exceptional circumstances.

2. The physician's duty is to provide appropriate information, such that the pregnant woman may make an informed and thoughtful decision, not to dictate the woman's decision.

3. A physician should not be liable for honoring a pregnant woman's informed refusal of medical treatment designed to benefit the fetus.

4. Criminal sanctions or civil liability for harmful behavior by the pregnant woman toward her fetus are inappropriate.

5. Pregnant substance abusers should be provided with rehabilitative treatment appropriate to their specific physiological and psychological needs.

6. To minimize the risk of legal action by a pregnant patient or an injured child or fetus, the physician should document medical recommendations made including the consequences of failure to comply with the physician's recommendations.

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APPENDIX B.8



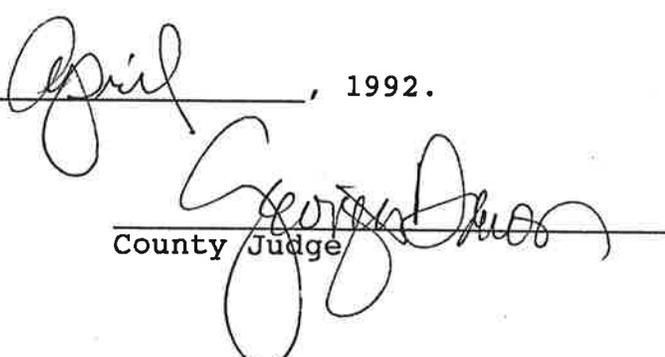
Stephen R. Dawson
Assistant States Attorney
Cass County Courthouse
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ORDER

After reviewing Plaintiff's Motion to Dismiss in the above-entitled action and after reviewing the records and files herein,

IT IS HEREBY ORDERED that the above-entitled action is dismissed with prejudice.

Dated this 10th day of April, 1992.



County Judge