

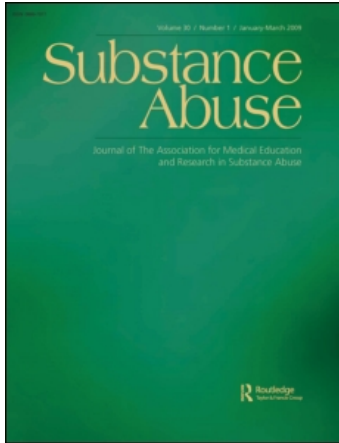
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Prenatal Toxicology Screening for Substance Abuse in Research: Codes and Consequences

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Prenatal substance abuse has long been identified as a risk factor for the developing fetus, and implicated in pediatric cognitive, neuropsychological, and physiologic problems. Conservative estimates suggest that prenatal substance abuse affects hundreds of thousands of pregnancies annually and is associated with developmental delays, learning disabilities, social disturbances, and lifelong health issues for the child. Prenatally substance-exposed children experience higher levels of child abuse and neglect, are more likely to need foster parenting, and have higher rates of subsequent substance abuse than nonexposed children (1, 2).

The scientific necessity to screen for substance abuse in research participants raises ethical issues when illicit drug use is uncovered. The impact of legislative policies restricting maternal rights in the setting of substance abuse needs to be considered by researchers as potentially intruding into confidential relationships between research participants and investigators. Moreover, the legal implications for substance-abusing pregnant research subjects, surprisingly, may not act as a deterrent to their participation in research studies altogether.

By its nature, research with pregnant women involves the protection of 2 research participants. Even observational studies in pregnancy require extra scrutiny by the institutional review board (IRB), with adherence to special requirements mandated for vulnerable populations. Complicated by ongoing contentious debate over maternal and fetal rights, the resolution of research dilemmas in pregnancy is often not ideal. It is important for those involved in perinatal research to be familiar not only with current controversies about the consequences of perinatal substance abuse for both mother and child, but also with policies guiding ethical obligation of the provider under these circumstances, and pertinent legislation directing provider action in certain cases.

THE HISTORY OF LEGISLATION AND POLICIES FOR PERINATAL DRUG ABUSE

Prior to 2003, federal policy was virtually nonexistent on the issue of substance-exposure in pregnancy. State legislation, where in place,

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typically required that pregnant women be given priority for drug and alcohol treatment if space was available. Reflecting only a cursory recognition of the complex management of this prenatal health issue, the inadequate number of treatment programs accepting pregnant women limited legislative utility (3). Moreover, concordant with a lack of federal guidelines regarding prenatal substance use, legislation at the state level varied widely, from supportive to punitive approaches.

The Child Abuse Prevention and Treatment Act (CAPTA) was originally enacted in 1974 (Public Law 93–247; United States Code Title 42, Chapter 67) to provide federal funding to states in support of prevention, assessment, investigation, prosecution, and treatment activities that addressed child abuse and neglect. In addition, CAPTA was developed to provide grants to public and nonprofit agencies for relevant programs and projects, and supports research, evaluation, data collection, and technical assistance to agencies fulfilling this mission. Through CAPTA, the Office on Child Abuse and Neglect is maintained, and the Child Information Gateway sustained to provide access to information and resources for safeguarding children (www.childwelfare.gov). Although successful in establishing national standards for child protection, the original CAPTA legislation did not address the issue of substance exposure in pregnancy.

CAPTA has been amended several times, most recently in 2003 when it was reauthorized to include the Keeping Children and Families Safe Act (Public Law 108–36). The Keeping Children and Families Safe Act (KCFSA) recognized the need for more comprehensive services to help the population of substance-using pregnant women. This legislation amended CAPTA to require that all states have in place protocols for responding to the problem of substance-exposed newborns, and to establish a plan of safe care for those identified as being affected by illegal substance abuse or withdrawal from prenatal drug exposure. The amendment aimed to link child welfare services with developmental, early intervention, psychological, and health services in order to support at-risk children. KCFSA specified that states have

... policies and procedures to address the needs of infants born and identified as affected by illegal substance abuse or withdrawal symptoms resulting from prenatal drug exposure, including requirement that health care providers involved in the delivery of care of such infants notify the child protective services of the occurrence of such condition in such infants, except that such notification shall not be construed to (i) establish a definition under Federal law of what constitutes child abuse, or (ii) require prosecution for any illegal action.

KCFSA, Section 106(b)(2)(A)(ii)

Although states were required to provide assurances of these provisions to be eligible for CAPTA funding, federal oversight in this area was unclear. The federal law did not address how to identify substance-exposed infants, and as a result, policies now vary widely among states. This diversity is apparent with some states favoring universal screening of newborns, and others supporting voluntary, or selective, testing.

In addition to this federal legislation, all 50 states have passed some form of a mandatory child abuse and neglect reporting law in order to qualify for funding under CAPTA. Only a few states, however, specifically define prenatal substance exposure as child abuse. In the few states that make this distinction (Minnesota, Wisconsin, South Dakota), legislation has been enacted authorizing either civil commitment or detention of women to protect a fetus from substance exposure. In other states (South Carolina, Illinois, Iowa), it is presumed that a newborn has been neglected and is removed from maternal custody when infant toxicology tests at birth demonstrate the presence of a nonprescription controlled substance. In the majority of states, however, it has not been determined that prenatal substance exposure constitutes a form of child abuse or neglect.

Even for states that are silent on the issue of positive prenatal maternal toxicology, a positive newborn infant toxicology screen presents pediatricians with a hospital discharge plan dilemma. Typically, this is addressed through referral to hospital social services departments or child protection agencies for evaluation. This is consistent

with the American Academy of Pediatrics guidelines for drug-exposed infants and children (4).

The extent to which governmental oversight and the perceived threat of enforcement of CAPTA actually direct provider decision-making and constrains practice and research is unknown. Strict enforcement of CAPTA presumably requires mandatory toxicology screening in all pregnant women with appropriate referral of all patients with positive test results. In theory, CAPTA policy could thus result in referral of women to underfunded programs, or removal of children into inadequate interim care systems. Accepting that there is no ideal solution for the dilemma of substance use in pregnancy, and that occasional flawed processes exist, the role of researchers and providers is to make practices as best as they can be, within the context of legal and policy constraints.

It is within this imprecise legal framework that perinatal and women's health research must be carried out. Researchers involved with the vulnerable population of pregnant women need to be familiar with the intersection of state and federal reporting mandates, as they apply to prenatal substance abuse and the basic principles of research.

The pregnant woman retains considerable liberty and privacy rights to autonomy and reproductive freedom under the United States Constitution, especially the fourteenth amendment. Amendment XIV recognizes the right of personal privacy, including the right of a woman to determine whether or not to bear a child. These rights, however, are not absolute. From the public health perspective, the pregnant woman's rights cannot be viewed or exercised apart from the state's interest in the developing fetus.

Despite this, criminal charges against substance-using pregnant women on grounds of child abuse have been struck down in almost all cases because courts have upheld the right to privacy and the right to bodily integrity. It has been determined that states could better protect fetal health through education and drug treatment (5).

Citing discriminatory targeting of lower socioeconomic groups for substance use testing and subsequently referral to child protective services, some professional organizations ad-

vocate for universal testing in order to promote just and equitable practices and maximize the likelihood of identifying at-risk infants (6). Conversely, other organizations, such as the American Academy of Pediatrics, oppose involuntary universal screening and mandatory reporting because it violates a women's right to privacy and confidentiality, and may compromise the relationship between patient and health care provider (4). Some experts oppose universal testing and reporting because of the unreliability of testing, and the lack of evidence that a mother who uses drugs while pregnant cannot subsequently parent (7).

Confounding the understanding of reporting legislation, there is a growing literature to suggest that many of the negative effects of prenatal substance exposure can be either overcome, or aggravated, depending on the postnatal environment. Beyond low birth weight, gestational age, or in utero substance exposure, social factors such as consistency of care, parental stress and depression, maternal education level, parent-child attachment, and home environment have now been increasingly shown to play a role in a child's development past infancy (1). To what extent this emerging contradictory body of evidence will alter current child abuse laws and reporting mandates, and in turn, research-related practices, remains to be seen.

In 2004, without legislation guiding clinician responsibility in most states, the American College of Obstetricians and Gynecologists (ACOG) determined that obstetricians are ethically obligated to address substance use as a part of routine prenatal care with all patients (8). Provider guidelines on how to screen pregnant women for substance abuse, discuss the potential impact of substance use with their patients, and connect them with appropriate comprehensive treatment and parenting preparation groups have subsequently evolved. A 2008 ACOG statement revision emphasized this point: With or without legal obligation, "physicians have an ethical obligation to learn and use techniques for universal screening, intervention, and referral to treatment in order to provide patients and their families with medical care that is state-of-the-art, comprehensive, and effective" (9).

IMPLICATIONS FOR RESEARCHERS

As fetal exposure to drugs is not considered child abuse outside of just a few jurisdictions, mandatory reporting of an incidental discovery of substance abuse in pregnant research volunteers by health researchers is currently not a general requirement. However, consistent with ACOG guidelines for clinical practice and general principles for safeguarding human research subjects, there is an ethical obligation to address the detection of substance use in a pregnant woman.

There are several ways in which researchers in other fields have approached the ethical obligation to address health risks discovered in the course of clinical research while still adhering to the principles of privacy and confidentiality. In 1989, Halbreich and Carson addressed the dilemma of discovering pregnancy in a female subject who was advised not to become pregnant during the course of a drug study. They wrote, "... a woman assumes the burden of imposing those risks on any fetus she might conceive. . . [In the case of pregnancy] perhaps the best course would be to discuss with the woman's physician the potential risks . . ." (10). In the resolution of this dilemma, these researchers were some of the first to recommend that investigators acquire, as part of the consent process, permission to share screening results implicit to pregnancy care with the participant's health care provider, thus facilitating appropriate interventions.

Research on human immunodeficiency virus (HIV) testing offers other insights for managing an investigator's responsibility for adequate follow-up care after the disclosure of test results. The Office of Human Research Protection addresses follow-up for HIV testing as such: "... whenever subjects will be informed of their HIV serostatus, appropriate pretest and posttest counseling must be provided. Counselors should be qualified to provide HIV test counseling and partner notification services. IRBs should ensure that such provisions are made" (11).

Similar to this approach for fulfilling an ethical responsibility, the perinatal researcher may choose to manage a positive prenatal toxicology test result by providing the participant with con-

tact information for an appropriate substance-treatment program and/or parenting classes. According to guidelines for clinical practice, "referral to treatment, especially if combined with training in parenting skills, is the clinically appropriate recommendation" (9). Implicit in this approach is respect for the autonomy of the pregnant woman, allowing her the final choice in prenatal decisions, including the decision whether or not to seek treatment.

For researchers in states where prenatal substance use carries the definition of child abuse, conditions for mandatory disclosure arise when a pregnant volunteer presents with a positive toxicology test result. To reduce the risks associated with a positive drug test, the investigator should address this possibility in the consent process. Howard and Beckwith suggest a statement such as the following (12):

Your participation (in this research) is separate from any involvement that you may have with the legal system. . . . Because prenatal substance abuse is reportable in this state as child abuse (neglect), if you agree to participate in our program, we will communicate with the legal system about any incidence of suspected child abuse (neglect), as required by state law.

Given the potential sanctions for substance abuse during pregnancy in some states, and the limits of confidentiality protections afforded to such research subjects, the gains of toxicology screening in prenatal research must be weighed against the potentially substantial risks to the volunteer (e.g., incarceration, criminal record). Although a growing literature implicating the overriding importance of the social environment to child development after perinatal drug exposure weakens the case for mandatory reporting, knowledge of local legislation is essential for those conducting perinatal research. Balancing scientific agendas against the best interests of the research participant is a primary responsibility of investigators and IRB members. The trade-off between potential benefits and risks of the research also merits serious consideration

before requiring urine toxicology screening in pregnant research subjects.

IMPLICATIONS FOR CLINICIANS

It is difficult to isolate the effects of prenatal substance exposure from those of maternal nutrition, prenatal care, poverty, education, prenatal growth, and postnatal environment, among others. Restrictions on research in vulnerable populations additionally have implications for the development of new knowledge in perinatal health.

Perinatal investigators attempt to examine a representative sample of women. Within this sample, substance-abusing women may reside. The actual and perceived legal implications for potential substance-abusing research participants may correspond with a greater reluctance by these women for research involvement compared to other potential participants. Additionally, obligation by the researcher to disclose the risks of toxicology screening may serve to avert potential drug-using subjects who did not initially perceive a problem in their consenting to research.

For these reasons, clinicians need to render caution in generalizing perinatal research findings to the population of substance-abusing pregnant women and their fetuses. Because of the dilemmas faced by researchers in the study of these subjects, as well as the problem of participant attrition, there is likely an underrepresentation of substance-abusing women in pregnancy research and perinatal clinical trials.

CONCLUSIONS

Based on current legal sanctions and IRB rules for protecting the vulnerable populations of pregnant research subjects and children, we recommend that studies involving prenatal toxicology screening for substance abuse include a plan to address the possibility of a positive test result. As noted here, it may suffice to refer the pregnant volunteer to a substance counseling/treatment program. Alternatively, the investigator may wish to include in the consent form the

possibility that discovery of a significant health risk to the fetus, including substance abuse, will be disclosed to the volunteer's health care provider for further evaluation. Regardless of the approach, a proactive, nonpunitive response to a positive toxicology in pregnancy, discovered during the course of research, is recommended in states without mandated reporting laws.

Applying general principles for safeguarding human research subjects, as well as those for vulnerable populations, we conclude that there exists an ethical obligation to address detection of substance abuse in a pregnant woman. Perinatal researchers and IRB members have a responsibility to know the applicable federal and state laws, as well as local referral policies governing prenatal substance use that may affect the research participants of projects they oversee. They should balance the potential effects of such laws and policies against the protections that are afforded to prospective study volunteers. In the context of inadequate protections, such as in states where punitive laws are in effect, the potential risks to prospective research subjects must be weighed against the benefits of the toxicology screen as part of the ethical analysis. Under certain conditions, pregnant women with a history of substance abuse may be less likely to volunteer. Future research is needed to explore substance abuse in pregnancy and develop ethical ways to inform perinatal questions within this complex legal system.

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