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A Search for Guidance: Examining Prenatal Substance Exposure Protocols

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Objectives: To describe key elements of a set of hospital prenatal substance exposure protocols, and to relate variations in protocol content to the state legislative environment and hospital characteristics. *Methods*: Nurse managers and hospital administrators with responsibility for perinatal care were asked to provide their hospital's prenatal substance exposure protocol. Using a structured coding form, two independent coders read and abstracted information from the 87 protocols received. Hospital and patient characteristics and the state's legal environment were cross-tabulated. *Results*: Only half of coded protocols included an implementation date; 37% lacked any goal or statement of purpose. Most covered the key components of prenatal substance exposure management, such as precipitants and guidelines for toxicology screening, but failed to present their contents clearly. Only a few discussed whether specific maternal consent is required for a maternal or a newborn toxicology screen. Protocols from states that had made some legislative response to prenatal substance exposure were more likely to provide reporting guidelines and a discussion of consent for a toxicology screen for mothers and newborns. Protocols were more likely to be found in larger hospitals and were more detailed in hospitals serving more affluent and less minority patient populations. *Conclusions*: More attention needs to be devoted to the development of prenatal substance exposure protocols, as their lack of clarity precludes most from meeting protocol development goals, such as encouraging standardized care. Associations between hospital characteristics, state legislative environment and protocol features suggest that legislative mandates could shape their development and features.

KEY WORDS: prenatal substance exposure; protocols; practice guidelines.

BACKGROUND

Prenatal substance exposure and its effects continue to generate considerable public policy concern. State legislatures have been active in crafting a range of policy approaches designed to prevent exposure and mitigate its consequences (1). But much of this policy lacks an empirical base.

One reason is that little empirical work has been directed toward understanding the role of the health care system in preventing and responding to prenatal substance exposure. Yet health care providers may be in a good position to reduce prenatal substance exposure or mitigate its consequences. Most pregnant women in this country receive some prenatal care, and women may be more motivated than usual during pregnancy to reduce or stop substance use. The vast majority of babies are born in medical settings, where exposure could be detected and managed. Further, medical practice informs social, legal, and ethical debates as much as it is shaped by them. How the health care system responds to prenatal substance exposure may significantly influence these debates and the policy choices that legislators perceive themselves to have.

Protocols increasingly have been touted as vehicles through which variations in practice can be reduced, quality of care enhanced, and cost of

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care contained (2). Protocols fulfill these goals by purportedly representing a consensus on appropriate care under specified conditions. Protocols represent a potential policy tool for improving the detection and management of prenatal substance exposure in particular because health care providers may not be highly motivated to detect it, and because detecting and managing it can be complex.

While the literature has not specifically addressed the contents of a useful prenatal substance exposure protocol, presumably such protocols should share the features of any effective protocol. Good protocols identify important decision points, key diagnostic criteria and screening tools, encourage communication among medical personnel, and guide referral and reporting. Specifically, each should indicate when it was drafted, by whom and for whom. There should be a stated revision schedule. It should deal with important issues such as clinical management, interdepartmental communication, and any necessary outside agency reporting (e.g., Child Protective Services and the like). Interdepartmental communication is particularly relevant to prenatal substance exposure since there are always, at some point, two patients. Consequently, appropriate detection and response often must involve multiple departments; communication across departments therefore is essential to the management process.

Effective prenatal substance exposure protocols should contain key content items such as maternal and newborn toxicology screening guidelines and precipitants. Protocols should provide clear guidance on consent required for both maternal and neonatal toxicology screening since lack of clarity surrounding consent requirements may discourage detection. There exists considerable uncertainty about whether the consent to treatment that all patients must sign upon admission to a hospital extends to a maternal toxicology screen, as this screen may not be medically necessary for the mother, and may result in significant negative outcomes such as a report to Child Protective Services. Prenatal substance exposure protocols should also indicate whether a physician's order is required for toxicology screening and identify the type of screen and relevant time limits for such screening. Because hospitalization times for normal deliveries have declined precipitously in recent years, the after-discharge management of prenatal substance exposure is an appropriate concern of health care providers and consequently should be addressed by any well-crafted protocol.

At least two states, California and Virginia, have mandated the development of prenatal substance exposure protocols in hospitals. In California, AB 391 was enacted in 1990. This legislation required the "health and welfare agency to develop needs assessment protocol for pregnant and postpartum substance abusing women and a review of referral systems." In Virginia, HB 813 was enacted in 1992 and required the "state secretary of health to develop treatment protocols and prenatal care providers to adopt screening protocols for substance abusing pregnant women; requires providers to inform patients about the effects of drug use on the fetus and to refer pregnant substance abusers to appropriate care."

Despite the potential importance of protocols in the detection and management of prenatal substance exposure, little is known about what prenatal substance exposure protocols actually look like or how they come to be developed. As part of a broader study of prenatal substance exposure, we analyzed prenatal substance exposure protocols from hospitals around the country.

Our analyses highlight what these protocols cover—and what they ignore. We look at basic characteristics such as implementation date, protocol motivation and goals, originating department, and intended audience. The analyses also address key content such as rules concerning obtaining maternal consent for maternal and infant toxicology screens, cross-department notification rules, and referral and follow-up directives. Finally, we relate observed variations among protocols to state legislative environment and hospital characteristics such as size and patient population, income level, and ethnicity.

METHODS

Surveys

Our protocol analysis was implemented within the context of a larger, national study of prenatal substance exposure (3). Through a survey of practicing obstetricians and pediatricians who see newborns fielded in 1995, we identified a total of 806 hospitals where respondents are most likely to deal with prenatal substance exposure. We sent at least one survey to each of these hospitals, depending on how perinatal nursing was structured. At the end of this survey, we asked respondents to enclose a copy of any protocol in use in their hospital for the "identification and/or management of substance exposure in pregnant women/neonates in this hospital."

At least one survey was returned from 510 of the 806 hospitals to which a survey was sent, an overall hospital response rate of 63%. One-third of hospital administrator and nurse manager respondents representing 166 hospitáls reported that their hospital had a prenatal substance exposure protocol.

We received a total of 87 sets of protocol materials, which represent 52% of hospitals described as having one. Sixteen of these protocols were dropped from our analyses. Exclusions occurred because the material was too general, e.g., focusing on substance use in all patients, because it was mistargeted, e.g., focusing on hospital employee substance use, or because the material was incomplete, e.g., a list of referral sources. The 71 protocols available for analysis represent the largest group of prenatal substance exposure protocols known to have been assembled for purposes of analysis. We used these protocols in the analyses that follow, supplemented by data from their associated hospital surveys when indicated.

Protocol Coding

We coded the protocols using a 33-item form. The form includes those elements that we believed would contribute to the clarity, authority, and usefulness of any prenatal substance exposure protocol, as discussed above. The items on the coding form fall into two broad categories, basic protocol characteristics and substantive contents.

In the first category, we coded year of implementation or revision, the presence of five key goals, including assess risk, identify needed services, prevent adverse consequences, identify substance-using pregnant women, and promote mother–infant health. We coded three key reasons *why* the protocol was written: 1) perceived mandate; 2) the desire to develop or implement a community practice standard; and 3) evidence of the negative physiologic effects of prenatal substance exposure. Coders looked for evidence concerning the origin of the protocol, e.g., a Department of Pediatrics, or a joint committee. They also coded mention of the intended audience.

In the second category, contents, coders noted the presence of information concerning maternal toxicology screening guidelines and precipitants, newborn toxicology screening guidelines and precipitants, maternal and newborn toxicology screening consent requirements and procedures, and whether a physician's order was specifically required to initiate a toxicology screen. Coders also indicated whether a timeframe for performance of maternal toxicology screening was specified; the same question was asked for newborn toxicology screening. Finally, the presence and nature of any notification rules was noted. The coding form ended with several items on referral and follow-up, including precipitants for referral, and directives concerning reporting to Child Protective Services agencies.

Analysis of Coded Data

One of the coders coded all 87 protocols. To assess interrater reliability, a second person coded 50 randomly selected protocols. Interrater reliability was assessed for each item on the coding form using the kappa statistic; median intercoder reliability was 0.64. We excluded items from our subsequent analyses on which the kappa was not >0.5.

We related coded protocol characteristics to state legislative environment for prenatal substance exposure, a variable described more fully in Zellman *et al.* (1), using chi square. Its three categories include no action (20 states), some type of public health response e.g., priority for drug treatment services for pregnant women); a statewide prevalence survey of substance-exposed births (20 states); and mandatory reporting of prenatal substance exposure by explicitly including it under the definition of child maltreatment (11 states).

We also related protocol content to hospital characteristics derived from the hospital survey described above, including hospital size, public or private aegis, percentage of poor patients, and patient ethnic distribution using Chi-square.

FINDINGS

Basic Protocol Characteristics

Recency

Consistent with the growing interest in protocols of late, most of our protocols were recent. Although only half of the coded protocols provided an implementation date, among those that did, all 35 were first implemented between 1988 and 1995; more than three-quarters (77%) of these were implemented between 1990 and 1995 ($N = 27$). Twenty-two older protocols had been revised between 1989 and 1997.

Protocol Motivation and Goals

More than one-third ($N = 27$) of the protocols did not include any goal or statement of purpose. Among those that did, coding goals and purpose was difficult; only two goals could be reliably coded. Fourteen percent ($N = 10$) of the protocols aimed to identify prenatally substance-exposed infants and 4% ($N = 3$) intended to identify substance-using patients. Ten protocols (14%) cited a law, code, or regulation as a factor in protocol development. Eight percent ($N = 6$) cited the desire to develop a community practice standard.

Originating Department or Agency

Twenty (28%) were unclear about the originating body. An administrative/policy department or group was listed in 24 (34%) of protocols as the originating body. A substance abuse committee and the department of obstetrics were listed less frequently, three (4%) and two (3%) times, respectively.

Intended Audience

"Nurse" was the intended audience in nearly two-thirds ($N = 47$) of the protocols. "Physician" or "Social Worker" were part of the intended audience in roughly one-half ($N = 37$; 41 respectively) of the protocols. Audience was "not stated or not clear" in another 20% ($N = 15$).

Contents

Almost two-thirds ($N = 45$) of protocols contained guidelines for obstetric management; more than three-quarters ($N = 55$) provided guidelines for newborn management, which represent the core content of any prenatal substance exposure protocol. Instructions for reporting information to agencies outside of the hospital, such as Child Protective Services (CPS) were included in less than half ($N = 32$) of the protocols. This means, of course, that over half did not include this very important information.

Maternal Toxicology Screening Guidelines and Precipitants

The majority (66%) of the protocols included or discussed guidelines for maternal toxicology screening ($N = 48$). Forty-one percent ($N = 29$) required and another 23% ($N = 16$) recommended a maternal toxicology screening under specified circumstances. Just under 3% ($N = 2$) recommended or considered a screening but did not discuss the specific circumstances under which one should be administered.

Table I. Maternal Toxicology Screening Precipitants

	Maternal screening		Newborn screening	
Toxicology Precipitant	Frequency	Percent	Frequency	Percent
Psychosocial problems (e.g., substance abuse history, prior CPS involvement)	36	50.7	40	56.3
Maternal symptoms (e.g., poor weight gain, untoward obstetrical event)	34	47.9	28	39.4
Inadequate prenatal care (e.g., none, late onset)	32	45.1	26	36.6
Prematurity (e.g., premature labor, abruptio placentae)	26	36.6	25	35.2
Neonate symptoms (e.g., small for gestational age, withdrawal symptoms)	21	29.6	36	50.7
Fetal symptoms (e.g., stress test findings)	12	16.9	7	9.9
Inappropriate delivery (e.g., ER delivery)	9	12.7	11	15.5
Maternal toxicology screen	—	—	13	18.3
All as policy	3	4.2	1	1.4

Note. Frequency refers to the number of protocols that included the listed precipitant and percent refers to the percentage of all fully-coded protocols ($N = 71$) that included the listed precipitant.

Table I, Columns 1 and 2, demonstrates that any discussion of toxicology screen precipitants was absent in nearly half of coded protocols. Yet these precipitants are important because they are signs that guide providers who may be uncertain about whether or not they should act on their suspicions and concerns and initiate a maternal screen. Toxicology screen precipitants most often described family problems such as substance abuse history, maternal weight gain or inappropriate behavior, or inadequate (including no) prenatal care. Neonate and fetal symptoms were less often coded as precipitants for maternal toxicology screens (approximately one-third of protocols). A few

protocols established a policy under which all mothers are tested.

Newborn Toxicology Screening Guidelines and Precipitants

More protocols discussed newborn than maternal toxicology screen precipitants (Table I, Columns 3 and 4). Family psychosocial problems and neonate symptoms were mentioned as toxicology screen precipitants on more than half of protocols ($N = 40$). Neonate symptoms were coded five times more frequently than fetal symptoms ($N = 36$; 7 respectively).

Maternal Toxicology Screening Consent

In our sample, 11 (15.5%) hospital protocols specified that a discussion with the mother was required prior to a maternal toxicology screen, and 9 required the mother's specific consent (beyond the general hospital admission consent) prior to her screen. In contrast, 9 (12.7%) protocols explicitly stated that no discussion (and, by implication, no specific consent) was required. Forty-two (59.2%) protocols did not contain any discussion of these issues.

Neonatal Toxicology Screening Consent

Eight protocols (11.3%) required a discussion with the mother and only two (2.8%) required maternal consent for a neonatal screen. In 10 of the protocols (14.1%) no discussion was explicitly required. The majority of the protocols (71.8%) made no mention of this issue.

Physician's Order

One-third ($N = 23$) of the protocols required an MD order for a toxicology screen. Only 4% ($N = 3$) specifically stated that an MD order was not required, while most (63%) did not discuss this issue ($N = 44$).

Timeframe of Screen and Type of Screen Employed

The majority of protocols (84% maternal ($N = 60$) and 74% neonatal ($N = 52$)) specified no timeframe during which a screen must be performed. Half ($N = 36$) of the protocols did not specify types of screens (e.g., urine, blood, hair, nails); of those that did, 49% ($N = 35$) indicated that a urine screen would be conducted; 10% ($N = 7$) stated that a urine screen and/or a serum screen would be run.

Notification Rules

Rules about notifying particular staff members about detected prenatal substance exposure were absent in 85% ($N = 60$) of protocols. Six percent ($N = 4$) of the protocols stated that a social worker had to be notified. Only 1% ($N = 1$) stated that the obstetrician had to be informed.

Referral and Follow-Up

Most protocols included referral guidelines (77%). Such guidelines typically suggested several different agencies. Child Protective Services was listed as a referral in 56% of protocols. A specialty clinic such as outpatient treatment, a neurologist, or genetics counselor was listed in 21% ($N = 15$). The Department of Health and home health services were mentioned in 6% ($N = 4$) and 11% ($N = 8$) of the protocols, respectively. Thirty percent mentioned another agency ($N = 21$). More specific instructions for reporting diagnostic information and concerns to agencies outside of the hospital, such as Child Protective Services, were included in less than half ($N = 32$) of the protocols. Psychosocial problems such as abuse history, homelessness, or prior child protective services involvement were a precipitant for referral or follow-up in 24 (34%) hospital protocols

State Legislative Environment Impact Analyses

Using nurse manager survey data from the original study (3), we found that the probability of reporting the presence of a protocol was associated with state legal environment through Chi-square, although the analysis just missed statistical significance ($p < 0.06$). In states that have made some response to prenatal substance exposure, hospitals are more likely to have a prenatal substance exposure protocol. State legal environment did bear on protocol contents to some degree, as shown in Table II. Protocols from

Table II. Protocol Motivation and Consent Specification as a Function of State Legal Environment

State legal environment[a]	Protocol Characteristics				
	Legal motivation cited	Medical/psychosocial motivation cited	Reporting information provided	Discussion of consent required for maternal toxicology screen	Verbal screen
No response ($N = 20$ states)	0	0	40	0	0
Public health response ($N = 20$ states)	13	13	38	30	15
Mandatory reporting of prenatal substance exposure ($N = 11$ states)	17	0	61	33	17

Note. Cell entries are percentages of protocols from states in legal environment that contain protocol characteristics described.
[a]Number of states = 51 because of the inclusion of the District of Columbia.

states that had made no response uniformly lacked legal or medical/psychosocial motivation statements; those from states that had made a public health or mandatory reporting response were more likely to cite such motivation. Protocols from mandatory reporting states were the most likely to include information about reporting. Protocols from states that had made either a public health or mandatory reporting response were more likely to include a discussion of consent for a maternal or newborn toxicology screen (Columns 3 and 4, respectively).

Hospital Characteristics

Contrary to what might have been expected, nurse managers who work in hospitals with majority White patient populations are significantly more likely to report the presence of a protocol ($p < 0.01$). When such a protocol exists, these hospitals with majority White patient populations were more likely to provide detailed precipitants for toxicology screens, as shown in Table III. They were also more likely to require maternal discussion or consent prior to a toxicology screen. Discussion or consent was also more likely to be required in hospitals with more affluent patient populations.

More consistent with expectations, hospitals that reported higher numbers of births per year were significantly more likely to report having a prenatal substance exposure protocol based on nurse manager reports ($p < 0.02$).

DISCUSSION

Collecting and coding these prenatal substance exposure protocols was a sobering experience in several respects. First, the small number of them is concerning. Only one-third of hospital administrator and nurse manager respondents reported that their hospital had such a protocol.

Table III. Coded Protocol Characteristics as a Function of Hospital Attributes

Population characteristics (Hospital patient)	Protocol characteristics				
	Newborn tox screen precipitants				
	Inadequate prenatal care	Prematurity	Psychosocial problems	Neonate symptoms	Discussion of consent required for maternal tox screen
Percent poor patients					
10% or less ($N = 7$)	72	71	71	71	29
11–30% ($N = 19$)	37	47	63	58	47
31–50% ($N = 17$)	41	29	65	47	12
51% or more ($N = 24$)	21	17	38	38	17
Majority White ($N = 41$)	41	44	66	63	34
Majority African American ($N = 7$)	14	0	14	14	14

Note. Cell entries represent percentage of hospitals with noted characteristics in their submitted prenatal substance exposure protocol.

Second, those that we did receive were not very well crafted. Our coding categories included the components of a prenatal substance exposure protocol that experienced project physicians considered to be critical components of all prenatal substance exposure protocols. As a group, these protocols met these requirements poorly. While almost two-thirds contained guidelines for obstetric management and more than three quarters provided guidelines for newborn management, the fact that not all provided this very basic, very crucial information in a prenatal substance exposure protocol raises serious concerns. Most did a rather poor job of describing precipitants for maternal and newborn screening, which seem critical given that some health care providers encounter prenatal substance abuse infrequently and others may be disinclined to respond, citing the need to focus on other more pressing issues (4). Most ignored the crucial issue of whether a specific consent is required for screening mother or newborn, and provided only limited guidance concerning referrals and reporting.

The literature on protocols suggest additional criteria by which this sample could be judged. For example, protocols have been widely touted as vehicles through which variations in practice can be reduced, quality of care enhanced, and cost of care contained (2). Further, they have been promoted as a means to exculpate physicians from frivolous malpractice suits. By supplanting the subjective "reasonable person" standard of care with objective measures, they have been proposed as a means of diminishing litigation costs (2, 5). The protocols we reviewed meet these goals rather poorly. They are insufficiently precise, and most fail to address one or more key components of appropriate detection and medical management of prenatal substance exposure.

Third, the authors of the protocols did little to encourage their use, increase their credibility or facilitate modifications and improvements to them. More than one-third did not include any goal or statement of purpose. Only half provided an implementation date, which in a few instances rendered the contents potentially invalid. For the majority, the originating department or agency was not apparent, making it difficult to raise questions or propose modifications.

More specific findings reveal that while most protocols do include key aspects of prenatal substance exposure management, several areas require more attention. For example, just over half of them include newborn screening guidelines. Other features that were frequently absent were an indication about the type of toxicology screen to be employed or a timeframe within which a toxicology screen must be performed. Given the legal consequences that may derive from a positive toxicology report, the protocols' silence on both these matters is difficult to understand.

Most protocols identified precipitants that health care providers should consider in pursuing potential prenatal substance exposure; they generally described psychosocial problems, maternal symptoms, and inadequate prenatal care. Neonate and fetal symptoms were not often described as potential precipitants for maternal toxicology screens, suggesting that pediatric staff may be expected to pay more attention to maternal symptoms than obstetric staff are expected to pay to neonate ones.

The mother's consent was more often required for a maternal screen than for a neonatal screen. This resonates with the findings of Birchfield *et al.* (6), who noted that newborn and labor units only rarely obtained maternal consent to test the infant, as the infant is seen as a separate patient. Often the protocols failed to address this extremely important issue at all. Clearer consent guidelines might facilitate response if staff members are holding back because of uncertainty.

Few protocols clearly indicated whether a doctor's order is required for a toxicology screen. These protocols' failure to clearly address these important issues cast doubt on their putative exculpatory value. The protocols also suggest that very little communication flows across departments. In our sample, 85% of the protocols did not present any discussion or rules about notifying particular staff members when a toxicology screen had been executed. Yet communication among hospital staff may be critical to ensuring appropriate care.

While such communication may be assumed, our earlier work revealed that departments of obstetrics and pediatrics may not in fact communicate, even when they hold information critical to the provision of high-quality care, e.g., positive toxicology screen results on a just-delivered mother or neonate. To ensure that vital communication occurs, protocol developers should explicitly state which staff members should be notified about findings from toxicology screens or self-reports.

In our analysis of the impact of state legal environments, we found evidence that hospitals do respond to features of the legislative environment. In states that had made some legislative response to prenatal substance exposure, hospitals were more

likely to report having a prenatal substance exposure protocol. Legislative activity may be one way to increase the number of hospitals that have executed such protocols. However, our data are clear that this pressure is not strongly felt; legislative activity is a limited tool at best if the goal is more widespread protocol development and use. Nor is it clear that the state is the most suitable agency for guiding protocol development or contents, since health care providers may not necessarily welcome this potential state intrusion into the provider–patient relationship.

Our investigation of hospital characteristics suggests that hospitals with lower percentages of poor patients and with majority White patient populations were more likely to have a protocol, and those protocols were more likely to provide detailed precipitants for toxicology screens. This finding was worrisome: prenatal substance exposure protocols are a desirable feature everywhere. However, if protocols encourage response, it is surely in higher-income, majority White-patient hospitals where they may do the most good, since it is there that stereotypes about substance users are most likely to suppress health care provider response. Our findings do suggest that hospitals may respond to clear external forces pushing them to develop practice guidelines.

A major limitation of this work is the small number of hospitals represented. However, this study did utilize protocols from more than half of the hospitals reported to have one. Certainly, the hospitals that sent protocols cannot be considered to be representative of any particular population. As a consequence, these protocols must be understood to be based on a convenience sample, but this sample represents the largest group of protocols gathered for purposes of analysis to date.

Despite these limitations imposed by our small sample, our coding categories can be considered to be crucial attributes of any prenatal substance exposure protocol. We encourage readers to use these categories as a checklist for protocol development.

Our analyses shed light on an important potential policy tool that is increasingly discussed, and clarify the degree to which our set of protocols addressed some of the particularly challenging issues in developing management guidelines for prenatal substance exposure. The relationships we found, although small, between state legislative response, key hospital characteristics, and protocol features suggest that legislative mandates may have the potential to encourage protocol development and shape protocol content. They also reveal differences in protocol specificity by hospital characteristics that may argue for such mandates.

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