Behind the Screen: Legal and Ethical Considerations in Neonatal Screening for Prenatal Exposure to Alcohol

Anna Zadunayski, Matthew Hicks, Ben Gibbard, & Glenys Godlovitch*

I. Foreword

In a recent Motherisk Clinical Practice Update published in Canadian Family Physician, the authors presented the following question from a family physician: “I have several patients whom I suspect are drinking during pregnancy. How can I find out for sure if they are?”1 In response, the Motherisk Update advised the use of brief standardised alcohol-use questionnaires that can be used to screen women for risk drinking during pregnancy, and of a screen that can be conducted using an infant’s first stool that may be indicative of prenatal alcohol exposure. The Update acknowledged that clinicians do not routinely ask patients about alcohol use.

The Motherisk Clinical Practice Update raises a number of important questions: Why is the physician concerned about alcohol use during pregnancy? What sort of maternal characteristics might make a physician suspect their patient is drinking during pregnancy? What methods are available to screen for prenatal alcohol exposure? What are the ethical and legal considerations in screening for prenatal alcohol exposure? Are there legal cases that we can learn from in the area of perinatal screening regarding substances of abuse?

II. Introduction

Fetal Alcohol Spectrum Disorder (FASD) is an umbrella term describing the range of physical, cognitive and neurobehavioral effects that can occur in an individual whose mother consumed alcohol during pregnancy.2 This is concerning

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1 Joey Gareri et al., “Screening for Fetal Alcohol Spectrum Disorder” (2005) 51 Canadian Family Physician 33 [Screening for FASD] [emphasis added].
as approximately 15-45% of women in Canada consume alcohol during pregnancy despite recommendations that women abstain. FASD is thought to be the most common non-genetic cause of mental, learning and behavioural disabilities in North America and is a serious lifelong condition. The impact of FASD is wide reaching, touching the life of the individual and the lives of family members and society as a whole. In contrast to other birth defects and genetic conditions, FASD has received attention from medical and public health professionals because it is a preventable condition. In Alberta, an estimated 29% of children in government care and at least 60% of the prison population have some sort of deficit associated with alcohol exposure, highlighting the need for members of the legal profession to have a better understanding of these conditions.

Early diagnosis, a supportive environment, and early intervention have been identified as crucial factors to optimise outcomes for affected individuals. However, the diagnosis of any given FASD is complex and often does not occur

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4 M. Hicks and S. Tough, Survey of Women Giving Birth in the Calgary Health Region (2003) [unpublished, archived at the University of Calgary, Faculty of Medicine, Department of Community Health Sciences]. In a 2003 survey of 1500 women giving birth in the Calgary Health Region, 44.5% of women reported some level of alcohol use during pregnancy.
7 P.D. Sampson et al., “Incidence of Fetal Alcohol Syndrome and the Prevalence of Alcohol-related Neurodevelopmental Disorder” (1997) 56 Teratology 317 [Incidence of FAS].
8 Neuropsychiatric Implications, supra note 2 at 177.
9 Dr. Robin Walker, Canadian Paediatric Society, “Statement of President, Dr. Robin Walker on Bill C-206” (10 March 2005), online: Canadian Paediatric Society <http://www.cps.ca/english/advocacy/reports/2005_C206.pdf> (The Canadian Paediatric Society (CPS) is a voluntary professional association representing approximately 2400 pediatricians, subspecialists, residents, and other child health care providers who advocate for the health and well being of children and youth).
until school age, if at all, at which point maximal benefit from early intervention and support may not be achieved. The use of fatty acid ethyl ester (FAEE) testing in infant meconium and scalp hair to screen for prenatal exposure to alcohol is a fairly recent scientific phenomenon, which has been proposed as an aid to medical professionals in the early identification of children who may be at risk for a FASD, thus enabling health care professionals to diagnose earlier.

This paper presents an overview of FASD, reviews FAEE screening, and then focuses upon the ethical and legal challenges inherent in the new screening technologies as they relate to providing care to women and their infants. This is followed by an analysis of a recent US Supreme Court case involving screening of pregnant women for the use of cocaine, which is relevant to the discussion. An American case is used to highlight the ethical and legal issues as no recent Canadian case was identified as pertinent to screening. While screening for FAEE in hair or meconium are the examples used for this discussion, the issues raised are not unique to these screening modalities. This paper argues that cautious consideration of the ethical and legal issues in caring for both women and their infants is required prior to drafting policies and practice guidelines for the use of screening for prenatal exposure to alcohol.

III. Fetal Alcohol Spectrum Disorder

Fetal alcohol syndrome [FAS] was first coined over 30 years ago by Jones et al., to describe a group of children born to mothers with histories of alcohol abuse who presented with several characteristic features including craniofacial abnormalities, growth restriction, and neurocognitive deficits. Since then, there has been a growing recognition of the range of deficits in a child that can accompany prenatal alcohol exposure. To describe this range of deficits, the term FASD was proposed by Streissguth et al. FASD, a descriptive term rather than a diagnosis, includes FAS, partial FAS, Alcohol-related Neurodevelopmental Disorder [ARND] and Alcohol-related Birth Defects [ARBD]. Currently, FASDs are believed to be underdiagnosed and many children are not diagnosed until they are school-aged. The prevalence of FAS/FASD commonly reported in the literature for urban

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14 Ibid.
18 Neuropsychiatric Implications, supra note 2 at 177.
19 Ibid.
21 B.B. Little et al., “Failure to Recognize Fetal Alcohol Syndrome in Newborn Infants” (1990) 144:11 American Journal of Disease in Childhood 1142 at 1145 [Failure to Recognize FAS].
populations is 0.5 to 3 cases per 1,000 live births for FAS, and approximately 1 to 12 cases per 1,000 live births for a FASD.\textsuperscript{22}

FASD includes a characteristic triad of deficits, namely, growth restriction, craniofacial abnormalities, and neurocognitive deficits.\textsuperscript{23} Affected individuals may exhibit a wide range of physical features, from growth restriction, central nervous system [CNS] defects, birth defects, and characteristic craniofacial abnormalities\textsuperscript{24} to normal growth and facial features. FASDs are most often unrecognisable at birth and can continue to go unrecognised as a child develops if neurocognitive deficits are present in the absence of physical manifestations.\textsuperscript{25} Affected individuals can have primary and secondary disabilities, and mental health comorbidities. Primary disabilities related to CNS dysfunction include cognitive impairment, attention deficit hyperactivity disorder, difficulties with language, communication, memory, learning, adaptive functioning and executive functioning.\textsuperscript{26} However, there is no one profile of primary cognitive deficits. Some affected individuals may have high intelligence quotients\textsuperscript{27}, but may be unable to interact appropriately in social situations.\textsuperscript{28} Cognitive and behavioural abnormalities often persist into adulthood.\textsuperscript{29} Secondary disabilities occur as a result of living with primary disabilities and may include mental health disorders, drug and alcohol addictions, disrupted school experiences, joblessness, homelessness, involvement with the law,\textsuperscript{30} custodial sentences as a result of criminal behaviour, and inappropriate sexual behaviour.\textsuperscript{31}

The primary and secondary disabilities of FASD have a significant impact economically, socially, and medically for Canada.\textsuperscript{32,33} The estimated cost for additional education, support for disabilities, incarceration, and health care per individual with FAS can be as high as $3.0 million over the lifetime of the individual.\textsuperscript{34} FASD touches not only the affected individual, but mothers, fathers, the entire family and the community, all at a terrific cost.\textsuperscript{35} Parents of individuals with FASD may find coping with primary and secondary disabilities to be a

\textsuperscript{22} Incidence of FAS, \textit{supra} note 7 at 322.
\textsuperscript{23} Recognition of the FAS, \textit{supra} note 17 at 999.
\textsuperscript{24} Craniofacial abnormalities that are most consistently seen with FAS include thin upper lip, smooth philtrum and small palpebral fissures.
\textsuperscript{25} Failure to Recognize FAS, \textit{supra} note 21 at 1145.
\textsuperscript{26} \textit{Challenge of Fetal Alcohol Syndrome, supra} note 12 at 6-8.
\textsuperscript{27} A.P. Streissguth, H.M. Barr & P.D. Sampson, “Moderate Prenatal Exposure: Effects on Child IQ and Learning Problems at Age 7 1/2 Years” (1990) 14 Alcoholism, Clinical and Experimental Research 662 at 663-664.
\textsuperscript{29} \textit{Ibid.}
\textsuperscript{30} Neuropsychiatric Implications, \textit{supra} note 2 at 177.
\textsuperscript{31} \textit{Challenge of Fetal Alcohol Syndrome, supra} note 12 at 162.
\textsuperscript{32} Health Canada, \textit{Joint Statement, supra} note 6.
\textsuperscript{33} \textit{Health is Everyone’s Business, supra} note 11 at 2.
\textsuperscript{34} \textit{Ibid.}
\textsuperscript{35} \textit{Challenge of Fetal Alcohol Syndrome, supra} note 12 at 162.
formidable task, especially if children are not appropriately supported in school or by health professionals, and may feel isolated by the common misunderstandings that result as children grow and develop. Young people with FASD are disproportionately represented in the juvenile criminal justice system\textsuperscript{36,37}, and generally require intense supervision and direction. This also applies to older individuals who have a history of criminal behaviour, but who have received conditional or suspended sentences.\textsuperscript{38,39}

There is some evidence to support improved outcomes for children with an FASD as a consequence of early diagnosis linked with early intervention and support.\textsuperscript{40,41} One study of individuals with FAS found that those who were diagnosed before the age of six had a lower rate of secondary disabilities.\textsuperscript{42} Those diagnosed early were less likely to have disrupted school experience, display inappropriate sexual behaviour, and have trouble with the law.\textsuperscript{43} There is a consensus in the literature and among experts in the area that early diagnosis and appropriate intervention and placement in a stable, nurturing environment are protective factors which can minimise secondary disabilities.\textsuperscript{44} However, early identification of the physical stigmata of FASD is challenging because of the difficulty inherent in assessing dysmorphology in infants and the considerable challenge in determining if the neuropsychological deficits that a child presents with are due to a prenatal alcohol exposure alone, as there are a multitude of non-alcohol related factors that have a significant impact on child development. Additionally, there is systematic underreporting and documenting of alcohol use during pregnancy, so clinical suspicion of prenatal alcohol exposure may not be raised.\textsuperscript{45,46}

\section*{a) Maternal Alcohol Consumption}

The current Health Canada Guidelines recommend that women should abstain from consuming alcohol if they are pregnant or are attempting to become pregnant as a safe level of alcohol consumption during pregnancy has not been

\textsuperscript{36} Health is Everyone’s Business, supra note 11 at 2.
\textsuperscript{39} Issues around sentencing of offenders were discussed thoroughly by Chartrand and Forbes-Chilibeck previously in this journal; for an excellent discussion see generally The Sentencing of Offenders, supra note 11.
\textsuperscript{40} Challenge of Fetal Alcohol Syndrome, supra note 12 at 6-8.
\textsuperscript{41} Risk Factors, supra note 13 at 235-236.
\textsuperscript{42} Ibid.
\textsuperscript{43} Ibid.
\textsuperscript{44} Ibid.
\textsuperscript{45} Canadian Perinatal Health Report 2000, supra note 3 at 8.
established. In Canada, rates of alcohol consumption during pregnancy were estimated using the 1996-1997 National Longitudinal Survey of Children and Youth [NLSCY]. In the Prairie Provinces, approximately 16.1% of women with young children who were surveyed reported drinking during pregnancy while, overall, 16.6% of women in Canada reported some drinking during their pregnancy. This study did not discuss many potentially important factors of prenatal alcohol exposure, including timing, frequency, regularity of consumption, and binge patterns.

The accuracy of self-reporting of alcohol consumption during pregnancy can be highly variable and is thought to significantly underestimate the true prevalence in the maternal population. This underestimate is attributed to difficulty in recall, shame, fear of law enforcement or loss of custody of children, denial of the problem by pregnant women and those close to them, lack of accessible treatment, and inconsistent intrapartum screening for alcohol and drug use by health care professionals. Self-report depends not only upon a mother responding truthfully, but also upon a clinician attentively asking the right questions. Chasnoff has noted that an informal interview of a mother inquiring about alcohol and drug exposure results in under-reporting, whereas a more formal and organised interview increases reporting five-fold. Maternal self-report of alcohol use during pregnancy can be valid, cost-effective and less invasive than the use of biomarkers in the context of an established and trusting relationship with a care provider in which questions around alcohol use are asked in a standardised fashion.

Empirical data suggest that women who choose to carry pregnancies to term often report decreasing alcohol and drug use during pregnancy. Many women

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50 Canadian Perinatal Health Report 2000, supra note 3 at 8.
51 The Prenatal Detection, supra note 46 at 348-350.
52 Canadian Perinatal Health Report 2000, supra note 3 at 8.
53 The Prenatal Detection, supra note 46 at 348-350.
56 Ibid.
57 Drug Use and Women, supra note 54 at 209-210.
58 British Columbia Reproductive Care Program, Guidelines for alcohol use in the perinatal period and fetal alcohol spectrum disorder, online: British Columbia Reproductive Care Program [http://www.rcp.gov.bc.ca/guidelines/Substance_Use/Alcoholguideline.pdf] [B.C. Guidelines].
60 M. Hicks, supra note 4.
61 Alcohol Use Prior to Pregnancy Recognition, supra note 5 at 104.
either reduce their consumption or stop drinking altogether when they begin trying
to conceive in the case of planned pregnancy or upon discovering that they are
pregnant.62 Researchers have observed negative outcomes in the neonates and
children of women who are heavy drinkers throughout pregnancy, but adverse
effects have also been tied to moderate drinking.63 Additionally, many women
maintain their usual pattern of drinking until pregnancy recognition, often at 4 to
8 weeks; this may include a pattern of binge drinking, defined as 5 or more drinks
in one sitting, perhaps several times per month.64

As alcohol use is legal and generally more “socially accepted” than other
substances, women of different backgrounds may be susceptible to its abuse. Risk
factors for substance abuse during pregnancy include: a history of sexual, physical
or emotional abuse, depression, low self-esteem, maternal education, maternal age,
marital status, maternal ethnicity, socio-economic status, and extent of prenatal
care.65,66,67,68,69,70 Alcohol use by women during pregnancy is, therefore, often at the
nexus of social and medical problems.71

Although the proportion of children affected by in utero exposure to alcohol
is unclear, one study found that approximately 40% of alcoholic women give birth
to infants with FAS.72 Alcohol is a teratogen that contributes to birth defects,
however, the exact mechanism by which alcohol damages the developing fetus is
unknown.73 Timing of exposure during fetal development, frequency of drinking
episodes and level of consumption are all thought to contribute to the risk of

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62 Ibid.
63 B. Sood et al., “Prenatal Alcohol Exposure and Childhood Behavior at Age 6 to 7 Years: I. Dose-Response Effect” (2001) 108.2 Pediatrics E34.
64 Alcohol use Prior to Pregnancy Recognition, supra note 5 at 104.
66 Characteristics of Pregnant Women, supra note 49 at 791-793.
71 Fetal Alcohol Syndrome, supra note 10.
72 Characteristics of Pregnant Women, supra note 49 at 791-793.
FASD. Variations in the manifestation of FAS features may be due to maternal age, the timing, pattern, and dose of alcohol exposure, prenatal diet, and other pre- and post-natal environmental factors. Reports indicate that women who engage in binge drinking during pregnancy are more likely to smoke cigarettes, use various illicit substances (e.g., stimulants, cannabis, opiates, hallucinogens, and inhalants) and to be young and single. These maternal characteristics and the genetic susceptibility of the child may also affect the likelihood and severity of disabilities in the child. However, the exact role that these factors play in fetal vulnerability to FASD remains undetermined.

Despite a well-established consensus in the medical and public health literature regarding the potential adverse consequences of prenatal alcohol exposure, alcohol continues to be used during pregnancy and is underreported in prenatal and paediatric medical records. Health advocacy groups maintain that screening and several brief interventions during pregnancy can support a reduction in maternal alcohol consumption, and there is some literature to support this view.

b) Screening Issues

As self-report of alcohol consumption is likely inaccurate and may provide a dramatic underestimate of the true prevalence of maternal alcohol consumption, standardised questionnaires used by health care professionals for clinical encounters have been developed. These include the AUDIT, CAGE, SMAST, TWEAK, and T-ACE questionnaires. Each of these scales has been validated in different populations and has varying sensitivity and specificity. Markers of exposure must be validated according to their ability to indicate both the true exposure (sensitivity) and lack of exposure (specificity). The instrument shown to be most sensitive in

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74 Increased Vulnerability to ARBDs, supra note 69 at 260-262.
77 Characteristics of Pregnant Women, supra note 49 at 791-793.
78 Fetal Alcohol Syndrome, supra note 10 at 627.
80 B.C. Guidelines, supra note 58.
81 Identification of High-risk Mothers, supra note 68 at 503-506.
84 Alcohol Screening Questionnaires, supra note 55 at 167-169.
85 Ibid.
the periconceptional population is the T-ACE, a screening tool of four questions. However, these tools alone do not accurately identify all mothers and infants at risk. As a result, the identification of infants at risk poses a significant challenge to physicians.

The timely diagnosis and support of infants and children affected by FASD is critical, not only to address immediate health needs, but also to minimise secondary disabilities. As such, screening tests that may aid in identifying individuals at risk for FASD continue to be developed and validated by researchers. Screens cannot be used as a diagnostic tool however, and a FASD diagnosis is made only after rigorous medical and psychological assessment. Public health advocates suggest that, where possible, routine screening policies for asymptomatic children be implemented so as to “diagnose shortly after birth those infants for whom early treatment will minimise serious, irreversible complications.” To support this position, advocates point to the anticipated cost effectiveness of screening associated with decreased secondary disabilities. This position must be balanced with the interests of all persons involved, including mothers and families, and issues of consent and voluntariness must not be overlooked. Any routine screening policy should be carefully considered, and should not be implemented without first ensuring that proper supports are in place for all concerned.

Recently, the ability of clinicians to determine prenatal alcohol exposure at or shortly after birth is believed to have improved with the availability of analyses for alcohol metabolites in hair, meconium and urine. Assaying for biomarkers in neonatal biological samples may provide information about maternal alcohol use, assist in the targeting of interventions and earlier identification of children at risk for developmental and health difficulties than previously possible, and allow for counselling that could influence future maternal behaviour in subsequent pregnancies.

86 Ibid.
87 Neuropsychiatric Implications, supra note 2 at 177.
88 British Columbia Reproductive Care Program, Neonatal Guideline 9 — Newborn Screening (November, 1999) at 1-5, online: B.C. Reproductive Care Program <http://www.rcp.gov.bc.ca> [Neonatal Guideline 9].
89 Ibid.
90 Ethyl Linoleate, supra note 15.
IV. Screening for Fatty Acid Ethyl Esters in Hair and Meconium as a Biomarker for Prenatal Alcohol Exposure

The presence of FAEE in meconium and hair has been identified as a putative biological marker ("biomarker") for prenatal exposure to alcohol during the second and third trimesters of pregnancy.92,93,94 Meconium, a neonate’s first stool, is a dark black or green, viscous material that is composed of intestinal secretions, amniotic fluid, fatty material, and xenobiotics that the fetus is exposed to prenatally.95 Meconium begins to accumulate between the 17th and 20th week of gestation and FAEEs are believed to remain stable in meconium96, thus, meconium may constitute a biological record of exposure for the last 20 to 23 weeks of pregnancy. Similarly, FAEEs are believed to be prenatally incorporated into the growing hair shaft of neonatal scalp hair and remain for the life of the hair (approximately 3 months after birth) as a potential marker of exposure.97,98 The timeframe or gestational age of prenatal alcohol exposure that FAEE in hair represents is undetermined.

In a secondary metabolic pathway, alcohol is esterified with free fatty acids to produce FAEE, which accumulate in fetal meconium.99 FAEE detected in neonatal tissues and metabolic products are likely produced by the fetus from ethanol that has been transferred to and metabolised by the fetus, rendering FAEE a biomarker reflective of true fetal exposure to ethanol.100 As such, accumulations of FAEE in meconium and hair above a population baseline are thought to be an indicator of maternal drinking in the later stages of pregnancy.101 FAEEs in serum have historically been biomarkers of acute and chronic alcohol consumption in adults and have been reported to accumulate in the blood of adult drinkers.102 It is important to note, however, that FAEEs have also been identified in meconium and hair samples from newborns of abstaining mothers, perhaps due to endogenous...
alcohol production. Although the literature suggests several advantages of screening for FAEE in meconium and hair, data must be interpreted so as to avoid adverse consequences for mothers, and particularly for abstaining mothers. Cut-off values (values correlated with no alcohol exposure) have been established by testing FAEE in the meconium of infants born to abstaining mothers in several populations, however, there was a substantial variation in what might be considered a baseline value. More research is needed to understand the relationship between prenatal alcohol exposure, endogenous alcohol production and accumulation of FAEE in hair and meconium.

Although FAEE assays may serve as a screen to assess whether a newborn may have been exposed to alcohol prenatally, there is no clear “gold” standard for prenatal exposure to alcohol. One difficult step in developing an accurate biomarker is validating that it correctly identifies exposure without false positives or false negatives. Screening programs would ideally identify all individuals potentially at risk for a disorder (high sensitivity) who might then go on for more rigorous assessment and diagnosis, as warranted. Studies to date have varied widely in populations screened, sample size and methodology of screening. In 1999, Bearer et al. found the sensitivity of FAEE testing in meconium was 72 % and the specificity was 51 % in distinguishing those who had at least one drink per week in the third trimester from those who abstained. Alcohol consumption prior to pregnancy (at least one drink per week) was used to indicate risk of elevated FAEE resulting in a sensitivity of 68% and a specificity of 48%. In later studies, those authors reported that levels of specific FAEE, increased in a dose-dependant manner with increases in maternal self-report of alcohol use. More recently Bearer et al. have reported FAEE sensitivity between 84-88% and specificity of 64-83.3% for drinks per drinking day with linoleic acid. Similarly, Chan et al.

103 Ethyl Linoleate, supra note 15 at 491.
104 Markers to Detect Drinking, supra note 91 at 214.
105 Ibid.
107 The Prevalence of Methamphetamine, supra note 59 at 1011. Confirmed also by personal interview of Alan R. Katz, M.D., M.P.H. (9 May 2006) Associate Professor, Department of Public Health Sciences and Epidemiology, John A. Burns School of Medicine, University of Hawaii, at the Kapi‘olani Medical Center for Women and Children, Honolulu, Hawaii.
109 The Prevalence of Methamphetamine, supra note 59 at 1002.
110 Ethyl Linoleate, supra note 15 at 491.
111 Ibid.
report sensitivity of 100% and specificity of 98.4% in a very small group of confirmed alcoholic women as compared to abstainers with total FAEE level.\textsuperscript{114,115} In a reanalysis of the data from Bearer’s work, Derauf \textit{et al.} found no association between maternal self-report and presence of FAEE in meconium.\textsuperscript{116} This highlights the need for further work before FAEE screening would be a scientifically sound method.

It has been suggested that targeted newborn screening programs for biomarkers for alcohol exposure could be used in cases where maternal alcohol use is suspected.\textsuperscript{117} Given the difficulties and documented inaccuracies in predicting who will consume alcohol during pregnancy and therefore, which mothers are good candidates for testing, there is limited evidence to support the use of current drug and alcohol testing strategies on a widespread basis.\textsuperscript{118} A well-designed screening program would ideally have high participation rates, would not damage the relationship between patient and clinician, and would not deter women from seeking prenatal care. If screens are to be adopted on a wider basis the medicolegal and ethical issues involved must be carefully considered. There is currently limited scientific evidence to support FAEE screening on either a targeted or universal basis. This paper will now review the ethical and legal issues that would caution against targeted or universal FAEE screening in neonates.

\section*{V. Ethical and Legal Considerations for Neonatal Screening for FAEE}

The following legal and ethical concerns are relevant to considering the use of screening for FAEE in meconium and hair for potential prenatal alcohol exposure. Much of what follows is framed in terms of ‘principlism’ based on the Belmont Report’s statement of principles and values, as advanced by Beauchamp and Childress and often taught in medical ethics classes in many medical schools.\textsuperscript{119} These include the key ethical concepts of beneficence, non-maleficence, autonomy and informed consent, and justice, which are most familiar to health professionals.\textsuperscript{120,121} Feminist consent theory [FCT] as it pertains to neonatal screening will also be reviewed.

\begin{itemize}
\item \textsuperscript{114} D. Chan, J. Klein & G. Koren, "Validation of Meconium Fatty Acid Ethyl Esters as Biomarkers for Prenatal Alcohol Exposure" (2004) 144:5 The Journal of Pediatrics 692.
\item \textsuperscript{115} Recent Developments in Meconium, \textit{supra} note 16 at 430-436.
\item \textsuperscript{116} Agreement Between Maternal Self-Report and Tobacco, \textit{supra} note 108 at 708-709.
\item \textsuperscript{117} Screening for FASD, \textit{supra} note 1 at 33.
\item \textsuperscript{118} M. Hicks \textit{et al.}, "Alcohol Use and Abuse in Pregnancy: An Evaluation of the Merits of Screening" (2003) 12 Canadian Child & Adolescent Psychiatry 77 at 79-80.
\item \textsuperscript{121} Canadian Medical Association, \textit{Code of Ethics (Update 2004)}, online: CMA <http://www.cma.ca/index.cfm/ci_id/2419/la_id/1.htm>.
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a) Informed Consent and the Right to Refuse Treatment

Informed consent is often a central factor in deliberations about whether medical interventions are right or wrong, good or bad. Two facets of the concept must be distinguished: ethical aspects that emerge from respect for others as a core value; and legal aspects that emerge from tort and criminal law underpinnings, particularly as pertains to battery. Although these ethical and legal facets are connected via common threads, in reality they function very differently. Informed consent, in its legal aspects, functions to head off legal liability in situations that might otherwise constitute a battery. Informed consent is a defence to an allegation of trespass after an alleged intrusion or threat, and negates liability in the face of evidence of a physical wrongdoing. Functioning as it does at the level of specific individuals and specific actions and specific occasions, it is understandable why there is such an insistence on written informed consent in the context of contemporary health care interventions. By contrast, in its ethical aspects, informed consent is a recognition of the other person or people as having an inherent personal worth and integrity, which is best facilitated by maximising the epistemic basis upon which they act. Informed consent is a mark of respect that lays out the groundwork for social interactions, and is not designed to head off potential blame or fault, but to show that “the other” is valued and appreciated as a person, thus enriching decision making.

The legality of all medical treatment is founded on the existence of consent or some other lawful authority, such as legislation or regulations. The overriding general principle is that no form of medical treatment can be given without the consent of the patient or the consent of some other person or court with the authority to give it, for example, as in the case of a child. No consent is obtained without the nature and effect of the proposed treatment being communicated to the patient or other person giving consent, and sufficient detail must be provided to enable the person consenting to understand, in broad terms, what the treatment involves and what is to be done. Consent may be communicated in writing, orally, or it may be inferred from the patient’s conduct.

Consent is not valid if it is obtained through duress or from a person lacking capacity. It is arguable also that consent is not valid if obtained through undue

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122 This research paper assumes, for the sake of legal argument, that meconium screening for in utero exposure to alcohol is “medical treatment”. It should be noted, however, that “medical treatment” may have differing definitions throughout the various Canadian jurisdictions. For example, the Ontario Health Care Consent Act 1996, S.O. 1996, c. 2, Sch. A., defines “course of treatment” as a series or sequence of similar treatments administered to a person over a period of time for a particular health problem. As such, there may be some debate about whether screening, in fact, constitutes “treatment” in that it is not a “course of treatment” and is merely diagnostic in nature. Further investigation is required.


124 Ibid. at 8-9.

influence or coercion. In any event, medical treatment in such circumstances will be a battery for which a physician will be held liable. Consent is not valid if the person consenting is not acting voluntarily or under her own free will. As such, physicians need to be aware of social and other factors in the patient’s background, which may make her liable to be forced by others to submit to or refuse treatment. An individual who is very tired, in pain or depressed will be much less able to resist having her free will overborne than one who is not.

b) Beneficence/Non-Maleficence

One could argue that a mother should consent to the screening of her infant because she is aware of the potential benefits to the child and it is the correlating responsibility of those who would like to provide the screen to provide evidence of the benefits. At this point, however, there is no evidence that screening for markers of alcohol exposure is beneficial either to mother or her child. It can be argued that FAEE screening is prima facie a beneficial screening tool in that early identification of exposed newborns may lead to earlier intervention and support; a common position of those that advocate the development of biomarkers of maternal alcohol use for primary and/or secondary prevention. Depending upon the jurisdiction, regulations may exist that govern how physicians must respond when indicators, such as meconium screening, identify maternal alcohol use during pregnancy. Some jurisdictions, particularly in the United States, require professionals to report women whose newborns screen positive for drug and alcohol exposure to local departments of health or human services, including child welfare and protective authorities. In all jurisdictions, but particularly where a jurisdiction mandates punitive measures and/or newborn apprehension in the face of a positive screen, considerations of universal vs. selective screening will certainly come into play. In some cases, obtaining a thorough and comprehensive maternal substance use history may continue be a preference. However, women who currently report alcohol use during pregnancy are not followed-up in a consistent or systematic fashion. Current methods of screening women, which include standardised questionnaires and self-report, may not result in improved medical management and prenatal care related to substance use may vary by health care provider. Further, if testing and identifying women at risk does not result in improved care or access to

126 As physicians are fiduciaries in relation to patients, it is also arguable that an action in battery may also be run concurrently with an action in the tort of breach of fiduciary duty, for which damages will be assessed under a separate heading and a different limitation period exists. Actions for breach of fiduciary duty may also be accompanied by aggravated and/or punitive damages awards.
127 Medical Treatment, supra note 123 at 13.
128 B.C. Guidelines, supra note 58.
130 American Academy of Pediatrics, Guidelines for Perinatal Care, 5th ed. (Ill.: American Academy of Pediatrics, 2002) at 249 [AAP Guidelines for Perinatal Care].
services then assessing exposure will not improve health and well being. In such cases, the motivation for and benefit of screening must be evaluated.

c) Justice: Implications for FAEE Screening

Given that there are no reliable risk factors for prenatal alcohol use, there is no prima facie valid justification (absent clinical indications at birth or in the early neonatal period) for why the newborns of some women should be singled-out for FAEE screening while others are not. Such a practice would be tantamount to stereotyping women. Selective screening for the newborns of women thought to be in high-risk categories, absent informed consent, would invariably correspond to particular racial and socio-economic groups and would constitute a policy of profiling. Further, in some jurisdictions, the consequences of stereotype-driven screening (including state-intervention and the apprehension of children) are what would keep some groups of women from seeking out adequate care.

The screening of infants must be undertaken with fairness and equity; typifying distributive justice. The harm associated with any screening program should not be borne by one group within a population. There is clear evidence in the literature of the potential injustices associated with perinatal screening programs for substance abuse. In particular, those of low socio-economic status, visible minorities, and young or single mothers may be unfair targets for screening. State interventions in Canada are disproportionately oppressive of poor women, Aboriginal women and women who are members of other racial and ethnic minorities. This finding is cause for concern and reflects both gender and ethnic biases that must be considered in the context of formulating Canadian policies and practice guidelines around FAEE screening for prenatal exposure to alcohol.Clinicians, health care providers, lawmakers, policy makers and analysts must acknowledge that contributing factors of poverty and minority status influences alcohol and drug addiction. The criminalization of alcohol and drug use targets the impoverished and medically and socially underserved groups.

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134 Prevalence of Alcohol Use During Pregnancy, supra note 132 at 1202.
136 Ibid.
One further ethical consideration that fits into the context of FAEE screening is based upon theories of “social agency”.\textsuperscript{137} The use of FAEE in hair or meconium as a biomarker for prenatal exposure to alcohol is relatively recent and is still a novel screening tool, which needs continued refinement. Is there a higher duty or ethical obligation to pursue FAEE screening that correlates to the medical profession’s ability to assist alcohol exposed infants as they continue to develop? Such questions illustrate that meconium screening, and perinatal screening\textsuperscript{138} in general, is a value-laden area worthy of increased attention by ethicists.

Finally, feminist consent theory [FCT], which recognises the unique situation and abilities of women in the context of decision-making, is sensitive to and focuses upon relative power imbalances between parties.\textsuperscript{139} FCT proffers a more robust version of consent, requiring much more than simple “voluntariness”; consent must also be meaningfully knowing and intelligent, and absent any advantage-taking.\textsuperscript{140} When applied to FAEE screening for prenatal exposure to alcohol, the discussion of informed consent raises a number of ethical questions: Would it be right to screen without a mother’s knowledge and consent? Can screening be compelled in non-emergent circumstances? If so, would it be right to compel screening? What are the ethical implications of a universal or mandatory screening policy? Conversely, might selective screening unjustly discriminate against particular racial or socio-economic groups? All of these questions should be considered in the context of formulating policies and practice guidelines for use of the FAEE in hair and meconium as a screening tool.

\textbf{d)  The Charter of Rights and Freedoms}\textsuperscript{141}

The issue of using FAEE in hair and meconium to screen newborns for prenatal exposure to alcohol raises several potential concerns from the constitutional law perspective. These include the right to equal treatment, informed consent and the right to self-determination and autonomy, reproductive rights and the right to privacy, which generally bring sections 1, 7, 8, and 24(1) of the Canadian Charter of Rights and Freedoms into play. Non-constitutional legal issues may include abuse of process or statutory power and breach of fiduciary duty. Section


\textsuperscript{138} Samantha Weyrauch, “Inside the Womb: Interpreting the Ferguson Case” (2002) 9 Duke J. Gender L. & Pol’y 81 at 84 [Inside the Womb]. “Perinatal” is defined as the period beginning after the twenty-eighth week of pregnancy through the twenty-eighth day following birth. “Prenatal” is broadly defined as the time after conception that precedes birth. Clayton L. Thomas, M.D., ed., Taber’s Cyclopedic Medical Dictionary (1993) at 1469, 1587.

\textsuperscript{139} Such as that which may indeed exist in some patient-physician relationships involving female patients.

\textsuperscript{140} Andrew E. Taslitz, “A Feminist Fourth Amendment?: Consent, Care, Privacy, and Social Meaning in Ferguson v. City of Charleston” (2002) 9 Duke J. Gender L. & Pol’y 1 at 77 [A Feminist Fourth Amendment]. This article provides an excellent argument using Feminist Consent Theory generally.

7 of the Charter dictates that every person has the right to life, liberty and security of the person, and the right not to be deprived thereof except in accordance with the principles of fundamental justice. Principles of fundamental justice include a right to privacy, given its great value to society. Children’s privacy interests, however, are better viewed as included within the section 7 right to security of the person and have been “read in” on the basis of “underlying dignity”. As indicated, some would quickly argue for a universal FAEE screening policy on the basis of the “best interests of children” and because a universal policy would be a prima facie neutral policy. However, the preceding discussion of informed consent, when read in conjunction with section 7 of the Charter, would preclude the implementation of a “mandatory” universal screening policy. At law, there would always need to be provision for an “informed refusal”.

e) Informed Refusal

A physician is not free to disregard a patient’s instructions. The denial of a patient’s right to autonomy and self-determination may be deemed a battery at law. The right to self-determination is protected by law so as to give patients the decisive role in the medical decision-making process. This right includes the right to refuse medical treatment, regardless of the opinions of others as to the imprudence of such a course. A patient’s right to self-determination is fundamental to all principles of individual autonomy. Where a competent patient refuses medical treatment, on whatever basis, the refusal, barring exceptional circumstances, cannot be overridden by a physician. In such circumstances, physicians must make a careful record of the medical advice given, together with the reasons for refusal.

Informed refusal must be considered in the context of selective or universal screening policies. The American Academy of Pediatrics does not recommend universal screening of women and children for substance use and exposure but, rather, recommends obtaining a thorough maternal substance use history, and offering an opportunity for maternal self-report. Collecting information pertinent to maternal substance abuse should ideally constitute a “well done, sensitively obtained history taken by someone that the mother trusts.” Toxicology screening

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142 As with other rights, this right will be balanced against the “reasonable limits” analysis provided for under s. 1 of the Charter. A s. 24(1) Charter analysis may come into play where an individual claims a remedy or relief as against the state where an alleged infringement has occurred.
145 Bioethics for Clinicians, supra note 135 at 1730-1731.
146 Ibid.
147 Medical Treatment, supra note 123 at 23.
148 AAP Guidelines for Perinatal Care, supra note 130 at 249.
149 Confirmed by interview of Chris Derauf, M.D. (9 March 2006), Director of the University of Hawaii Integrated Pediatric Residency Program and Principal Investigator for the Hawaii site of the NIDA-funded Infant Development, Environment and Lifestyle (IDEAL) Study, the first longitudinal, prospective study of prenatal methamphetamine exposure and child development, at the Kapi‘olani Medical Center for Women and Children, Honolulu, Hawaii.
is only recommended when clinical indications of use or exposure are present and, where such is the case, documentation should preclude an early discharge from hospital (assuming a hospital setting) after birth in addition to an appropriate plan for follow-up care.\textsuperscript{150}

Newborn screening is the process of testing an asymptomatic population for biomarkers of a disease that can be treated. In Canada, some universal policies exist for the screening of newborns, including screening for Phenylketonuria [PKU] and Congenital Hypothyroidism (Cretinism)\textsuperscript{151} and, although screening mandates vary widely between provinces, hospitals are encouraged to develop and implement routine procedures for such screening. As FAEE screening for prenatal exposure to alcohol continues to be a novel screening tool, there are presently no universal policies respecting its implementation and use in the Canadian health care system. Three Canadian jurisdictions have undertaken preliminary meconium screening studies and pilot projects to date. What many Canadians may not know, and contrary to popular belief, is that universal neonatal screening in Canada is not, in fact, mandatory. For parents who refuse newborn screening in British Columbia for example, “Informed Refusals” and “Informed Deferrals” exist, to be completed by a discharging health professional and included in hospital records, so as to mitigate against liability.\textsuperscript{152} This is the corollary of, and is consistent with, the Canadian law of informed consent to medical treatment, as discussed above.

VI. Comment on an American Case in Point: 
\textit{Ferguson v. City of Charleston}

Rapid and recent developments in prenatal care, combined with an increase in knowledge of fetal development, have led to a higher scrutiny of maternal behaviour during pregnancy in some cases.\textsuperscript{153} It is trite law, however, that there is no common law jurisdiction to declare non-consensual medical intervention to be lawful in order to protect the interests of an unborn child.\textsuperscript{154} In most jurisdictions, legislative and judicial branches of government have respected the primacy of competent adult women’s autonomy and self-determination in making non-emergent health care choices. The recent American case of \textit{Ferguson v. City of Charleston}\textsuperscript{155}, however, illustrates that, in some jurisdictions, lawmakers can be quick to partner with medical professionals to implement health policies that disregard women’s autonomy under the guise of “best interests of the child” (or unborn child). While this is not an example under Canadian law and involves screening for drug use in a maternally derived sample rather than a sample from an infant, the

\textsuperscript{150} AAP Guidelines for Perinatal Care, supra note 130 at 249.

\textsuperscript{151} L. Eggertson, “Canada Lags on Newborn Screening” (2005) 173:1 CMAJ 23. Also confirmed by interview of Julie Lauzon, M.D. (4 May 2006) Department of Medical Genetics, Alberta Children’s Hospital, Calgary, Alta.

\textsuperscript{152} Neonatal Guideline 9, supra note 88.

\textsuperscript{153} Inside the womb, supra note 138 at 81.

\textsuperscript{154} Medical Treatment, supra note 123 at 100.

\textsuperscript{155} City of Charleston v. Ferguson, 532 U.S. 67 at 67 (2001).
issues raised and the analysis and discussion are relevant to FAEE screening in hair and meconium of newborns.

a) Facts

In the 1990s, the Medical University of South Carolina (MUSC), in collaboration with local authorities, developed a selective drug screening policy in conjunction with police and prosecutors that required pregnant and post-partum women to be tested for cocaine through urinalysis. Women in need of obstetrical care at the public hospital were screened if they presented with a certain “drug profile” or certain other factors.156 Women were tested for any of the following factors: (1) separation of the placenta from the uterine wall; (2) intrauterine fetal death; (3) no prenatal care; (4) late prenatal care (beginning after 24 weeks gestation); (5) incomplete prenatal care (fewer than five visits); (6) preterm labour with no obvious cause; (7) a history of cocaine use; (8) unexplained birth defects; and (9) intrauterine growth retardation with no obvious cause.157 A positive test resulted in a mandatory referral to a substance abuse program, and a report to state authorities. Additionally, MUSC informed the police of positive screening results, who subsequently threatened to arrest the women who did not agree to enter into a substance abuse program. Women who failed to comply with the substance abuse program were arrested, and any woman who tested positive for cocaine after giving birth was arrested “as soon as medically possible”.158

The MUSC selective drug screening policy was communicated to women through a Solicitor’s Letter explaining the consequences of a positive screen and non-compliance, and each selected woman was required to sign. The MUSC policy also provided that urine samples from women meeting the profile were collected so as to ensure that results could be used in subsequent criminal proceedings against the women.159 Under the MUSC regime, several women were selectively subjected to screening, all of which were Medicaid beneficiaries and had “no choice but to seek out perinatal care at MUSC”, because it is a public hospital.160 Six women were screened during active labour or immediately after delivery, and three women were screened during preterm labour. Two of the screens were from a woman who was “seriously ill and in excruciating pain”.161 In the end, ten women, each of whom tested positive for cocaine on two occasions, were arrested and charged with “distribution of cocaine to a minor”.162

156 Ferguson v. City of Charleston, 308 F.3d 380 at 388 n.4 (4th Cir. 2002).
157 Ibid.
159 Inside the Womb, supra note 138 at 84.
160 Hospitals Must Obtain Informed Consent, supra note 158 at 456.
161 Ibid.
162 Ferguson v. City of Charleston, 186 F.3d 469 at 475 (4th Cir. 1999).
b) Cause of Action and Disposition

Some of the women, through legal aid, brought an action for damages against MUSC and the City of Charleston. In the main, the action was framed as a constitutional challenge in abuse of process, privacy and lack of due process, turning on issues of informed consent, voluntariness, coercion and duress. The lower courts approved and upheld the MUSC screening policy. On appeal, the primary legal question was whether involuntary drug screening performed on pregnant women without consent violated the Fourth Amendment of the United States Constitution.

The US Supreme Court remanded the case back to the 4th Circuit in 2001, and the case was finally disposed of in 2002. It was determined that the selective screening policy was contrary to the protection provided by the Fourth Amendment. Screening had been conducted without informed consent, and constituted an unjustifiable invasion of privacy. The Supreme Court held that because the hospital was public, its staff members were “government actors” and subject to the Fourth Amendment. The screening constituted a “search” which was not justified by a “special need”. Unless the women consented, the screening test itself and the act of reporting a positive result to the authorities were considered “unreasonable searches”, even despite the MUSC policy’s law enforcement purpose. The Court rejected the assertion that the screening policy was designed to serve a “special need” to coerce the women to participate in substance abuse treatment programs.163

c) Analysis and Discussion

Ferguson was the first American Supreme Court case involving maternal-fetal conflict in the context of addiction.164 The Court indicated that consent to screening would have been “deemed”, but only if the women knew that “the request was not being made by medical personnel for medical purposes, but rather by agents of law enforcement for the purposes of crime detection”.165 One further issue was that there was no evidence on the record that the women would have received treatment at MUSC had they refused to provide urine samples. One can infer from the facts of the case that no opportunity for an “informed refusal” had presented itself.

What happened at MUSC constituted a state-sanctioned “fishing expedition” into the private lives of birthing women and proves that state interests do exist in the context of pre- and perinatal screening. When framed from the women’s perspective, that a screening program of this nature and consequence could be implemented so recently, and with so much institutional, administrative and community support, demonstrates how important it is to engage in careful, considered

163 Inside the Womb, supra note 138 at 85.
164 Ibid.
165 Hospitals Must Obtain Informed Consent, supra note 158 at 456.
policy drafting in the context of guiding modern medical decision-making. Where competing state interests do exist, they must be balanced very carefully along with the interests of privacy and self-determination in women’s health choices.

Some authors argue that the MUSC staff’s recognition of the dangerous activity in which some women were engaged, and the subsequent intervention on behalf of those women, was justified and necessary to prevent harm; the medical professionals had a social obligation to intervene. Others may posit that mandatory screening was acceptable under the principle of “first, do no harm”, arguing that screening, in and of itself, was not “harming” the women. These positions are important to consider, and have some arguable validity, particularly in consideration of the unborn children involved in the Ferguson case. At a first glance, it seems easy to justify the MUSC screening policy; many women were using cocaine late into their pregnancies, which was a serious problem that the medical personnel felt compelled to solve. But the Canadian legal reality, however, is that constitutional law, as the supreme law, upholds a woman’s right to refuse medical treatment. Where a woman is competent and refuses medical intervention, that decision is to be respected, even where others disagree or believe that an unborn child may suffer as a result.

The Ferguson case is an important case, in that it demonstrates just how difficult it can be for law enforcement and medical professionals to work together and proactively solve public health problems in some situations. It is also representative of the fact that well-intended, collaborative policies, when not carefully considered from all perspectives, can indeed cross the line from beneficence to advantage-taking and exploitation. The physicians in South Carolina that were involved in the selective screening policy effectively became agents of the state; arguably an untenable position from the perspective of any physician. Assuming the dual role of primary health care provider and law enforcement agent involves a great potential for compromised professional integrity and objectivity.

To some degree, physicians are already stakeholders. To marry physicians to state interests, such as law enforcement, creates an atmosphere in which it is very

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166 Inside the Womb, supra note 138 at 86. 
167 Anne S. Kimbel, “Pregnant Drug Abusers are Treated Like Criminals or Not Treated at All: A Third Option Proposed” (2002-2003) 19 Journal of Contemporary Health Law and Policy 521 at 523. One interesting observation is that, where this argument is made, women are referred to universally as “patients”, not “women”. To do so disengenders the analysis and masks the inherent marginalization of an entire “class” of patients, which is, in part, the reason why the argument fails.
170 Bioethics for Clinicians, supra note 135 at 1729.
171 A Feminist Fourth Amendment, supra note 140 at 23.
difficult to provide good, objective, evidence-based medical decision-making and care. Further, it erodes confidence and trust, which are the foundation of the patient-physician relationship.

VII. Conclusions

Implementing any mandatory FAEE screening policy, or a selective or universal policy without room for an informed refusal or deferral, would be contrary to current Canadian legal principles regarding informed consent and would, in fact, infringe upon the section 7 Charter rights of women. If FAEE screening moves into the mainstream, and perhaps becomes part of the standard of care for children who are suspected of having been exposed to alcohol in utero, there will likely be a group of women who would agree to screening regardless of whether the screening policy was universal or selective, mandatory or voluntary. Such women would want to seek out information on how to approach future medical care in the face of a positive screening result, and many of these women would at least strongly consider further diagnostic efforts, early intervention and support as necessary.\textsuperscript{172}

There will likely be a second group of women who would not voluntarily agree to screening because they would not consider their newborns at risk, but who, under a mandatory or universal system, for any number of reasons, may get back a positive screening result. Many of these women would also consider further diagnostic efforts, intervention and support as necessary.\textsuperscript{173}

A third group of women, however, would be very resistant to screening because they would not wish to know, or for others to know, whether their newborn was affected. Should any non-voluntary screening policy be implemented, these women may make the decision to stay outside of the health care system and forego pre- and antenatal care. This would be a tragedy, as it is these women (and their future newborns) who, arguably, are most in need of good medical care. Alternatively, these women may seek medical care and submit to screening because they have decided that screening and health care are more important than their already compromised rights to self-determination and privacy.\textsuperscript{174} Not all women will easily fall into one of the three categories, but it does highlight the sensitivity of the issues and the rights at stake, while providing an analytical framework within which to engage in further debate.

It cannot be said that the legal and ethical issues raised by the preceding discussion around FAEE screening in hair and meconium, and discussions around perinatal screening in general, are resolved. This is because advances in medical

\textsuperscript{172}Mandatory HIV Testing, supra note 131 at 180. This analytical framework was initially structured in the context of HIV screening, but it is applicable to meconium screening as well.

\textsuperscript{173}Ibid.

\textsuperscript{174}Ibid. One can also make an argument that parental-autonomy and freedom of choice would also be infringed under this scenario, although Canadian law is silent, as opposed to settled, on the existence of such rights.
technology, including screening technology, are ongoing and increase our ability to assess for prenatal exposure to potential teratogens. Ongoing refinement of the legal and ethical concerns related to perinatal screening in general, and uniquely to FAEE screening in meconium and hair, are required. Policies and guidelines relevant to neonatal screening will need to be drafted with the impact upon the rights of both children and their mothers in mind.