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Legal and Ethical Implications of Newborn Screening for Prenatal Exposure to Drugs and Alcohol: The Case for Policy Development and Law Reform

Zadunayski, Anna Corynne

UNIVERSITY OF CALGARY

Legal and Ethical Implications of Newborn Screening for Prenatal Exposure to Drugs and Alcohol: The Case for Policy Development and Law Reform

by

Anna Corynne Zadunayski

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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies for acceptance, a thesis entitled **"Legal and Ethical Implications of Newborn Screening for Prenatal Exposure to Drugs and Alcohol: The Case for Policy Development and Law Reform"** submitted by Anna Corynne Zadunayski in partial fulfilment of the requirements of the degree of Master of Science.

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Supervisor, Dr. Glenys Godlovitch, Community Health Sciences

_____

Dr. Sue Ross, Community Health Sciences & Obstetrics

_____

Dr. Reg Sauve, Community Health Sciences & Paediatrics

_____

Professor Jennifer Koshan, Faculty of Law

_____

Date

Abstract

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. Novel tools for the detection of prenatal exposure to drugs and alcohol are currently being explored in research and in practice. Neonatal hair and meconium are two novel screening matrices. National clinical practice guidelines regarding neonatal hair and meconium screening do not currently exist. Health care providers have questions regarding new screening modalities, including what constitutes an indication to screen, whether informed consent is required, and the uses to which screening results will be put. This study found that screening results have been used as evidence in the Canadian courts in multiple contexts, and argues that policies and guidelines for screening practices, along with judicial education, is essential to protect the rights and interests of both children and mothers.

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For my daughters

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List of Symbols, Abbreviations and Nomenclature

Symbol/Abbreviation	Definition
AAP	American Academy of Pediatrics (US)
ADHD	Attention Deficit Hyperactivity Disorder
AHFMR	Alberta Heritage Foundation for Medical Research
ALF	Alberta Law Foundation
APGAR	Appearance, Pulse, Grimace, Activity, Respiration
ARND	Alcohol-Related Neurodevelopmental Disorder
BCCEWH	British Columbia Centre of Excellence for Women's Health
BCRCP	British Columbia Reproductive Care Program
CA	Court of Appeal
CanLII	Canadian Legal Information Institute
CAPTA	Child Abuse Prevention and Treatment Act (US)
CAS	Children's Aid Society
CBS	Canadian Bioethics Society
CMA	Canadian Medical Association
CNS	Central Nervous System
CHREB	Conjoint Health Research Ethics Board
FAEE	Fatty Acid Ethyl Ester
FAS	Fetal Alcohol Syndrome
FASD	Fetal Alcohol Spectrum Disorder
FCT	Feminist Consent Theory
FHES	Fraser Health Ethics Service
GST	Goods and Services Tax
HBI	Hotchkiss Brain Institute
IDEAL	Infant Development, Environment, and Lifestyle Study (US)
MA	Methamphetamine
MCFD	British Columbia Ministry of Children and Family Development
NAS	Neonatal Abstinence Syndrome
NICU	Neonatal Intensive Care Unit
NIDA	National Institute on Drug Abuse (US)
NIH	National Institutes of Health (US)
PKU	Phenylketonuria
QB	Court of Queen's Bench
SIDS	Sudden Infant Death Syndrome
SCC	Supreme Court of Canada
TCPS	Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

List of Definitions

Analytical Toxicology: A subfield of the science of the adverse effects of drugs and poisons specifically dealing with the detection of drugs and other toxic compounds in matrices including urine, saliva, blood and hair.

Dizygotic twins: Two babies produced in the same pregnancy, that have different placentas and a different genetic makeup. The diffusion, biotransformation of drugs in placenta and fetal drug metabolism can be quite different between such twins, leading to varying concentrations of drug metabolites in dyzygotic twins.

Fatty Acid Ethyl Ester (FAEE): In a secondary metabolic pathway, alcohol is esterfied with free fatty acids to produce FAEE, which accumulates in fetal meconium. FAEE detected in neonatal metabolic products results from ethanol transferred to and metabolized by the fetus, rendering FAEE a biomarker reflective of fetal alcohol exposure. The use of FAEE testing in neonatal meconium and scalp hair to screen for prenatal exposure to alcohol is a recent scientific phenomenon proposed as an aid in the early identification of children at risk for Fetal Alcohol Spectrum Disorder (FASD), enabling the social goal of earlier diagnosis and intervention by health professionals.

Fetal Alcohol Spectrum Disorder (FASD): 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. FASD is thought to be the most common non-genetic cause of mental, learning and behavioral disabilities in North America and is a serious, preventable lifelong condition.

Fetal Alcohol Syndrome (FAS): FAS is a phrase coined several decades ago, used to describe a group of children, born to mothers with histories of alcohol abuse, presenting with several characteristic features including craniofacial abnormalities, growth restriction, and neurocognitive deficits.

Meconium: 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.

Neonatal: The newborn period beginning on the day that a human infant is born, through to the twenty-eighth day following birth.

Perinatal: The period beginning after the twenty-eighth week of pregnancy, through to the twenty-eighth day following birth.

***Pharmacokinetic*:** The presence and duration of a drug in the human body is dictated by a set of pharmaco (drug) kinetic (movement) principles: absorption, distribution, metabolism, and excretion.

Primary Disability: Primary disabilities related to FASD include growth restriction, birth defects, craniofacial abnormalities, and central nervous system (CNS) dysfunction including cognitive impairment and attention deficit hyperactivity disorder (ADHD).

Secondary Disability: 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, inappropriate sexual behavior, involvement with the law and custodial sentences as a result of criminal behavior.

Epigraph

"The ethical dilemma faced by the physician involves the conflict between a duty to promote care for the baby and mother together and a duty to prevent latent harms … Specific clinical situations in newborns will require drug metabolite testing but should remain the exception to the rule. Protection of these newborns from neglect or abuse after birth is best achieved by comprehensive care planning to ensure a safe nurturing environment."

--- Dr. Paul Byrne,
Staff Neonatologist, Stollery Children's Hospital, Edmonton.

Chapter 1: Introduction

Historical Introduction

Fetal alcohol syndrome (FAS) was first identified in the medical literature as a health issue in the 1970s.[1] However the historical recognition of maternal substance abuse can be clearly seen as early as William Hogarth's *London Scenes* (1751), particularly the cartoon entitled *Gin Lane*, where one can see an image of a woman sitting on the steps, a bottle in one hand and her baby falling away from her grasp. *Gin Lane* depicts a serious issue of substance abuse, impacting people throughout lifespans; young, middle-aged, old, living, dead, employed and unemployed.[2]

By contrast, Hogarth's *Beer Street* depicts an image of prosperity and wellbeing, seemingly associated with the consumption of beer rather than gin, contrary to contemporary scientific knowledge. In Hogarth's time, the real concern was with gin consumption, which had reached epidemic proportions in the 1700's as a result of the removal of taxes and commercial licenses. In *Beer Street* we see as a token of prosperity and results of good lifestyle choices, the pawnbrokers' symbol falling and occupying a position below that of the spire. In *Gin Lane*, however, the pawnbrokers' symbol overrode the position of the spire.

[1] K.L. Jones & D.W. Smith, "Recognition of the Fetal Alcohol Syndrome in Early Infancy" (1973) 2:7836 Lancet 999 [hereafter "Recognition of FAS"].

[2] One of two prints issued in 1951 by English artist William Hogarth, *Gin Lane* depicts the despair of a society impacted by alcohol consumption. See generally: D. Bindman, *Hogarth* (London: Thames and Hudson, 1985).

Illustration 1. *Gin Lane* by William Hogarth (1751)

Illustration 2. *Beer Street* by William Hogarth (1751)

Canadian legal challenges were brought before the courts in the 1880s and thereafter regarding laws designed to prohibit or regulate the production, sale, distribution and consumption of alcohol. In part the challenges were driven by religious outlooks, in part by political and public health advocates and in part by free enterprise, commercial individuals and organizations. The stakes were high: the courts were to determine the legality and regulation of the sale, purchase and consumption of alcohol. At stake were the rights of the provincial and the federal legislative bodies to make law. In *The Effect of Alcohol on the Canadian Constitution … Seriously,* the Honorable Mr. Justice Fish of Supreme Court of Canada (SCC) describes the role of alcohol cases in the development of Canadian constitutional law this way:

> "A quick list of key constitutional cases from the late 19th and early 20th century reads like a liquor board document: *Local Prohibition*[3]; *Manitoba License Holders*[4]; *Canada Temperance Federation*[5]; *Nat Bell Liquors*[6]; *Consolidated Distilleries*[7]; *Canadian Pacific Wine*[8]; *Brewers and Maltsters.*[9]" [10]

To these we can add: *The Queen* v. *Fredericton*[11]; *Russell* v. *The Queen*[12]; and, *Hodge* v. *The Queen.*[13] Each of these cases in its own way helped develop Canadian Constitutional jurisprudence with such things as "the national dimension test", "the paramountcy test", "the pith and substance test", "the emergency test" (referred to by at

[3] *Ontario (AG)* v. *Canada (AG)*, [1896] AC 348.
[4] *Manitoba (AG)* v. *Manitoba License Holders' Association* (1901), [1902] AC 73.
[5] *Ontario (AG)* v. *Canada Temperance Federation*, [1946] AC 193, 2 DLR 1.
[6] *R.* v. *Nat Bell Liquors Ltd*, [1922] 2 AC 128, 65 DLR 1.
[7] *Consolidated Distilleries Ltd* v. *The King*, [1933] AC 508, 3 DLR 1.
[8] *Canadian Pacific Wine Co* v. *Tuley*, [1921] 60 DLR 315.
[9] *Brewers and Maltsters Association of Ontario* v. *Ontario (AG)*, [1897] AC 233.
[10] M.J. Fish, "The Effect of Alcohol on the Canadian Constitution ... Seriously" (2011) 57 McGill LJ 189 at 193 [hereafter "Effect of Alcohol on the Canadian Constitution"].
[11] *The Queen* v. *Fredericton (Mayor)*, [1880] 3 SCR 505.
[12] *Russell* v. *The Queen*, [1882] 7 App Cas 829.
[13] *Hodge* v. *The Queen* (1883), [1883-1884] 9 App Cas 117.

least one constitutional law lecturer as the "nation on a binge test"[14]) and the "public order and safety" test for the federal warrant to create laws for the entire country.

Canadian Legal System

This section is divided into three parts for an enhanced understanding of the legal system within which novel screening modalities for prenatal drug and alcohol exposure may come to play a role: 1) sources of law; 2) the Canadian Constitution and the court hierarchy; and 3) the doctrine of precedents.

It is critical that health care professionals are aware of the legal framework that might apply to novel screening modalities if only in order to be able to (1) provide accurate information to stakeholders including patients, institutions and staff, and (2) understand the potential legal consequences of screening, including the potential for unanticipated uses of screening results and of potential consequences of screening. Given that much of what follows involves a discussion of the Canadian legal system, it is helpful for the reader to have a schematic of the structure and authorities of that system.

[14] Rowland Harrison, Constitutional Law Lectures, University of Calgary, 1979-80 (source: personal communication from Dr. Glenys Godlovitch, a former student of Mr. Harrison).

Sources of Law Regarding Health Care

Canada is a federal, democratic monarchy, with three branches of government comprising the Canadian legal system: legislative, executive, and judicial. The legislative branch of government creates legal statutes and regulations, the executive branch formulates and implements government policies, and the judiciary[15] adjudicates legal disputes. The primary sources of Canadian law include constitutional convention, statute law (both federal and provincial), and case law.[16] Thus what determines the legality of neonatal screening for prenatal substance-exposure is a mixture of federal legislation, provincial legislation, constitutional conventions and case law.

Canada has two different levels of legislative power: the federal legislature (Parliament) and each of the provincial legislatures. The *Constitution Act, 1867* [17] delineates the division of powers between the federal government and the provinces. Section 92 (the express provincial powers) occupies a subordinate yet refining role to section 91 (the federal powers). Section 91 confers extremely broad powers on the federal legislature "to make laws for the peace, order and good government of Canada, <u>in relation to all matters not coming within the classes of subjects by this act assigned exclusively to the legislatures the provinces".</u> Contrary to popular belief, the power to make law about

[15] "Judiciary" is a collective reference to judges, appointed by federal and provincial governments to adjudicate a variety of disputes and preside over criminal law proceedings.
[16] In Canada, the common law is the collection of rules that are formulated in legal decisions or judgments. Judge made law – sometimes called "case law" is a collection of legal decisions or precedents that have come before the Canadian judiciary. The common law has developed according to the doctrines of (a) *stare decisis*, a Latin phrase meaning "the decision stands" which effectively precludes relitigation once the appellate avenues have been exhausted, and (b) precedent, wherein the principles developed in earlier court cases are applied in later cases on the basis of precedent. Thus, the principle of s*tare decisis* is generally known as the rule of precedent.
[17] *The Constitution Act, 1867* (UK), 30 & 31 *Victoria,* c 3.

health care is not expressly assigned to the provinces. Indeed nowhere in the Constitution is there a mention of capacity to make laws about health or health care. The provinces have the power, such as it is, according to convention and case law, and recent cases acknowledge legislative competence over health care to the provinces, including power to create and run hospitals.[18] Cases from the Supreme Court of Canada (SCC), such as *Auton* and *Chaoulli* coming after the *Canadian Charter of Rights and Freedoms,* have generally advanced the interpretation in favour of the provincial powers.[19] As such, the provinces have general legislative authority over provision of health care.

The federal power found in the *Canada Health Act* [20] while seemingly about health is more accurately construed as fiscal federalism at work. While the *Canada Health Act* enunciates five key health care values common to all Canadians,[21] the statute itself is not law about health or health services, but is about financial facilitation of hospital services in the provinces. The *Act* effectively shifts money around among the provinces in an attempt to ensure that Canadians have equal access – irrespective of their province of residence - to health care services provided in a hospital setting where those services fit the five key values. The *Act* allows transfer payments of federal revenue to provinces that demonstrate they maintain provincial public insurance schemes to ensure their residents have access to "necessary" or "required" medical services in a hospital. Health care provided outside of hospitals is not within the purview of the *Canada Health Act*.

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[18] See for instance, *Auton (Guardian ad litem of)* v. *BC* 2004 SCC; [2004] 3 S.C.R. 659; *Chaoulli et al* v. *AG Quebec et al* [2005]1 S.C.R. 791, 2005 SCC 35.

[19] *Constitution Act, 1982,* being Schedule B to th*e Canada Act,1982,* (UK) 1982, c11. Especially relevant are sections 1, 7, 8 and 15, discussed in more detail later in Chapter 5.

[20] *Canada Health Act*, RSC 1985, c. C-6.

[21] *Canada Health Act, ibid,* sections 8-12, state the core values to be comprehensive, universal, portable, public, accessible coverage for hospital health services that are variously described as medically necessary or required.

The Canadian Constitution and Jurisdictional Hierarchies

As outlined above, the *Constitution Act, 1867* [22], makes no reference to "health." The general jurisprudential approach where the law is silent, is that matters are determined by case law and judicial interpretation.[23] In this context, it is key to understand how the Canadian courts (and the cases they decide) stand in relationship to each other.

The *Constitution Act, 1867* expressly establishes the federal power to create a court of last jurisdiction (recognized as the Supreme Court of Canada (SCC))[24] and furthermore, it establishes the sole federal authority to create and appoint judges to the SCC and to the courts of inherent jurisdiction anywhere in Canada (these are referred to as section 96 judges – sitting in the Court of Queen's Bench and its equivalent in other provinces). But the *Constitution Act, 1867* provides for the administration of justice by the provinces and thus it is left to the provinces to appoint provincial court judges.[25]

[22] *The Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (UK), 1982, c 11.
[23] See generally: Driedger, E.A. *The Construction of Statutes* (Canada: Butterworths, 1983).
[24] *Constitution Act, 1867, section 99.* The power is instantiated in the *Supreme Court Act, RSC 1985*.
[25] *Constitution Act, 1867, section 92(14).*

Illustration 3. Overview: Canada's Court System (Source: Department of Justice)

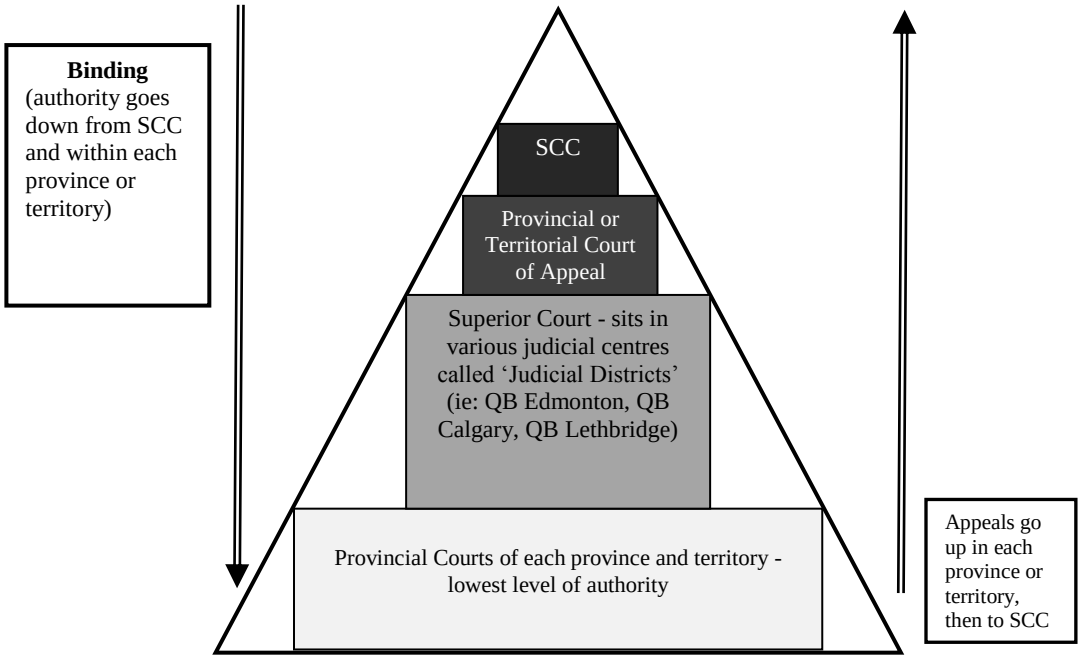
Each province has its own judicial nomenclature and is independent of the other provinces except to the extent that Supreme Court of Canada decisions are binding on all provinces. Roughly, the provinces adjudicate independently of each other (none is binding authority on any other)[26] and within each province there are three main levels of court: The lowest level – in Alberta this is called "provincial court" – is capable of dealing with most criminal matters, child and family matters and small claims. The next level – the courts of inherent jurisdiction – have full power to deal with all the matters from the lowest level,

[26] Higher courts will generally have persuasive authority in other provinces.

including some appeals.[27] The highest level in each province is the appellate level.[28] Authority can be construed as reaching downward; appeals go from bottom upward. Below is a diagram setting out the Canadian court hierarchy showing the authority and appeal structures. At the very top, overriding all lower courts is the Supreme Court of Canada (SCC); in the next (subordinate to the SCC) are the provincial and territorial appellate courts; below them (and subordinate to them in each respective province or territory but equal to each other within their respective provinces) are the courts of inherent jurisdiction (for example, the Court of Queen's Bench of Alberta). At the bottom are the provincial and territorial courts. The diagram illustrates the direction a case may take, if appealed through the system.

[27] In Alberta, for example, this level of court is called the "Court of Queen's Bench".
[28] In Alberta, for example, this level of court is called the "Court of Appeal".

Illustration 4. Canadian Court Hierarchy [29]



[29] Precedence: binding precedents within each jurisdictional hierarchy; persuasive from another province (no matter what level of court) or a court within the same province where there is no binding authority; Appeals go up from the bottom; binding precedence goes down from the top.

Doctrine of Precedents [30]

Perhaps to the surprise of clinicians and their patients, a factually relevant court decision from another province is not indicative of the local province's law unless that other province's law has been approved by the Supreme Court of Canada (SCC). For example, a judge from one province may consider a court decision from another province. However, unless the decision has the endorsement of the SCC, the judge will not have erred by failing to mention the decision from another province, even when the decision originates from a higher rank of court in another province. This is part of the theory of legal precedents.

There are two ways in which legal precedents work: they might be binding or they might be persuasive. What is a binding precedent judgment within the province where the decision is made is only persuasive in other provinces. It is like thinking about, for example, Australian cases and how they might work in Alberta. An Alberta judge might take them into consideration and might find them applicable for the local case. But by contrast, a Queen's Bench judge in Alberta cannot ignore or substantially depart from a relevant decision from Alberta's Court of Appeal, at least not unless the judge gives reasons to distinguish the case s/he has to decide.

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[30] The Doctrine of Precedents is closely related to *stare decisis*; the policy of the courts to abide by or adhere to principles established by decisions in earlier cases. The common law has traditionally adhered to the precedents of earlier cases as sources of law. Under *stare decisis*, once a court has answered a question, the same question in other cases must elicit the same response from the same court or other lower courts in that jurisdiction. See *Black's Law Dictionary, 6th Edition* (St. Paul: West Publishing, 1990) at 1176 and 1406.

Binding authority cannot be ignored or overturned by a lower court in that jurisdiction and it must be followed. Where it gets complicated within a province is when there is no decision from the provincial court of appeal to rely on. In that case, each Queen's Bench judge has full power to make a judicial determination. There is no legal doctrine of first-past-the-post as among judges in the same level creating a binding status on judges in other courts at the same level. But, in practice, a judge will not ordinarily depart from a peer judge's decision without giving a reason (sometimes the reason is put as simply as "in my opinion my brother judge, Justice J, erred"). This level of precedence is called horizontal precedence. Sometimes this expression is applied about judgments from parallel level courts in other jurisdictions (such as other provinces) that fall under the same ultimate appeal authority (the Supreme Court of Canada).

One of the legal challenges relevant to the current study topic, was the legal challenge to the right to buy, sell and consume alcohol. The outcome of the constitutional challenges was that the sale, purchase and consumption of alcohol were ultimately held to be matters that could appropriately be regulated by each province.[31] However, that is not the end of the matter: the definition and regulation of alcoholic content of beverages is construed as falling under the federal *Food and Drugs Act* regulations.[32] Thus, Canada has an amalgam of systems of regulations. But across all frameworks runs the common thread that when alcohol consumption occurs among women in early pregnancy, there is a correlated risk of damage to the developing fetus. It is this damage that results in physiological, neurological and developmental impediments known as fetal alcohol spectrum disorder (FASD).

[31] See generally: Effect of Alcohol on the Canadian Constitution, *supra* note 10.
[32] *Food and Drugs Act*, RSC 1985, c F-27.

Relevance: The FASD Context

As early as 1970, fetal alcohol syndrome (FAS) was identified by physiological morphology as a distinct condition.[33] As understanding has grown, the literature has become more refined and it is now more common to speak of two concepts: fetal alcohol spectrum disorder (FASD) and FAS, being a subset of FASD.

Children with a documented FASD are children who are known by clinicians to have been exposed to alcohol while *in utero* and have one or more deficits indicative for, but not conclusive of, a diagnosis of FAS.[34] But the causal connections of the factual associations between *in utero* exposure and FASD are currently insufficiently well understood in terms of timing, frequency or quantum of exposure as well as other environmental and genetic factors. Currently it is not possible to set out the necessary and sufficient conditions that produce FASD. FASD covers the range of deficits: for example some children may not have the phenotypic symptoms, but have the cognitive deficits. By contrast, FAS is a diagnosable syndrome attributed to fetal exposure to alcohol with certain discriminating phenotypic characteristics and cognitive impairment.

In practice, the distinction is important because it is only a positive FAS diagnosis that entitles a person to potentially access certain resources.[35] Without a positive FAS diagnosis, many children will not be eligible for access to FAS services including

[33] Recognition of FAS, *supra* note 1 at 999.
[34] Simply stated, FAS and FASD are two different conditions. Not all children with a documented FASD will be diagnosed with FAS.
[35] Personal communication from Dr. Ben Gibbard, Developmental Pediatrician, University of Calgary, 18 May 2006.

developmental pediatric interventions and supports. More detail is provided in the definitions in Chapter 3, the Literature Review.

Contemporary approaches to prenatal care, coupled with an enhanced knowledge of fetal development, have resulted in higher scrutiny of maternal behavior in pregnancy.[36] Ongoing advances in screening technology are increasing the ability to assess prenatal exposure to teratogens, including drugs and alcohol.[37] But, the use of the screening has gone beyond the original goal of providing optimal care to patients; rather, the results of such tests may be used within the justice system, in both criminal and civil law contexts. Hair and meconium screening results are now being used as evidence within the Canadian criminal justice system.[38] It is in this expanded context that the justification of neonatal screening for *in utero* exposure to drugs and alcohol confronts existing legal principles regarding informed consent to medical intervention.

The legality of all medical treatment, including screening, is founded upon the existence of consent.[39] [40] Except for emergent matters, no form of non-emergent health care delivery can be undertaken without informed consent. The criminalizing of certain health statuses is thought to be a reflection of the public, peace, order and good order powers of the federal government.[41] Currently, there is no jurisdiction to declare non-

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[36] S. Weyrauch, "Inside the Womb: Interpreting the *Ferguson* Case" (2002) 9 Duke J. Gender L. & Pol'y 81 [hereafter "Inside the Womb"].
[37] Meconium screening is one of the methods for evaluation of potential exposure to teratogens.
[38] *R.* v. *K.M.*, 2007 CanLII 13937 (ON S.C., 03/07/07).
[39] R. Francis & C. Jonhnston, *Medical Treatment: Decisions and the Law* (London: Butterworths, 2001) at 5 [hereafter "*Medical Treatment*"].
[40] See also, for example: *Hopp* v. *Lepp* (1980) 13 CCLT 66 at73; [1980] 2 SCR 192; *Reibl* v. *Hughes* (1980) 14 CCLT 1 at 6,11; [1980] 2SCR 880; and *Malette* v. *Shulman* (1987) 43 CCLT 62 at 94.
[41] At the time of writing, May 2012, decision is pending (judgment reserved) from the Supreme Court of Canada in two criminal law appeals, *Mabior* and *D.C.*, both challenging the legality of a provision of the Criminal Code that make it a criminal offence for an HIV positive person not to disclose that status to sexual partners. The appeals were heard on February 8th 2012. *R.*v. *Mabior,* 2008 MBQB 201 (CanLII), *R.* v.

consensual medical intervention to be lawful in order to protect the interests of an unborn child.[42] Policies and guidelines relevant to screening must be drafted with the rights and interests of both children and mothers in mind.[43]

A broad review of the existing Canadian screening policies and practices demonstrates a lack of standardization. *A fortiori,* there is no national policy that reflects relevant input from all key stakeholder groups.[44] This thesis aims to help address that gap. Given the difficulties and documented inaccuracies in predicting who will consume alcohol during pregnancy, and therefore which individuals are good candidates for screening, there is limited evidence to support the use of current strategies on a widespread basis.[45] A well-designed screening program would ideally have high participation rates, would not damage the relationship between woman and clinician, and would not deter women from seeking prenatal care. If screening programs are to be adopted on a wider basis, the legal and ethical issues must be carefully considered.

There is currently limited evidence to support screening for prenatal exposure to alcohol on either a targeted or universal basis.[46] Despite this, legal precedent now exists for the admission of screening evidence in Canadian courts ranging through criminal law, divorce, civil and child welfare matters. Some Canadian researchers and clinicians are

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Mabior, 2009 MBCA 93 (CanLII), *R.*v. *Mabior,* 2010 MBCA 93 (CanLII); *R* v. *D.C.*; *D.C.* v. *R.,* 2010 QCCA 2289 (CanLII).

[42] *Medical Treatment, supra* note 39 at 5.

[43] A. Zadunayski, *et a*l, "Behind the Screen: Legal and Ethical Considerations in Neonatal Screening for Prenatal Exposure to Alcohol" (2006) 14 Health Law Journal 105-127 [hereafter "Behind the Screen"].

[44] 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, Alberta.

[45] M. Hicks, *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 [hereafter "Evaluation of the Merits of Screening"].

[46] Behind the Screen, *supra* note 43 at 116.

advocating for universal screening[47], and the first Canadian universal screening pilot studies are currently under way in Ontario and Prince Edward Island, seeking to evaluate the clinical utility of meconium analysis as a tool for detecting neonates at risk for FASD.[48] The technology was initially developed to identify substance-exposed children, so as to facilitate earlier interventions and supports by developmental pediatricians and other health professionals.[49] Screening was not developed as a punitive measure for women who use substances during pregnancy or for use as evidence in criminal justice proceedings.

In the United States, screening for *in utero* exposure to cocaine and other substances absent a clinical indication and/or maternal consent has been characterized as an "unreasonable search and seizure" contrary to a woman's constitutional rights under the fourth amendment.[50] Until such time as clear policy is written on the use and purpose of this screen, the Canadian judiciary should be wary of using it as evidence in criminal justice or other legal proceedings such as child protection or family law matters. Further legal research and informed analysis is required, which was a major drive for this project.

[47] R. Hopkins *et al* "Universal or Targeted Screening for Fetal Alcohol Exposure: a Cost-effectiveness Analysis" (2008) 69 Journal of Studies on Alcohol and Drugs 510-519.
[48] I. Zelner *et al* "Universal Screening for Prenatal Alcohol Exposure: A Progress Report of a Pilot Study in the Region of Grey Bruce, Ontario" (2010) 32 Ther Drug Mont 305-311.
[49] While many early articles regarding meconium screening make this point, see generally: C.F. Bearer, *et al*. "Validation of a New Biomarker of Fetal Exposure to Alcohol" (2003) 143(4) J Pediatr 463-469.
[50] *Ferguson* v. *City of Charleston*, 308 F.3d 380 at 388 n.4 (4th Cir. 2002).

Introducing the research topic

The primary purpose of this study is to identify and examine the novel methods to screen for *in utero* exposure to drugs and alcohol, from the perspectives of law and ethics. The overall goal of the study is to inform and influence the development of screening policy and clinical practice guidelines. The specific research design used in this thesis is described in Chapter 2. Chapter 3 describes and examines in more detail the literature related to the topic. Study results are presented in Chapter 4, and Chapters 5 outlines the discussion. Conclusions and recommendations are presented in Chapter 6.

Chapter 2: Research Design & Methodology

Research Questions

The central research questions of this study are presented in Table 1.

Research Questions
What methods are available to screen for prenatal exposure to drugs and alcohol? Of these methods, which are currently implemented in the Canadian studies and which have been considered by the Canadian courts?
What are the medical-legal and ethical-legal considerations in screening for prenatal exposure to drugs and alcohol? What information must stakeholders, policy-makers and the judiciary have regarding screening?
Are there legal cases that we can learn from in the area of perinatal or neonatal screening regarding substances of abuse? If so, how might the cases be used to inform screening policy?

Study Design

A pragmatic, transdisciplinary[51] mixed-methods research design was employed to answer the above research questions, including three distinct phases: a systematic literature review, a multi- jurisdictional case law review using advanced legal research methods, and

[51] An approach to health research that transcends traditional boundaries, integrating the natural, social and health sciences in a humanities context. See generally, B. Choi & A. Pak, "Multidisciplinarity, Interdisciplinarity and Transdisciplinarity in Health Research, Services, Education and Policy: Definitions, Objectives, and Evidence of Effectiveness" (2006) 29 Clin Invest Med 351-364.

professional stakeholder interviews. Systematic literature and case law reviews and analyses,[52] supplemented by in-depth, semi-structured and unstructured individual interviews with key stakeholders including clinicians, scientists, epidemiologists, ethicists, lawyers and other health law professionals and policy-makers were employed in order to survey and address questions pertaining to current screening modalities and their implementation, use and efficacy. Advanced legal research methods[53] and theory were used to inform a discussion of the legal and ethical considerations associated with the use of such modalities. Feminist legal theory[54] was also used to inform the analysis, given that a key component of this study included an examination of legal cases regarding neonatal hair and meconium screening in the context of exploring how the law is responding to the needs of women.[55] Pertinent civil, family law, criminal law, and medical jurisprudence was identified using advanced legal research methods appropriate to multiple jurisdictions, including (but not limited to) Canada and the United States where known cases existed at the inception of this study.

Feminist Legal Theory

Feminist legal theory and feminist jurisprudence examines how women and women's perspectives are treated under the law and how the law responds to the needs of

[52] The literature and case law review for this study began in January 2006, yielding one peer-reviewed publication, and is presently ongoing.
[53] E. Kwaw, *The Guide to Legal Analysis, Legal Methodology and Legal Writing* (Toronto: Emond Montgomery Publications, 1992) at 13 [hereafter "*Guide to Legal Analysis*"].
[54] K. Bartlett, "Feminist Legal Methods" (1990) 100 Harvard Law Review, 829, reproduced in H. Barnett, *Sourcebook on Feminist Jurisprudence* (London: Cavendish Publishing, 1997) at 93.
[55] *Guide to Legal Analysis*, *supra* note 53 at 13.

women,[56] adopting a contextual approach to the analysis of laws, legal systems and legal cases that exemplify the disparate or unequal treatment of men and women. Similarly, feminist ethics – largely based here on the writings of Gilligan and Sherwin – relating to health care emphasizes the importance of evaluating ethical dilemmas in a contextualized, narrative way; endorsing the inclusion of context as a central element in moral reasoning.[57]

It is contended by feminist theorists that the common law as traditionally developed has been utterly insensitive to women's perspectives and thus is not adequately informed render fair, equitable and appropriate decisions in highly nuanced cases. Feminist legal theory is based in the recognition that while all persons are supposed to be equal under the law, the equality rules that exist in contemporary society have not necessarily yielded the equal treatment of all before the law.[58] Feminist theorists contend that the focus in traditional common law is largely male-oriented and derived from property and commercial models, thereby overlooking the caring relationships and kinship bonds that are more typical of women and their societal and familial roles. A feminist approach is therefore extremely relevant and well suited to this study given the distinct tension that exists between the interests of mothers and newborns in the context of screening modalities that reveal information about both; while screening for *in utero* exposure to drugs and alcohol may potentially benefit identified newborns, absent considered practice guidelines and legal protections, screening protocols may also have the potential to adversely impact

[56] *Guide to Legal Analysis, supra* note 53 at 13.
[57] Sherwin, S., *No longer Patient: Feminist Ethics and Health Care* (Philadelphia: Temple University Press, 1992) at 76-77 [hereafter "*No Longer Patient*"]. Also, see generally: Gilligan, C., *In a Different Voice: Psychological Theory and Women's Moral Development* (Cambridge: Harvard University Press, 1982). The importance of evaluating ethical dilemmas and moral problems related to health care in a contextualized way that emphasizes narrative will become apparent in Chapters 4 and 5, where the details of specific cases involving meconium screening for *in utero* exposure to drugs and alcohol are explored.
[58] *Guide to Legal Analysis, supra* note 53 at 13.

mothers, mother-child and other family-child relationships.[59] A review of the literature reveals that legal cases involving neonatal hair and meconium screening evidence are likely to be informed, in the main, by expert testimony and research premised upon the benefits of screening for newborns. Yet such research may have failed to take into consideration potential for an adverse legal or social impact of screening results for mothers, and it is in this way that supposedly objective scientific research, and a supposedly objective and neutral common law, can inadvertently subordinate the needs and interests of women. Simply stated, (1) screening protocols which are predicated upon beneficence toward newborns may have a discriminatory impact upon women in both a clinical and legal context and (2) while the scientific research is a necessary component, it is not sufficient because the clinical researchers undertaking the supposedly objective, scientific studies lack the specialist training and skills of jurists and ethicists necessary to provide sufficient background to inform policy development and law reform.

While feminist legal scholars do not bring a unique and uniform methodology to legal research, feminist scholarship seeks to analyze jurisprudence through a particular lens; using narrative and context to identify, examine and question engendered approaches to justice, along with the role that the legal system plays in impacting the status of women within society.[60] This study attempts to (1) identify and describe the current literature and jurisprudence relating to the use of meconium screening in both the clinical context and

[59] While multiple examples exist, see generally *British Columbia Birth Registry No. 2006-59-039985 (Re)*, 2010 BCCA 137, wherein Neilson J.A. (on behalf of the British Columbia Court of Appeal) described that a newborn was removed from his mother's custody immediately after his birth because a sample of his meconium tested positive for drug metabolites, indicating the mother had used drugs during the second trimester of her pregnancy. The baby was placed for adoption, without the mother's consent. In that case the mother regained custody of her son when he was three and a half years old, after appealing the case to the British Columbia Court of Appeal.

[60] *Guide to Legal Analysis, supra* note 53 at 13.

within the legal system, while also (2) using qualitative methods to analyze themes highlighting the importance of the consideration and protection of the interests of mothers, alongside the interests of their newborns. Thus the feminist approach rejects the competitive proportionality test as among competing rights-claims, but rather advocates for an integrated, holistic approach to women, along with their children and families, as interrelated in a complex, contextual matrix of overall interests.[61]

Data Collection

Systematic Literature Review

A systematic, methodological literature review [62] was employed to identify published medical, legal and ethics research pertaining to the recent scientific phenomenon of neonatal hair and meconium screening for fatty acid ethyl esters (FAEEs) and other drug metabolites. The literature and case law review helped to identify key researchers, stakeholders and policy-makers in the area, the research ethics boards and institutional review boards that have approved existing studies, as well as practice guidelines, informed consent policies, or the absence thereof.

A literature review pertaining to legal and ethical challenges of neonatal meconium screening involved surveying the results of related studies and publications to identify gaps in the scientific and legal literature. This undertaking involved identification and

[61] See generally, for example, S. Sherwin, *No Longer Patient, supra,* note 57.
[62] J.W. Creswell, *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches Third Edition* (Thousand Oaks: Sage Publications, 2009).

refinement of key words and search term combinations, searches of online and specialized databases, and the grouping of studies into categories related to science, epidemiology, law, ethics, health economics and social work. The search terms used were partially derived from primary searches of the existing literature, but were also augmented by personal communications with stakeholders in the field. A literature search was conducted in PubMed, Medline via Ovid, and Hein Online via LegalTrac, with a combination of search words including <<meconium>>, <<ethics>>, <<law>>, <<screen>>, <<drug>>, <<alcohol>>, and <<fetal alcohol spectrum disorder>>. Literature searches combined yielded over 5600 hits related to meconium, but only 4 publications related to meconium screening and law or ethics, once results related to meconium aspiration syndrome and birth trauma were eliminated as irrelevant to the study.

The literature search was limited to the period from September 2006 to May 2012. Only articles in the English language were included for the purposes of this study. The search demonstrated a clear evolution of the literature (and resultant literature gaps) over a six year period. Surveying the literature regarding neonatal meconium screening helped to identify areas of discussion that appeared to be lacking or debated within the literature and, in turn, helped to define the research questions for this study.

Stakeholder Interviews

The interview phase of the study consisted of face-to-face interviews with key stakeholders to discuss themes identified through the systematic literature and case law reviews, including responses to potential legal and ethical challenges of meconium

screening. The interviews were conducted concurrently with and informed by the ongoing literature and case law reviews. Research participants were identified as the literature review and case law analyses progressed, with participants purposefully selected in order to help the researcher understand and clarify the research questions, and additional interviews added, as necessary. The interviewees were contacted by email and/or telephone together with letters of invitation and informed consent forms.[63] A minority of identified participants (n = 2) declined to be interviewed, or failed to reply to the researcher's correspondence. Interviews were held at a time and place of the interviewees' convenience and choosing. The duration of the interviews ranged between one and three hours depending on distance travelled, along with the interviewees' availability and information.

In-person interviews were held in Calgary, Hawaii, Vancouver, and Prince Edward Island. Participants were encouraged to give their own perceptions and accounts, based upon their respective areas of expertise and experiences of neonatal screening and, as such, interviews involved unstructured and generally open-ended questions intended to elicit the views and opinions of participants. This method of inquiry allowed for the collection of data in the natural setting of the participants and was intentionally chosen so as to gather spontaneous, unedited information. Detailed notes were taken and reviewed following each session, however sessions were not recorded and transcribed. Content of the interview notes was analyzed for emergent themes, with similarities and differences between both participants and participant sites compared. Follow up conversations were held where there was any perceived need for further clarification or comment. Some of the follow up

[63] See Appendix D: Letter of Invitation.

conversations were at the request of the researcher; others were at the initiative of the interviewee.

Advanced Legal Research

Traditional and online advanced legal research methods were employed to identify relevant journal articles and jurisprudence in the areas of neonatal hair and meconium screening, screening evidence, maternal substance use, child welfare, family law, and consent and battery. Purposive sampling[64] of all cases reported within the Canadian Legal Information Institute (CanLII)[65] and LexisNexis[66] databases involving the judicial consideration of (or references to) neonatal hair and/or meconium screening results were identified and included in a Table of Cases according to decision-date.[67] Cases were coded according to court level and case-type classification. Interpretive content analysis was performed with relevant themes identified for cases where neonatal hair and/or meconium screening evidence was considered or referenced by the judiciary. Reported medical malpractice cases involving meconium aspiration in the context of birth trauma were discarded as irrelevant to the study. Legal cases involving the consideration of adult hair analysis were also discarded as irrelevant to the study.

[64] Given the limited number of scholars with expertise in the area being researched, the sample was selected by the researcher based upon articles and cases deemed appropriate for the study.
[65] www.canlii.org. The Canadian Legal Information Institute (CanLII) is a public online, nonprofit database managed by the Federation of Law Societies of Canada.
[66] www.lexisnexis.ca. LexisNexis Canada is a private, for-profit provider of legal information and services for legal professionals, law firms, corporations, government and academic institutions.
[67] See Appendix A: Table of Cases.

Recruitment

Research participants included key stakeholders: medical professionals, researchers, legal professionals, ethicists and policy-makers. A number of potential research participants were identified through the systematic literature and case law reviews. One research participant was identified at a relevant scholarly meeting.[68] The researcher described and explained the study to research (interview) subjects via telephone and email contact, and thereafter through a letter of invitation (explaining the study, the ethics review process and the consent protocol)[69] in keeping with the consent protocol required by the Conjoint Health Research Ethics Board (CHREB).[70] Early on in the study, legal undertakings were employed regarding the approved consent protocol to expedite the interview process. A short list of identified research participants is included in Table 2.

[68] 20th Annual Canadian Bioethics Society Conference, "Just Evidence" June 11-14, 2009. http://fhs.mcmaster.ca/bioethicsconference/ (accessed: 21 May 2012).
[69] See Appendix D: Letter of Invitation.
[70] Conjoint Health Research Ethics Board, Position Statement: Consent, August 2008. http://fp.ucalgary.ca/medbioethics/chreb/policy.html (accessed: 2 May 2012).

Table 2. List of Research Participants

Participants	City	Province/ State	Profession	Centre
Dr. Ben Gibbard	Calgary	Alberta	Physician (Developmental Pediatrician)	Alberta Children's Hospital
Dr. Matthew Hicks	Calgary	Alberta	MD/Ph.D. (Neonatology fellow)	University of Calgary
Dr. Julie Lauzon	Calgary	Alberta	Physician (Geneticist)	Alberta Children's Hospital
Dr. Paul Byrne	Edmonton	Alberta	Physician (Neonatologist)	Stollery Children's Hospital
Dr. Brendan Leier	Edmonton	Alberta	Clinical Ethicist	Alberta Health Services
Ms. Sarah Gebauer	Vancouver	British Columbia	Ethics Coordinator	Fraser Health
Dr. Chris Derauf	Honolulu	Hawaii	Physician (Pediatrician)	University of Hawaii
Dr. Alan R. Katz	Honolulu	Hawaii	Epidemiologist	University of Hawaii

Ethical Considerations

In compliance with the requirements of the *Tri-Council Policy Statement,*[71] University of Calgary requirements and provincial privacy law, an application was made to the CHREB for research ethics review and approval. A disclosure of conflict of interest

[71] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2010.

was duly made by the thesis supervisor, Dr. Glenys Godlovitch, who occupied the role of Chair of the CHREB; she recused herself from all consideration of the application. This study, including recruitment documents, consent forms, and template question frames, was approved by the CHREB at the University of Calgary.[72] As this study involved collecting information from stakeholders about their programs of research and ethical dimensions of their professional undertakings, participation of research subjects was voluntary, and based on informed consent. The purpose and sponsorship of this study was duly explained to all research participants. Attached as Appendices C and D are the approval and renewals and invitation letter for participating in the study.

Data analysis

A mixed-methods approach, including qualitative and legal research methods, was used for data collection within this study. Data derived from the systematic literature review, case law review and interviews was described, organized and analyzed according to research themes. Where possible, an exploration of the research participants' views and perceptions were included in the analysis, which developed from the information supplied. Feminist legal theory was used to analyze legal materials, journal articles and jurisprudence.

[72] See Appendix C: Certification of Institutional Ethics Review.

Chapter 3: Literature Review

This chapter describes and examines the literature[73] detailing the scientific, legal, ethics, health-economics and social work literature pertinent to screening for *in utero* exposure to drugs and alcohol. Over the past three decades, much of the published literature regarding screening for maternal substance use in pregnancy has focused upon alcohol exposure within the context of identifying children at risk for Fetal Alcohol Spectrum Disorder (FASD). Only more recently has there been an increase in the number of studies focused upon screening for illicit or illegal substances of abuse[74], and the literature base continues to evolve.[75]

The rationale for bringing together the scientific, legal, ethics, and social work literature is that it reflects societal values and norms encapsulating the role of the state in terms of duties and responsibilities for the welfare of dependents, in particular, infants. In law, for example, the doctrine of *parens patriae* construes the state as the ultimate steward for all minors and incompetents who are otherwise not in the legal care of some competent adult. It is on this basis that the state may displace a parent's ordinary custodial role if the

[73] The material covering the period to 2006 in section 1, Scientific Literature is based on material previously published as A. Zadunayski *et al*, "Behind the Screen" *supra* note 43. See Appendix E: Publication Agreement and Copyright Licence. It has been extensively updated and revised to reflect the scientific literature as at time of writing, in May 2012.

[74] Popular drugs of abuse vary according to geography and population, but tend to include: marijuana, cocaine, crack, heroin, amphetamines, methamphetamines, inhalants, opioids such as methadone and oxycodone, and new club drugs such as 'ecstasy' or PMMA. See generally: T.S. Rosen, *et al*, "Infants of Addicted Mothers" in Fanaroff, A.A. & Martin, R.L., eds, *Neonatal-Perinatal Medicine*, 7th ed (St. Louis: Mosby, 2001) 661-673.

[75] C. Wallman *et al*, "Implementing a Perinatal Substance Abuse Screening Tool" (2011) 11 Advances in Neonatal Care 255 at 266 [hereafter "Perinatal Substance Abuse Screening"].

parent is found not to be discharging their responsibilities appropriately. The approach underpins child welfare legislation in its various and varied forms across Canada.

Scientific Literature

Over the past three decades, much of the published literature regarding screening for maternal substance use in pregnancy has focused upon alcohol exposure within the context of Fetal Alcohol Spectrum Disorder (FASD). Due to changes in maternal substance-use trends[76] as well as technological advances in neonatal screening including drug-residue testing in hair and drug-metabolite screening in meconium, there has been a recent increase in the number of studies focused upon screening for illicit substances of abuse.[77]

Setting the Context: Fetal Alcohol Spectrum Disorder

While drug and alcohol use in pregnancy is associated with increased morbidity for women and children[78], the scientific literature regarding the identification of children at risk for sequelae resulting from alcohol exposure has tended to focus upon screening within the context of FASD. However, the literature must be understood as highly nuanced (and

[76] *Ibid*. at 255. While illicit drugs can have similar effects to alcohol on fetuses, and published data is available for some illicit drugs such as heroin and cocaine, data is lacking for some other popular drugs such as methamphetamine and other amphetamines.
[77] R. Araojo *et al*, "Substance Abuse in Pregnant Women: Making Improved Detection a Good Clinical Outcome" (2008) 83 Clinical Pharmacology & Therapeutics 520 [hereafter "Substance Abuse in Pregnant Women"]. Since the mid-1990's, neonatal hair and meconium screening for exposure to popular drugs of abuse have been used to varying degrees in clinical practice.
[78] *Ibid*.

possibly biased) in that it is known that not all mothers who consume alcohol during pregnancy give birth to babies that go on to develop a FASD. The understanding of FASD is typically a reconstruction working backwards from a child who appears to have developmental deficits to identifying that the child was exposed *in utero* to alcohol. Issues of sensitivity and specificity have arisen in the context of meconium screening for *in utero* exposure to drugs and alcohol, and the causal association between a positive meconium screen and a diagnosis of FASD or FAS is not certain.[79] [80] Given the potential for false negatives and false positives with such screening modalities, combined with a lack of correlation with maternal self-report[81], and a lack of certainty around which infants will be impacted or helped, the ethics of current screening practices in various jurisdictions must be carefully examined.

Fetal Alcohol Spectrum Disorder (FASD) is an umbrella term describing the range of physical, cognitive and neurobehavioral deficits that can occur in an individual whose mother consumed alcohol during pregnancy.[82] This is concerning as approximately 15-45%[83] [84] [85] of women in Canada consume alcohol during pregnancy despite

[79] See D. Chan *et al*, "Fetal Exposure to Alcohol as Evidenced by Fatty Acid Ethyl Esters in Meconium in the Absence of Maternal Drinking History in Pregnancy" (2004) 26(5); Ther Drug Monit : 474-481. At present, there is no causal relationship between a positive meconium screen and a diagnosis of FAS; a positive screen is not a diagnosis.
[80] See also: M. Hicks (2007) *Meconium alcohol and drug screening*. PhD thesis, University of Calgary, Calgary, Alberta [hereafter "*Meconium Alcohol and Drug Screening*"].
[81] Derauf, C., *et al*, "Agreement Between Maternal Self-Reported Ethanol Intake and Tobacco Use During Pregnancy and Meconium Assays for Fatty Acid Ethyl Esters and Cotinine" (2003) 158 *Am J Epidemiol* : 705-709 [hereafter "Maternal Self-Report"].
[82] A. Streissguth *et al*, "Neuropsychiatric Implications and Long-term Consequences of Fetal Alcohol Spectrum Disorders" (2000) 5 Seminars in Clinical Neuropsychiatry 177 [hereafter "Neuropsychiatric Implications"].
[83] Health Canada. Canadian Perinatal Health Report, 2000. Ottawa: Minister of Public Works and Government Services Canada; 2000. Cat. No. H49-142/2000E, p. 6.
[84] *Meconium Alcohol and Drug Screening, supra*, note 80.
[85] R.L. Floyd, *et al* "Alcohol Use Prior to Pregnancy Recognition" (1999) 17 Am J Prev Med 101 at 104 [hereafter "Alcohol Use Prior to Pregnancy Recognition"].

recommendations that women abstain.[86] 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.[87] The impact of FASD is wide reaching, touching the life of the individual and the lives of family members and society as a whole.[88] [89] In contrast to other birth defects and genetic conditions, FASD has received attention from medical and public health professionals precisely because it is a preventable condition.[90] 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 fetal alcohol exposure, highlighting the need for members of the legal, social work and medical professions to have a better understanding of these conditions.[91]

Early diagnosis, a supportive environment, and early intervention have been identified as crucial factors to optimise outcomes for affected individuals.[92] [93] However, the diagnosis of any given FASD is complex and often does not occur until school age, if at all, at which point maximal benefit from early intervention and support may not be

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[86] Health Canada. Joint statement: prevention of fetal alcohol syndrome (FAS), Fetal Alcohol Effects (FAE) in Canada. Ottawa: Health Canada; 1996. Cat. No. H39-348/1996E.
[87] P.D. Sampson *et al*, "Incidence of Fetal Alcohol Syndrome and the Prevalence of Alcohol-related Neurodevelopmental Disorder" (1997) 56 Teratology 317 [hereafter "Incidence of FAS"].
[88] "Neuropsychiatric Implications", *supra* note 82 at 177.
[89] Canadian Pediatric Society: Statement of President, Dr. Robin Walker on Bill C-206. http://www.cps.ca/english/proadv/reports/2005_C206.pdf (Accessed: January 12, 2006). The Canadian Pediatric 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.
[90] C. Weisner, "Fetal Alcohol Syndrome" (2005) 293 JAMA No.5: 627.
[91] Alberta Health and Wellness. Health is everyone's business: a snapshot of some of Alberta's wellness initiatives. Edmonton: Alberta Health and Wellness – Communication Branch; 2000, at p.2. See also generally: L. Chartrand and E. Forbes-Chilibeck, "The Sentencing of Offenders With Fetal Alcohol Syndrome" (2003) 11 Health L.J. 35 [hereafter "The Sentencing of Offenders"].
[92] S. Mattson and E. Riley, "Neurobehavioural and Neuroanatomical Effects of Heavy Prenatal Exposure to Alcohol" [hereafter "Neurobehavioural and Neuroanatomical Effects "] in A. Streissguth and J. Kanter, J., eds., *The Challenge of Fetal Alcohol Syndrome: Overcoming Secondary Disabilities*, (Seattle: University of Washington Press, 1997), at 6-8.
[93] A.P. Streissguth, et al. "Risk Factors for Adverse Life Outcomes in Fetal Alcohol Syndrome and Fetal Alcohol Effects" (2004) 25 Journal of Developmental & Behavioral Pediatrics No. 4, 228 at 235-236.

achieved.[94] 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[95] [96], which has been proposed as an aid to healthcare professionals in the early identification of children who may be at risk for a FASD, thus enabling health care professionals to mobilize earlier interventions and supports.

Prevalence and Incidence of FASD

Fetal alcohol syndrome (FAS) was first identified over 30 years ago by Jones *et al.*[97] 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.*[98] FASD, a descriptive term rather than a diagnosis, includes FAS, partial FAS, Alcohol-related Neurodevelopmental Disorder (ARND) and Alcohol-related Birth Defects (ARBD).[99] Currently, FASDs are believed to be under diagnosed and many children are not diagnosed until they are school-aged.[100] [101] The prevalence of FAS/FASD commonly reported in the

[94] *Ibid.*
[95] C.F. Bearer, *et al*, "Ethyl Linoleate in Meconium: A Biomarker for Prenatal Alcohol Exposure" (1999) 23 Alcohol Clin Exp Res 487 at 491.
[96] D. Chan, *et al*, "Recent Developments in Meconium and Hair Testing Methods for the Confirmation of Gestational Exposures to Alcohol and Tobacco Smoke" (2004) 37 Clinical Biochemistry No. 6, 429 at 430-436.
[97] Recognition of FAS, *supra* note 1 at 999.
[98] Neuropsychiatric Implications, *supra* note 82 at 177.
[99] *Ibid.*
[100] S.K. Clarren, *et al*, "Screening for Fetal Alcohol Syndrome in Primary Schools: A Feasibility Study" (2001) 63 Teratology 3 at 4.

literature for urban 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.[102]

FASD includes a characteristic triad of deficits, namely, growth restriction, craniofacial abnormalities, and neurocognitive deficits.[103] Affected individuals may exhibit a wide range of physical features, from growth restriction, central nervous system (CNS) defects, birth defects, and characteristic craniofacial abnormalities[104] 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.[105] 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.[106] However, there is no one profile of primary cognitive deficits. Some affected individuals may have high intelligence quotients[107], but be unable to interact appropriately in social situations.[108] Cognitive and behavioural abnormalities often persist into adulthood.[109] Secondary disabilities occur as a result of living with primary disabilities and may include mental health disorders, drug and alcohol addictions, disrupted

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[101] B.B. Little, *et al*, "Failure to Recognize Fetal Alcohol Syndrome in Newborn Infants" (1990) 144 American Journal of Diseases in Childhood No. 11, 1142 at 1145 [hereafter "Failure to Recognize FAS"].
[102] Incidence of FAS, *supra* note 87 at 322.
[103] Recognition of the FAS, *supra* note 1 at 999.
[104] Craniofacial abnormalities that are most consistently seen with FAS include thin upper lip, smooth philtrum and small palpebral fissures.
[105]Failure to Recognize FAS, *supra* note 101 at 1145.
[106] Neurobehavioural and Neuroanatomical Effects, *supra* note 92 at 6-8.
[107] A.P. Streissguth, *et al*, "Moderate Prenatal Exposure: Effects on Child IQ and Learning Problems at Age 7 1/2 Years" (1990) 14 Alcohol Clin Exp Res 662 at 663-664.
[108] A.P. Streissguth, *et al*, "Fetal Alcohol Syndrome in Adolescents and Adults", (1991) 265 JAMA 1961 at 1963-1966.
[109] *Ibid.*

school experiences, joblessness, homelessness, involvement with the law[110], custodial sentences as a result of criminal behaviour, and inappropriate sexual behaviour.[111]

The primary and secondary disabilities of FASD have a significant impact economically, socially, and medically for Canada.[112] [113] 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.[114] FASD touches not only the affected individual, but mothers, fathers, the entire family and the community, all at a terrific cost.[115] Parents of individuals with FASD may find coping with primary and secondary disabilities to be a 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[116] [117] 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. [118]

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[110] "Neuropsychiatric Implications" *supra* note 82 at 177.
[111] N. Novick, "FAS: Preventing and Treating Sexual Deviancy"[hereafter "Preventing Sexual Deviancy"], in A. Streissguth and J. Kanter, eds., *The Challenge of Fetal Alcohol Syndrome: Overcoming Secondary Disabilities*, *supra* note 92 at 162.
[112] Health Canada. Joint statement: Prevention of Fetal Alcohol Syndrome (FAS), Fetal Alcohol Effects (FAE) in Canada. Ottawa: Health Canada; 1996. Cat. No. H39-348/1996E.
[113] Alberta Health and Wellness. Health is Everyone's Business: A Snapshot of Some of Alberta's Wellness Initiatives. Edmonton: Alberta Health and Wellness – Communication Branch; 2000, at 2.
[114] *Ibid.*
[115] Preventing Sexual Deviancy, *supra* note 111 at 162.
[116] Alberta Health and Wellness. Health is Everyone's Business: A Snapshot of Some of Alberta's Wellness Initiatives. Edmonton: Alberta Health and Wellness – Communication Branch; 2000at 2.
[117] D. Fast, *et al*, "Identifying Fetal Alcohol Syndrome Among Youth in the Criminal Justice System" (1999) 20 *J. Dev Behav Pediatr* 370 at 371.
[118] D. Fast, *et al*, "The Challenge of Fetal Alcohol Syndrome in the Criminal Legal System" (2004) 9 Addiction Biology 161 at 164.

The Importance of Early Diagnosis, Intervention and Support

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.[119] [120] One study of individuals with FAS found that those who were diagnosed before the age of six had a lower rate of secondary disabilities.[121] Those diagnosed early were less likely to have disrupted school experience, display inappropriate sexual behaviour, and have trouble with the law.[122] There is a consensus in the literature and among many 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.[123] 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 believed to be systematic underreporting and documenting of alcohol use during pregnancy so clinical suspicion of prenatal alcohol exposure may not be raised.[124] [125]

[119] Neurobehavioural and Neuroanatomical Effects, *supra* note 92 at 6-8.
[120] A.P. Streissguth, *et al*, "Risk Factors for Adverse Life Outcomes in Fetal Alcohol Syndrome and Fetal Alcohol Effects" (2004) 25(4) Journal of Developmental & Behavioral Pediatrics 228 at 235-236.
[121] *Ibid.*
[122] *Ibid.*
[123] *Ibid.*
[124] Health Canada. Canadian Perinatal Health Report, 2000. Ottawa: Minister of Public Works and Government Services Canada; 2000. Cat. No. H49-142/2000E at 8.
[125] J.M. Stoler, *et al*, "The Prenatal Detection of Significant Alcohol Exposure with Maternal Blood Markers" (1998) 133 J Pediatr 346 at 348-350 [hereafter "The Prenatal Detection"].

Maternal Substance Use in Pregnancy: Lessons from the Literature on Maternal Alcohol Consumption

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 established.[126] 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.[127] This study did not discuss many potentially important factors of prenatal alcohol exposure, including timing, frequency or regularity of consumption, and binge patterns.[128]

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.[129] [130] 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.[131] [132] [133] [134] Self-report

[126] Health Canada. Joint Statement: Prevention of Fetal Alcohol Syndrome (FAS), Fetal Alcohol Effects (FAE) in Canada. Ottawa: Health Canada; 1996. Cat. No. H39-348/1996E.
[127] Health Canada. Canadian Perinatal Health Report, 2000. Ottawa: Minister of Public Works and Government Services Canada; 2000. Cat. No. H49-142/2000E at 6.
[128] J. Gladstone, *et al*, "Characteristics of Pregnant Women Who Engage in Binge Alcohol Consumption" (1997) 15 CMAJ 789 at 791-793 [hereinafter "Characteristics of Pregnant Women"].
[129] Health Canada. Canadian Perinatal Health Report, 2000. Ottawa: Minister of Public Works and Government Services Canada; 2000. Cat. No. H49-142/2000E at 8.
[130]The Prenatal Detection, *supra* note 125 at 348-350.
[131] Health Canada. Canadian Perinatal Health Report, 2000. Ottawa: Minister of Public Works and Government Services Canada; 2000. Cat. No. H49-142/2000E at 8.
[132]"The Prenatal Detection", *supra* note 102 at 348-350.

depends not only upon a mother responding truthfully but also upon a clinician attentively asking the right questions.[135] 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.[136] Maternal self-report of alcohol use during pregnancy can be valid, cost-effective and less invasive than the use of biomarkers[137] 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.[138] [139] [140] Many women 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.[141] 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.[142] Additionally, many women maintain their usual pattern of drinking until

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[133] I. Chasnoff, "Drug Use and Women. Establishing a Standard of Care" (1989) 562 Ann N Y Acad Sci 208 at 209-210 [hereafter "Drug Use and Women"].
[134] K.A. Bradley, *et al*, "Alcohol Screening Questionnaires in Women: A Critical Review" (1998) 280 JAMA 166 at 167-169 [hereafter "Alcohol Screening Questionaires"].
[135] *Ibid.*
[136] "Drug Use and Women", *supra* note 133 at 209-210.
[137] British Columbia Reproductive Care Program: Guidelines for use in the perinatal period and fetal alcohol spectrum disorder. http://www.rcp.gov.bc.ca/guidelines/substance_use/alcoholguideline.pdf (accessed: 1 February 2006).
[138] C. Derauf, *et al*, "The Prevalence of Methamphetamine and Other Drug Use During Pregnancy in Hawaii" (2003) Journal of Drug Issues 1001 at 1010 [hereafter "The Prevalence of Methamphetamine"].
[139] *Meconium Alcohol and Drug Screening*, *supra* note 80.
[140] "Alcohol Use Prior to Pregnancy Recognition", *supra* note 61 at 104.
[141] *Ibid.*
[142] B. Sood, *et al*, "Prenatal Alcohol Exposure and Childhood Behavior at Age 6 to 7 Years: I. Dose-Response Effect" (2001) 108 Pediatrics e34.

pregnancy recognition, often at four to eight weeks; this may include a pattern of binge drinking, defined as five or more drinks in one sitting, perhaps several times per month.[143]

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.[144] [145] [146] [147] [148] [149] Alcohol use by women during pregnancy is therefore often at the nexus of social and medical problems.[150]

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.[151] Alcohol is a teratogen that contributes to birth defects, however the exact mechanism by which alcohol damages the developing fetus is unknown. [152] Timing of exposure during fetal development, frequency of drinking episodes and level of

[143] Alcohol Use Prior to Pregnancy Recognition, *supra* note 85 at 104.
[144] T.K. McNamara, *et al*, "Social Support and Prenatal Alcohol Use" (2006) 15(1) Journal of Women's Health 70 at 70-76.
[145] Characteristics of Pregnant Women, *supra* note 128 at 791-793.
[146] S.J. Astley, *et al*, "Fetal Alcohol Syndrome (FAS) Primary Prevention Through FS Diagnosis: I. A Comprehensive Profile of 80 Birth Mothers of Children with FAS" (2000) 35 Alcohol Alcoholism 509 at 510-511 [hereafter "Identification of High-Risk Mothers"].
[147] *Ibid*, at 503-506.
[148] J.L. Jacobson, *et al*, "Increased Vulnerability to Alcohol-related Birth Defects in the Offspring of Mothers Over 30" (1996) 20(2) Alc Clin Exp Res 359 at 360-362 [hereafter "Increased Vulnerability to ARBDs"].
[149] S. Teagle and C., "Substance Use Among Pregnant Adolescents: A Comparison of Self-reported Use and Provider Perception" (1998) 22 (3) Journal of Adolescent Health 229 at 233-237.
[150] Fetal Alcohol Syndrome, *supra* note 90 at 627.
[151] Characteristics of Pregnant Women, *supra* note 128 at 791-793.
[152] G. Koren, "Maternal Drug Abuse: Effects on the Fetus and Neonate", in R. Polin, W. Fox, and S. Abman, eds., *Fetal and Neonatal Physiology*, Volume One, 3rd Edition, (Philadelphia: Saunders, 2004) at 234 [hereafter "Maternal Drug Abuse"].

consumption are all thought to contribute to the risk of FASD.[153] [154] 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.[155] 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.[156] [157] 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.[158] Health advocacy groups maintain that screening and several brief interventions during pregnancy can support a reduction in maternal alcohol consumption[159], and there is some literature to support this view.[160] [161] [162]

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[153] Increased Vulnerability to ARBDs, *supra* note 148 at 260-262.
[154] H.M. Barr, A.P. Streissguth, "Identifying Maternal Self-reported Alcohol Use Associated with Fetal Alcohol Spectrum Disorders" (2001) 25(2) Alcohol Clin Exp Res 283 at 285-286.
[155] A.P. Streissguth and P. Dehaene, "Fetal Alcohol Syndrome in Twins of Alcoholic Mothers. Concordance of Diagnosis and IQ" (1993) 47 American Journal of Medical Genetics 857.
[156] Characteristics of Pregnant Women, *supra* note 128 at 791-793.
[157] Fetal Alcohol Syndrome, *supra* note 90 at 627.
[158] T.K. McNamara, *et al*, "Risk During Pregnancy--Self-report Versus Medical Record" (2005) 193(6) American Journal of Obstetrics & Gynecology 1981 at 1983-1984.
[159] British Columbia Reproductive Care Program: Guidelines for use in the perinatal period and fetal alcohol spectrum disorder. http://www.rcp.gov.bc.ca/guidelines/substance_use/alcoholguideline.pdf (accessed: 1 February 2006).
[160] Identification of High-Risk Mothers, *supra* note 146 at 503-506.
[161] T.M. Grant, *et al*, "Preventing Alcohol and Drug Exposed Births in Washington State: Intervention Findings From Three Parent-child Assistance Program Sites" (2005) 31(3) Am J Drug Alcohol Abuse 471 at 479-484.
[162] G. Chang, *et al*, "Brief Intervention for Prenatal Alcohol Use" (2005) 105 Obstet Gynecol 991 at 994-997.

Screening Issues: Tools for Detection of Perinatal Substance Use

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 a 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.[163] Markers of exposure must be validated according to their ability to indicate both the true exposure (sensitivity) and lack of exposure (specificity).[164] The instrument shown to be most sensitive in the periconceptional population is the T-ACE, a screening tool of four questions.[165] 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.[166] 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 of asymptomatic children be implemented so as to "diagnose shortly after birth those infants for whom early treatment will minimise serious, irreversible

[163] Alcohol Screening Questionnaires, *supra* note 134 at 167-169.
[164] *Ibid.*
[165] *Ibid.*
[166] Neuropsychiatric Implications, *supra* note 82 at 177.

complications."[167] To support this position, advocates point to anticipated cost effectiveness of screening associated with decreased secondary disabilities.[168] 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.[169] 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.[170]

Meconium Screening: A Biomarker for Prenatal Substance 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.[171] [172] [173] Meconium, a neonate's first stool, is a dark black or

[167] British Columbia Reproductive Care Program: Neonatal Guideline 9 – Newborn Screening, 1-5 (November 1999). http://www.rcp.gov.bc.ca (accessed: 1 February 2006).
[168] *Ibid*.
[169] C.F. Bearer, *et al*, "Ethyl Linoleate in Meconium: A Biomarker for Prenatal Alcohol Exposure" (1999) 23 Alcohol Clin Exp Res 487at 491 [hereafter "Ethyl Linoleate"].
[170] C.F. Bearer, *et al*, "Markers to Detect Drinking During Pregnancy" (2000) 25 Alcohol Research & Health 210 at 211 [hereafter "Markers to Detect Drinking"].
[171] *Ibid.*

green, viscous material that is composed of intestinal secretions, amniotic fluid, fatty material, and xenobiotics that the fetus is exposed to prenatally.[174] Meconium begins to accumulate between the 17th and 20th week of gestation and FAEEs are believed to remain stable in meconium[175], 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 three months after birth) as a potential marker of exposure.[176] [177] The timeframe or gestational age of prenatal alcohol exposure that FAEE in hair represents is undetermined.

In a secondary metabolic pathway, alcohol is esterfied with free fatty acids to produce FAEE, which accumulate in fetal meconium.[178] 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.[179] 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.[180] FAEE in serum have historically been biomarkers of acute and

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[172] D. Chan, *et al*, "Placental Handling of Fatty Acid Ethyl Esters: Perfusion and Subcellular Studies" (2001) 310 Journal of Pharmacology and Experimental Therapeutics 75 [hereafter "Placental Handling"].
[173] D. Chan , *et al*, "Recent Developments in Meconium and Hair Testing Methods for the Confirmation of Gestational Exposures to Alcohol and Tobacco Smoke" (2004) 37(6) Clinical Biochemistry 429 at 430-436 [hereafter "Recent Developments in Meconium"].
[174] C. Moore, *et al*, "Prevalence of Fatty Acid Ethyl Esters in Meconium Specimens" (2003) 49 Clinical Chemistry 133.
[175] Markers to Detect Drinking, *supra* note 170 at 211.
[176] D.L. Caprara, "A Guinea Pig Model for the Identification of In Utero Alcohol Exposure Using Fatty Acid Ethyl Esters in Neonatal Hair" (2005) 58(6) Pediatr Res 1158 at 1160-1162.
[177] D.L. Caprara, "Baseline Measures of Fatty Acid Ethyl Esters in Hair of Neonates Born to Abstaining or Mild Social Drinking Mothers" (2005) 27(6) Ther Drug Monit 811 at 813-814.
[178] Maternal Drug Abuse, *supra* note 152, at 235.
[179] Placental Handling, *supra* note 172 at 75.
[180] *Ibid*.

chronic alcohol consumption in adults and have been reported to accumulate in the blood of adult drinkers.[181] It is important to note, however, that FAEE have also been identified in meconium and hair samples from newborns of abstaining mothers perhaps due to endogenous alcohol production.[182] [183] 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.[184] [185] More research is needed to understand the relationship between prenatal alcohol exposure, endogenous alcohol production and accumulation of FAEE in hair and meconium.

Epidemiology of Meconium Screening

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.[186] [187] 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

[181] B.L. Soderberg, *et al*, "Preanalytical Variables Affecting the Quantification of Fatty Acid Ethyl Esters in Plasma and Serum Samples" (1999) 45 (12) Clinical Chemistry 2183 at 2186-2189.
[182] Ethyl Linoleate, *supra* note 169 at 491.
[183] Markers to Detect Drinking, *supra* note 170 at 214.
[184] *Ibid.*
[185] D. Chan, *et al*, "Population Baseline of Meconium Fatty Acid Ethyl Esters Among Infants of Nondrinking Women in Jerusalem and Toronto" (2003) 25(3) Ther Drug Monit 271 at 275-277.
[186] The Prevalence of Methamphetamine, *supra* note 138 at 1011. Confirmed also by personal communication with Alan R. Katz, M.D., M.P.H., 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, March 9, 2006.
[187] Maternal Self-Report, supra note 81 at 708-709.

(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.[188] 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.[189] 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%.[190] 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.[191] 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.[192] Similarly, Chan *et al* 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.[193] [194] In a reanalysis of the data from Bearer's work Derauf *et al* found no association between maternal self-report and presence of FAEE in meconium.[195] This highlights the need for further work before FAEE screening would be a scientifically sound method.

Meconium Screening Protocols: Targeted versus Universal Screening

[188] The Prevalence of Methamphetamine, *supra* note 138 at 1002.
[189] Ethyl Linoleate, *supra* note 169 at 491.
[190] *Ibid.*
[191] C.F. Bearer, *et al*, "Validation of a New Biomarker of Fetal Exposure to Alcohol" (2003) 143(4) J Pediatr 463 at 466-468.
[192] C.F. Bearer, *et al*, "Fatty Acid Ethyl Esters: Quantitative Biomarkers for Maternal Alcohol Consumption" (2005) 146(6) J Pediatr 824 at 826-829.
[193] D. Chan, *et al*, "Validation of Meconium Fatty Acid Ethyl Esters as Biomarkers for Prenatal Alcohol Exposure" (2004) 144(5) J Pediatr 692.
[194] Recent Developments in Meconium, *supra* note 173 at 430-436.
[195] Maternal Self-Report, *supra* note 81 at 708-709.

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.[196] 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.[197] 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 meconium screening on either a targeted or universal basis.[198]

Legal Literature

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.[199] 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

[196] J. Gareri, *et al*, "Screening for Fetal Alcohol Spectrum Disorder" (2005) 51 Canadian Family Physician 33 [hereafter "Screening for FASD"].
[197] Evaluation of the Merits of Screening, *supra* note 45 at 79-80.
[198] L. Marcellus, "Is Meconium Screening Appropriate for Universal Use? Science and Ethics Say No" (2007) 7 Advances in Neonatal Care 214 [hereafter "Meconium Screening: Science and Ethics Say No"].
[199] Inside the Womb, *supra* note 36 at 81.

the interests of an unborn child.[200] 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.

Ferguson v. City of Charleston

Current legal considerations concerning meconium can be traced back to a non-meconium American case, *Ferguson* v. *City of Charleston,* a 2001 case from South Carolina. That case considered the power of the state to interfere with a pregnant woman during and immediately after delivery of her baby. It is a recent seminal case in the legal literature regarding screening for maternal drug use in pregnancy. It has spawned considerable discussion in the feminist legal literature but more importantly it has impacted clinical practice.

The case of *Ferguson* v. *City of Charleston* [201] illustrates that, in some jurisdictions, lawmakers can be quick to partner with healthcare professionals to implement health policies that disregard women's autonomy under the guise of "best interests of the child" (or unborn child). While *Ferguson* 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 issues raised by the case and the analysis and discussion subsequently generated within the medico-legal literature are relevant to meconium screening in newborns.

[200] *Medical Treatment, supra* note 39 at 100.
[201] *City of Charleston* v. *Ferguson*, 532 U.S. 67, 67 (2001).

Facts

In the 1990's, 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.[202] 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.[203] 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".[204]

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

[202] *Ferguson* v. *City of Charleston*, 308 F.3d 380, 388 n.4 (4th Cir. 2002).
[203] *Ibid.*
[204] K. Gehringer, "Informed consent: Hospitals Must Obtain Informed Consent Prior to Drug Testing Pregnant Patients" (2003) 31 American Journal of Law and Medicine 455, [hereafter "Hospitals Must Obtain Informed Consent"].

samples from women meeting the profile were collected so as to ensure that results could be used in subsequent criminal proceedings against the women.[205] 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.[206] 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".[207] 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".[208]

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, which guards against unreasonable searches and seizures.

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

[205] Inside the Womb, *supra* note 36 at 84.
[206] Hospitals Must Obtain Informed Consent, *supra* note 204 at 456.
[207] *Ibid*.
[208] *Ferguson* v. *City of Charleston*, 186 F.3d 469, 475 (4th Cir. 1999).

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 assertion that the screening policy was designed to serve a "special need" to coerce the women to participate in substance abuse treatment programs was rejected by the Court.[209]

Analysis and Discussion

Ferguson was the first American Supreme Court case involving maternal-fetal conflict in the context of addiction.[210] 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".[211] 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

[209] Inside the Womb, *supra* note 36 at 85.
[210] *Ibid.*
[211] Hospitals Must Obtain Informed Consent, *supra* note 204 at 456.

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 policy drafting in the context of guiding modern medical decision-making.[212] Where competing state interests do exist[213], 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.[214] 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 *Ferguson*. 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.[215] But the Canadian legal reality, however, is that constitutional law, as the supreme law, upholds a woman's right to refuse medical treatment.[216] Where a

[212] Behind the Screen, *supra* note 43 at 124.
[213] Inside the Womb, *supra* note 36 at 86.
[214] A.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 de-genders the analysis and masks the inherent marginalization of an entire "class" of patients, which is, in part, the reason why the argument fails.
[215] C. Sinha, "*Ferguson* v. *City of Charleston and Child Welfare*" (2002) 9 Duke Journal of Gender Law & Policy 171.
[216] *Malette* v. *Shulman et al* (1990), 67 D.L.R. (4th) 321, 37 O.A.C. 281, [1991] 2 Med. L.R. 162. Other Canadian decisions relevant to the discussion of a woman's constitutional right to refuse medical treatment

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.[217]

Ferguson 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[218] 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 marry physicians to state interests, such as law enforcement, creates an atmosphere in which it is very difficult to provide good, objective, evidence-based medical decision-making and care.[219] Further, it erodes confidence and trust, which are the foundation of the patient-physician relationship.

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include *Dobson (Litigation Guardian of)* v. *Dobson*, [1999] 2 S.C.R. 753, 174 D.L.R. (4th) 1, and *Winnipeg Child and Family Services (Northwest Area)* v. *D.F.G.*, [1997] 3 S.C.R. 925, 152 D.L.R. (4th) 193.

[217] E. Flagler, *et al*, "Bioethics for Clinicians: 12. Ethical dilemmas that Arise in the Care of Pregnant Women: Rethinking "Maternal-Fetal Conflicts" (1997) 156(12) CMAJ 1729 at 1730 – 1731, [hereafter "Bioethics for Clinicians"].

[218] A. Taslitz, "A Feminist Fourth Amendment?: Consent, care, privacy, and social meaning in *Ferguson* v. *City of Charleston*" (2002) 9 Duke Journal of Gender Law & Policy 1 at 77, [hereafter "A Feminist Fourth Amendment"]. This article provides an excellent argument using Feminist Consent Theory generally.

[219] Behind the Screen, *supra* note 43 at 125.

Ethics Literature

It is critical to recognize the distinction between law and ethics.[220] By its nature, a legal analysis of neonatal hair and meconium screening practices will be very different from an ethics analysis. Law is a matter of societal convention, hence it is quite possible that in any given matter there may be no applicable law, yet ethical underpinnings may still exist. Additionally, it is possible that any given legal decision regarding neonatal hair or meconium screening may not be informed by ethical principles or analysis.

The ethics literature regarding novel tools for the detection of *in utero* exposure to drugs and alcohol is extremely limited and focuses upon meconium screening. While several studies contain the word "ethics", the ethics of neonatal hair and meconium screening is largely understudied. The first paper regarding ethical considerations in neonatal screening for prenatal exposure to alcohol was published in 2006, exploring the issues through the lenses of 'principlism' and feminism.[221]

In 2007, Lenora Marcellus followed suit, applying traditional ethics principles of autonomy, beneficence, nonmaleficence and justice to the subject.[222] Marcellus highlighted the principles of autonomy and justice, identifying informed consent, right of refusal, reproductive autonomy, and cost-benefit ratio as key concerns "representing personal, economic and societal consequences."[223] She commented that, among the factors to

[220] The distinction is well-discussed in the Hart-Fuller debate of 1958. Hart, H.L.A. "Positivism and the Separation of Law and Morals" (1958) 71(4) Harvard Law Review 593-629; Fuller "Positivism and Fidelity to Law – A Reply to Professor Hart" (1958) 71(4) Harvard Law Review 630-672.
[221] Behind the Screen, *supra* note 43.
[222] P. Rodney *et al*, "Our Theoretical Landscape: A Brief History of Health Care Ethics" in J. Storch, P. Rodney, and R. Starzomski, eds. *Toward a Moral Horizon: Nursing Ethics for Leadership and Practice* (Toronto: Pearson Education, 2004) at 56-76.
[223] Meconium Screening: Science and Ethics Say No, *supra* note 198 at 208. See also: *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. The National

consider in the context of meconium screening were the ethics of program development and expansion, with researchers needing to build ethical discussion into research programs.[224] More recently, Professor Bernard Dickens has commented on the ethical duty of clinicians to inform mothers when meconium is going to be tested, but he stopped short of suggesting that consent should play a role. In a theoretical discussion of universal meconium screening, Dickens raised the "ethical concerns of cost-effectiveness" and the allocation of scarce resources.[225]

In summary, the scant ethics literature regarding meconium screening has focused upon standard principles of applied clinical ethics, with arguments focusing upon maternal autonomy (informed consent), beneficence (best interests of the child) and distributive justice (allocation of resources). While Marcellus has argued, largely from a maternal perspective, that there is currently not enough evidence to support screening on a targeted or universal basis, Dickens has argued from the beneficence viewpoint that the interests of the child should supersede those of mothers who consume drugs and alcohol in pregnancy.

Social Work Literature

Child protection workers and, more recently, hospital social workers have faced complex challenges in accurately assessing maternal substance abuse in the interest of

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Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 18 April 1979. Department of Health, Education, and Welfare.

[224]Meconium Screening: Science and Ethics Say No, *ibid*, at 214.

[225] B.M. Dickens, "Legal and Ethical Considerations in Meconium Testing for Fetal Exposure to Alcohol" (2011) 18 J Popul Ther Clin Pharmacol e471 [hereafter, "Legal and Ethical Considerations"].

effective child protection.[226] To date, the literature regarding hospital and child protection social work responses to substance-exposed newborns in the context of novel screening modalities such as neonatal hair and meconium has been relatively scant, and varies between jurisdictions. In the United States, federal legislation mandates that local protective agencies be informed regarding substance-exposed newborns[227], which sometimes places health care professionals in a difficult position. In that jurisdiction, when it is known that a mother has abused substances in pregnancy, hospital staff must inform child welfare authorities in accordance with the Child Abuse Prevention and Treatment Act (CAPTA).[228] That legislation further mandates state government policies and procedures to address the needs of infants exposed to illicit drugs or affected by withdrawal symptoms resulting from prenatal drug exposure[229], such as in the case of neonatal abstinence syndrome (NAS).[230] Naturally, hospital social workers in any jurisdiction would benefit from clear protocols for assessing prenatal substance exposure.

The Motherisk Laboratory at the Hospital for Sick Children in Toronto, Canada has published a Drug Testing Newsletter for Children's Aid Societies[231] since 2005, to update child protection workers on new aspects and discoveries of drug testing in hair and meconium, and to provide a forum in which social workers could receive information and

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[226] M. Moller *et al*, "A Review of Substance Abuse Monitoring in the Social Services Context: A Primer for Child Protection Workers" (2010) 17 Can J Clin Pharmacol e177 [hereafter "Primer for Child Protection Workers"].
[227] K. Drescher Burke, "Substance-Exposed Newborns: Hospital and Child Protection Responses" (2007) 29 Children and Youth Services Review 1503 [hereafter "Substance-Exposed Newborns"].
[228] *The Child Abuse Prevention and Treatment Act* (CAPTA), as amended by 42 (Public Health and Welfare) USC Chapter 67 – Child Abuse Prevention and Treatment and Adoption Reform, 2010.
[229] Substance-Exposed Newborns, *supra*, note 227.
[230] Neonatal Abstinence Syndrome (NAS) refers to a cluster of problems that occur in neonates who were substance-exposed prenatally, including mottling, irritability, increased muscle tone, hyperactive reflexes, rapid breathing, seizures and inability to feed, among other things. See: ADAM Medical Encyclopedia, PubMed Health, http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0004566/ (accessed: 31 May 2012).
[231] Children's Aid Societies (CAS) are independent organizations in Ontario, Canada that are empowered by the Ontario government to carry out child protection services in that province. In short, the CAS is the child welfare authority for Ontario.

ask questions regarding screening practices.[232] Recently, experts at Motherisk also published a Substance Abuse Monitoring Primer for Child Protection Workers, to educate child protection workers about different matrices for drug testing, and the applicability of each to substance abuse monitoring.[233] Additionally, a small number of Canadian studies regarding meconium screening have been published, and are likely to inform social work practices in the near future.[234] [235]

What is clear from the literature review is that scientific research has made great strides in identifying and developing novel screening tools for the detection of prenatal exposure to drugs and alcohol. Neonatal hair and meconium samples can be screened to determine prenatal substance abuse and, in the case of meconium, that information is available for the second and third trimesters of pregnancy. Canadian child protection workers and hospital social workers can have access to information regarding *in utero* substance exposure if neonatal samples are collected and analyzed. Unlike the United States, Canada does not have federal child welfare legislation regarding substance-exposed newborns rather, as discussed in Chapter 4, child welfare legislation (and the regulations thereunder to guide practices) is left to the provinces. Hospital and child protection social workers in all Canadian jurisdictions would benefit from clear protocols and practice guidelines pertaining to assessment of prenatal substance abuse, particularly as screening results begin to inform Canadian legal cases.

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[232] Motherisk Drug Testing Newsletter for Children's Aid Societies; http://www.motherisk.org/prof/casNewsletter.jsp (Accessed: 31 May 2012).
[233] Primer for Child Protection Workers, s*upra* note 226 at e177.
[234] Universal Screening for Prenatal Alcohol Exposure, *supra* note 48. This study also considered community health programs and services for children identified as substance-exposed; an important component of social work practice.
[235] CBC News, "Baby Poop Study Tracks Alcohol Use" (8 November 2011); http://www.cbc.ca/news/canada/prince-edward-island/story/2011/11/08.pei-meconium-study-584.html (accessed 20 May 2012). This news story describes a universal meconium screening study in Prince Edward Island that began in 2010; the first time a Canadian province has participated in such a study.

Chapter 4: Results

As described in Chapter 2, data collection to address the research questions for this study involved a systematic literature review, a Canadian case law review, and in-person interviews with stakeholders in Alberta, British Columbia, and Hawaii.

Literature Review

Traditional matrices for the detection of prenatal drug exposure in newborns have included blood and urine, however novel screening modalities for the detection of prenatal exposure to drugs and alcohol have been developed and used in North America over the last several years. In time, and with research, neonatal hair and meconium screening has started to move into the mainstream, with an increasing number of jurisdictions undertaking screening. Sweat, saliva, and umbilical cord blood can also be used. In the United States, some researchers have incorporated anonymous screening into research protocols, in order to obtain prevalence data regarding neonatal exposure to substances of abuse that is not traceable to individual mothers due to the federal requirement of mandatory child protection reporting. For some other studies, Certificates of Confidentiality have been obtained, to protect the information of research subjects.[236]Meconium screening studies have been

[236] Confirmed by personal communication with Chris Derauf, M.D., 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

undertaken in a few Canadian jurisdictions including Alberta[237], the Yukon[238], Ontario[239], and Prince Edward Island.[240] These studies have taken a variety of approaches, particularly regarding the issue of informed consent.

Case Law Review

A review of the legal databases described in Chapter 2 revealed 85 indexed, reported cases referencing neonatal hair or meconium. Twenty of those cases were relevant to this research study. The relevant cases were divided into three categories according to case type: family law, criminal law, and child protection.[241]

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prenatal methamphetamine exposure and child development, at the Kapi'olani Medical Center for Women and Children, Honolulu, Hawaii, March 9, 2006.

[237] M. Hicks *et al*, "Alcohol and Drug Screening of Newborns: Would Women Consent?" (2009) 31 J. Obstet Gynaecol Can 331.

[238] Fetal Alcohol Canadian Expertise (FACE) Research Roundtable, 12 September 2011, Stanhope, P.E.I.: http://ken.caphc.org?xwiki/bin/view/FASDScreeningToolkit/Ethics+of+Meconium+Testing+as+Screening+Tool+for+FASD (accessed: 23 May 2012).

[239] Universal Screening for Prenatal Alcohol Exposure, *supra* note 48.

[240] Fetal Alcohol Canadian Expertise (FACE) Research Roundtable, 12 September 2011, Stanhope, P.E.I.: http://ken.caphc.org?xwiki/bin/view/FASDScreeningToolkit/Ethics+of+Meconium+Testing+as+Screening+Tool+for+FASD (accessed: 23 May 2012).

[241] Cases selected for in-depth discussion were chosen for the compelling narratives that they presented. While all of the cases identified in the case law review were connected to meconium screening evidence in some way, the cases explored in detail in Chapters 4 and 5 were selected because of the detailed fact scenarios contained within the written legal judgments, and for what they revealed about the lived experiences and the situated social contexts of the women and families involved.

Table 3. List of Relevant Canadian Legal Cases

Date	*Case Name*	*Citation*	*Case Type*	*Summary*
2006	*CAS Niagara* v. *D.B.*	2006 CanLII 2767 (ON S.C.) (Feb 2006)	Child Protection	Twin boys apprehended at birth - crown wards, no access, adoption
2007	*R.* v. *K.M.*	2007 CanLII 13937 (ON S.C.) (Mar 2007)	Criminal Law	Criminal sentencing: shaken baby - meconium screening evidence admitted
2007	*Cas Halton* v. *C.(C.L.)*	2007 ONCJ 595, (Dec 2007)	Child Protection	Positive drug screen at birth - apprehended - temporary care - supervision order
2008	*Catholic CAS Toronto* v. *K.A.*	2008 ONCJ 148 (Feb 2008)	Child Protection	Negative screen for drugs at birth - apprehended - crown wardship, no access, adoption
2008	*Garrity* v. *Garrity*	2008 CanLII 29594 (ON S.C.) (Jun 2008)	Divorce, Custody, Access	Husband seeks to deny mother access to children pending screening results
2008	*CAS Simcoe* v. *AFL*	2008 CanLII 16074 (ON S.C.) (Apr 2008)	Child Protection	Children apprehended - positive meconium - crown wards, no access, adoption
2008	*CAS Toronto v. Y.B.*	2008 ONCJ 800 (Nov 2008)	Child Protection	Positive meconium - child placed in temporary care - supervision order with conditions
2009	*CAS Northumberland v. H.T.*	*2009 CanLII 40 (ONSC)* (Jan 2009)	Child Protection	Positive meconium - crown ward, no access, adoption
2009	*CAS Waterloo v. A(LJA)*	2009 ONCJ 226 (Feb 2009)	Child Protection	Access to 9 year old child apprehended at birth due to maternal alcohol use
2009	*BC Birth Reg 59-039985*	2009 BCSC 599 (Feb 2009)	Child Protection/Family Law	Infant apprehended at birth d/t maternal drug use - adopted absent consent
2009	*Catholic CAS Hamilton v. C.I*	2009 CanLII 25613 (ONSC) (May 2009)	Child Protection	Positive meconium and hair - crown wards, no access, adoption
2009	*Durham CAS* v. *T.W.*	2009 CanLII 58609 (ON S.C.) (Oct 2009)	Child Protection	Infant twins apprehended d/t maternal drug screen - children returned to mother
2010	*R. v. P.H.*	2010 MBQB 8 (Jan 2010)	Criminal Law	Criminal sentencing: shaken baby - court relies heavily on R. v. K.M. (above)
2010	*BC Birth Reg 59-039985*	2010 BCCA 137 (Mar 2010)	Child Protection/Family Law	Appeal: adoption order set aside - mother regains custody of 3.5 year old child
2010	*FCS v. SW / BY*	2010 ONSC 2585 (May 2010)	Child Protection	Infant girl apprehended at birth - crown wardship, no access, adoption
2011	*CAS Niagara v. T.B.*	2011 ONSC 2702 (Apr 2011)	Child Protection	Infant boy apprehended shortly after birth - crown ward, no access, adoption
2011	*CAS Waterloo v. J.L.M.*	2011 ONCJ 734 (Jul 2011)	Child Protection	Positive meconium screen - children apprehended months later - crown wards
2011	*CAS Waterloo v. K.M.*	2011 ONCJ 733 (Sep 2011)	Child Protection	Positive meconium - child apprehended at birth - crown ward, no access
2011	*Nova Scotia (CS) v. N.L.*	2011 NSSC 369 (Sep 2011)	Child Protection	Baby girl apprehended at birth - temporary care order - supervised access
2011	*CAS Toronto v. T.S.*	2011 ONCJ 732 (Dec 2011)	Child Protection	Baby boy apprehended at birth - multiple factors - crown ward, no access

Pitfalls of Meconium Screening Evidence in the Canadian Courts: Creating a 'Legal Fiction'

Given that neonatal hair and meconium screening are relatively novel methods for the detection of prenatal exposure to drugs and alcohol, there is some potential for test results to be misunderstood, misinterpreted or misused by the courts.[242] A search of the Canadian jurisprudence referencing meconium screening evidence reveals that the courts, through child welfare authorities, have been aware of and considering meconium screening results dating back to at least 2006. In *British Columbia Birth Registry No. 2006-59-039985 (Re)*[243] the Court referred to a positive meconium screening result in considering whether to dispense with the birth mother's consent to the adoption of her infant son. In oral reasons for judgment dated February 26, 2009, the Honourable Mr. Justice Brooke (in Chambers) stated,

> "The child was born December 17, 2006 at Kelowna. ... The birth parents have both abused drugs, including cocaine. The child was removed from their custody by the Director of Child, Family and Community Services on December 17, 2006. A sample from the child's meconium was found positive for cocaine and benzoylegonine. ... With regard to the cocaine and benzoylegonine, the lab report exhibited ... suggests that a positive meconium result indicates *in utero* exposure to drugs from the sixteenth week of pregnancy."[244]

[242]I. Zelner, *et al*, "Neonatal Screening for Prenatal Alcohol Exposure: Assessment of Voluntary Maternal Participation in an Open Meconium Screening Program" (2012) 46 Alcohol 269 at 274 [hereafter "Open Meconium Screening Program"].
[243]*British Columbia Birth Registry No. 2006-59-039985 (Re)*, 2009 BCSC 599.
[244]*Ibid*, at paras 1, 2 and 6.

The above quote must be read in the context of what is known regarding the timing and utility of meconium screening: (1) the child was apprehended by the Director of Child, Family and Community Services on the day of his birth, before any meconium screening results would have been available (and potentially prior to the passing of meconium, given that some newborns do not pass meconium within the first 24 hours of life)[245] and (2) a dated laboratory report describing and interpreting the positive meconium screening result was available to the judge at the time of the reasons for judgment. The fact that the screening result is mentioned by the Court implies that is was a factor taken into consideration, however the weight placed upon the positive screening result is not clear from the reasons for judgment. Nevertheless, when the birth mother successfully appealed the decision to the British Columbia Court of Appeal, the Honourable Madam Justice Neilson stated,

> "The child was removed from the parents' custody immediately after his birth by the Director of Child, Family and Community Services, *because* a sample of his meconium tested positive for cocaine and benzoylegonine, indicating the mother had used drugs after the 16th week of the pregnancy."[246] [emphasis added]

While a positive meconium sample could not have been the reason that the child was apprehended on the day of his birth, as the results and interpretive analysis take several days or weeks to be returned from the testing laboratory, the above quote from the British Columbia Court of Appeal would appear to draw a causal inference between the child's apprehension and the positive meconium screening result. While most healthcare

[245]*See* A Primer for Child Protection Workers, *supra* note 226 at e183, wherein: "Meconium is optimally collected within twenty-four hours of birth; however some neonates are known to pass meconium for several days after birth thereby enabling later sample collection. After three days post-partum, it is highly unlikely that meconium will still be available."
[246]*British Columbia Birth Registry No. 2006-59-039985 (Re),* 2010 BCCA 137, at para 3.

professionals are aware that a multiplicity of factors often inform a decision to remove a child from the custody of a birth parent and that a positive meconium screen, in and of itself, would likely not be a sufficient basis to apprehend a child,[247]a layperson reading the decision of the British Columbia Court of Appeal might not have that awareness. The mischaracterization of the nexus between the positive meconium screening result and the child's apprehension by a Court with significant persuasive authority creates, in essence, a 'legal fiction'[248], carrying with it the risk of inaccurate perceptions by those reading the case, and arguably constitutes a "misuse" of the screening result by the Court.[249]

A similar pitfall is revealed in *Children's Aid Society of Toronto* v. *Y.B.*[250], wherein the Court noted that a baby girl was "born with cocaine in her meconium", which indicated use of crack cocaine within 72 hours of birth by her mother who had admitted to cocaine use about twice per month during pregnancy. This mischaracterization of the positive meconium screening result by the Court suggests a fundamental misunderstanding as to the nature of the screen: unlike blood or urinalysis, which can detect recent exposure to illicit substances and are of use in cases of acute toxicity[251], meconium analysis serves as a longitudinal measure of substance exposure over time, presenting a record or 'snapshot' of prenatal exposures during the second and third trimesters of pregnancy, not just the

[247] Confirmed by personal communication with Dr. Gideon Koren, Division of Clinical Pharmacology & Toxicology, The Hospital for Sick Children, Toronto, Ontario, at Neonatal Grand Rounds, University of Calgary, Alberta [9 November 2010]. Dr. Koren's remarks were part of a presentation in a series of educational rounds at the University of Calgary and Alberta Children's Hospital in November 2010.
[248] A 'legal fiction' is defined by Black's Law Dictionary, 6th ed., as an "assumption of fact made by a court as a basis for deciding a legal question." In other words, a 'legal fiction' is a fact assumed or created by courts which is then used in order to apply a legal rule.
[249] Open Meconium Screening Program, *supra* note 242 at 274.
[250] *Children's Aid Society of Toronto* v. *Y.B.*, 2008 ONCJ 800, at paras 3 and 38.
[251] Primer for Child Protection Workers, *supra* note 226 at e179-e180.

presence or absence of a substance at the time of testing.[252] Unlike in the *British Columbia Birth Registry* case (above) where it was unclear what, if any, weight the Court was placing upon the positive meconium screening result, in *Children's Aid Society of Toronto* v. *Y.B.*, the positive meconium screening result was specifically identified as a basis for the finding that the newborn girl was in need of protection.[253] If the Courts are using positive meconium screening results to inform legal decisions regarding child custody then they should, at a minimum, have an accurate understanding of what a positive screen means.[254] By extension, if the legal consequence of a positive meconium screen could be possible apprehension of a child by child welfare authorities, then healthcare providers should consider both the intended and unintended consequences of detection.[255]

Family Law Cases

The 2008 family law case of *Garrity* v. *Garrity*[256] raised the unexpected discussion of drug screening evidence when a woman brought a costs application against her former husband regarding a motion brought in the child custody dispute stemming from the breakdown of their marriage. Early in the proceedings, Mr. Garrity had sought an order denying Mrs. Garrity access to the children of their marriage pending delivery of satisfactory drug screening results, including hair follicle testing results. Mr. Garrity intended to use

[252]Koren, G. *et al*, "Novel Methods for the Detection of Drug and Alcohol Exposure During Pregnancy: Implications for Maternal and Child Health", (2008) 83 Clin Pharmacol Ther 631-634 [hereafter "Novel Methods"].
[253]*Children's Aid Society of Toronto* v. *Y.B.*, 2008 ONCJ 800, at para 3.
[254]The Motherisk Lab at The Hospital for Sick Children in Toronto, Ontario advertises testing, interpretation and educational services through the Motherisk Drug Testing Newsletter for Children's Aid Societies. http://www.motherisk.org/prof/casNewsletter.jsp (accessed: 24 May 2012).
[255]Substance Abuse in Pregnant Women, *supra* note 77 at 521.
[256] *Garrity* v. *Garrity*, 2008 CanLII 29594 (ONSC).

positive drug screening results against Mrs. Garrity in their child custody dispute and, for a time, was withholding access to the children pending the test results. Eventually, Mr. Garrity abandoned his request, and the entire case went to a settlement conference, however Mr. Garrity was ordered to pay indemnity costs of $11,375.00 plus GST with respect to the drug screening motion. The Court recognized that this was a significant sum of money for a father to pay however, "when making an allegation of criminal and irresponsible behavior against another person"[257] parties must exercise caution. Further, Turnbull, J. noted that Mr. Garrity had no jurisdiction to ignore the original custody and access order that was in place regarding the children and "take the law into his own hands."[258] It was not just for Mr. Garrity to decide himself that "access would be according to what he felt was best for the children without giving Mrs. Garrity a chance to be heard."[259]

Although *Garrity* v. *Garrity* references adult hair follicle testing for illicit drug and alcohol metabolites in the context of a custody dispute over young children, the case brings to light the potential for drug screening evidence to make its way into family law cases generally, whether pertaining to adults or newborns. The admission of neonatal hair and meconium screening evidence into family law cases would constitute an unanticipated use of an otherwise beneficent screen, not contemplated by researchers or clinicians utilizing screening for purposes related to child health. *Garrity* v. *Garrity* illustrates the potential for screening results to be used in unanticipated ways, not related to implementing timely interventions and supports for exposed children, and not within the contemplation of clinicians at the time of ordering the screen or counseling parents regarding the impact of a positive screening result. Without the benefit of clinical practice guidelines regarding the

[257] *Ibid*, per Turnbull, J. at para 42.
[258] *Ibid*.
[259] *Ibid*, at para 17.

documentation and uses of neonatal hair and meconium screening, and given recent unchallenged decisions regarding the admissibility of meconium screening evidence in the courts,[260] it is only a matter of time before such results are used in family law cases regarding divorce and child custody and access.

Criminal Law Cases

Use of Meconium Screening Evidence in the Canadian Criminal Justice System: A Comment on R. v. K.M.[261]

Shortly after this research study began, the first Canadian case dealing directly with meconium screening evidence in a criminal sentencing decision was heard in Ontario, wherein opposing counsel specifically argued a motion regarding the admissibility of novel meconium screening results. The case has since been cited as a leading shaken baby syndrome sentencing decision in Manitoba.[262] What follows is a detailed description of *R.* v. *K.M.*, along with a comment on the implications and applications of the case.

Facts

K.M. was born in 1983. Her first son was born at the William Osler Health Centre in Brampton in the summer of 2003 by emergency caesarean section. He was three weeks premature, weighing 4.4 lbs. He was admitted to NICU, and was discharged when he was three weeks old, weighing just over five lbs. K.M. was discharged from hospital about two

[260] *R.* v. *K.M.*, 2007 CanLII 13937 (Ontario Superior Court of Justice).
[261] *R.* v. *K.M.*, 2007 CanLII 13937 (Ontario Superior Court of Justice).
[262] *R.* v. *H.P.H.*, 2010 MBQB 8.

weeks before her son. Prior to discharge, a hospital social worker had been in touch with the Children's Aid Society (CAS), because medical staff were concerned that she was not bonding with her baby.

Following discharge, the K.M. visited her baby only sporadically, and there were several days when neither she nor the baby's father called or visited the hospital. Once her baby came home, K.M. had a friend who moved in to help with baby care. Like many premature babies, he was fussy and cried often. K.M. experienced moments of extreme frustration. On September 4, 2003, when the baby was 30 days old, K.M.'s friend returned to her own home. K.M. and her partner took their son to the Georgetown walk-in clinic for an uneventful, mandatory weigh-in, as stipulated by CAS. That evening, the baby was being cared for by friends overnight. The next afternoon, K.M. was alone with her baby for the first time, as her partner had to work. Early that evening, she phoned her partner and told him that their baby was pale and shaking. She did not call an ambulance, but instead waited for her partner to return home to take the baby to the hospital. K.M. stayed home.

Upon arrival, the baby was transferred to Brampton for a CAT scan, which indicated that the baby had suffered a series of subdural haematomas and blood was pooling in his brain.[263] He was rushed by ambulance to the Hospital for Sick Children ("Sick Kids") in Toronto.

While at Sick Kids, the baby continued to show signs of worsening brain injury. His life-threatening symptoms included seizures, abnormal body stiffness (hypertonicity),

[263] A subdural haematoma is bleeding into the space between the brain and the dura, which is the membrane surrounding the brain, and is caused by a tearing of the veins that stretch between the dura and the actual brain tissue. This type of injury can occur through blunt force to the head, shaking which results in shearing forces through indirect acceleration and deceleration and/or forceful compression of the head.

an extreme palor, irritability, a bulging fontanel showing swelling of the brain tissue, and respiratory problems including difficulty breathing and an increased heart rate. There were bruises on both sides of his head, and skeletal surveys revealed fractures of the proximal right tibia (the knee) and distal left tibia (the ankle). Additionally, the baby experienced several retinal haemorrhages in both eyes, along with an almost completely detached right retina and mild traumatic retinoschisis. This constellation of injuries was consistent with one incident.

The baby's injuries were determined to have been the result of his having been vigorously shaken. No surgery was performed, and the baby was placed on a number of anti-seizure medications to slow the bleeding. Neurosurgery was not required. The Halton Regional Police were notified, and an officer attended K.M.'s home in the early morning of September 6, 2003. She was taken to the police station where she provided a statement, and denied having shaken her baby. The baby remained at Sick Kids until September 15, 2003, was discharged to the care of CAS and was later adopted.

K.M. continued to deny any wrongdoing, was arrested on October 23, 2003, and released on a recognizance. While on judicial interim release, she and her partner had another child, a daughter, in 2004, who was apprehended at birth. Meconium screening revealed that K.M.'s daughter had been exposed to cocaine and cannabis *in utero*.[264]

Cause of Action and Decision

K.M. pled guilty to a charge of aggravated assault pertaining to her baby boy, under section 268 of the Canadian *Criminal Code,* and was sentenced in 2007 in accordance with

[264] *R.* v. *K.M*., 2007 CanLII 13937 (Ontario Superior Court of Justice), at paras 17 - 19.

the guidelines contained under ss. 726, 487.04 and 487.051. She was sentenced to twelve months' incarceration and three years' probation on the mandatory terms set out in section 732.1(2) of the *Code* and the following special conditions imposed by the sentencing judge:

(1) Report to probation services as required by probation services;

(2) Remain within Ontario unless written permission to go outside the jurisdiction is obtained from a court or a probation officer;

(3) Abstain from the consumption of drugs except in accordance with a medical prescription;

(4) No contact or communication with her children;

(5) Take anger management counselling as directed by probation services; and

(6) Not be in the presence of any child under the age of 12 years except in the presence of an adult other than the father of her children.

Reasons

K.M. had a history of Attention Deficit Hyperactivity Disorder (ADHD) with poor impulse control and depression. She had been raised in a family where there was physical and emotional deprivation, abuse and violence, primarily as a result of parental alcohol consumption. The Court concluded that immaturity, a deprived background and a difficult pregnancy resulted in her being totally overwhelmed by the care of her infant son. During the proceedings, she denied any illicit drug use or excessive alcohol consumption. The baby boy's adoptive mother provided a victim impact statement to the Court. Although his speech was delayed, he had otherwise met developmental milestones but continued to be

closely monitored for residual effects, including cognitive delays, arising from the head trauma.

In determining a fit sentence, the Court opined that K.M. was guilty of "the most serious specie of assault in the hierarchy of assault crimes", aggravated assault endangering life, punishable by a maximum of 14 years' imprisonment. Court-identified aggravating factors included that fact that the victim was her 30 day-old infant son, he was injured within three hours of her returning from a night away, she failed to summon emergency medical assistance when she knew he was likely in crisis, she stayed at home instead of travelling to the hospital, she "took an unnecessary risk with yet another child's life through cocaine and cannabis consumption while pregnant" and her degree of remorse was difficult to determine. The Court imposed a sentence intended to reflect K.M.'s high degree of moral culpability and the fact that she continued to present a "risk to the community" should she become pregnant again. In the Court's view, the wider public interest expressed through the principles of denunciation and deterrence warranted nothing less than incarceration.[265]

Expert Testimony before the Court: Interpreting the Screening Evidence

In the K.M. case, the Court relied heavily upon the expert scientific evidence of Joey Gareri, an expert in clinical pharmacology and biomedical technology, and Laboratory Manager at the Toronto Hospital for Sick Children (HSC) Fetal Toxicology Laboratory, who testified that neonatal hair and meconium samples are used to identify *in utero* substance exposure, with meconium providing information as to substance exposure

[265] *R.* v. *K.M.*, 2007 CanLII 13937 (Ontario Superior Court of Justice), at paras 29 and 34.

from approximately the 13th week of pregnancy onward, and neonatal hair providing similar information from approximately the 22nd week of pregnancy onward. He also testified that these particular screening modalities could indicate one-time or regular use of a particular substance.[266]

Within the sentencing decision, there was much discussion as to the admissibility of the meconium screening evidence, particularly in light of the fact that the evidence was obtained from the infant victim's baby sister, who was born post-offence and following the laying of the criminal charge. Further, because she was apprehended at birth, her meconium sample had been collected presumably to detect whether she had been exposed to drugs and alcohol *in utero* and not for the primary purpose of prosecuting a criminal charge of aggravated assault. It is not known how the meconium screening results came to be made available to the prosecution. Despite the objections of defence counsel, the Court admitted the evidence for the purpose of the sentencing hearing, emphasizing the broad judicial discretion to admit evidence so as to obtain the "fullest information possible regarding the background of the offender."[267] The ruling regarding admissibility of the meconium screening evidence was not appealed.[268]

Implications of the Case

Prior to *R.* v. *K.M.*, the courts seem to have referenced neonatal hair and meconium screening only in passing. Due to the detailed discussion of the meconium screening results

[266] *R.* v. *K.M.*, 2007 CanLII 13937 (Ontario Superior Court of Justice), at paras 17 and 18.
[267] *R.* v. *Gardiner* (1982), 69 C.C.C. (2d) 477 (S.C.C.) at paras 513-514.
[268] Unfortunately, it is not possible to ascertain whether any *Charter* application or arguments were presented by counsel in the K.M. case, as the Court file has since been destroyed (personal communication with Andrew S. Clarke, Benson Percival Brown LLP, Toronto, Ontario (3 October 2009)), and defence counsel declined to respond correspondence related to this study.

by the Court, *R.* v. *K.M*. has become an important decision, standing for the legal proposition that meconium screening evidence can be admitted for the purpose of informing criminal sentencing decisions. But in *R.* v. *K.M*., the Court went even further, linking the positive meconium screen to the moral culpability of K.M. as a mother who "took an unnecessary risk with yet another child's life through cocaine and cannabis consumption while pregnant," and characterizing her as a "risk to the community" should she become pregnant again.[269] While the Court highlighted the "wider public interest expressed through the principles of denunciation and deterrence", on a careful reading of the case it is difficult to determine whether the Judge was referring to the crime of aggravated assault against a young infant or the "crime" of consuming illicit substances while pregnant. In any event, *R*. v. *K.M*. has since been used by the Manitoba Court of Queen's Bench as a "related child abuse precedent" for shaken baby syndrome.[270]

Child Protection Cases

Framing the Clinical Dilemma: Children's Aid Society of Halton Region v. C.(C.L.)[271]

Without clear policies or clinical practice guidelines to establish standards and define professional roles and responsibilities in the context of neonatal hair and meconium screening, it is inevitable that child welfare workers and health care professionals will experience confusion regarding these novel screening modalities, and will have questions,

[269] *R.* v. *K.M*., 2007 CanLII 13937 (Ontario Superior Court of Justice), per Hill, J. at paras 29 and 34.
[270] *R.* v. *H.P.H*., 2010 MBQB 8, at para 23.
[271] *Children's Aid Society of Halton Region* v. *C.(C.L.)*, 2007 ONCJ 595.

for example, about which newborns to screen absent a clear clinical indication, whether consent is required, who can provide consent, who to take instructions from, and what to document for the health care record. Without clear guidance, clinicians are likely to experience tensions between competing autonomies, beneficence (doing the right thing), nonmaleficence (not causing harm) and justice (provision of nondiscriminatory health care, along with equitable distribution of scarce health care resources). Such tensions are illustrated in *Children's Aid Society of Halton Region* v. *C.(C.L.)*, a 2007 Ontario case where questions about professional boundaries, responsibilities and consent to screening arose at the Oakville Trafalgar Memorial Hospital.

Facts

C.L.C. was born in 1985, and became pregnant with her second child at 21 years of age. She and her partner were both former wards of the Children's Aid Society growing up. The Children's Aid Society of Halton Region became involved with the couple in March 2006 when C.L.C. was 21 weeks pregnant with her first child. She had been smoking marijuana and cigarettes on a daily basis, claiming that marijuana eased her anxiety and panic attacks. Her daughter was born prematurely at 34.5 weeks, and kept in hospital until she reached a weight of five pounds. The baby was discharged into C.L.C.'s care upon her promise to cut back on marijuana use and to smoke outside of the home. Based on concerns about quality of care, the Children's Aid Society proposed a voluntary service agreement, which C.L.C. and her partner refused to sign. The Society decided to commence protection proceedings in which a supervision order and parenting capacity assessment would be sought

however, before those steps were taken, the baby died as a result of sudden infant death syndrome (SIDS) while being cared for by her maternal grandmother in Barrie, Ontario.

In September 2007, an employment case manager for Ontario Works[272] contacted the Society; C.L.C. was pregnant with her second child and due in six weeks but had indicated that she wanted nothing to do with social services. As a result, the Society made an unannounced visit upon C.L.C., who had been seeing her obstetrician regularly and refused the support services and referrals to community resources that were offered. Alerts were sent to various hospitals to notify the Society when C.L.C. gave birth in order to allow the Society to intervene at that time.

On October 26, 2007 the staff at Oakville Trafalgar Memorial Hospital notified the Society that C.L.C. was about to deliver. The Society contacted the hospital and, approximately 20 minutes later, was advised that C.L.C. had given birth to a baby boy weighing 6 pounds 6 ounces with Apgars of 9 and 9.[273] The Society requested that the baby be screened for drugs, given C.L.C.'s history of drug use, and also requested that the hospital staff ask the mother to consent to screening.

C.L.C. and her baby both tested positive for high levels of marijuana. As a result, the same day, the Society met with C.L.C. and her partner in the hospital to discuss their plan of

[272] Ontario Works is a social services support program run under the governance of the Ontario Ministry of Community and Social Services. Ontario Works can provide money for food and housing to individuals who are unemployed as well as access to employment services. http://www.mcss.gov.on.ca/en/mcss/programs/social/ow/index.aspx (accessed: 28 May 2012).

[273] The Apgar score is a simple and repeatable method to quickly and summarily assess the health of a neonate immediately after birth. The score, ranging from zero to 10, is determined by evaluation on five criteria (Appearance, Pulse, Grimace, Activity, Respiration). The test is done at one and five minutes after birth; repeated later for low scores. Scores below three are critically low, four to six fairly low, and seven to 10 generally normal. A score of 10 is uncommon, particularly for newborns at high altitudes, and does not substantially differ from a score of nine. Apgar scores can be indicative of the future health of newborns, as Apgar scores and mental capacity are directly proportional; while not predictive of long-term neurobehavioral outcome, a newborn with a high Apgar score will often have enhanced neurocognitive ability. See generally: American Academy of Pediatrics, Guidelines for Perinatal Care, 6th Edition (Illinois: American Academy of Pediatrics, 2007). In the case at bar, the full-term baby boy had favorable Apgars; a *prima facie* indication that he was a normal, healthy newborn.

care for the child. The meeting was also attended by three Halton Regional Police officers. C.L.C. and her partner became upset, declining to accept any help from the Society, however C.L.C. did sign a consent for the Society to speak with her obstetrician. Given the positive drug test results, coupled with parental unwillingness to use support services, the Society apprehended the baby. Thereafter, the baby was taken to Joseph Brant Memorial Hospital where hair follicle testing was ordered.

Cause of Action and Disposition

By order made on October 31, 2007, the baby was placed in the temporary care and custody of the Society on a "without prejudice"[274] basis, subject to parental access. C.L.C. and her partner exercised access regularly and diligently. The Court found that C.L.C. and her partner were young, inexperienced parents who struggled with mental health issues and drug issues. However, the couple appeared to be committed to their desire to raise their child; suffering a "tremendous loss as a result of the death of their first baby" and "struggling to prevent a second loss."[275] On a motion for temporary care and custody, the Court did not give a great deal of weight to the fact that both parents, at various stages, were wards of the Society. The Court also recognized that, in this case, the Society was likely more vigilant because the couple's first baby had passed away, "although there was no evidence to suggest that the parents' conduct … contributed to the baby's death."[276]

[274] "Without Prejudice" in this context means that parental rights and privileges are not permanently waived or lost; the matter is open to determination or settlement, subject to further proceedings, and has not yet been fully decided. *See generally*: Black's Law Dictionary, Sixth Ed. (St. Paul, Minnesota: West Publishing Co., 1990) at 1603.
[275] *Children's Aid Society of Halton Region* v. *C.(C.L.)*, 2007 ONCJ 595, per Wolder, J. at paras 12 and 14.
[276] *Ibid*, at paras 14 and 15.

After considering all the evidence, the Court found that the baby could be protected adequately by way of a supervision order upon appropriate terms and conditions, including requiring both parents to abstain from the use of marijuana and tobacco in their home. Notwithstanding prior resistance to available supports, the Court was of the view that "the parents should be given an opportunity to parent their child."[277] The baby was returned to C.L.C. and her partner under supervision of the Society on December 14, 2007, at approximately two months of age.

Analysis and Discussion

Children's Aid Society of Halton Region v. *C.(C.L.)* provides a compelling factual illustration of the dilemmas that are created for clinicians and health care professionals who are asked to undertake neonatal hair and meconium screening on newborns without the benefit of clear clinical policies or practice guidelines. In this case, hospital staff were asked to intervene and screen the newborn of a mother who was not known to them and presented to deliver a presumably healthy full-term baby who was not yet the subject of an apprehension order. Hospital staff, who had a clear legal duty to both mother and baby, were given instructions by a third party to screen a full-term baby with a normal birth weight and normal Apgars. While a maternal history of drug use, coupled with a previous infant loss due to SIDS likely constituted a clinical indication to screen, the fact remains that hospital staff were instructed to screen by a third party who, at the time, arguably had no legal jurisdiction

[277] *Ibid*, at para19.

to make the request.[278] For this reason, the Children's Aid Society (CAS) suggested that hospital staff attempt to obtain parental consent.

The clinical dilemma presented in *Children's Aid Society of Halton Region* v. *C.(C.L.)* involves tensions between the state interest in protecting drug exposed children, maternal autonomy, the duty of clinicians to promote a plan of care that is in a child's best interest, and the just utilization of scarce health care resources. The case also raises critical questions regarding how hospitals should handle such situations. While it is of the utmost importance to promote the health interests of newborn children and protect them from latent harms, it is also important for health care professionals to avoid a conflict of interest in doing so. Until such tensions are resolved, neonatal hair and meconium screening for *in utero* exposure to drugs and alcohol should remain the exception, not the rule.[279]

While the facts vary between individual cases, the themes that emerge from *Children's Aid Society of Halton Region* v. *C.(C.L.)* are not unique. In the case of *Children's Aid Society of London and Middlesex* v. *A.K. & C.S.*[280], a woman who had previously admitted to using cocaine and marijuana in her pregnancies and was known to the Children's Aid Society was visited by a Child Protection Supervisor and two police officers while she was in hospital and about to give birth. Her baby boy was apprehended at birth on the basis of maternal mental health and drug abuse problems, as well as a "generally chaotic and

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[278] The distinction can be made clear by recognizing the difference between legal jurisdiction and legal grounds: While legal jurisdiction might be found in terms of legislation enabling certain executive conduct, the actual application of the legislation in any given case could be dependent on there existing sufficient cause or reason to apply the law. An example can be derived by consideration of search and seizure law: it might be permissible under law for a police officer to search a vehicle for open liquor bottles, but in order for the officer at the scene to sear h that particular vehicle, he or she must have cause to believe that the search is warranted. Additionally, except in emergent circumstances, instructions for the provision of health care to children are normally accepted only from the legal guardian of the child.

[279] P. Byrne, "Neonatal Drug Screening: Is it Justified in Babies of Drug Abusing Mothers" (2007) 17 Health Ethics Today 5 at 6.

[280] *C.A.S.* v. *A.K. & C.S.*, 2010 ONSC 2520 (Ontario Superior Court of Justice, Family Court).

unstable lifestyle."[281] The baby was placed in a foster home and, at 31 months of age, was ultimately made a ward of the crown, without parental access, for the purposes of adoption by his foster family.

Implications of Systemic Delay and Divergent Legislation

In addition to questions regarding hospital protocols and the interrelationship between child welfare authorities and health care professionals caring for birthing mothers and babies who are impacted by substance abuse, the legal cases also reveal themes of divergent child protection legislation between jurisdictions and potential pitfalls of systemic delay. The 15 Canadian child protection cases referencing neonatal hair or meconium screening were decided in British Columbia, Ontario and Nova Scotia, with the age of the child at disposition (when the case was decided) ranging from two to 39 months depending, in part, on whether the matter was appealed. In at least one case, a positive meconium screen informed the decision to apprehend a child, who was thereafter returned to her family at 17 months of age.[282]

In Ontario, the *Child and Family Services Act* [283] provides the path which must be considered in a disposition hearing, with strict time limits for cases where the court has found that it is not in a child's best interests to live with his or her parent. For children under the age of six years, section 70 of the *Act* prevents the court from making an order of Children's Aid Society wardship for more than 12 months. A single extension of up to six

[281] *Ibid*, at para 5.
[282] *Children's Aid Society of Toronto* v. *Y.B.*, 2008 ONCJ 800, wherein the Court was not convinced that drug use, without more, necessarily leads to bad parenting behavior or creates an environment of risk for a child. While the Children's Aid Society was correct to have concerns, the Court concluded that the child could be placed with her mother and partner under a supervision order with specific terms ensuring the safety of the child. By this time, the family had missed a significant portion of the child's infancy.
[283] *Child and Family Services Act*, RSO 1990, c C.11.

months may be allowed where it is in a child's best interests, otherwise, a judge must either return the child to his or her parent, or make an order of Crown wardship, with or without parental access. A number of Crown wardship orders are made without parental access, in order to enhance the adoptability of the child. In short, parents in Ontario may have a relatively short window of opportunity to address addiction issues and organize their lives, or risk permanently losing access to their children.

By contrast, the *Children and Family Services Act* [284] in Nova Scotia, for example, allows for more judicial latitude in making disposition orders, the legislative purpose of the *Act* being "to promote the integrity of the family, protect children from harm, and to ensure the best interests of children."[285] A judge presiding over a review hearing in Nova Scotia will be guided more by "best interests" (including whether there has been a change in parental circumstances) and less by strict statutory time constraints. As such, a family facing a particular set of circumstances in one province may experience a different ultimate outcome than a family in another province.[286]

As neonatal hair and meconium screening evidence is beginning to play a role in child protection proceedings in some Canadian jurisdictions, policy makers should be aware of the pitfalls of both systemic delay and of divergent outcomes for children and families based on different child welfare legislation throughout the provinces. Clinicians and policy makers need to be aware of the potentially divergent consequences of screening in different jurisdictions, particularly if screening results are being used to inform decisions regarding child apprehension.

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[284] *Children and Family Services Act*, SNS 1990, c 5.
[285] *Nova Scotia (Community Services)* v. *N.L.*, 2011 NSSC 369, at paras 28 and 29.
[286] It is submitted that this potential for different outcomes, depending not on facts but on province of hearing, could be argued not to be in accordance with *Charter* equality rights. At the time of writing there is no case law specifically on the point however.

Table 4. Child Protection Cases: Age of Child at Disposition

Date	*Case Name*	*Citation*	*Jurisdiction*	*Summary*	*Legislation*	*Child Age at Apprehension*	*Child Age at Disposition*
2006	*CAS Niagara* v. *D.B.*	2006 CanLII 2767 (ON S.C.) (Feb 2006)	Ontario	Twin boys apprehended at birth - crown wards, no access, adoption	*Child and Family Services Act*, R.S.O. 1990, c. C-11	Newborn	10 months
2007	*Cas Halton* v. *C.(C.L.)*	2007 ONCJ 595 (Dec 2007)	Ontario	Positive drug screen at birth - apprehended - temporary care - supervision order	*Child and Family Services Act*, R.S.O. 1990, c. C-11	Newborn	2 months
2008	*Catholic CAS Toronto* v. *K.A.*	2008 ONCJ 148 (Feb 2008)	Ontario	Negative screen for drugs at birth - apprehended - crown wardship, no access, adoption	*Child and Family Services Act*, R.S.O. 1990, c. C-11	Newborn	12 months
2008	*CAS Simcoe* v. *AFL*	2008 CanLII 16074 (ON S.C.) (Apr 2008)	Ontario	Children apprehended - positive meconium - crown wards, no access, adoption	*Child and Family Services Act*, R.S.O. 1990, c. C-11	Newborn	24 months
2008	*CAS Toronto v. Y.B.*	2008 ONCJ 800 (Nov 2008)	Ontario	Positive meconium - child placed in temporary care - supervision order with conditions	*Child and Family Services Act*, R.S.O. 1990, c. C-11	Newborn	17 months
2009	*CAS Waterloo v. A(LJA)*	2009 ONCJ 226 (Feb 2009)	Ontario	Access to 9 year old child apprehended at birth due to maternal alcohol use	*Child and Family Services Act*, R.S.O. 1990, c. C-11	Newborn	9 years (107 months)
2009	*BC Birth Reg 59-039985*	2009 BCSC 599 (Feb 2009)	British Columbia	Infant apprehended at birth d/t maternal drug use - adopted absent consent	*Adoption Act*, R.S.B.C. 1996, c. 5	Newborn	39 months
2009	*Durham CAS* v. *T.W.*	2009 CanLII 58609 (ON S.C.) (Oct 2009)	Ontario	Infant twins apprehended d/t maternal drug screen - children returned to mother	*Child and Family Services Act*, R.S.O. 1990, c. C-11	Newborn	35 months
2010	*BC Birth Reg 59-039985*	2010 BCCA 137 (Mar 2010)	British Columbia	Appeal: adoption order set aside - mother regains custody of 3.5 year old child	*Adoption Act*, R.S.B.C. 1996, c. 5	Newborn	39 months
2010	*FCS v. SW / BY*	2010 ONSC 2585 (May 2010)	Ontario	Infant girl apprehended at birth - crown wardship, no access, adoption	*Child and Family Services Act*, R.S.O. 1990, c. C-11	Newborn	13 months
2011	*CAS Niagara v. T.B.*	2011 ONSC 2702 (Apr 2011)	Ontario	Infant boy apprehended shortly after birth - crown ward, no access, adoption	*Child and Family Services Act*, R.S.O. 1990, c. C-11	Newborn	12 months
2011	*CAS Waterloo v. J.L.M.*	2011 ONCJ 734 (Jul 2011)	Ontario	Positive meconium screen - children apprehended months later - crown wards	*Child and Family Services Act*, R.S.O. 1990, c. C-11	5 months	32 months
2011	*CAS Waterloo v. K.M.*	2011 ONCJ 733 (Sep 2011)	Ontario	Positive meconium - child apprehended at birth - crown ward, no access	*Child and Family Services Act*, R.S.O. 1990, c. C-11	Newborn	9 months

Date	*Case Name*	*Citation*	*Jurisdiction*	*Summary*	*Legislation*	*Child Age at Apprehension*	*Child Age at Disposition*
2011	*Nova Scotia (CS) v. N.L.*	2011 NSSC 369 (Sep 2011)	Nova Scotia	Baby girl apprehended at birth - temporary care order - supervised access	*Children and Family Services Act*, S.N.S. 1990, c. 5	Newborn	12 months
2011	*CAS Toronto v. T.S.*	2011 ONCJ 732 (Dec 2011)	Ontario	Baby boy apprehended at birth - multiple factors - crown ward, no access	*Child and Family Services Act*, R.S.O. 1990, c. C-11	Newborn	21 months

Interviews

The themes that emerge from the relevant legal cases are reflected in a number of the interviews that were conducted in order to supplement this research, namely that (1) novel screening modalities such as meconium screening are becoming a 'hot topic' in clinical practice and professional guidelines do not yet exist; (2) health care professionals are worried about potential conflict of interest in agreeing to state requests for screening; (3) clinicians have concerns about potential negative implications of positive screening results including alienating women from accessing the health care system; along with (4) potential unknown future uses that screening results might be put to. In particular, the NIH-funded meconium screening studies in Hawaii seeking to collect prevalence data regarding methamphetamine (MA) exposure involved the anonymization of meconium samples due to mandatory reporting of illegal substance use in that jurisdiction.[287] [288]

[287] Confirmed by personal interview with 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 MA exposure and child development, at the Kapi'olani Medical Center for Women and Children, Honolulu, Hawaii.

[288] Later in the IDEAL study, after 2006, a NIDA Certificate of Confidentiality was obtained, assuring the confidentiality of information regarding maternal drug use, superseding mandatory reporting of illegal substance use by health care professionals in the State of Hawaii. The certificate, which did not exclude the reporting of evidence of child abuse or neglect, was explained to mothers during the consent process. See:

Ethics Policy Consultation: Meconium Screening Practices at Surrey Memorial Hospital[289]

In 2009, leaders from the Department of Obstetrics and Neonatology at Surrey Memorial Hospital contacted the Fraser Health Ethics Service (FHES) for an ethics policy consultation regarding meconium screening of newborns. Requests from the British Columbia Ministry of Children and Family Development (MCFD) for meconium screening of newborns at Surrey Memorial was becoming increasingly common, and health care professionals who felt conflicted were interested in development of an internal meconium screening policy. The clinicians at Surrey Memorial were of the view that meconium screening was appropriate where there was a clinical indication, and only with consent obtained from a legal guardian. Given the number of requests from the Ministry, some clinicians had concerns about use of valuable resources.

The question for the ethics policy consultation was: "What should Fraser Health's response be to requests for meconium testing?" The stakeholders involved in the consultation agreed, that: (1) meconium screening was a reliable test for drug use in pregnancy; (2) meconium screening can have false positives; (3) front line staff did not have clear direction as to how to deal with MCFD requests for meconium screening; (4) a physician order for meconium screening was required; (5) the British Columbia Centre of Excellence for Women's Health (BCCEWH) did not endorse meconium testing; (6) there

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Smith, L.M., *et al*, "Motor and Cognitive Outcomes Through Three Years of Age in Children Exposed to Prenatal Methamphetamine" (2011) 33 Neurotoxicol Teratol 176 at 178.

[289] The process, results and recommendations of this ethics policy consultation were presented at the 20th Annual Canadian Bioethics Society (CBS) Conference "Just Evidence", June 11-14, 2009 at Hamilton, Ontario. An abstract was published in the Conference Proceedings: Gebauer, S. *et al*, "The Use of Meconium Testing: A Regional Health Authority's Response to a Growing Practice" http://fhs.mcmaster.ca/bioethicsconference/documents/Program%20Booklet%20Printers%20F.pdf (accessed: 31 May 2012), and confirmed by personal interview with Ms. Sarah Gebauer, Leader, Clinical Ethics, Fraser Health Ethics Service (24 August 2009) at Surrey, British Columbia.

was a lack of follow-up resources available to assist women at risk for prenatal substance abuse; (7) there are legal dimensions to the issue of meconium testing; and (8) meconium testing would have an impact on adoptions and potentially a life-long impact on the child.

The ethics policy consultation meetings involved a systematic articulation and prioritization of health care team values. Stakeholders discussed a number of options, including: (1) universal meconium screening of newborns; (2) meconium screening only in the face of a clinical indication; (3) meconium screening only with informed consent of a parent or legal guardian; (4) meconium screening upon MCFD request; (4) meconium screening when directed by court order; (5) meconium screening at the discretion of an attending physician; and (6) do not use meconium screening. Out of this discussion, the stakeholders were able to clarify and articulate their key values: (1) best interests - to protect the safety and wellbeing of newborns while avoiding undue harms; (2) support for mothers – build trusting relationships and empower women to make healthy choices while respecting autonomy and choice; (3) education – ensure that all health care professionals, including social workers, understand what meconium screening provides; (4) effectiveness – only screen meconium for a good reason, acting upon reliable evidence and true facts; (5) efficacy – only screen meconium if something helpful can be done with a positive result; (6) cohesiveness – keep families together as much as possible; and (7) consistency – be consistent in approaches and responses.

Based on the articulated values and a careful exploration of all options as informed by a literature review and analysis undertaken by the Fraser Health Ethics Service, the Department of Obstetrics and Neonatology at Surrey Memorial elected, as a matter of Department policy, to not use meconium screening. The findings and recommendations of

the ethics policy consultation process were approved by Surrey Memorial and informed internal policy guidelines for the "*Care of Women and Children Whose Lives are Impacted by Substance Use*."[290] While a minority of clinicians disagreed with the recommendations and opted not to follow them, the Department was comfortable with the recommendations and the process used in developing them.

The experience of uncertainty at Surrey Memorial Hospital prior to the ethics policy consultation is likely reflective of the experience of many health care organizations in the face of novel screening technology and increased governmental requests for screening in the context of child protection, particularly given the recent plethora of scientific literature and the use of screening evidence in the courts. Like the team at Surrey Memorial, health care teams need education, along with clear policies and guidelines regarding the use of novel screening technologies such as neonatal hair follicle and meconium testing.

[290]This is an internal policy of the Fraser Health Authority. Confirmed by personal interview with Ms. Sarah Gebauer, Leader, Clinical Ethics, Fraser Health Ethics Service (24 August 2009) at Surrey, British Columbia.

Chapter 5: Analysis & Discussion

A number of themes have emerged from the literature review, case law review and supplementary interviews conducted in the context of this research, highlighting legal and ethical complexities inherent in newborn screening for prenatal exposure to drugs and alcohol. Absent carefully drafted clinical practice guidelines, along with adequate protections and supports, neonatal hair and meconium screening may lead to latent harms. Screening evidence may be used in the courts with unanticipated consequences, and can create a number of challenging clinical dilemmas for health care professionals. These themes indicate 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 novel screening modalities for prenatal exposure to drugs and alcohol.

Discussion: Ethical and Legal Considerations for Neonatal Hair and Meconium Screening

The following legal and ethical concerns are relevant to considering the use of screening for biomarkers in meconium and hair for potential prenatal drug and alcohol exposure. Much of what follows is framed in terms of 'principlism' based on the Belmont Report's statement of principles and values[291], and on relational ethics typical of feminist

[291] The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979. Department of Health, Education, and Welfare. http://www.nihtraining.com/ohsrsite/guidelines/belmont.html (accessed: 17 June 2006).

approaches introduced in Chapter 3, and it is in that light that legal and ethical implications of novel practices of neonatal screening for *in utero* exposure to drugs and alcohol will be explored. Such consideration must include the key concepts of autonomy and informed consent, beneficence, nonmaleficence, and justice, which are most familiar to health professionals.[292] [293] However, as the legal cases considered herein have revealed, attention to context and narrative is also essential.[294]

Divergent Approaches to Ethics Analysis: Autonomy and Best Interests

Two competing approaches clash predominantly in ethical analyses regarding health care decision making. The competing approaches are the 'individualist' approach – exemplified by emphasis on autonomy, self-determination and informed consent[295], and the consequentialist approach – exemplified by emphasis on "best interests" and focused on individual outcomes.[296] The former – often referred to as the deontological approach – encompasses voluntariness and respect for personal autonomy as the test for ethical value (thus on issues of consent and understanding); the latter – often called the utilitarian approach – focuses on identifying causal routes to best outcomes as the ethical litmus test (thus informed consent occupies, at best, a subordinate role). The distinction between these approaches is the subject of the analysis: one emphasizes the perspective of the mother and

[292] *Ibid*. Supplemented, however, by consideration of equality rights found in the *Canadian Charter of Rights and Freedoms.*
[293] Canadian Medical Association Code of Ethics (Update 2004); http://www.cma.ca/index.cfm/ci_id/2419/la_id/1.htm (accessed: June 17, 2006).
[294] DeRenzo, E.G. *et al*, "A Feminist Model for Clinical Ethics Consultation: Increasing Attention to Context and Narrative" (1997) 9(3) H E C Forum 212-227.
[295] Meconium Screening, Science and Ethics Say No, *supra* note 198.
[296] Legal and Ethical Considerations, *supra* note 225. See also Apprendix F: Robert Veatch's *Ethics Matrix.*

her choices, while the other focuses upon outcome for the child. Further, a corollary of the discussion is consideration of the roles of the clinicians, both as professionals and as individual citizens, who may owe multiple duties.

As exemplified by the literature and legal cases, the interests of mother and newborn may not always fully coincide and clinicians are sometimes placed in a position to decide whose interests take priority, both ethically and legally. Compounding this is the creation of new information about two individuals – which may subsequently become evidence – that is derived from screening. In this context, clinicians may potentially occupy a dual role of fiduciary and investigator, caught in a complex and problematic tension of service provider, investigator and advocate.[297]

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.[298] Although these ethical and legal facets are connected via common threads, in

[297] This dilemma brings to mind the bloodhound vs watchdog analogy raised in *Re Kingston Cotton Mills (No 2)*, [1896] 2 Ch 279 (CA), wherein the nature of professional duties were discussed in the context of auditors. Their Lordships held that auditors are to be like watchdogs, not bloodhounds or detectives. The analogy can be applied to health care professionals who have a responsibility to watch out for their patients, but who face a conflict of interest when asked to take on an investigative function by the state.

[298] Nelson, E., "The Fundamentals of Consent", in J. Downie, T. Caulfield, and C. Flood, eds. *Canadian Health Law and Policy, 2nd Edition* (Markham: Butterworths, 2004), at 125. Medical treatment of any kind, without the consent of the person being treated amounts, in law, to battery, simply defined as any unauthorized physical interference with the person, whether or not such interference causes physical injury. This is the case even where the treatment is deemed to be in the person's best interest. In *Malette* v. *Shulman*

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 potentially 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 others) as a self-guiding person(s) having an inherent personal worth and integrity, which is best facilitated by maximizing 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.[299]

The legality of all medical treatment[300] 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

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(1990), 72 O.R. (2d) 417 (C.A.), even though a blood transfusion saved the patient's life, her action in the tort of battery was successful because the treatment was without consent.

[299]Behind the Screen, *supra* note 43 at 117.

[300] It is assumed, for the sake of argument, that meconium screening for *in utero* exposure to alcohol is "medical treatment" *contra*, B.M. Dickens, Legal and Ethical Considerations, *supra* note 225 at e471-e474. It should be noted, however, that "medical treatment" may have differing definitions throughout the various Canadian jurisdictions. For example, section 2(1) of the Ontario *Health Care Consent Act*, 1996, S.O. 1996, c. 2, Sch. A., defines "treatment" as "anything that is done for a therapeutic, preventive, palliative, diagnostic, cosmetic, or other health-related purpose" and includes a "course of treatment" or "plan of treatment." Not all Canadian jurisdictions have the benefit of similar legislation. While 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, however it is likely that screening is diagnostic (identifying substance-exposed newborns), preventive (could lead to early intervention and support to prevent secondary disabilities) and is undertaken for a health-related purpose and therefore meets the definition of "treatment" under the *Act*. Further investigation is required.

example, in the case of a child.[301] 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.[302]

Consent is not valid if it is obtained through duress or from a person lacking capacity.[303] It is arguable also that consent is not valid if obtained through undue influence or coercion. In any event, medical treatment in such circumstances will be a battery for which a physician will be held liable.[304] 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.[305] [306]

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[301] *Medical Treatment*, *supra* note 39 at 5.
[302] *Ibid*, at 8-9.
[303] For a discussion regarding capacity see generally *Starson* v. *Swayze*, [2003] 1 S.C.R. 722, 2003 SCC 32, dealing specifically with the issue of patient refusal by a patient under a mental health certificate to consent to proposed medical treatment.
[304] 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. See, for example, *Norberg* v. *Wynrib* (1992), 92 D.L.R. (4th) 449 (S.C.C.).
[305] *Medical Treatment*, *supra* note 39 at 13.
[306] This tension is readily apparent in the legal cases where birthing women are visited by child welfare and law enforcement authorities: *Children's Aid Society of Halton Region* v. *C.(C.L.)*, 2007 ONCJ 595; *C.A.S.* v. *A.K. & C.S.*, 2010 ONSC 2520, and is also apparent in cases where a woman's choice of hospital is questioned or criticized by the courts as an attempt to evade the authorities: *Durham Children's Aid Society* v. *R.S.*, 2004 CanLII 52104 (ONSC).

Beneficence/Nonmaleficence

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.[307] At this point, however, there is little evidence that screening for biomarkers of drug or alcohol exposure is actually beneficial either to mother or her child. It can be argued that screening is *prima facie* a beneficial screening tool in that early identification of exposed newborns may lead to earlier interventions and supports; a common position of those that advocate the development of biomarkers of maternal alcohol use for primary and/or secondary prevention.[308] Depending upon the jurisdiction, regulations may exist that govern how physicians must respond when indicators, including novel screening modalities, identify maternal drug and 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.[309] 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

[307] Legal and Ethical Considerations, *supra* note 225 at e473.
[308] British Columbia Reproductive Care Program (BCRCP): Guidelines for use in the perinatal period and fetal alcohol spectrum disorder. http://www.rcp.gov.bc.ca/guidelines/substance_use/alcoholguideline.pdf (Accessed: February 1, 2006), *supra* note 136.
[309] *Guidelines for Identifying Substance-Exposed Newborns*. A Publication of: The Governor's Action Plan on Child Protective Services Reform, Substance-Exposed Newborn Committee (Arizona: January 2005). http://www.governor.state.az.us/cps/documents/SenGuidelines.pdf (accessed: 12 January 2006).

history may continue be a preference.[310] However, women who currently report drug or alcohol use during pregnancy are not always followed-up in a consistent or systematic fashion. Current methods of screening women in the clinical setting, which include standardized 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 services then assessing exposure will not improve health and well being and may even be detrimental.[311] In such cases, the motivation for and benefit of screening must be evaluated.

Justice: Implications for Neonatal Hair and Meconium Screening

Given that there are no reliable risk factors for prenatal drug or alcohol use[312], there is no *prima facie* valid justification (absent a clinical indication at birth or early in the neonatal period) for why the newborns of some women should be singled-out for 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.[313] Further, in some

[310] American Academy of Pediatrics, Guidelines for Perinatal Care, 5th Edition (Illinois: American Academy of Pediatrics, 2002) at 249 [hereafter "AAP Guidelines for Perinatal Care"].
[311] The potential for stigmatization of a child identified as exposed but without access to beneficial interventions and supports may mean that screening results in more harm than good.
[312] *Meconium Alcohol and Drug Screening, supra* note 80.
[313] E. Nicholson, "Mandatory HIV Testing on Pregnant Women: Public Health Policy Considerations and Alternatives" (2002) 9 Duke Journal of Gender Law & Policy 174 at 183 [hereafter "Mandatory HIV Testing"].

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.[314]

The screening of infants must be undertaken with fairness and equity. Fairness and equity are viewed by many as typifying distributive justice.[315] 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.[316] [317] In particular, those of low socio-economic status, visible minorities, and young or single mothers may be unfair targets for screening.[318] State interventions in Canada are disproportionately oppressive of poor women, Aboriginal women and women who are members of other racial and ethnic minorities.[319] 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 neonatal hair and meconium screening for prenatal exposure to drugs and 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

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[314] This tension is illustrated in cases where women avoid care in order to evade child welfare authorities, or birth in an unsafe environment so that the state will not know about their birth. See, for example: *Children's Aid Society of the Niagara Region* v. *T.B.*, 2011 ONSC 2702, where in an Ontario woman gave birth to her sixth child at the Shipwreck Motel in St. Catharines.

[315] The concept of justice is a core principle or value driving ethical behavior and decision-making in health care. Among other things, justice implies fairness in action in relation to others. One perspective of justice in health care is that the same policies and rules will apply equally to all persons in like situations, and that like cases will be treated alike. See generally: B. Fremgen, *Medical Law and Ethics, 2nd Edition* (New Jersey: Prentice Hall, 2006) at 10.

[316] I. Chasnoff, *et al*, "The Prevalence of Illicit-drug or Alcohol Use During Pregnancy and Discrepancies in Mandatory Reporting in Pinellas County, Florida" (1990) 322 N Engl J Med 1202 [hereafter "Prevalence of Alcohol Use During Pregnancy"].

[317] G.J. Annas, "Testing Poor Pregnant Women for Cocaine – Clinicians as Police Investigators" (2001) 344 N Engl J Med No. 22, 1729 at 1730-1732.

[318] Prevalence of Alcohol Use During Pregnancy, *supra* note 316 at 1202.

[319] Bioethics for Clinicians, *supra* note 217.

criminalization of alcohol and drug use targets the impoverished and medically and socially underserved groups.[320]

One further ethical consideration that fits into the context of neonatal hair and meconium screening is based upon theories of "social agency",[321] and the obligation to use new medical technologies responsibly. Screening neonatal hair or meconium for biomarkers of prenatal exposure to alcohol is relatively recent and is still a novel tool, which needs continued refinement.[322] Is there a higher duty or ethical obligation to pursue only screening that correlates to the medical profession's ability to assist drug or alcohol exposed infants as they continue to develop? Such questions illustrate that meconium screening, and perinatal screening[323] in general, is a value-laden area worthy of increased attention by clinical ethicists.

Finally, feminist consent theory (FCT), which recognizes the unique situation and abilities of women in the context of decision-making, is sensitive to and focuses upon relative power imbalances between parties.[324] 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.[325] When applied

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[320] *Ibid.*
[321] R. Rhodes, "Genetic Links, Family Ties, and Social Bonds: Rights and Responsibilities in the Face of Genetic Knowledge" (1998) 23 Journal of Medicine and Philosophy 10 at 10 and 24.
[322] *See*: P. Wang *et al* "*In utero* Drugs of Abuse Exposure Testing for Newborn Twins" (2010) 63 J Clin Pathol 259 at 261, wherein the authors describe discordant results between meconium samples of dizygotic twins (drug metabolites were undetectable in the meconium of twin A but were detectable in twin B), concluding that more research is indicated in order to completely understand the role of the placenta in the biotransformation of drugs. Studies revealing discordant meconium screening results in twin pregnancies are significant in light of the fact that the courts are admitting meconium screening evidence in child protection and criminal justice proceedings.
[323] Inside the Womb, *supra* note 36 at 84. "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 (Taber's Cyclopedic Medical Dictionary 1469, 1587 (Clayton L. Thomas, M.D., ed., 1993)).
[324] Such as that which may indeed exist in some patient-physician relationships involving female patients.
[325] A Feminist Fourth Amendment, *supra* note 218 at 77.

to neonatal hair or meconium screening for prenatal exposure to drugs or 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 neonatal hair and meconium as a screening tool.

The *Charter of Rights and Freedoms* [326]

The issue of using novel modalities to screen newborns for prenatal exposure to drugs or alcohol raises several potential concerns from the constitutional law perspective.[327] These include the right to equal treatment, informed consent and the right to self-determination and autonomy, reproductive rights, freedom of conscience and the right to privacy, which generally bring sections 1, 2, 7, 8, 15 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 2 of the *Charter* guarantees the fundamental freedom of conscience and religion, subject to certain limits.[328] Freedom of conscience protects systems of belief

[326] *Canadian Charter of Rights and Freedoms*, Part 1 of the *Constitution Act*, 1982, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c.11.
[327] Behind the Screen, *supra* note 43 at 120.
[328] Section 2(a) of the *Charter* is subject to section 1 (limitation clause) wherein limits on the freedom will be valid if coming within reasonable limits prescribed by law that are demonstrably justified in a free and

which might not be characterized as religious, and has been discussed in the health care context in the past, specifically in the context of freedom of choice.[329] [330] It is foreseeable that a woman or family might object to neonatal meconium or hair screening on the basis of freedom of conscience given the need to respect individual decision making in matters of fundamental personal importance, and stakeholders should therefore be prepared to address and respect this scenario. As shall be argued below, the opportunity for an informed refusal may be satisfactory in this regard.

Section 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.[331] Principles of fundamental justice include a right to privacy, given its great value to society.[332] 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".[333] As indicated, some would quickly argue for a universal meconium screening policy on the basis of the "best interests of children" and

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democratic society. As such, freedom of conscience is a qualified right in Canada. See generally, P. Hogg, *Constitutional Law of Canada, 1998 Student Edition* (Toronto: Carswell, 1998) at 815.

[329] *R.* v. *Morgentaler* [1988] 1 S.C.R. 30, 44 D.L.R. (4th) 385, wherein Madam Justice Wilson commented that abortion prohibitions of the *Criminal Code* impacted a woman's right to freedom of conscience as guaranteed by section 2(a) of the *Charter*.

[330] While similar American provisions such as the *American Bill of Rights* contain no reference to freedom of conscience, the matter has arisen in the context of newborn metabolic screening including PKU screening. In the case of *In Re Interest of Anaya*, 276 Neb. 825, the Anaya family objected to the screening of their newborn son, on several bases, including the invasiveness of the heel prick procedure and their freedom to make personal health care decisions for their son as a family. Their son was ultimately apprehended by the state so that a screening regimen could be undertaken, which resulted in an agonizing legal battle for the Anaya family.

[331] As with other rights, this right will be balanced against the "reasonable limits" analysis provided for under section 1 of the *Charter*. A section 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.

[332] The protection of privacy as a fundamental value is enshrined in multiple sections of the Charter, including ss. 7 and 8. Privacy interests are not only protected in search and seizure cases under section 8, but also in certain circumstances under section 7. See *Cash Converters Canada Inc*. v. *Oshawa (City)*, 2007 ONCA 502 at paras 29-30.

[333] *Winnipeg Child and Family Services* v. *K.L.W.*, [2002] 2 S.C.R. 519, 2000 SCC 48 (Supreme Court of Canada), at para. 96.

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".

Section 8 of the *Charter* guarantees the right to be secure against unreasonable search and seizure. As alluded to previously in Chapter 3, the recent seminal case of *Ferguson* v. *City of Charleston*[334] dealt with this issue, albeit an American constitutional challenge. Nevertheless, in that case, screening without informed consent constituted an unjustifiable invasion of privacy. Health care professionals in the case were seen by the Court as "government actors" and their screening policies and practices constituted an unreasonable and unjustified search. While constitutional law is quite different as between Canada and the United States, once cannot help but think that similar reasoning would apply to screening in the Canadian context. Given that neonatal hair and meconium reveal information about two people, namely mother and newborn, one could argue that screening without informed consent could violate the search and seizure provisions under section 8 of the *Charter*.

Section 15 of the *Charter* provides that all persons are equal under the law, with the right to equal benefit of the law without discrimination based upon a number of grounds, including sex. Simply stated, section 15 indicates that men and women are equal under the law. This equality right is problematic when viewed in the context of neonatal hair and meconium screening however, because such screening reveals information about maternal behavior alone. The same information cannot be revealed about men, due to the biological reality that only women can become pregnant and bear children. But the legal cases

[334] *Ferguson* v. *City of Charleston*, 308 F.3d 380, 388 (4th Cir 2002).

referencing meconium screening as discussed in Chapter 4 would establish that screening evidence is being admitted into evidence in multiple contexts including criminal law, family law and child protection cases. As such, it would seem that women do not necessarily have the equal benefit of the law when it comes to new screening modalities. Meconium screening evidence would never be used against a man in an aggravated assault or other criminal law case. Similarly, such evidence would never be used against a father in a child custody or divorce case. This reality must be acknowledged and addressed by clinician stakeholders undertaking screening at the front line of health care delivery as well as by the judiciary when asked by the Crown or other party to admit screening results into evidence.

Informed Refusal

A physician is not free to disregard a patient's instructions.[335] The denial of a patient's right to autonomy and self-determination may be deemed a battery at law.[336] 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.[337] Where a competent patient refuses medical treatment, on whatever basis, the refusal, barring exceptional circumstances, cannot be overridden by a physician. In such circumstances,

[335] *Malette* v. *Shulman et al* (1990), 67 D.L.R. (4th) 321, (Ontario Court of Appeal) at para. 24.
[336] Bioethics for Clinicians, *supra* note 217 at 1730-1731.
[337] *Ibid*.

physicians must make a careful record of the medical advice given, together with the reasons for refusal.[338]

Informed refusal must be considered in the context of selective or universal screening policies. The American Academy of Pediatrics (AAP) 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.[339] Collecting information pertinent to maternal substance abuse should ideally constitute a "well done, sensitively obtained history taken by someone that the mother trusts."[340] Toxicology screening 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.[341]

One size fits all?

Implementing any mandatory meconium 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 could infringe upon the

[338] *Medical Treatment, supra* note 39 at 23.
[339] AAP Guidelines for Perinatal Care, *supra* note 310 at 249.
[340] Confirmed by personal communication with Chris Derauf, M.D., 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, 9 March 2006.
[341] AAP Guidelines for Perinatal Care, *supra* note 310 at 249.

Charter rights of women.[342] If meconium screening moves into the mainstream, and perhaps becomes part of the standard of care for children who are suspected of having been exposed to drugs or alcohol *in utero*, there will likely 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.[343]

There will likely 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.[344]

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.[345][346] 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

[342] Behind the Screen, *supra* note 43 at 126.
[343] Mandatory HIV Testing, *supra* note 313 at 180. This analytical framework was initially structured in the context of HIV screening, but it is applicable to meconium screening as well.
[344] *Ibid*.
[345] Meconium Screening: Science and Ethics Say No, *supra* note 198 at 212.
[346] *See also*: Open Meconium Screening Program, *supra* note 242 at 274.

important than their already compromised rights to self-determination and privacy.[347] 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 novel screening modalities, and discussions around perinatal screening in general, are resolved. This is because advances in medical 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 neonatal hair and meconium screening, are required. In this light, policies and guidelines relevant to neonatal screening for *in utero* exposure to drugs and alcohol will need to be drafted with the impact upon the rights of both children and their mothers in mind.[348]

[347] Mandatory HIV Testing, *supra* note 313 at 180. 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. *See also*, *B.(R.)* v. *Children's Aid Society of Metropolitan Toronto*, 1995 CanLII 115 (SCC), [1995] 1 S.C.R. 315.
[348] Behind the Screen, *supra* note 43 at 127.

Chapter 6: Conclusion and Recommendations

Since the mid 1990's novel screening tools, including neonatal hair and meconium screening, have been developed by scientific researchers to identify substance-exposed newborns. From a developmental pediatric perspective, the benefits of early detection are clear: early identification of substance-exposed children can result in the mobilization of timely interventions and supports, and can help some children to overcome secondary disabilities. From this vantage point, neonatal hair and meconium screening may be seen as a beneficent tool, revealing information that can enable clinicians to provide the best possible care in the longer term.

While the science behind neonatal hair and meconium screening is remarkable, having advanced rapidly over the last decade, the health care community does not have the benefit of policies, protocols or clinical practice guidelines relating to the use(s) of these screens. Recently, screening evidence has informed child protection and social work practices, and we are now seeing neonatal hair and meconium screening results being used in Canadian legal cases. Although screening has tremendous potential to help children, we must also consider unanticipated harms, particularly from the perspective of mothers, who are beginning to ask questions:

> "I know shortly after my delivery my doctors will take Leo to get a meconium sample. Which I am completely ok with. I do have past substance abuse problems but have been completely clean since July 27 of 2006. It's been kind of hard to get a straight up answer from my doctors about how this is going to take place. Very frustrating! I'm not worried at all about the results of the test, I just want to know the process of it. Does anyone know anything about this?"[349]

[349] Community Baby Center, "Has Anyone had the Hospital do a Meconium Drug Screening Right After Delivery?" posted 10/12/2010;

In order to provide women and families with accurate and complete information regarding neonatal hair and meconium screening, the health care community must have accurate and complete information regarding what a positive screen means, what will be done with the results, and what support systems and resources are in place to support children (and families of children) who are identified by a positive screen. Health care providers must not only understand the science behind the screen, but also the potential social and legal implications, including how screening results may be used (or misused) in the courts.

Strengths and Limitations

This is the first study to survey and identify legal cases referencing neonatal meconium screening in Canada. The Literature Review presented in Chapter 3 identified a growing and evolving body of scientific knowledge regarding novel screening modalities for identifying *in utero* exposure to drugs and alcohol including neonatal hair and meconium screening. The Literature Review also identified a paucity of information and analysis regarding the legal and ethical implications of such screening modalities.

This is the first study to report a growing body of jurisprudence related to meconium screening. The case law review, undertaken between 2006 and 2012, demonstrated the evolution of Canadian jurisprudence regarding meconium screening from a time when there were no reported cases, to the present, where there is now a relative abundance of cases. No other Canadian study has undertaken this type of research, nor has a study captured and

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http://community.babycenter.com/post/a24660187/has_anyone_had_the_hospital_do_a_meconium_drug_screening_right_after_delivery (accessed: 23 February 2011).

framed the ethical arguments in the context of the narratives presented by actual legal cases. It is hoped that this research will enhance the understanding of stakeholders, and aid in the development of protocols and practice guidelines, as well as education regarding further research in the area of new modalities of screening for *in utero* exposure to drugs and alcohol.

This study also has a number of limitations. Given the body of scientific and epidemiologic literature regarding neonatal hair and meconium screening that has grown since the mid-1990's, it was very challenging to review all of that literature. It would have been interesting to see how issues of sensitivity and specificity have evolved, in different jurisdictions, as screening modalities have continued to approach a gold standard.[350] The legal, ethics, health economics and social work literature was more navigable in that regard.

As indicated in Chapter 2, the case law review was undertaken over a six year period using two legal databases, namely CanLII and LexisNexis and employing specific search terms including "neonatal hair" and "meconium." While a number of cases were identified over time, enough to bring many of the challenging issues to light, not all cases were captured by the review. Unreported cases were not available in the databases, and not all reported cases were captured by the search terms used, likely due to indexing systems used at the time when cases are uploaded to the databases. For example, a quick search of "meconium" in WestLaw[351] on the eve of submission revealed more cases, primarily from British Columbia, which had not been indexed in either CanLII or LexisNexis. This finding

[350] In the context of meconium screening for *in utero* exposure to alcohol, this work was undertaken by Dr. Matt Hicks at the University of Calgary, and published in 2007. *See generally*, *Meconium Alcohol and Drug Screening*, *supra* note 80.

[351] WestLaw is a legal information tool and database available through purchase by Thomson Carswell through the E-Carswell research package. See: www.westlawcanada.com. Access to this legal database was not readily available to the researcher at the inception of this study.

was not surprising, given the discussion in Chapter 4 regarding the ethics policy consultation undertaken by the Fraser Health Ethics Service (FHES) in response to a growing number of cases in that jurisdiction, whereas CanLII only revealed one case referencing "meconium screening" from British Columbia.

The literature and case law reviews in this study were supported by selective stakeholder interviews, with stakeholders from the health care field who were willing to participate. Not all identified stakeholders choose to participate by way of an interview. Despite letters of invitation, legal professionals identified by the case law review were invited to participate, but did not respond. Some health care professionals also did not respond. One scientific expert declined to be interviewed, given his role in some of the legal cases discussed herein and concerns about possible conflict of interest. Finally, the voices of Canadian women and families were not included in this study. Stakeholder interviews included a variety of professionals, however, the most compelling perspective of all, that of birthing women was not directly solicited.[352]

[352] But see: *Meconium Alcohol and Drug Screening*, wherein survey data from over 1500 women in the Calgary Health Region was collected to capture maternal perspectives regarding meconium drug and alcohol screening, including questions around informed consent and circumstances under which women would be willing to consent to such screening.

Recommendations

Policy Development: The Need for Clinical Practice Guidelines

Health care professionals, hospital administrators, social workers, and child protection workers would all benefit from clinical practice guidelines in order to inform clinical decisions regarding neonatal hair and meconium screening. Absent practice guidelines, different organizations may take a variety of approaches, ranging from not screening at all to universal screening. This means that substance-exposed children in different jurisdictions may receive different benefits and have different access to services. It also means that women in different jurisdictions may face different realities. Principles of beneficence, nonmaleficence and distributive justice all inform the need for carefully considered clinical practice guidelines regarding the use of screening. Ideally such guidelines would address privacy protections and supports, with the interests of both children and mothers in mind while concurrently providing strategies for empowerment and stereotype avoidance. In turn, clinical practice guidelines could inform health policy regarding the use of novel tools for the detection of prenatal exposure to drugs and alcohol.

Law Reform: The Need for Judicial Education

This study reveals that neonatal hair and meconium screening results have been considered in at least 20 Canadian legal cases (including one appellate case) in a variety of

contexts ranging from family law to child protection to criminal law, absent any clinical practice guidelines. Meconium screening evidence has been considered by the judiciary since at least 2006, and yet the screening tool is one that continues to evolve. While, in some of the cases, the courts have had the benefit of expert scientific interpretation and testimony from toxicologists at Motherisk, that has not been true for all of the cases, and the scientific information is changing overtime.

Neonatal hair and meconium screening was developed in the interest of helping substance-exposed children, however, the narratives contained within the legal cases help us to see the potential other consequences of screening. The current reality is that, without appropriate protections or law reform, screening results will likely continue to be used in marriage and custody disputes and in criminal law cases. The Canadian judiciary would benefit from education around the uses and aims of screening, so that unintended consequences and potential injustices can be avoided. Further, this issue must be considered in light of the child welfare legislation that exists within the different provinces of Canada, so that complete and proper information regarding the implications of screening can be made available to stakeholders in all jurisdictions.

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Appendix A: List of Cases

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Children's Aid Society of the Niagara Region v. *D.(B.)*, 2006 CanLII 2767 (ON S.C.).

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Nova Scotia (Community Services) v. *N.L.*, 2011 NSSC 369.

R. v. *Gardiner* (1982), 69 C.C.C. (2d) 477 (S.C.C.).

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R. v. *K.M.*, 2007 CanLII 13937 (ON S.C.).

R. v. *Morgentaler* [1988] 1 S.C.R. 30, 44 D.L.R. (4th) 385.

Reibl v. *Hughes*, [1980] 2 SCR 880.

Re Kingston Cotton Mills (No 2), [1896] 2 Ch 279 (CA).

Winnipeg Child and Family Services (Northwest Area) v. *D.F.G.*, [1997] 3 S.C.R. 925.

Winnipeg Child and Family Services v. *K.L.W.*, [2002] 2 S.C.R. 519, 2000 SCC 48.

Starson v. *Swayze*, [2003] S.C.J. No. 33 (June 6, 2003).

Appendix B: List of Legislation

Adoption Act, R.S.B.C. 1996 c.5.
Canada Health Act, RSC 1995, c. C-6.
Canadian Charter of Rights and Freedoms, Part 1 of the Constitution Act, 1982, being Schedule B to the Canada Act 1982 (U.K.), 1982, c.11.
Child and Family Services Act, R.S.O. 1990, c. C-11, as amended.
Children and Family Services Act, SNS 1990, c. 5.
Child, Youth and Family Enhancement Act, R.S.A. 2000, c. C-12.
Consent to Treatment Act, 1992, R.S.O. 1992, Ch. 31 (repealed, March 29, 1996).
Criminal Code, RSC 1985, c. C-46.
Food and Drugs Act, RSC 1985, c F-27.
Health Care Consent Act, S.O. 1996, c. 2, Sch. A.
The Constitution Act, 1867 (UK), 30 & 31 *Victoria*, c. 3.

Appendix C: Certification of Institutional Ethics Review

Appendix D: Invitation Letter

Anna Zadunayski, BA, LL.B., MSc (student)
Department of Community Health Sciences
University of Calgary, Faculty of Medicine
3330 Hospital Drive NW
Calgary AB T2N 4N1
Tel: 403.288.5213
Fax: 403.283.8524
Email: aczadunayski@shaw.ca

Dr. Glenys Godlovitch, BA, LL.B., PhD
Director, Office of Medical Bioethics
University of Calgary, Faculty of Medicine
3330 Hospital Drive NW
Calgary AB T2N 4N1
Tel: 403.210.9757
Fax: 403.283.8524
Email: omb@ucalgary.ca

November 18, 2008

LETTER OF INVITATION

Title: Legal and Ethical Implications of Newborn Screening for Prenatal Exposure to Drugs and Alcohol: The Case for Policy Development and Law Reform

A Master's Thesis Project

Investigators:

Principal Investigator:
Dr. Glenys Godlovitch,
Office of Medical Bioethics
Faculty of Medicine
University of Calgary
Tel: 403.210.9757
Fax: 403.283.8524
Email: ggodlovi@ucalgary.ca

Student Investigator:
Anna Zadunayski
Community Health Sciences
Faculty of Medicine
University of Calgary
Tel: 403.288.5213
Fax: 403.283.8524
Email: aczadunayski@shaw.ca

Dear (Research Participant);

Please accept this invitation to participate in the above-referenced research project regarding legal and ethical implications of newborn screening for prenatal exposures. You have been identified through our literature review as an individual with insight in this area. Participation as a key informant would involve an interview of approximately one hour in length. In-person and/or telephone interviews will be conducted in December 2008 and January 2009. Detailed information about the project is included in this letter and further information about your potential participation can be found in the attached consent form. We would sincerely appreciate your contribution to this timely topic in maternal and child health.

Study Information

A review of the current literature pertaining to new modalities of neonatal screening for drug and alcohol metabolites reveals a noteworthy lack of information relating to patient selection, informed consent, and ultimate use of screening results. While it is apparent that metabolite screening using neonatal hair and meconium is available in some jurisdictions, little is known about what, if any, informed consent protocols and clinical practice guidelines are in place, particularly for targeted screening or screening absent a clinical indication. As such, this study will attempt to explore:

1. What methods are available to screen for prenatal exposures to drugs and alcohol? Of these methods, which are currently implemented in Canada? Which methods have been considered by the Canadian courts?

2. What are the medical-legal and ethical-legal considerations in screening for prenatal alcohol exposure? What information must stakeholders, policy-makers and the judiciary have regarding screening?

3. Are there legal cases that we can learn from in the area of perinatal or neonatal screening regarding substances of abuse? If so, how might the cases be used to inform screening policy?

Study Goal

This study acknowledges that prenatal exposure to drugs and alcohol constitutes a critical public health issue, and that early diagnosis, interventions and supports are crucial for optimizing outcomes for affected individuals. Well-designed screening programs are important; ideally having high participation rates whilst protecting the relationship between women and clinicians, and not deterring women from seeking prenatal care. A careful study of the legal and ethical considerations in drug and alcohol metabolite screening is essential to guide policy, inform the judiciary, and shed light upon best clinical practices in order to protect the interests of Canadian women and children alike. As such, this study is a

true collaboration of lawyers, ethicists, clinicians and health researchers and has great potential for yielding inclusive, well-rounded policy guidelines and recommendations for submission to key stakeholders. The results of this timely study will be disseminated at scholarly healthcare, law and bioethics conferences, as well as in the related literature.

Action Steps

The attached consent form will provide you with additional information about the study. We will follow-up with you, however please remember that participation in this research study is entirely voluntary, and you may decline to be interviewed or withdraw your participation at any time.

Summary

This research study will involve a comprehensive, principled legal and ethical review to inform emerging health policy, programs and guidelines regarding newborn screening for *in utero* exposure to drugs and alcohol, and to inform the Canadian judiciary regarding the potential uses and implications of screening evidence. The study is designed to collect and analyze relevant information regarding the use and efficacy of new forms of newborn screening for prenatal exposure to drugs and alcohol, along with any informed consent protocols that might be in place, and any existing legal cases and outcomes. The ultimate goal is to clarify the rights and responsibilities of all parties involved in the screening, and to make policy recommendations for this important (but not uncontroversial) clinical practice. It is anticipated that recommendations for law reform will stem from the study results.

We hope that you will agree to be interviewed for this study. If you have any questions or concerns regarding this research, please do not hesitate to contact us at any time. Thank you in advance for your interest and time.

Sincerely,

Anna Zadunayski, BA, LL.B.
Graduate Student

Appendix E: Publication Agreement and Copyright Licence

Appendix F: Veatch's *Ethics Matrix* [353]

This matrix was created by Robert Veatch to illustrate the relationships between and among consequentialist approaches to ethics (left hand column) and deontological approaches to ethics (right hand column). The rows reflect individual relationships (top row) compared with societal relationships (bottom row). For example, an individual who advances a patient's claim of informed consent/freedom of choice is appealing to the top row, right hand column whereas an individual who appeals to best likely outcomes for a patient is appealing to consequentialist arguments on the left column. This matrix is for guidance only; it is not without limitations and has many challengers, especially regarding an argument that justice and fairness are misplaced as occupying the bottom right box.

	Consequentialist Principles (What are the likely effects) (Ties in to evidence-based medicine)	***Duty-based Principles*** (What are the duties/rights) (Ties in to personal liberties and choices)
INDIVIAUL	Hippocratic Utility Beneficence/Non-malfeasance (Patient's best interests, medical paternalism)	Respect for Persons Autonomy, Fidelity, Veracity (Patient's preferences)
SOCIAL	Social utility Greatest happiness/greatest number (Public health programmes, preventive medicine, quarantine, mandatory testing)	Justice Fairness (Rare conditions, special needs support services, research)

[353] R. Veatch, "Resolving Conflicts Among Principles: Ranking, Balancing, Specifying" (2005) 5(3) Kennedy Institute of Ethics Journal 212.