Genetic and Metabolic Screening of Newborns: Must Health Care Providers Seek Explicit Parental Consent?

Sheila Wildeman and Jocelyn Downie

New technologies for genetic and metabolic screening of newborns—such as tandem mass spectrometry and DNA microarray

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2 We refer to “genetic and metabolic” screening throughout this paper in order to capture both those tests aimed at detecting disorders which are congenital (e.g. tests for phenylketonuria and MCAD deficiency) and those tests aimed at detecting disorders which are congenital (e.g. most cases of hypothyroidism).

On our use of the term “screening,” we note that one approach to the definition of “newborn screening” tends to emphasize its population-wide orientation, or its character as a form of mass testing. The 1997 Task Force on Genetic Testing (N. Holtzman & M.S. Watson, eds., Promoting Safe and Effective Genetic Testing in the United States: Final Report of the Task Force on Genetic Testing (Baltimore: Johns Hopkins University Press, 1998) [hereinafter Safe and Effective Genetic Testing]) adopts the following definition of genetic “screening,” drawn from a National Research Council report: “a search in a population for persons possessing certain genotypes that 1) are already associated with disease or predispose to disease, 2) may lead to disease in their descendants, or 3) produce other variations not known to be associated with disease” (at 6). The Task Force further defines “genetic test” as including “[p]renatal, newborn and carrier screening, as well as testing in high risk families” (ibid.).

Another way of defining “newborn screening” focuses on the filter-like nature of the screen and the fact that a further follow-up test is necessary to diagnose any individual infant. Ellen Wright Clayton describes newborn screening as “the analysis of a child’s blood – or, less commonly, urine or stool – to look for abnormal levels of enzymes, metabolites, or other chemicals. If an abnormal result occurs, the test is repeated or further testing is performed to reach a diagnosis” (“Screening and Treatment of Newborns” (1992) 29 Houston L. Rev. 85 at 95 [hereinafter “Screening and Treatment of Newborns”]). However, the development of genetic-based technologies promises to make screening less an initial stage of risk-assessment (following which confirmatory diagnosis is necessary) and more a simple establishing of the fact of a genetic predisposition to disease or genetic abnormality.

We question the appropriateness of the terminology of “newborn screening” rather than, for instance, “mass genetic and/or metabolic testing of newborns.” The latter phrase does not carry with it the implication that the screen is not itself an intervention in the life of the individual child (i.e. not a diagnostic test or one of a set of diagnostic tests) but simply an exercise of public policy directed at the population as a whole. In this paper, we adopt the terminology of “newborn screening” for ease of reference, but wish to emphasize here that newborn screening programs are simply programs of mass genetic and/or metabolic testing.

3 Tandem mass spectrometry has been called “the most important development in newborn screening since the addition of screening for congenital hypothyroidism in the mid-1970s.” (H.
technology (the “DNA chip”)—have rapidly expanded the number of heritable conditions that can be detected presymptomatically. With the development of these technologies, genetic and metabolic screening programs around the world have been confronted with a series of challenging ethical and legal issues, including: which conditions should be targeted in the tests included in comprehensive newborn screening programs, which genetic or metabolic tests can parents request, and whether parental consent is required before conducting screening tests. Among the concerns with respect to an expanded repertoire of

Levy, “Editorial” (1998) 44:12 Clinical Chemistry 2401 at 2401. This technology, first introduced in the early 1990s, involves automated analysis of a single blood sample through the separation and quantification of ions “based on their mass/charge (m/z) ratios” (American College of Medical Genetics / American Society of Human Genetics Test and Technology Transfer Committee Working Group Statement, “Tandem Mass Spectrometry in Newborn Screening” (July/August 2000) 2:4 Genetics in Medicine 267 at 267 [hereinafter “Tandem Mass Spectrometry”]). In comparison with traditional bacterial assay methods, tandem mass spectrometry “greatly expands newborn screening coverage of the metabolic disorders,” identifying up to 10 amino acid disorders in addition to PKU—including maple syrup urine disease and homocystinuria, which were included in some newborn screening programs but required a separate bacterial assay—as well as identifying “important disorders of organic acid degradation [e.g. propionic academia] and fatty acid oxidation [e.g. MCAD deficiency]” (Levy, ibid, and see “Tandem Mass Spectrometry,” ibid. at 268, Table 1). In addition, tandem mass spectrometry is claimed to dramatically reduce the rate of false positive results from that associated with the bacterial assay method (suggested in one study to be 1.5%) (Levy, ibid., and see Chace et al., “Use of phenylalanine-to-tyrosine ratio determined by tandem mass spectrometry to improve newborn screening for phenylketonuria of early discharge specimens collected during the first 24 hours” (1998) 44:12 Clinical Chemistry 2405).

W. Henn (in “Genetic screening with the DNA chip: a new Pandora’s box?” (1999) 25:2 J. of Medical Ethics 200 at 201) writes:

Earlier than expected even by most experts, the ‘DNA chip’ appears to overcome the technical limitations of genetic mass screening through the synthesis of computer and DNA technologies. A silicon chip, as used for microelectronic circuits, is photochemically covered by a microarray of exactly defined short sequences of synthetic DNA; a thumbnail-sized chip can harbor up to 400,000 different such oligonucleotides. These standard sequences can be simultaneously checked for identity with the corresponding sequences of a proband’s genome; the evaluation is done automatically with a computerized laser scanner. The whole procedure only takes a few hours. This ‘massively parallel’ approach to genome analysis addresses a huge amount of genetic parameters from one blood or tissue sample in a single step. Thus it is ideally suited for the rapid and cheap identification of mutations in disease-relevant genes. Of particular interest is the fact that even heterozygous mutations are readily detected, thus making the DNA chip the ideal tool for genetic screening.

In short, “[t]he DNA chip allows the testing of many more genetic parameters in a much shorter time and at much lower prices than conventional gene analysis” (ibid.).

Henn also suggests: “[t]he dissociation between genetic disposition and somatic disease allows the diagnosis of late-onset hereditary diseases many years before the onset of symptoms as well as the detection of individual risk factors disposing to multifactorial disease. This predictive aspect of genetic diagnosis opens new perspectives for preventive medicine but also for genetic discrimination” (at 200).

Commentator Diane Paul has suggested that the new technology of tandem mass spectrometry and other new technologies in development “will lead to more testing for conditions that are untreatable and/or whose incidence and variation in expression is poorly understood, that families will be unnecessarily alarmed as test results of unknown significance are investigated, and that resources for follow-up will be inadequate” (D. Paul, “Contesting Consent: The Challenge to Compulsory Neonatal Screening for PKU” (Winter 1999) 42:2 Perspectives in Biology and Medicine 207 at 213) [hereinafter “Contesting Consent”]. She also raises concerns of privacy and confidentiality.

The 1999 Task Force on Newborn Screening suggested in its report, Serving the Family From Birth to the Medical Home: A Report from the Newborn Screening Task Force Convened in
tests is the potential for harm (e.g. discrimination on the basis of disability) suffered by those receiving positive test results for conditions which are not or are only marginally amenable to treatment.

We were recently asked to assist a health care organization to develop a policy with respect to such questions and concerns that have arisen with the development of new screening technologies. We decided to start by examining the legitimacy of the approach taken to parental consent to the established newborn screening tests (i.e. those that have been traditionally included in newborn screening programs, such as tests for phenylketonuria (PKU) and hypothyroidism). That is, we asked whether the approach in our jurisdiction (Nova Scotia) and in many jurisdictions in the US as well as Canada—to perform routine screening tests on newborns without explicit parental consent—is legally defensible. If so, we could then consider the legitimacy of extrapolating to new tests knowing that the foundation upon which we were seeking to build was secure. Somewhat to our surprise, we concluded that the current approach to parental consent to newborn screening—again, an approach based on the understanding that explicit consent is not required—is not legally defensible.

In this paper, we provide some background on the history of newborn screening and the legal context within which questions regarding consent must be answered, and then turn to the various arguments that can be made for and against the current approach to parental consent to genetic and metabolic tests administered as part of provincial/territorial newborn screening programs. In the end, we conclude that either practice should be changed to align it with current law such that explicit parental consent is sought for the established tests, or that advocates for maintaining current practices should lobby for legislation permitting newborn screening in the absence of explicit parental consent. The approach to the issue of consent to the new tests can then be built upon a legally defensible foundation.

A. Newborn Screening Practices


[hereinafter Serving the Family], that:

In the United States, technological advances have had, and will continue to have a significant impact on the sensitivity, specificity, and scope of newborn screening. Pressure is mounting to deploy new diagnostic capabilities despite professing limited knowledge of their risk and benefit, or their analytical or clinical validity and utility. Presently, tandem mass spectrometry offers, and shortly, DNA-based technology will offer the possibility of using one test or simpler tests to detect a larger group of genetic conditions. Furthermore, as the Human Genome Project is completed, the impetus and opportunity to translate genetic knowledge and technology into public health practice will increase (at 392-393).

The Task Force report reflects on this state of affairs as follows:

With these new technologies comes the ability to detect individuals affected by genetic conditions for which there is no clear advantage to early testing, no early or effective treatment, or no available treatment. How should we best use these emerging diagnostic capabilities in our newborn screening systems and, more generally, in improving the health outcomes of our children? (at 393).
1. United States

a. Mandating that screening be offered

Newborn screening in the U.S. began in the early 1960s, with the development of an improved test for detecting PKU through bacterial assay analysis of blood samples taken from infants and stored on filter paper (the “Guthrie test”).\(^6\) Despite initial concerns raised by the American Academy of Pediatrics about the accuracy of this test and the effectiveness of treatment, by 1973, legislation mandating the screening of newborns for PKU had been put in place in forty-three states.\(^7\) Much of the force behind the legislative action to regulate medical practice in this area was generated by lobby groups including the National Association for Retarded Citizens and March of Dimes Birth Defects Foundation. Support for mandatory offering of newborn screening was also reportedly in place in state health departments and the Kennedy Administration’s Presidential Advisory Commission on Mental Retardation.\(^8\)

Subsequently, some have suggested that in fact the screening programs established through such forms of political pressure were premature. While the specificity and sensitivity of the Guthrie test were later improved, that test’s early use led to a significant number of false positives as well as false negatives. It has further been argued that treating infants who did not in fact have PKU through phenylalanine-restricted diets led to mental deterioration and to death in some cases.\(^9\)

Diane Paul suggests that given the rarity of PKU and absence or infrequency of detected cases in some jurisdictions following the institution of screening programs, some jurisdictions, such as Washington DC, were soon questioning the usefulness of these programs. At this point, however, rather than dismantle the programs, “[o]ne response was to load more tests on the original.” Paul continues: “[b]y the end of the 1960s, a variety of other rare metabolic disorders were being detected with the same filter paper blood specimen

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\(^7\) Serving the Family, ibid. at 390.


employed for PKU screening. Most of these disorders could not be treated as effectively as PKU and at least one (histidinemia) was benign.\textsuperscript{10}

Though a committee of the National Research Council and others advised legislatures against too hastily mandating mass screening for new conditions, Paul argues that “new tests were added without even the degree of pilot testing to which the Guthrie test was subjected.”\textsuperscript{11}

The 1970s saw a number of states add to universal PKU screening programs tests for other metabolic disorders including congenital hypothyroidism, histidinemia, homocystinuria, galactosemia, maple syrup urine disease, and tyrosinemia, as well as hemoglobinopathies, notably sickle cell disease.\textsuperscript{12} Newborn screening for hepatitis B virus was introduced in some states in the 1980s, and screening for cystic fibrosis was legislatively mandated in Colorado in 1988.\textsuperscript{13} This latter addition was to be particularly controversial, as there was no consensus in the medical community that effective treatment for the disorder was available.\textsuperscript{14} Similar concerns have been raised over screening in some jurisdictions (such as Pennsylvania) for Duchenne muscular dystrophy.\textsuperscript{15}

\begin{enumerate}
\item \textsuperscript{10} “Appendix 5,” \textit{ibid.} at 147.
\item \textsuperscript{11} \textit{Ibid.}
\item \textsuperscript{12} “A History,” \textit{supra} note 7 at 60. Katherine Acuff writes, in “Prenatal and Newborn Screening: State Legislative Approaches and Current Practice Standards” in Faden \textit{et al.}, eds., \textit{supra} note 7, 121 at 125-126 [hereinafter “State Legislative Approaches”]: The establishment of screening programs for hemoglobinopathies, including sickle cell disease, is provided by statute (or regulations) by 30 states and Puerto Rico. . . In 26 of the states, the District of Columbia, and Puerto Rico, all newborns are screened. . In Massachusetts and New Jersey, pilot screening programs were expanded to statewide screening of all newborns in 1990. In four states, pilot screening of all newborns in high-prevalence areas have been established, with expansion to statewide screening anticipated by the end of 1991. In North Carolina and Georgia, selective screening of the nonwhite population is done.
\item \textsuperscript{13} “A History,” \textit{ibid.} Diane Paul notes in “Contesting Consent,” \textit{supra} note 4 at 212, that at that time (1999), four states screened newborns for cystic fibrosis.
\end{enumerate}
In 2001, legislation requiring newborn screening in the U.S. varies from state to state in respect to the conditions for which screening is to be performed. While some statutes list a specific set of conditions for which screening is required,16 others end with a catch-all clause allowing the state health department some flexibility in adding further tests, or leave the conditions to be targeted completely within the discretion of the state health department or other agency.17 In such cases, the list of conditions included in the jurisdiction’s screening battery may change with some frequency. Some states feature separate legislation establishing screening programs for sickle cell disease.18

But for citations to both sides of the issue, see Ontario Law Reform Commission, Report on Genetic Testing (Toronto: Queen’s Printer, 1996) at 181, n. 114.

15 The Institute of Medicine Committee on Assessing Genetic Risks noted in Assessing Genetic Risks, supra note 13 at 261:
Increasingly, however, testing is suggested for untreatable disorders. In such instances, the justification is not the benefit to the newborn but the benefit to the parents for future reproductive plans. For such reasons, several countries – and some states in the United States (e.g. Pennsylvania) – screen newborns for Duchenne muscular dystrophy. This medical intervention has no immediate medical benefit for the newborn, and carrier screening of the parents could be obtained through other methods, even when (as in the case of Duchenne muscular dystrophy and some other conditions) they may not realize they are at risk.

16 See e.g. the Iowa Administrative Code, 641 - 4.1(136A) ("Newborn screening policy"): "[i]t shall be the policy of the state of Iowa that all newborns shall be tested for hypothyroidism, phenylketonuria (PKU), galactosemia, hemoglobinopathies, and congenital adrenal hyperplasia (CAH).“ Acuff wrote in “State Legislative Approaches,” supra note 11 at 163, n. 9:
In addition to Alabama, six states have statutes with disease-specific newborn screening language, with no catchall provision. These states are Arkansas, Iowa, Louisiana, New Hampshire, New Jersey, and Texas. Notwithstanding the PKU-specific language of New Hampshire’s statute, by virtue of the state’s participation in the New England Regional Newborn Screening Program, all New Hampshire newborns are automatically screened for galactosemia, hypothyroidism, maple syrup urine disease, and homocystinuria.

17 See Michigan’s Public Health Code (Act 368 of 1978) 333.5431, which specifies that a health professional in charge of the care of or at the birth of an infant shall administer a test for “(a) Phenylketonuria; (b) Galactosemia; (c) Hypothyroidism; (d) Maple syrup urine disease; (e) Biotinidase deficiency; (f) Sickle cell anemia; (g) Congenital adrenal hyperplasia; (h) Other treatable but otherwise disabling conditions as designated by the department.” See also the General Laws of Massachusetts (Title XVI, Public Health) c. 111, §110A (“Tests of newborn children for treatable disorders or diseases”): “[i]the physician attending a newborn child shall cause said child to be subjected to tests for phenylketonuria, cretinism and such other specifically treatable genetic or biochemical disorders or treatable infectious diseases which may be determined by testing as specified by the commissioner. The commissioner may convene an advisory committee on newborn screening to assist him in determining which tests are necessary.” Finally, see Wyo. Stat. Ann. §35-4-801: “(a) Every child born in the state of Wyoming. . . . shall be given medical examinations for detection of remedial inborn errors of metabolism and for detection of major hearing defects. The screening shall be conducted in accordance with accepted medical practices and in the manner prescribed by the state department of health. (b) The specific tests to be done shall be determined by a committee consisting of [a set of specific listed officials and designates].

18 Katherine Acuff writes, in “State Legislative Approaches” supra note 11 at 126: “[a]lthough the authority for sickle cell screening is sometimes contained in the general newborn screening statutes, it is often provided in separate sickle cell-specific legislation. In most jurisdictions, statutory language provides for mandatory screening of newborns, generally allowing a parent to object only upon religious grounds.”
Hiller et al., in a 1997 study, observed that:

All but 2 states have specific legislation that requires newborn-screening programs; Delaware and Vermont have general health statutes that provide authority for the operation of their newborn-screening programs. In 46 of 49 states where the information was ascertained, there are broadly drawn statutes that allow certain changes in the newborn-screening program without new legislation.19

The authors add that “[v]arious protocols for follow-up of infants whose initial screens are inconclusive or positive are required by statute or regulation in 43 of 51 states.”20

According to the recent report of the Newborn Screening Task Force convened in Washington in May of 1999, current state practice in respect to newborn screening is as follows:

All state programs now include screening tests for PKU and congenital hypothyroidism. More than 40 programs screen for sickle cell disease and 48 screen for galactosemia. Some newborn screening systems include tests for congenital adrenal hyperplasia, homocystinuria, maple syrup urine disease, and biotinidase deficiency. . . A few states also include screening tests for cystic fibrosis, tyrosinemia, additional metabolic conditions, and/or other conditions such as congenital infections (ie, HIV). Over half of the states now require all newborns be screened for hearing loss.21

b. Parental consent/refusal

The approach taken to parental consent under the different state laws on newborn screening also varies. The 1999 Newborn Screening Task Force reports that:

Forty-nine states have specific legislation that requires newborn screening; 3 states have provisions for informed decision-making. Currently, Maryland has a voluntary newborn screening program, Wyoming uses an informed consent model, and Massachusetts recently began using an

20 Ibid.
21 Serving the Family, supra note 4 at 391.
informed consent process in a pilot newborn screening program.  

In Maryland, newborn screening is voluntary by authority of the statute which creates the state’s Advisory Council on Hereditary and Congenital Disorders and regulations under that statute. Wyoming legislation and state regulations also require that written consent be obtained from a child’s parent or guardian before any screening test may be performed.

To be distinguished from those states which require explicit parental consent to newborn screening are those which permit parental refusal (a distinction to be explored further in this paper). Hiller et al., in their 1997 study which involved surveys of those responsible for screening programs across the U.S. as well as a review of state legislation, report that “parental refusal of newborn screening is permitted in all states except South Dakota.” The authors further note that “[t]hirty-three states permit objection to testing only on

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22 Ibid. at 409.

23 Maryland Public Health Code Annotated §§13-101 to 13-111 (see esp. § 13-102(10)): “[p]articipation in a hereditary and congenital disorders program should be wholly voluntary, and all information obtained about any individual in a hereditary and congenital disorders program should be kept confidential. . .”). State regulation (COMAR) 10.52.12.05 provides:

(C) Approval of Parent or Guardian. (1) Before administration of the test, the parent or guardian shall be informed fully of the reasons for the test and of his or her legal right to refuse to have the test performed on the child. An individual who has been provided and has signed a written explanation of the test approved and furnished by the Department shall be considered fully informed. (2) A parent’s or guardian’s consent, if given, shall: (a) Be recorded on a form to be provided by the Department; and (b) Become part of the child’s medical record. (3) A parent’s or guardian’s refusal of the newborn screening test shall: (a) Be recorded on a form to be provided by the Department; and (b) Become part of the child’s medical record.

24 Wyo. Stat. Ann. §35-4-801(c): “[i]nformed consent of parents shall be obtained and if any parent or guardian of a child objects to a mandatory examination the child is exempt from subsection (a) of this section” (subsection (a) requires screening for detection of metabolic diseases and hearing defects in newborn children). Regulations made under the statute (“Mandatory Screening of Newborn Infants for Inborn Errors of Metabolism,” c. 1, §3, “Consent for Screening”) state: “[c]onsent for screening can be from natural parents, either custodial parent, a sole guardian, single parent having custody or prospective adoptive parents or parent of whom the child’s custody has been released. No test shall be performed until the written consent of the natural parents, or the custodial parent or the guardian or the adoptive parents is obtained. If any parent or guardian objects to the mandatory testing for a child, then his objection shall be in written form and the child is exempt from such testing.”

25 “Public Participation” supra note 18 at 1281. On examination of South Dakota Codified Laws 34-24-17 et seq. and the Administrative Rules of South Dakota, title 44:19, it is not clear whether parental refusal is actually disallowed, or rather is simply potentially to be challenged in court. Section 44:19:02:05 of the Administrative Rules states that “[t]he parents, guardian, or custodian of each infant is responsible for having blood tests for metabolic diseases performed within the first seven days of an infant’s life, preferably between the third and fifth day of life. The attending physician, other health professional, hospital, or public health facility shall notify the parents, guardian, or custodian of each infant of the responsibility to have the newborn screening tests performed.” The section closes: “[i]f a parent, guardian, or custodian refuses consent for newborn screening to be completed for any infant, the attending physician, other health professional, hospital, or public health facility shall notify legal counsel for the department by telephone . . . within 24 hours after the refusal.”
religious grounds, while 17 allow parental refusal for religious and/or personal reasons.”

**c. Informing parents (even if explicit consent not required)**

There are at least two important kinds of information that might be disclosed to parents even where explicit consent to testing is not required: information about the tests themselves, and information about the legal force of parental refusals.

With respect to informing parents about the tests, the 1997 Hiller study revealed that “[f]orty-nine of 51 states reported that educational materials are available to parents. Thirty-two states are required by law or regulation to have educational programs or materials for parents and/or the general public.” This study also revealed that “[m]any respondents [to the study] emphasized that hospital practices regarding parental education vary within the same state.”

With respect to informing parents about the legal force of parental refusals, the 1999 Task Force found that “[p]arents may not be told directly that they have the opportunity to refuse, and for some parents, mandatory offering may be confused with mandatory screening.”

The Hiller study found that “[o]f the 48 state newborn-screening programs that do not utilize informed consent and that allow parental refusal, only thirteen of these “specifically require parental notification or the distribution of educational materials prior to testing.” The study continues: “[o]f these 13, only Kansas, Minnesota, and Washington require that parents be informed of

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26 “Public Participation,” ibid.
27 Ibid.
28 Ibid. Note too that Faden et al., in a 1982 article “A Survey to Evaluate Parental Consent as Public Policy for Neonatal Screening” (1982) 72:12 Am. J. of Public Health 1347 at 1347 [hereinafter “A Survey to Evaluate Parental Consent”], stated that even in those states that permit parental refusal on religious or other grounds, “the screening is nonetheless compulsory for all practical purposes. That is, the exigencies of the situation are such that there is usually no opportunity for parents to voice objections. For example, the heel prick is routinely drawn in the nursery, not in the presence of the parents, and is done without the parents’ awareness.” See also “Contesting Consent,” supra note 4 at 208, citing a 1992 Wisconsin study which found that “only 22 percent of the parents surveyed knew that they had a right to refuse testing on religious grounds for PKU, galactosaemia, maple syrup urine disease, and hypothyroidism (the standard newborn screening battery in Wisconsin), while only 37 percent knew they could refuse participation for any reason in the experimental screening program for cystic fibrosis (CF). Indeed, three-quarters of the parents did not even know that CF was included in the screening program” (citing A. Tluczek et al., “Parents’ knowledge of neonatal screening and response to false-positive cystic fibrosis testing” (1992) 13 J. Devel. Behav. Pediatr. 181).
29 Serving the Family, supra note 4 at 409.
30 “Public Participation” supra note 18 at 1281. The authors further note: “[m]ultilingual educational materials or translation services are reported to be available in 27 states. Only California has a specific requirement that a mother be provided with information in a language that she understands.” Reference here is made to Cal. Code Regs 17.9.6504.
their legal right to refuse testing on religious grounds.” The authors sum up the situation of states that allow parental refusal but do not mandate informed consent practices as follows:

In California, the District of Columbia, and Wisconsin, parents must be given reasonable opportunity to object to newborn screening. In other states where parental refusal is permitted in theory, there are no legal or regulatory assurances that parents will be given adequate opportunity to refuse screening, or even that they will be made aware of its existence.  

2. Canada

a. Mandating that screening be offered

In 1974, Haworth et al. published the results of their survey of Canada’s government-supported programs for the diagnosis and treatment of metabolic and genetic diseases. The survey reflected that at that time, “[n]ine provinces [had] screening programs for detection of hereditary metabolic diseases in the newborn . . . The first was initiated in 1963; the latest in 1969.” The authors of the study further observed that “[t]he principal objective of the screening programs is to detect diseases amenable to medical intervention. In most provinces this objective is confined to phenylketonuria and other hyperphenylalaninemica states. Capillary blood samples collected on filter paper from the infant’s heel are most commonly used for the screening tests.”

As to early differences between newborn screening programs, the authors stated:

Two provinces (Manitoba and Québec) elected a broader mandate for disease diagnosis at the onset of their programs; Prince Edward Island has recently expanded its program to embrace other aminoacidopathies. One program, in Québec, is continually revising its technology and currently espouses three types of screening: for the purpose of intervention; for reproductive counselling; and for enumeration and surveillance.

31 Ibid.
33 Ibid. at 1147. The survey (updated to 1973) indicates that the earliest provincial screening program was that of P.E.I. (1963), with B.C. next in 1964. The last programs initiated according to the survey were those of Québec and Alberta (1969), while Newfoundland at that time had no provincial program.
34 Ibid.
The authors further observed that “[t]he cost of genetic screening in the newborn is borne by the provincial departments of health, and families do not pay directly for the service,” and added that compliance with screening programs “exceeds 83% and, with only two exceptions, is greater than 90%.”

On the issue of whether these screening programs were mandated by government authority, the authors stated:

Genetic screening programs in Canada are voluntary; there are no health laws or regulations which enforce screening for genetic disease. The viability in the provincial programs more often than not reflects the initiative of individuals or groups who usually hold no position in government but who act as advisers to their programs. The diverse nature of the provincial programs undoubtedly reflects the interests of their advisers.

Almost thirty years later, the majority of provinces and territories still do not have legislation specifically mandating newborn screening in Canada. Nonetheless, each province and territory has implemented routine newborn screening practices. Bartha Knoppers writes: “Neonatal screening is applied to all newborns delivered in Canadian hospitals and is used to detect disorders at birth. Currently, such testing is usually restricted to diagnosis of disorders which can and must be treated immediately by special diet, hormones, or other interventions in order to avoid the immediate deterioration of the newborn’s health.”

The following chart illustrates the specific conditions targeted by newborn screening programs in each province (as best we can determine).

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36 Ibid. at 1148.
37 Ibid.
38 An exception is Saskatchewan’s Hospital Standards Regulations, 1980, Sask. Reg. 331/79, s. 53, which mandates testing for phenylketonuria and hypothyroidism. See note 152, infra. In addition, in Québec, a regulation under the Health and Social Services Act, R.S.Q. c. S-4.2, entitled Regulation respecting the fixing of screening examinations required at the time certain users are admitted or registered, O.C. 503-96, 24 April 1996, G.O.Q. 1996.II.2201, s. 1, states: “[a] public or private institution under agreement that operates a hospital centre shall make a by-law respecting the fixing of screening examinations required at the time certain users are admitted or registered, in accordance with the standards made under paragraph a of section 15 of the Medical Act imposes on the Bureau of the Ordre des médecins du Québec a duty to “advise the Minister of Health and Social Services on the quality of medical care provided in the centres operated by the institutions and the standards to be followed to improve the quality of such care.”
39 On the nature of newborn screening practices in the Territories see note 40, infra.
41 To the best of our knowledge, newborn screening in the Yukon, Northwest Territories, and Nunavut requires sending samples to the province of closest proximity for laboratory analysis, which
### Disorders included in provincial screening programs

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is then conducted in accordance with provincial policy. The Science Council of Canada publication *Genetics in Canadian Health Care* (Ottawa: Supply and Services Canada, 1991) states that “[s]creening and follow-up for newborns in the Northwest Territories and Yukon is done in British Columbia, Alberta, Manitoba, and Québec on the basis of proximity; the specific tests undertaken depend on which province does the screening” (at 104, Table 1). Communications with employees at the Department of Health in the Northwest Territories and in Nunavut and at the Department of Laboratory Medicine & Pathology at the University of Alberta Hospitals in Edmonton, Alberta suggest to us that this is the practice still.

Except where noted, the following information is taken from the 1996 Illinois survey, *Newborn Screening 1996: An overview of newborn screening programs in the United States, Canada, Puerto Rico and the Virgin Islands* (Springfield, Ill.: Illinois Department of Public Health, 1996) [hereinafter 1996 Illinois survey]. Newborn screening practices in Canada’s territories were not addressed in that survey. See note 40, supra.


While the 1996 Illinois survey, *ibid.*, does not indicate Duchenne muscular dystrophy as one of the conditions included in Manitoba’s screening tests, the Manitoba Public Health website states that the Newborn Screening Section is responsible for: “screening all newborn babies for phenylketonuria (PKU), galactosemia, congenital adrenal hyperplasia and screening male infants for Duchenne’s muscular dystrophy.” Online: Manitoba Public Health <http://www.gov.mb.ca/ health/publichealth/cpl/newborn.html> (accessed 13 September 2001). We have been informed that screening for Duchenne muscular dystrophy is a pilot program only.

The website of the New Brunswick Department of Health and Wellness, online: New Brunswick Department of Health and Wellness <http://www.gnb.ca/0048/ english/directory/depts2.htm> (date accessed: 13 September 2001), states: “[a]ll babies born in New Brunswick hospitals are screened for two possible congenital disorders: phenylketonuria (PKU) and hypothyroidism.” However, the 1996 Illinois survey, *ibid.*, indicated that at least at that time, the New Brunswick programme included screening for these conditions as well as biotinidase deficiency, congenital adrenal hyperplasia, and cystic fibrosis.

Screening for MCAD deficiency is now possible in Nova Scotia with the recent acquisition of the technology for tandem mass spectrometry. Telephone interview with Rebecca Attenborough, Coordinator, Reproductive Care Program (Nova Scotia) (14 September 2001).

This information about Ontario’s screening program is taken from the 1996 Illinois survey, *supra* note 41, and was confirmed in communications with the Ministry of Health and Long-Term Care. The Ministry of Health and Long-Term Care website notes in a September
b. Parental consent/refusal

In the most comprehensive recent survey on newborn screening policy and practice in Canada, the results in respect to parental consent/refusal are confusing. There is some information about whether parents are allowed to refuse. However, it is not clear how this information relates to informed consent. On the four page survey is a section headed “Parental Refusal” and in this section respondents were asked to indicate “yes” or “no” to the following statements:

1. Allowed
2. Justification required
   a. Religion
   b. Other
3. Documentation required
   a. Notation in infant’s chart
   b. “Informed Dissent” form signed and witnessed
   c. Written documentation by primary care provider
   d. Written notification to program, i.e., laboratory or health department

The responses were as follows:

Alberta: allows refusal – justification required (religious; other);
B.C.: allows refusal – justification required (religious; other);
Manitoba: allows refusal – justification required (religious; other);
New Brunswick: allows refusal – justification required (religious; other);  
Newfoundland: allows refusal – no justification required;
Nova Scotia: allows refusal – justification required (religious; other);
Ontario: allows refusal – justification required (“any personal ground”);
P.E.I.: refusal not allowed;

1999 description of its “Healthy Babies, Healthy Children” program that among the services to be provided under that program is “universal screening at birth for all newborns”: “Healthy Babies, Healthy Children Program - Update” (September, 1999), online: Ontario Ministry of Health and Long-Term Care <http://www.gov.on.ca/health/english/pub/child/hbabies2.html> (date accessed: 13 September 2001). In addition, the Guidelines for the Healthy Babies, Healthy Children Program (Phase I) include, under ss. 3.3.1 (“Screening and Assessment”), the statement: “[t]he Office for Integrated Services for Children has established an expert panel to select/recommend a screening tool and an assessment instrument for the Healthy Babies, Healthy Children program. These common tools will be used across the province. Communities can choose to add elements to the screening and assessment tools to meet their needs, but are required to use the basic tools”: “Guidelines for the Healthy Babies, Healthy Children Program (Phase I)” online: Ontario Ministry of Health and Long-Term Care <http://www.gov.on.ca/health/english/pub/child/hbabies.html> (date accessed: 13 September 2001). Whether these common tools are to include tools for metabolic screening is not clear.

48 1996 Illinois survey, supra note 41.
49 What follows is a summary of the various provincial yes/no answers provided to the questions noted above. Ibid.
50 The response to this question from the New Brunswick respondent, as indicated in the 1993 (as opposed to the most recent, 1996) edition of the Illinois survey (supra note 41) stated: “human rights – rarely occurs.”
Québec: allows refusal – justification required (religious; other).\textsuperscript{51}

Saskatchewan: allows refusal – justification required (not religious; other).\textsuperscript{52}

Given the way the statements are worded and the section headed, no conclusions can be confidently drawn about consent practices in respect to newborn screening in Canada. It is likely that the fact that refusals are “allowed” in most of the provinces does not imply that an informed consent process is followed. That is, it is likely that parents are not asked for their consent but if they refuse of their own accord, their refusals will be respected in provinces/territories where parental refusal is “allowed.”\textsuperscript{53}

\textbf{c. Informing parents (even if explicit consent not required)}

Informational materials relating to newborn screening may be given to parents in Canadian jurisdictions even where explicit parental consent is not required. Examples from B.C. and Nova Scotia are illustrative.

The B.C. Ministry of Health and Ministry Responsible for Seniors includes on its website fact sheets entitled the “Health Files”, copies of which are placed in a binder in “each of the province’s 120+ health units and departments and certain other offices (i.e. Government Employee Health Services, Native Health Centres, physicians offices/clinics and Nursing Stations).”\textsuperscript{54}

One of the Health Files fact sheets addresses newborn screening.\textsuperscript{55} It states: “In their first week of life, all babies in B.C. are offered a simple blood test.” The fact sheet describes the practice of newborn screening (heel prick and lab analysis) and the rationale for screening (“This is an important test to find those few babies who may have a rare disorder that can cause permanent mental retardation. With early detection and treatment, mental retardation from these rare disorders can be avoided”). It then describes in lay terms each of the disorders included in the screening program and the appropriate treatment. The

\textsuperscript{51} The response to this question from the Québec respondent in the 1993 Illinois survey stated: “discussion with parents usually settles their acceptance.”

\textsuperscript{52} That is, in the category of “Justification required,” the Québec respondent marked “No” in response to the qualifier “a. Religion” and “Yes” in response to the qualifier “b. Other.” The wording of the question is ambiguous. We would assume that marking a “yes” to both “religious” and “other,” as most of the respondents did, indicates that any form of justification, including religious, is accepted. From the Québec respondent’s response, it is unclear whether a religious justification is not accepted or rather is not required.

\textsuperscript{53} We are extrapolating from experience in our own province, Nova Scotia; anecdotal evidence that informed (and written) parental consent is not sought in other provinces; the lack of legislation and clear policies on consent to newborn screening in Canada; and the U.S. experience.

\textsuperscript{54} Citation taken from the website of the Ministry of Health and Ministry Responsible for Seniors, online: British Columbia Ministry of Health and Ministry Responsible for Seniors <http://www.hlth.gov.bc.ca/hlthfile/whatare.html> (date accessed 13 September 2001).

fact sheet further addresses the questions: “Will the needle prick hurt my baby?” (answer: “It will only cause a moment of discomfort”), “When will the results be ready?” (answer: “The results are usually ready in a few days”), and “What if the result is positive?” (answer: “You will be referred to a doctor who is experienced in treating these disorders”). It then addresses the best time for testing (“. . . during the first week of life. Day 2 or 3 is best”), and notes that “[b]abies born in the hospital but discharged within a few hours of delivery, will either return to hospital for testing or have the test done during a home visit within the first week of life.” The fact sheet concludes with the suggestion that the reader direct any questions to her midwife, public health nurse, hospital nursing staff or family doctor.56

The emphasis in the B.C. materials on “offering” babies the test is somewhat confusing, for while this implies voluntariness, the notion of offering the test to babies rather than parents implies no effective opportunity for parental refusal. Also it is not clear whether or how it is ensured that parents read the fact sheet before testing is done.

The Nova Scotia Newborn Screening Committee of the Atlantic Research Centre (supported by the Nova Scotia Department of Health) has produced a brochure on the province’s screening program.57 The program is characterized as “designed to identify babies with two types of ‘invisible’ birth defects within a few weeks of birth, so they can be started on treatment before they develop any brain damage.” The brochure specifies that the testing is for PKU and hypothyroidism, and describes the heel prick procedure. However, on the third page of the brochure, after a description of these two disorders, the brochure states: “[t]he early detection and successful treatment of these conditions is the result of continuing medical research directed towards the prevention of mental handicaps. Occasionally, specimens also may be tested for other disorders.” It is not indicated specifically which other disorders might be targeted in the newborn screening program.

The brochure describes the procedure for notification of the family physician if testing is positive, and advises parents:

[i]f you are notified that the baby should be re-tested or needs additional tests, don’t delay. In many cases, the repeat test will show that the baby is not in fact affected. On the other hand, if he or she has PKU or congenital hypothyroidism, it is important to find out for sure and begin treatment as soon as possible.

56 Ibid.
57 Nova Scotia Newborn Screening Committee, Atlantic Research Centre (supported by Department of Health, Government of Nova Scotia), “Nova Scotia Newborn Screening Program” (undated) [unpublished, archived at Dalhousie University Health Law Institute].
Finally, the brochure advises parents to ensure that their newborn has had the screening tests: “[a]sk your doctor about it.”

We have been unable to locate any published data about provincial/territorial practices with respect to informing parents about the legal force of parental refusals of testing. It is likely, however, that few parents are given such information.58

B. Newborn Screening Reports

A number of guidelines, reports and recommendations have been prepared in recent years, in a number of countries and by a variety of organizations, aimed at articulating the bases of defensible newborn screening policies. The recommendations arrived at with respect to parental consent have in the main been closely intertwined with concerns about new forms of testing technologies and the possibility that screening programs may forego the traditionally accepted criteria of screening for early-onset, treatable conditions and the related objectives of protecting the infant’s best interests. Thus much concern is directed at the potential for including in screening batteries tests for conditions the identification of which would be directed primarily at reproductive planning on the part of parents and/or furthering medical knowledge about the incidence and etiology of disease. However, these reports do also address the issue of parental consent and their recommendations with respect to this issue are our focus here.

1. International

The World Health Organization has set out the following guidelines on “Voluntary use of genetic screening and testing” in its Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services:59

There shall be no compulsory genetic testing of adult individuals or populations.
Every test shall be offered in a way that individuals and families are free to refuse or accept according to their wishes and moral beliefs.
All testing should be preceded by adequate information about the purpose and possible outcomes of the test and potential choices that may arise.

58 Again, we are extrapolating from the U.S. experience as well as that of our own province, Nova Scotia, and the lack of legislation and clear policies with respect to consent to newborn screening in Canada.
This section of the document adds a statement which addresses genetic testing of children and specifically newborn screening, here adopting a best interests criterion:

Children shall only be tested when it is for the purpose of better medical care, as in the case of newborn screening when early treatment will be of benefit to the child.

2. United States

a. Institute of Medicine (1994)

The 1994 Institute of Medicine (IOM) Report Assessing Genetic Risks makes recommendations concerning parental consent to newborn screening which are linked to a prior limitation on the types of tests that should be included in newborn screening programs. According to the Committee on Assessing Genetic Risks which prepared the report, “mandatory screening” (used here by the Committee to indicate the mandatory “offering” of screening and not mandatory parental acceptance of it) should be implemented only where “there is strong evidence of benefit to the newborn from effective treatment at the earliest possible age.”

On the issue of parental consent, the Committee observed of newborn screening programs in the U.S. that “although the majority of states allow objection to screening on some grounds, very few statutes require that the parents or guardians of an infant either be sufficiently informed that they can choose whether or not their infant should submit to the screening or be told they have the right to object.”

The Committee further took note of the 1990 report of the Council of Regional Networks for Genetic Services (CORN) indicating that “for 1990, voluntary programs reported reaching 100 percent of newborns in their states,” and a 1982 Maryland study which had indicated that Maryland’s voluntary newborn screening program then featured a lower or similar parental refusal rate in comparison to non-voluntary programs. The Committee also observed the following benefits of voluntariness in newborn screening programs:

There are additional benefits from voluntariness in newborn screening. Informing parents about newborn screening in

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60 Assessing Genetic Risks, supra note 13.
61 Ibid. at 262.
62 Ibid. at 260.
64 “A Survey to Evaluate Parental Consent,” supra note 27 at 1347-52.
advance of testing allows quality assurance: parents can check to see if the sample was actually drawn. As children are being released from the hospital increasingly early, due to insurance pressures, they might receive a false negative result because blood levels of phenylalanine have not yet risen sufficiently to be detected if elevated. Informed motivated parents may need to bring their babies to be screened after release from the hospital in order to ensure an accurate test result. The recommended informed consent process can provide the necessary education and motivation that will be required to make the return trip far better than mandatory programs.\(^6^5\)

Therefore, the Committee recommended “that newborn screening programs be voluntary.”\(^6^6\)


The Final Report of the 1997 Task Force on Genetic Testing, Promoting Safe and Effective Genetic Testing in the United States,\(^6^7\) while appearing to take a position similar to that of the 1994 IOM Committee on the issue of voluntariness in genetic testing generally,\(^6^8\) introduces a key distinction between certain tests for which parental consent need not be sought (those tests meeting criteria of analytical validity and clinical utility, in service of the best interests of the infant) and other tests (not meeting such criteria) for which parental consent should be sought and, if given, documented in writing.\(^6^9\) In this way, the 1997 Task Force both relaxes the requirement, presented as an absolute in the IOM report, that the standard criteria of benefit to the newborn must be met in order for a test to be included in a screening battery at all (the Task Force position being perhaps more reflective of the reality of screening practices in response to the development of new technologies and research opportunities), and suggests a justification for testing without consent where the standard criteria for inclusion in a screening battery are met.

Thus, the 1997 Task Force admits the possibility of proceeding without parental consent in the case of newborn screening, given certain conditions:

If informed consent is waived for a newborn screening test [here it appears the suggestion is not that the parents have

\(^{65}\) Assessing Genetic Risks, supra note 13 at 262.

\(^{66}\) Ibid. at 276.

\(^{67}\) Safe and Effective Genetic Testing, supra note 1.

\(^{68}\) The first of its “overarching principles” is that of informed consent: “[t]he Task Force strongly advocates written informed consent, especially for certain uses of genetic tests, including clinical validations studies and predictive testing. The failure of the Task Force to comment on informed consent for other uses does not imply that it should not be obtained” (Ibid. at 12).

\(^{69}\) Ibid.
waived consent, but that policy-makers have done so], the analytical and clinical validity of the test must be established, and parents must be provided with sufficient information to understand the reasons for screening. By clinical utility, the Task Force means that interventions to improve the outcome of the infant identified by screening have been proven to be safe and effective.  

At the same time, the 1997 Task Force suggests that screening for the primary purpose of determining carrier status, which by definition is not “of primary benefit to the infant screened,” may proceed only with the informed (and the Task Force specifies: written) consent of the parents. The 1997 Task Force here further acknowledges that state and medical authorities may be too quick to add screening tests before they have been “validated and interventions are established to prevent or reduce clinical problems” (the cystic fibrosis screen is used as an example), and suggests that “[f]or those disorders for which newborn screening is available but the tests have not been validated or shown to have clinical utility, written parental consent is required prior to testing".

Thus the 1997 Task Force endorses screening without consent so long as the tests in issue are accepted as analytically valid and clinically effective, while leaving open the possibility that tests not meeting such criteria may be included in screening batteries and extended to particular infants where explicit (indeed written) parental consent is obtained. However, no argument or justification is given for the position that explicit consent is not required for screening tests that meet the criteria of analytical validity and clinical utility.

c. Task Force on Newborn Screening (1999)

A key impetus of the 1999 Task Force on Newborn Screening was to lay the groundwork for national (US) standards for screening, particularly with respect to the disorders that should be targeted by screening programs in light of technological advances.

On the issue of parental consent, the 1999 Task Force in its report Serving the Family From Birth to the Medical Home takes a position that may be characterized as falling between that of the 1994 IOM Committee and that of the 1997 Task Force on Genetic Testing. That is, it endorses a model of informed refusal. The essential position is expressed as follows – and as such apparently encompasses (or seeks to encompass) both the informational and decision-making components of informed decision-making: “[b]efore newborn

70 Ibid.
71 Ibid.
72 Ibid. at 13.
73 Serving the Family, supra note 4 at 391-94.
74 Ibid. at 395.
screening, parents (on behalf of their children) have the right to be informed about screening, and have the right to refuse screening.\footnote{75}

In arriving at this position, the 1999 Task Force traces certain arguments for and against voluntariness in screening programs. “There are several arguments in favour of not seeking parental permission for newborn screening. First, and perhaps most important, is that screening and potential detection is in the interest of the child and the parents’ objections should not hinder that screening process.”\footnote{76} To this first argument the 1999 Task Force responds, recalling the distinction made by the 1997 Task Force between early-onset, treatable conditions for which reliable tests are available and conditions not meeting those criteria: “[t]his may be more compelling for PKU than for diseases where the benefits of screening would be less clear-cut, as with Fragile X syndrome.”\footnote{77} The deciding factor in the 1999 Task Force position rejecting the best interests justification for involuntary screening appears to be a pragmatic one, based on the observation that state laws on screening already contemplate a right of parental refusal: “[a]s most state newborn screening laws make accommodations for parents who refuse testing, this argument does not seem to be the basis of the current approach.”\footnote{78}

The 1999 Task Force report continues, “[a] second argument is that it is not feasible or it is too costly to talk to parents and ask permission.” Here the 1999 Task Force report, like the IOM report, invokes “early studies of the Maryland newborn screening system” (a voluntary model) and the finding that “the cost and time involved in the Maryland program did not appear to be prohibitive.” To this is added the qualification that “[t]he current approach in Maryland is a simple ‘goodwill’ informed consent for the total screening package and does not allow for separate consent or refusal for each disorder.”\footnote{79}

Further, like the IOM, the 1999 Task Force takes the position that a program encouraging informed decision making by parents will assist in ensuring that parents comply with any recommendations for further testing and follow up.\footnote{80}

However, the 1999 Task Force also appears to endorse the distinction (put forward by the 1997 Task Force on Genetic Testing) between informed consent requirements for tests not meeting best interests criteria of analytical validity

\footnotesize
\begin{itemize}
\item \footnote{75}{Ibid.}
\item \footnote{76}{Ibid. at 410.}
\item \footnote{77}{Ibid., citing D. Nelkin, “The Social Dynamics of genetic testing: the case of Fragile X” (1996) 10 Med. Anthropology Q. 537.}
\item \footnote{78}{Ibid.}
\item \footnote{79}{Ibid., likely referring to “A Survey to Evaluate Parental Consent,” supra note 27 (though not directly citing the studies in question).}
\item \footnote{80}{Ibid.}
\end{itemize}
and clinical utility, and relaxed consent requirements where such criteria are met. For the 1999 Task Force, the distinction is embodied in references to the “right of refusal” in respect of tests meeting these criteria, and “informed consent,” associated by the 1999 Task Force specifically with written consent, in respect of tests that do not meet the criteria. Thus the 1999 Task Force suggests that “[w]ritten documentation of consent is not required for the majority of newborn screening tests, for example, those tests of proven validity and utility.” 81 Yet with the prospect of further newborn screening tests for which treatment efficacy is unknown, the report suggests that “the ethical, legal, and social demands to obtain documentation of permission for newborn screening may increase.” 82 While the law recognizes no distinction between written and oral consent (except in specific pieces of legislation), then, the adoption of this distinction by the 1999 Task Force may be taken to imply that a less rigorous process of ensuring informed parental decision-making is required when tests meet the criteria than when tests are more controversial.

This distinction is also reflected in references by the 1999 Task Force to situations in which parents should be given an “opportunity to refuse,” and alternatively, to situations in which they should be canvassed for their “informed consent.” As we have seen, the 1999 Task Force states that, as a general rule, “[p]arents should always be informed of testing and have the opportunity to refuse testing.” 83 It further states that “[i]n discussions about newborn screening with health professionals, parents refuse to have their newborn tested, this refusal should be documented in writing and honored.” 84 Yet to this is added: “[i]n a newborn screening test is investigational or in the process of being developed, the benefits or potential risks have yet to be demonstrated, and identifiers are not removed from the specimen, informed consent should be obtained from parents and documented.” 85

The implication that these conditions must be met in order to warrant the obtaining of informed consent suggests once again that more care is to be taken to ensure that parents have reflected upon and authorized screening for their child in respect of less established forms of test than to ensure this where established screening tests are at issue.

Finally, the endorsement by the 1999 Task Force of “shared decision making” as “a model for informed consent” in the context of newborn screening may also be taken to suggest a potential relaxation of parental authority to consent to or refuse screening. The report states:

81 Ibid. at 411.
82 Ibid. at 410.
83 Ibid. at 411.
84 Ibid.
85 Ibid.
Shared decision-making refers to a conversation, between the health professional and the patient/parent, where relevant information is disclosed. Most of the discussion between professionals and parents regarding the care of children is relatively informal. Nonetheless, health professionals talk with parents not only because they have to, to treat the child, and not just because they may think that the parents will be more “compliant” if they buy into the plan; but more importantly because health professionals respect the independent and important role parents play. For this reason the Task Force emphasized the importance of the conversation, not the documentation to achieve shared decision-making.86

In this emphasis on “shared decision-making,” is the Task Force endorsing an alternative to the standard model of informed consent such that the authority of the legally-recognized decision maker is now to be shared with the health care provider – arguably a dilution of or departure from the legal requirements of informed consent? Or is the Task Force simply indicating the key role that communication between health care providers and parents must play in the process of parental decision-making about whether screening is in their child’s best interests?87 It is arguable that the Task Force is suggesting, once again, that less care needs to be taken to ensure that autonomous authorization to proceed with newborn screening tests is given by the designated decision-maker (the parent)—and to ensure that this decision-maker indeed understands that s/he has the authority to decide this issue —than in other cases in which informed consent is required.88

However, while the issue of how emphatically parents are to be made aware of their authority to refuse or accept screening tests is arguably treated

86 Ibid. at 410.

87 For a critique of the model of shared decision-making as undermining the requirements of free and informed consent, see R. Faden & T. Beauchamp, A History and Theory of Informed Consent (New York: Oxford University Press, 1986) at 279. Faden and Beauchamp argue that while there is an historical relationship between medical decisionmaking and informed consent, it is an error “to treat informed consent and shared decisionmaking as anything like synonymous.” They therefore endorse the description of effective communication associated with shared decisionmaking models, but reject the position that “the idea of informed consent entails that the patient and physician ‘share decisionmaking,’ or ‘reason together,’ or reach a consensus about what is in the patient’s best interest.” Rather, they suggest that the core of informed consent is that the individual “authorizes autonomously.” They critique in particular the position of Jay Katz as stated in the following texts: President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Making health care decisions : a report on the ethical and legal implications of informed consent in the patient-practitioner relationship (Washington, D.C.: President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1982), Vol. 1 at 15; The Silent World of Doctor and Patient (New York: The Free Press, 1984) at 87; and “The Regulation of Human Research – Reflections and Proposals” (1973) 21 Clinical Research at 785 (cited in Faden & Beauchamp, ibid. at 295, n. 13).

88 Faden and Beauchamp suggest that “[i]n authorizing, one both assumes responsibility for what one has authorized and transfers to another one’s authority to implement it. There is no informed consent unless one understands these features of the act and intends to perform that act. That is, one must understand that one is assuming responsibility and warranting another to proceed” (ibid. at 280).
with some ambiguity, the 1999 Task Force does suggest that there must be a strong informational or educational foundation to consent practices.

Parents need to be informed about the benefits and potential risks of the tests and treatments, the policy for storage and use of specimens, and the mechanism by which families will receive the test results. Of particular importance in informing parents is their understanding of why they should respond to abnormal results, how to respond, and the possibility of false-positive results.89

The 1999 Task Force report further includes some practical suggestions on implementing such educational objectives.

One practical strategy for educating parents is for prenatal health care professionals to provide this information early on during the course of prenatal care. Ideally, this could be accompanied by educational material and/or videotapes provided during one of the third trimester prenatal visits, with a brief review by office or clinic staff.90

. . . Prospective parents should receive information about newborn screening during the prenatal period. Pregnant women should be made aware of the process and benefits of newborn screening and their right of refusal before testing, preferably during a routine third trimester prenatal care visit.91

. . . Parent knowledge should be reinforced after delivery by educational materials and discussion as needed by the infant’s pediatrician or primary care health professional and/or knowledgeable hospital staff.92

Ultimately, the question is what to make of the 1999 Task Force’s pressing the distinction between granting parents the “opportunity to refuse” screening and obtaining “informed consent” from them. The distinction may merely be reflective of concerns to document consent in cases more likely to lead to litigation. However, the possibility remains that this distinction invites screening programs to implement less rigorous processes of enabling informed parental decision-making (including the explicit acknowledgment of parental authority to make the decision) where established tests are in issue.

89 Serving the Family, supra note 4 at 410.
90 Ibid.
91 Ibid. at 410-11.
92 Ibid. at 411.
3. Canada


The Ontario Law Reform Commission’s (OLRC’s) 1996 Report on Genetic Testing recommends that “explicit parental consent should not be required for newborn screening for diseases that are immediately treatable but irreversible if left to be discovered clinically.”\(^{93}\) In this way the OLRC’s stance is close to that taken a year later in the U.S. by the 1997 Task Force on Genetic Testing and then in 1999 by the Task Force on Newborn Screening (described above). However, unlike the 1997 and 1999 U.S. Task Forces, but similar to the 1994 IOM Committee, the OLRC poses in absolute terms the requirement that tests not meeting the standard best interests criteria should not be included in screening batteries. The OLRC recommendations state: “[w]here there are no timely medical or psychosocial benefits, or where the benefits will not accrue until adulthood (as in the case of carrier status or adult-onset diseases), the Commission recommends that children should not be tested for genetic conditions.”\(^{94}\) In contrast, the 1997 and 1999 Task Forces recommended that such tests may be undertaken as long as written consent is obtained.\(^{95}\)

The OLRC further introduces a third category of test, stating that “[w]here the balance of benefits and harms is uncertain, and the family requests testing, such requests should be presented to an ethics committee (possibly the hospital’s own committee, where available) for determination.”\(^{96}\)

Therefore the OLRC poses three categories of newborn screening, with different approaches to the necessity and even the possibility of parental consent: 1) tests for which no explicit parental consent is required as they are in the infant’s best interests; 2) tests which may not be undertaken and thus for which no parental consent may be given (tests that are contrary to the best interests of the infant); and 3) tests the utility and validity of which are uncertain, and concerning which referral to an ethics committee is required. The report also recommends that parental consent be sought for “the banking of newborn screening data and samples.”\(^{97}\)

With respect to the first category of tests, the OLRC Report notes the contrast between the conclusions on parental consent reached in the 1994 United

\(^{93}\) Ontario Law Reform Commission, supra note 13 at 200.

\(^{94}\) Ibid.

\(^{95}\) The latter position is reflected in the following statement of J.M. Gilmour (“Minors,” in Downie & Caulfield, supra note 39, 179 at 212): “When the purposes of testing broaden and are no longer limited to screening to detect treatable metabolic disorders, then reliance on a presumption of consent, or arguments based on the interests of the newborn or other public policy rationales to justify such testing without explicit parental consent become much less persuasive.”

\(^{96}\) Ontario Law Reform Commission, supra note 13 at 200.

\(^{97}\) Ibid.
States IOM Report (that the offering of newborn screening should be mandatory, but participation based on informed consent processes), and earlier studies on ethics and genetics which "considered this to be the only form of genetic testing for which no explicit parental consent was necessary."\(^98\) The OLRC report bases its position on the non-necessity of parental consent on a best interests argument:\(^99\) "whether one presumes the consent of the parents, uses the informed refusal approach, or mandates screening by law, the rationale for mandatory screening is that it is in the child's interest to be 'found' through screening."\(^100\)

The report continues by suggesting a set of legal justifications for non-voluntary practices of newborn screening:

It is also argued that the right of the child to enjoy the best state of health possible [under the U.N. *Convention on the Rights of the Child*, (adopted Nov. 10, 1989), art. 24], the obligations of parents under criminal [art. 215(1)(a) of the *Criminal Code*] and civil law [arts. 599ff *Civil Code of Quebec*] and those of the youth protection authorities [*Child and Family Services Act*, R.S.O. 1990, c. C.11] are such that screening is mandated.\(^101\)

The OLRC therefore adopts a best interests rationale for certain screening tests (such as the established tests for PKU and hypothyroidism) which, along with other legal and ethical imperatives, apparently obviates the need for parental consent. The report further observes that legal justification for non-voluntary newborn screening programs may be found in the doctrine of the state's *pares patriae* power: "the seeking out of a child at risk where clinical diagnosis would be too late and where treatment is available could also be considered an exercise of the *pares patriae* powers and duties of the state to protect the incapable."\(^102\)

We take issue with these suggestions in the analysis section, below.

The OLRC report also briefly rehearses a few arguments on the administrative or logistical difficulties of implementing an informed consent

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\(^99\) This position is also taken by B. Knoppers (Project Director of the OLRC Report) in “Newborn Screening and Informed Consent” in J.-P. Farriaux & J.-L. Dhondt, eds., *New Horizons in Neonatal Screening* (Amsterdam: Excerpta Medica, 1994) 15 at 15-16.

\(^100\) Ontario Law Reform Commission, *supra* note 13 at 180.

\(^101\) Ibid.

\(^102\) Ibid. at 180-181.
process in this context, as contrasted with “the current practice of requesting or presuming permission immediately after birth.” We also consider this form of argument in the analysis section, below.

C. The Law and Parental Consent to Newborn Screening

In order to address the specific issue of parental consent with respect to newborn screening, it is necessary to briefly revisit the law in Canada on consent to health care interventions in general and parental consent in particular.

1. Consent to health care interventions

a. General principles

The Supreme Court of Canada has approved the statement that “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body.” This right is protected not only at common law but also under s.7 of the Canadian Charter of Rights and Freedoms.

In the medical context, the right to be free from offensive bodily contact and the value of autonomy underpinning that right form the basis of a patient’s right to refuse treatment – even where the treatment is necessary to preserve the patient’s life or health. Picard and Robertson, in their text on health law in Canada, state that “[t]he corollary of the patient’s right to medical self-determination is the requirement of consent. Save in exceptional circumstances, medical treatment must not be administered without first obtaining the patient’s valid consent.” Consent may be written or oral, unless legislation specifically requires written consent.

At common law, an intentional, unconsented-to act of physical interference or touching (whether or not in the context of medical treatment) constitutes the tort of battery and may also constitute the criminal offence of assault. On the other hand, proceeding with treatment where consent is insufficiently informed

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103 Ibid. at 181.
107 Ibid. at 42.
108 L.N. Klar, Tort Law, 2d ed. (Scarborough: Carswell, 1996) at 104.
109 Ibid. at 41-47; B. Sneiderman et al., Canadian Medical Law (Scarborough: Carswell, 1995) at 22.
may lead to liability for negligence. Professional discipline proceedings may also result where a health care provider has purported to treat a patient with no or insufficiently-informed consent. In addition, the requirement of consent is specifically protected in certain provincial statutes.

In a battery action, the onus is on the defendant to prove that consent was indicated in respect to the procedure that was performed (in the sense of “go ahead and do ‘x’”) and also that such consent is not vitiated by reason of fraud or misrepresentation, deceit, threat or coercion. In contrast, in a negligence action the plaintiff must establish (prior to the issue of causation of harm) that the health care provider breached his or her duty of care, in that the consent given was inadequately “informed.”

The duty to inform the patient is satisfied where the patient is given information about the nature of the proposed treatment and any alternative treatments, as well as any material risks (and also “unusual” risks, where the consequences of these materializing is particularly deleterious) of treatment and non-treatment. “Material” risks need not be physical, but may extend to those posed “to the patient’s ability to live his life by reasonable criteria, including his ability to earn a livelihood, provide for his family and afford his children opportunities for education.” Disclosure of risks must specifically take into account those consequences that would be relevant to a reasonable person in the particular patient’s position.

In its decision in Reibl v. Hughes, the Supreme Court of Canada rejected the position on informed consent expressed at the Court of Appeal, that “the manner in which the nature and degree of risk is explained to a particular patient is better left to the judgment of the doctor in dealing with the man before him.” Rather, Justice Laskin wrote:

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10 Reibl v. Hughes, supra note 103 at 890; and see Klar, ibid. at 107.
14 A discussion of the informational requirements of informed consent is found in B. Dickens, “Informed Consent” in Downie & Caulfield, supra note 39, 117 at 129-31; also see Klar, supra note 107 at 306-15.
15 Dickens, ibid. at 120.
16 ibid. at 119.
17 Supra note 103 at 894.
The Ontario Court of Appeal appears to have adopted a professional medical standard, not only for determining what are the material risks that should be disclosed but also, and concurrently, for determining whether there has been a breach of the duty of disclosure ... To allow expert medical evidence to determine what risks are material and, hence, should be disclosed and, correlatively, what risks are not material is to hand over to the medical profession the entire question of the scope of the duty of disclosure, including the question whether there has been a breach of that duty.\(^{118}\)

Therefore, it is not professional standards as such that determine the content of material disclosure, but a convergence of those standards and an awareness of the particular patient’s “interests and reasonable expectations.”\(^{119}\) In order to obtain such information, if it is not known or otherwise available to the treatment provider, “it must be sought by the physician asking appropriate questions and giving proper attention to the patient’s responses.”\(^{120}\)

b. Treatment vs. testing

There is no basis in law to draw a blanket distinction between treatment and testing in the assessment of consent in the medical context.

Examples from other contexts support the claim that it is not the case that there are fewer protections of autonomy with respect to testing than with respect to treatment. It has been suggested that public health legislation mandating treatment of certain communicable diseases does not necessarily give public officials or medical practitioners the authority to test individuals, at least where those individuals do not suspect that they may have the disease in question.\(^{121}\) Moreover, the common law recognizes that consent to the taking of a blood sample for a specific purpose does not necessarily authorize the performance of a subsequent test on that blood for purposes not conveyed to the donor, particularly where the additional test may reveal a condition subject to social stigma and other potential deleterious consequences.\(^{122}\) That is, actual or implied consent must be given to performance of the test in issue in order for the

\(^{118}\) Ibid.

\(^{119}\) Dickens, supra note 113 at 122.

\(^{120}\) Ibid. at 124.

\(^{121}\) See Picard & Robertson, supra note 105 at 50, n. 65.

\(^{122}\) Canadian AIDS Society v. Ontario (1995), 25 O.R. (3d) 388 (Gen. Div.); and see Picard & Robertson, ibid. However, note that while the court in Canadian AIDS Society found that “a reasonable blood donor in 1984 and until September 26, 1985 did not consent in fact or by implication to the storage and subsequent testing of their blood” for HIV, the court further held that the analysis of the donors’ common law rights was “inextricably intertwined with the Charter,” and that while testing the blood samples without the knowledge of the donors violated the s.7 right to life, liberty and security of the person, it was not contrary to the principles of fundamental justice in the circumstances of this case.
common law requirement of consent to be met. Therefore, it can be concluded that the law with respect to consent to treatment applies with respect to consent to testing.

c. Consent in the case of infants and immature minors

Authority to consent to treatment of an infant or minor who is incapable of making a treatment decision is vested in the parent(s) or guardian(s). This authority is recognized both at common law and in certain provincial statutes. La Forest J. describes the best interests presumption underpinning this authority as follows, in the Supreme Court of Canada decision B.(R). v. Children’s Aid Society of Metropolitan Toronto: “[t]he common law has long recognized that parents are in the best position to take care of their children and make all the decisions necessary to ensure their well-being . . . . This recognition was based on the presumption that parents act in the best interest of their child.” 123

Baylis et al., writing on the bases of parental authority in decision-making about children’s participation in research, suggest a moral as well as a legal basis for giving parents rights and responsibilities with respect to decision-making about medical interventions in children’s lives. While the issue they are addressing in this passage is specifically research, the grounds invoked are arguably those also supporting parental authority to consent to or refuse treatment (or testing).

Society entrusts parents with responsibility for protecting their children from harm and for promoting their children’s interests. This parental responsibility typically requires decisionmaking on behalf of children regarding issues that range from the mundane to the very complex; at the complex end of the spectrum is decisionmaking regarding participation in some kinds of research. The general responsibility for decisionmaking on behalf of children is conferred on parents for several reasons. First, it is widely believed that parents are the persons most likely to know their children’s interests and thus be in a position to promote them. This belief about parents having privileged knowledge of their children’s interests, coupled with the belief that parents invariably care the most about their children, provides a firm foundation for the claim that parents are the legitimate decisionmakers. A further moral claim that might be advanced by parents (or on their behalf) concerns the fact that parents (in addition to their children) may bear some of the consequences (ranging from inconvenience to serious harm) of a decision regarding their child’s participation in research. 124

d. Limits on parental decision-making authority

A parent’s or guardian’s authority to consent to or refuse treatment on the part of a child is restricted in law by the requirement that this authority is limited to the making of health care decisions that are in the best interests of the child. Parents who fail to provide their children with necessary medical treatment may be subject to criminal liability as well as child protection proceedings. In addition, an application may be made to the court to exercise its parens patriae jurisdiction to protect the child’s best interests.

Therefore, where parents refuse a procedure deemed by health professionals or others to be medically necessary, there are essentially two ways to seek to override that parental decision: application to a court for a declaration that the child is “in need of protection” under provincial child welfare legislation and for consequent transfer of custody (or any incident of guardianship) to the relevant child welfare authority; and application to a court for exercise of its parens patriae powers through an order authorizing the treatment.

The standard employed by the courts in determining when the state’s parens patriae power should be engaged and treatment authorized or guardianship transferred is generally posed as one of “necessity.” If it is established that a parental decision on medical care conflicts with prevailing medical opinion that the treatment is necessary to the life or health of the child, then the court is likely to override parental authority. This appeal to a standard of medical necessity has been characterized by La Forest J. as a restriction on state intervention in all but the most extreme cases.

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125 B.(R.) v. Children’s Aid Society of Metropolitan Toronto, supra note 122 at 370-371; Picard & Robertson, supra note 105 at 75.
126 Gilmore, supra note 94 at 180-181; Picard & Robertson, ibid. at 76-79.
127 Ibid. See also Hepton v. Maat, [1957] S.C.R. 606 at 607-608, cited in B.(R.) v. Children’s Aid Society of Metropolitan Toronto, supra note 122 at 370: “when through a failure, with or without parental fault, to furnish that protection [presumed to be the parental role under the common law], [the child’s] welfare is threatened, the community, represented by the sovereign, is, on the broadest social and national grounds, justified in displacing the parents and assuming their duties.”
130 In proceedings brought under child welfare legislation, the articulation of the standard will of course generally track the wording of the relevant legislation. See e.g. Saskatchewan (Minister of Social Services) v. P.(F.), supra note 127; Re R.K.; supra note 127; and Re K. (L.D.) (1985), 48 R.F.L. (2d) 164 (Out. Prov. Ct.).
In recent years, courts have expressed some reluctance to interfere with parental rights, and state intervention has been tolerated only when necessity was demonstrated. This only serves to confirm that the parental interest in bringing up, nurturing and caring for a child, including medical care and moral upbringing, is an individual interest of fundamental importance to our society.\footnote{131}

\textbf{e. Exceptions to the requirement of consent}

\textit{i. Emergencies}

One established exception to the requirement of consent to medical treatment is the “emergency exception.” This requires that: 1) the patient be incompetent to consent to or refuse the contemplated treatment (or incapable of communicating consent or refusal); 2) no duly authorized surrogate decision maker is immediately available to consent to or refuse treatment; and 3) treatment is necessary to preserve the life or health of the patient.\footnote{132} This also requires that the patient (while competent) or surrogate has not refused the intervention prior to the emergency arising.\footnote{133}

\textit{ii. Legislation}

Provincial legislation, such as public health legislation and in some provinces, mental health legislation,\footnote{134} may obviate the need for consent to certain specified medical treatments. Public health legislation in particular may impose mandatory treatment and/or testing with regard to communicable diseases including AIDS, hepatitis, meningitis, tuberculosis, and syphilis.\footnote{135}

\textbf{f. Exception to the requirement of \textit{explicit} consent}

The implied consent doctrine is not as such an exception to the legal requirement of consent but rather a form of non-express consent, “implied from the words or conduct of the patient.”\footnote{136} Therefore, it may be categorized as an exception to the requirement of \textit{explicit} consent. There are at least two types of implied consent that can be drawn out of discussions of implied consent in the

\begin{footnotesize}
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\item \footnote{131} \textit{B. (R.)} v. \textit{Children’s Aid Society of Metropolitan Toronto}, supra note 122 at 370-71.
\item \footnote{132} Nelson, supra note 111 at 105-107; Gilmour, \textit{supra} note 94 at 182-83; Picard & Robertson, \textit{supra} note 105 at 50-54.
\item \footnote{133} Picard & Robertson, \textit{ibid.} at 54.
\item \footnote{134} Note that such provisions must be scrutinized in light of the guarantees of the \textit{Charter}, \textit{supra} note 104.
\item \footnote{135} Sneiderman \textit{et al.}, \textit{supra} note 108 at 239-43; and see \textit{e.g. Health Act}, R.S.N.S. 1989, c. 195, ss. 76(1), 93.
\item \footnote{136} Picard & Robertson, \textit{supra} note 105 at 46.
\end{itemize}
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literature. We have termed these subsumed consent and inferred-from-conduct consent.

Before considering these two types of implied consent in detail, it is important to make two comments that apply to both types. First, as this issue will generally arise in the context of a claim in battery (i.e. a claim that no valid consent, express or implied, was given in respect to the procedure in question – as opposed to the issue in negligence law of whether consent was fully informed), the onus is on the defendant to prove in his or her defence that there was consent (or a reasonable apprehension of consent).\textsuperscript{137} Second, as Picard and Robertson note, the doctrine of implied consent may invite disputes at common law, in particular where doctor and patient disagree “on the extent of the implied consent.”\textsuperscript{138} That is, there is some considerable confusion and room for disagreement about this exception to the requirement of explicit consent.

\textit{i. Subsumed consent}

A key aspect of the informational requirements of a valid consent is the specificity of the treatment consented to. Erin Nelson writes that “[i]n order for both doctor and patient to be clear about the scope of the consent and the precise treatment which is being consented to, it is essential that the consent be obtained in reference to the treatment being proposed.”\textsuperscript{139} However, some suggest that this apparently categorical principle is subject to a form of qualification which takes us to the doctrine of subsumed consent – wherein, for example, an explicit consent is given to a treatment plan and consent to a particular intervention is said to be subsumed under that explicit consent.

There are two possible forms of subsumed consent (albeit not carefully distinguished in the literature). The first arises where the intervention in issue is in effect a sub-procedure of, or is necessarily incidental to, the procedure explicitly consented to. Klar writes, with reference to this form of implied consent: “[w]here there is consent to a surgical operation, there is an implied consent to procedures, such as the administration of anaesthetics, necessary to carry out the surgery.”\textsuperscript{140} Nelson defends this form of subsumed consent as follows: “[w]hile it is important to refer specifically to the treatment that consent


\textsuperscript{138} Picard & Robertson, \textit{supra} note 105 at 47.

\textsuperscript{139} Nelson, \textit{supra} note 111 at 112, citing \textit{Schweizer v. Central Hospital} (1974), 6 O.R. (2d) 606 (H.C.) (consent given for operation on toe; consent to spinal fusion not encompassed in that explicit consent, though the Workers’ Compensation Board had approved both surgeries); and \textit{Parmley v. Parmley}, [1945] 4 D.L.R. 81 (S.C.C.) (consent given to removal of two teeth; consent to removal of all teeth not encompassed in that explicit consent).

is being requested for, a general consent to a procedure likely also covers sub-procedures which are necessary or usual with respect to the procedure consented to. “141 Conceptually this makes sense, as the patient would still know what, in broad terms, will be done to him or her (and, moving to a negligence analysis of the quality of informed consent, the patient would still know what the material risks and benefits of all of the procedures will be – as the risks of a particular procedure are a cumulation of the risks of all sub-procedures).

The second possible form of subsumed consent arises where the explicit consent to a particular procedure contains a blanket consent to other unspecified procedures. Some variation on the general phrase “such further or other procedures as may be found necessary” may be found in many standard consent forms. However, the position that procedures unrelated to the main procedure consented to may be folded into such a broadly worded consent is tenuous at best.

Starting with the distinction between subsumed procedures for which consent is validly implied in a broader or related explicit consent and those for which consent cannot be legitimately read into that explicit consent, Sneiderman et al. in Canadian Medical Law142 write: “[s]ome written consent forms seek to overcome this distinction [between procedures subsumed in the original consent and those that are not] by stating that the surgeon, in addition to the stipulated procedure, ‘shall have the right to carry out any further procedure that may be deemed advisable, desirable, beneficial or convenient and in the patient’s best interests.’”143 They then note, however, that:

It would be unwise for physicians to rely on words such as these because, in most cases, judges will refuse to uphold them. The reasons are clear. When the consent form is signed the patient’s attention is focused upon the primary ailment and, if the consent form is read at all, it is read quickly and without reflection. There is no true consent to a term which purports to give a “carte blanche” to the surgeon.144

Nonetheless, Sneiderman et al. concede that blanket consents to extended procedures may be found to be valid in some cases. For instance, in Pridham v. Nash, the Court allowed that a blanket clause which was attached to a specific consent to the procedure of laparoscopy, and which extended consent to “additional procedures as may be necessary or medically advisable during the

141 Nelson, supra note 111 at 112, citing Taylor v. Hogan (1994), 370 A.P.R. 37 (Nfld. C.A.), in which “the court held that a consent to a laparoscopy includes consent to remove adhesions, which had to be removed in order for the surgeon to have a clear view of the abdomen.”

142 Supra note 108.

143 ibid. at 28-29.
144 ibid. at 29.
course of such procedures,” was effective in respect to an extended procedure that was “curative” and of “a minor nature.”

In the end, we conclude that implied consent may be demonstrated where there is a necessary connection between the procedure consented to and the subprocedures performed. It may not be demonstrated where there is no such connection (the procedures are unrelated) and there was no blanket consent clause in the explicit consent. Even where there is such a blanket consent clause in the explicit consent, implied consent may not be demonstrated where the procedures are unrelated and the nature of the extended or additional procedure is other than minor. It is unclear whether a court would accept a claim of implied consent where the procedures are unrelated, there is a blanket consent clause in the explicit consent and the nature of the extended or additional procedure is minor.

Situations in which implied consent is less likely to be established, as described above, are not rendered more amenable to a finding of implied consent by the fact that, in the health care provider’s opinion, the unrelated intervention is in the best interests of the patient. If postponing the additional unrelated intervention would threaten the life or health of the patient, then the emergency exception may apply and implied consent would then not be available or needed. If postponing the additional unrelated intervention would not threaten the life or health of the patient, then the health care provider should wait until an explicit consent to the intervention can be sought from the patient.

**ii. Inferred-from-conduct consent**

Klar writes of implied consent that “[a]s with consent in other contexts, consent to medical treatment can be in oral or written form, express or implied. It has been suggested that individuals who submit themselves to a doctor for treatment impliedly consent to all necessary procedures.” He adds: “a patient who in some way co-operates with the doctor may be taken as having impliedly consented to the procedure.” Among generally accepted claims of inferred-from-conduct consent in law are the inferring of consent for venipuncture from a patient’s presenting her arm to a physician and the inferring of consent for a dental examination from a patient’s opening his mouth while in a dental chair.

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149 *O’Brien v. Cunard S.S. Co.*, 28 N.E. 266 (Mas. 1891); Picard & Robertson, supra note 105 at 46-47.
The traditional test for the common law rule of inferred-from-conduct consent (expressed in medical terms) appears to be whether a person in the shoes of the health care provider would reasonably infer from the circumstances that the patient consented.\textsuperscript{150} It is important to note that the test is not whether the patient (or any reasonable patient) \textit{would have} consented on a reasonable analysis of these or other circumstances, but rather whether it was reasonable for the health care provider to infer from the circumstances that the patient \textit{did} in fact consent.

Unfortunately, there is little guidance to be found in the common law as to what constitutes reasonable inferences in the context of health care. This area of law remains grey and contentious (particularly in light of important developments since the original cases were decided, i.e., the introduction of the \textit{Charter} and the evolution of the jurisprudence on implied consent and on the factors vitiating consent in battery\textsuperscript{151}).

\textbf{g. Conclusion}

Thus it can be concluded that as a general rule, parents have decision-making authority with respect to treatment and testing of their young children. Prior to treating or testing a young child, health care professionals must get the parents' free and informed explicit consent to the treatment or testing unless one of the exceptions to the requirement of consent has been met, or unless the health care professionals can demonstrate that parental consent was implied (this to avoid liability in battery) as well as informed (this to avoid a breach of the duty of care in negligence). This conclusion can be operationalized by working through the following questions:

\textsuperscript{150} The statement in \textit{O’}\textit{Brien v. Cunard S.S. Co.}, \textit{ibid.}, is as follows: “\textit{[i]f the plaintiff’s} behavior was such as to indicate consent on her part, [the defendant] was justified in his act, whatever her unexpressed feelings may have been” (at 266); and similarly, “\textit{[i]n determining whether she consented, [the defendant] could be guided only by her overt acts and the manifestations of her feelings}” (\textit{ibid.}). These statements are made following the imperative that attention be paid to “surrounding circumstances.” The American Law Institute’s Second Restatement of the Law states, at c. 45, s. 892(2): “\textit{[i]f words or conduct are reasonably understood by another to be intended as consent, they constitute apparent consent and are as effective as consent in fact.”}

\textsuperscript{151} See e.g. \textit{Toews (Guardian ad litem of) v. Weisner}, [2001] B.C.J. No. 30 (S.C.) at paras. 19-22 (on the need for sensitivity to circumstances in determining implied consent) and at para. 24 (suggesting the importance of the principle of autonomy, or the requirement that “health care providers must always respect the fundamental principle that all individuals control access to their own bodies,” to the analysis of implied consent). And see \textit{Allan v. New Mount Sinai Hospital} (1981), 109 D.L.R. (3d) 634 (Ont. H.C.) at 641: “[s]ilence by a patient, however, is not necessarily a consent. Whether a doctor can reasonably infer that a consent was given by a patient, or whether he cannot infer such consent, and must respect the wishes of the patient, as foolish as they may be, always depends on the circumstances.” Note that the Ontario Court of Appeal allowed an appeal of this decision on the basis that the trial judge had erred in placing liability on the ground of battery that was not pleaded: (1981), 125 D.L.R. (3d) 276 (Ont. C.A.). See also \textit{Norberg v. Wynrib, supra} note 136 at 246-47. Although, as further discussed below, the reasons of La Forest J. (for three members of a six-person court) in that case focus upon the importance of the principle of respect for autonomy, understood as the capacity for self-determination, those reasons ultimately deploy the doctrine of unconscionability as a means of vitiating consent, as opposed to specifically questioning the defendant’s inference concerning implied consent.
Is there free and informed explicit parental consent to the treatment and/or testing? 
If so, treat and/or test.
If not, is there an emergency or legislation that authorizes treatment and/or testing without consent? 
If so, treat and/or test
If not, can the health care professional demonstrate that there is parental consent to the treatment and/or testing that is free and informed, and is subsumed in a broader consent or that can be inferred from the parents’ conduct? 
If so, treat and/or test. 
If not, is the treatment and/or testing in the best interests of the child in the opinion of the health care provider? 
If no, do not treat and/or test. 
If so, seek an order from the court (under child protection legislation or the court’s parens patriae jurisdiction) to treat and/or test. 
If given an order, treat and/or test. 
If not, do not treat and/or test.

2. Arguments for not requiring explicit parental consent for newborn screening

We have seen that under the law on consent in Canada, health care providers must have consent to touch or otherwise interfere with a patient unless one of the established exceptions to the consent rule is met. In addition, where consent is required, health care providers have a duty to ensure that consent is informed. In the context of newborn screening, this means that, prima facie, informed parental consent must be sought.

The position that it is nonetheless unnecessary to seek explicit parental consent to newborn screening might be based on one of several alternative forms of justification. It could be that the need for consent is obviated or not required, under a legal exception to the requirement of parental consent to medical intervention involving a child, or it could be that consent is implied in the circumstances surrounding the screening procedure. Alternatively, the argument may be made that it is simply impractical to implement informed consent practices in the context of newborn screening. We will examine arguments under all three of these headings.

a. Consent is not required

i. Emergencies

It might be argued, for instance in light of the need to perform certain screening tests such as the test for PKU shortly after birth, that there is not time to seek or obtain parental consent and therefore that the circumstances of testing constitute an “emergency.” However, this exception applies to situations that are unanticipated, in which there is no time to seek appropriate consents. This is not
the case with newborn screening, for which parental consent may be sought in the prenatal period. Furthermore, even if consent is not sought in the prenatal period, in almost all instances there is certainly time to seek an informed consent from parents after the birth and before non-treatment will result in harm to the child. While there may be the occasional newborn for whom testing is a real emergency, this is certainly not so of all newborns (as would be required to justify mass screening programs bypassing consent on the basis of the emergency exception).

Furthermore, the 1982 Maryland study relied upon by the 1994 IOM Committee and 1999 Task Force indicated that the numbers of infants tested did not diminish as a result of the informed consent process. Difficulty obtaining timely consents does not appear to have arisen as an issue in that study. Therefore, on both theoretical and empirical grounds, without further evidence indicating the contrary, we would argue that the emergency exception does not justify a mass exception to the general consent rule.

ii. Legislation

In Canada, newborn screening is not addressed in any legislation explicitly mandating testing in the absence of parental consent. Therefore, unless a common law basis can be found to support the practice of screening without parental consent, such practices are not supported in law in Canada.

b. Consent is implied

Having found that the position that parental consent to newborn screening is not required does not hold up when assessed in light of the available legal exceptions to consent, we turn to the issue of whether parental consent may be implied in the circumstances of newborn screening.

i. Subsumed consent

152 “A Survey to Evaluate Parental Consent,” supra note 27 at 1350-51. See Assessing Genetic Risks, supra note 13 at 261, and Serving the Family, supra note 4 at 410.

153 As indicated at note 37, supra, Saskatchewan’s Hospital Standards Regulations, 1980, include the following at s. 53:

(1) All newborn shall be tested for phenylketonuria and hypothyroidism. Blood samples for the Guthrie test for phenylketonuria shall be taken from all newborn after they have been on milk or protein diet for forty-eight hours and before they leave the hospital. The taking of the test for phenylketonuria and the results shall be recorded on the patient’s health record.

(2) If for any reason these tests are not performed before discharge, the medical health officer of the appropriate health region or city health department must be notified.

Similar language in s. 52 of the regulations mandates Rhesus testing of pregnant women and treatment of Rhesus negative women by injection following delivery or abortion. We would argue that these regulations do not explicitly remove the right of consent, and further, must be interpreted in light of the Charter as preserving the right of consent.
It has been argued that the form of implied consent reviewed above under the heading of “subsumed consent” justifies current newborn screening practices with respect to parental consent.\textsuperscript{154}

However, as we suggested above, consent to a procedure which is unrelated to that for which consultation and intervention have been sought will not be implied, even where that secondary procedure is deemed advisable by a health care professional (\textit{e.g.} where a doctor performing a cesarean section determines it is also medically advisable to sterilize the patient) unless, possibly, there is a blanket consent to other necessary care.\textsuperscript{155} So subsumed consent to newborn screening can only be found if screening can meaningfully be described as a sub-procedure of a procedure for which parents have given explicit consent or if it can be considered to have been captured under a blanket consent clause attached to an explicit consent to something else.

Claims with respect to subsumed consent to newborn screening would likely be made in relation to general consents signed on admission, i.e., consents to “newborn care.” We must therefore ask whether a consent to “newborn care” or “neonatal care,” as is commonly obtained in the neonatal context (often with an attached blanket clause expressing consent to other “necessary or incidental” procedures), is sufficiently encompassing of newborn screening procedures to automatically “subsume” those procedures.\textsuperscript{156} That is, can the argument from subsumed consent be used to justify genetic tests performed without explicit parental consent, as part of an ongoing intervention understood as neonatal or newborn care? The issue appears to be the closeness of connection of the intervention consented to (newborn care) and that additionally provided (the tests).

In the first place, it can be argued (and the courts have indicated) that an instance of the sub-procedure form of subsumed consent must involve sub-procedures that are necessary to achieve or are necessarily incidental to the broader procedure to which consent is explicitly given (as anaesthetic is

\textsuperscript{154} This approach (among others) is suggested in the Ontario Law Reform Commission’s \textit{Report on Genetic Testing}, \textit{supra} note 13 at 182.

\textsuperscript{155} See \textit{Murray v. McMurphy}, \textit{supra} note 145. However, note that in \textit{Brushett v. Cowan}, \textit{supra} note 139, the Newfoundland Court of Appeal reversed a trial court finding of battery where a doctor took a bone biopsy during surgery although the patient had consented specifically to a muscle biopsy only. The Court of Appeal held that the wording of the consent form (which included consent to “such further and alternative measures as may be found to be necessary. . .”) viewed in light of the general intent of the surgery (to correct the patient’s leg trouble), established sufficient consent to cover an ongoing investigative process, including the bone biopsy.

\textsuperscript{156} We were provided consent forms from a Canadian hospital specializing in the area of newborn and maternal care which make broad reference to consent to “newborn care” and “normal maternal care” (forms on file with the authors). The forms in issue extend consent to “such additional or alternative diagnostic, operative or treatment procedures as in the opinion of the medical staff performing the procedure mentioned above are considered incidental to, or immediately necessary and vital to the health and life of the patient.” We have extrapolated from this practice by a leading hospital that such broadly-worded consents are not unusual in this context.
necessary to certain surgeries).\textsuperscript{157} Where there is room for reasonable disagreement about whether the secondary procedure could reasonably be said to be implied in the consent given, the necessity of the procedure to the broader intervention consented to, or the degree of harm that may result from the subsumed procedure, the doctrine of subsumed consent will not necessarily prevail. In particular, contention will likely arise, and implied consent will be more difficult to establish, where the broader procedure is so vague (e.g., “to promote the health of the patient” or “newborn care”) as not to give any reasonable indication of what the subsumed constituents might be, and/or when there is room for an interests-based disagreement as to the propriety of embarking on some particular sub-procedure rather than another in order to achieve the patient’s desired outcome (or in this case, to act in the child’s best interests).

The argument that consent is implied by a blanket clause within an explicit consent to another procedure also fails with respect to newborn screening. Again, as noted by Sneideman \textit{et al.}, valid consent cannot be demonstrated on the basis of a term in a consent form which purports to give the health care provider “carte blanche” in addition to a specific consent to which the patient’s attention is reasonably directed.\textsuperscript{158}

Where we have seen the courts accept a claim of implied consent based on a blanket clause within an explicit consent, the additional procedure has been minor and there has been a significant nexus between the procedure consented to and the additional procedure performed. In \textit{Pridham v. Nash}\textsuperscript{159} (the laparoscopy case described above), for example, an explicit consent was given to a diagnostic procedure to discover the source of pain and the additional procedure performed was a low-risk therapeutic procedure to cure the pain. In addition, there was a risk involved in getting an explicit consent to the additional procedure (i.e., the need for an additional surgery and general anaesthetic). While some may argue that newborn testing is minor, others would disagree. The performance of the test itself does not pose more than minor risk (it requires just a heel prick) but the results of the test can be harmful as well as beneficial, and there are risks such as false positives.\textsuperscript{160} More significantly, as indicated above, there is no significant nexus between the procedure consented to (newborn care) and the additional procedure. Finally, there is no risk to seeking an explicit consent to the additional procedure (i.e., to newborn screening). The situation that this form of implied consent was designed to address is simply not found in the context of newborn screening.

\textsuperscript{157} Klar, \textit{supra} note 107 at 104; and see e.g. \textit{Taylor v. Hogan}, \textit{supra} note 140.
\textsuperscript{158} Sneideman \textit{et al.}, \textit{supra} note 108 at 29.
\textsuperscript{159} \textit{Supra} note 144.
\textsuperscript{160} On the risks of even the established newborn screening tests (including the risk of false positives), see e.g. “Contesting Consent,” \textit{supra} note 4 at 213-15 and G. Annas, “Mandatory PKU Screening: The Other Side of the Looking Glass” (1982) 72:12 Am. J. of Public Health 1401.
Given that a single health care provider would be ill-advised to rely on an implied consent based on a blanket consent clause in an explicit consent form, it seems indefensible to base provincial or territorial programs on such a model of implied consent, especially in light of the fact that legitimate options are available.

**ii. Inferred-from-conduct**

Let us now consider whether newborn screening in the absence of parental refusal can pass the test for inferred-from-conduct consent. In particular, can a health care provider reasonably infer consent from the absence of a parental refusal to newborn screening?

Fleming suggests that in some circumstances it may be that silence gives rise to a reasonable inference of consent, stating: “[f]ailure to resist or protest indicates consent if a reasonable person who is aware of the consequences and capable of protest or resistance would voice his objection.” Following this form of reasoning, the inferred-from-conduct approach may be claimed by some to justify an opt-out model of consent in the context of newborn screening, whereby the health care provider will proceed to test unless the parents actively object.

In response, we start with what we take to be the non-contentious point that it is clearly not reasonable to infer consent (even at the minimal level of “go ahead”) from silence or the absence of objection where the parents have not been given any information at all about newborn screening, nor been informed that screening tests are typically or always done. The general public has little or no awareness of these programs or of the tests included in such programs. Furthermore, we would argue that it is also clearly not reasonable to infer consent from an absence of refusal where the parents have not been told that they may refuse newborn screening. Without that information, it is likely that parents would feel that it would simply be useless to state a refusal.

The stronger argument for an opt-out model of consent rests on practices such as those described by Picard and Robertson, i.e. where parents are given an informational brochure (which includes information about the tests as well as the parents’ right to refuse newborn screening), and on that basis, the lack of an objection is understood as consent. It is notable that in such a situation there is still not even such a minimal form of positive expression of assent as the extending of one’s arm for a blood sample.

Let us dissect the inference that is suggested to be reasonable in this circumstance. The first assumption that is required, in instances where the parent

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161 Fleming, *supra* note 136 at 80.
162 Picard & Robertson, *supra* note 105 at 47: “[i]n most [newborn screening] programs the parents are given a brochure informing them about the program and advising them that the screening will be carried out unless they object.”
is given a brochure but the procedure is not discussed (the giving of a brochure apparently being the minimal informational basis for inferring consent on this model), is that the parent has read the brochure and so understands the nature of the procedure and tests in issue, and understands as well that she or he may refuse these tests. This would be the minimal inference required to meet a claim in battery (i.e., that consent was indicated with reference to the specific procedure in issue, at the minimal level of “go ahead and do ‘x’”). Moreover, the further assumption required to meet a claim in negligence would be that, having read the brochure, the person was informed, or could reasonably be regarded as understanding the material risks of the procedure and tests in issue.

We would argue that the assumption that the parents have read the brochure and as a result understand the nature of the procedure and tests in issue, as well as the fact that they have a right of refusal, is an unreasonable one. Whether in the context of a prenatal visit or the brief post-delivery period before discharge from hospital, it is simply not reasonable to assume from mere distribution of a brochure that parents have appreciated the nature of newborn screening tests and the fact that these tests will be undertaken unless refused.

However, if the parents have been given information about the nature of the proposed newborn screening tests through discussion with a health care provider—or through a brochure, with an oral check that the parents have in fact read the brochure—and in addition, have been told in discussion that they have the right to refuse these tests, a more compelling case might be made for consent as a reasonable inference from absence of parental refusal. Nonetheless, we would again argue that it is not a reasonable inference. This is a more complex and contested position to defend.

Those who argue for an opt-out model on this basis may place particular emphasis on the innocuous nature of the procedure and tests in issue (e.g. the low risk of proceeding with the tests and the significant harm that may occur to a child if the test is not performed) as a basis for inferring that a parent who is aware of the proposed tests and the harms that the tests are intended to prevent, and is not objecting is in fact consenting. This argument might be made particularly in respect to tests for conditions such as PKU and hypothyroidism, where the benefits of testing are generally recognized as well-established and the risks of testing are generally regarded as insignificant.

But the issue is not the reasonableness of consenting per se (given the risks and benefits of the tests in issue), but whether a parent’s lack of refusal may legitimately be understood as indicating his or her consent. One response to the emphasis on the reasonableness of the inference given the low risk and potentially great benefit of testing is to consider the forms of counter-analysis that parents may contemplate. For example, given the inconsistency of practice between jurisdictions with respect to which tests are included in screening programs, parents might contemplate the risk that any particular jurisdiction’s list of “established” tests includes tests that are not adequate to the criteria of certainty of benefit or lack of harm. In particular, if testing is done for late-onset conditions with no clearly effective treatments, parents may contemplate the
risks of potential insurance and employment discrimination against those labelled as genetically deviant. Moreover, individual parents might consider, even with respect to the established tests, the remarkably low probability that their own child is in fact affected with the relevant disorder (i.e., approximately 1 in 14,000 will have PKU) and pose this probability over against the probability and risks of false positive results (suggested by some, for instance, to potentially interfere with the bonding process), or over against the potential harms of contravening their religious or other beliefs which may form a key part of familial identity.163

Yet even if a parent had such concerns, would it not be reasonable to expect that she or he would voice them in an objection if indeed she or he did not wish to consent? A second level of argument which responds more directly to the issue of the parent’s silence takes account of the growing emphasis in Canadian law on the imperative of developing the common law in accordance with Charter values— including in particular the value of autonomy (reinforcing the need to ensure under a battery analysis that consent is free and voluntary, and under a negligence analysis that consent is informed)—as well as the imperative of applying the law to any particular set of facts in a manner that is sensitive not only to that immediate factual context but also to the wider social and historical context shaping power relations or forms of disadvantage that may be at play in the case at hand.164 Thus the question of whether a reasonable inference of consent may be made in this context is one that must be broached with particular sensitivity to circumstances that may suggest that the parents’ silence and inaction may derive from causes other than consent, and may in fact indicate constrictions upon the free and voluntary exercise of parental decision-making.

Upon citing Fleming’s proposition that failure to resist or protest may indicate consent in certain circumstances, La Forest J., writing for himself and two others in the sexual battery case Norberg v. Wynrib (in which the trial judge had found implied consent and held that this consent was voluntary), first noted the legal qualification that consent, whether express or implied, may be vitiates by fraud, deceit, or force. He then extended the analysis of factors that may vitiate consent in the following statement:

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163 For arguments on the risks of PKU testing and other established screening tests, and the suggestion that determining what constitutes a “reasonable judgment” about consent to such tests may involve “disputed facts as well as conflicting principles,” see “Contesting Consent,” supra note 4 at 214, and see also Annas, supra note 159. The argument that false positives may interfere with the bonding process is canvassed in “Contesting Consent,” ibid. at 215 and in “Screening and Treatment of Newborns,” supra note 1 at 135.

In my view, this approach to consent [presuming voluntariness of an apparent consent unless it is vitiating by one of the following factors: force or threat of force, intoxication, or fraud or deceit as to the nature of the defendant’s conduct] in this kind of case is too limited. As Heuston and Buckley on the Law of Torts (19th ed. 1987) at pp. 564-65, put it: “A man cannot be said to be ‘willing’ unless he is in a position to choose freely; and freedom of choice predicates the absence from his mind of any feeling of constraint interfering with the freedom of his will.” A “feeling of constraint” so as to “interfere with the freedom of a person’s will” can arise in a number of situations not involving force, threats of force, fraud or incapacity. The concept of consent as it operates in tort law is based on a presumption of individual autonomy and free will. It is presumed that the individual has freedom to consent or not to consent. This presumption, however, is untenable in certain circumstances. A position of relative weakness can, in some circumstances, interfere with the freedom of a person’s will. Our notion of consent must, therefore, be modified to appreciate the power relationship between the parties.165

The reasons of La Forest J. then apply this insight through recourse to the doctrine of unconscionability as a means of vitiating consent (this requiring a power-dependency relationship involving inequality as well as exploitation). However, we would argue that the insight may also be applied to assist in the determination of whether consent can be legitimately inferred from silence in circumstances indicating some significant constraint upon a person’s will. We note in connection with this proposition that several courts, in assessing the reasonableness of finding implied consent to medical interventions, have emphasized that such an analysis must include an appreciation of all relevant circumstances surrounding the intervention.166

Consider, then, the circumstances of parents confronted with newborn screening practices. Following the jurisprudential emphasis on the importance of a contextual analysis, one may begin by contemplating the social and historical context shaping parents’ and health professionals’ attitudes to consent requirements and in particular attitudes to the parental authority to consent to or refuse medical treatment on behalf of their children. This context may be understood to comprehend a relatively recent historical progression from a more paternalistic model of the role of health professionals to the modern emphasis on autonomy.167 However, the paternalistic model arguably remains entrenched in the minds of many—patients, parents, and health care providers—when they are

165 Norberg v. Wynrib, supra note 136 at 246-47.
166 See, e.g., Allan v. New Mount Sinai Hospital, supra note 150 at 641; Toews (Guardian ad litem of) v. Weisner, supra note 150 at para. 19; and O’Brian v. Cunard S.S. Co., supra note 148 at 266.
faced with the prospect of medical intervention. It is arguable that the paternalistic model may be particularly entrenched where the intervention in issue is directed at an infant or child. Here it is notable that some of those writing on the issue of newborn screening have suggested that the state’s 

*parents patriae* power may justify screening without parental consent, without actual engagement of that power through the courts or through the effect of an Act of the legislature. We would suggest that, given the historical and psychological power of the model of paternalism in health care, the discrepancy in professional status between most parents and their health care providers, and the trend in hospital policies toward increased efficiency in the form of decreasing the time parents spend in hospital following delivery, new parents may be particularly vulnerable to the belief that decisions about the health care of their infants are simply out of their hands.

Turning to some of the more specific factual circumstances of parents confronted with the prospect of newborn screening, we note that it is most likely that before being presented with the relevant brochure or entering discussion about newborn screening with a health care provider, the vast majority of parents are unlikely to know anything at all about the newborn screening program in the province or territory. They are unlikely to know anything about which tests are included in a screening program or which conditions may be revealed by those tests, the procedures required for conducting newborn screening, the technology applied in newborn screening, or the implications of gaining health information from newborn screening. Furthermore, where this information is given only after the child is born (as we take to be a common practice), parents have just been through what has probably been a gruelling labour and delivery. Parents are in a vulnerable position not only in terms of information imbalance but also power—or at least perceived power—imbalance. They may fear that they will alienate their health care providers and thereby compromise the care of their newborn if they refuse. Finally, they are being told of a *mass* screening program, with the obvious implication that in the opinion of the medical profession and even the state all newborns should be screened and refusals are exceptional. All these factors considered, parents may feel that raising an objection is in essence disturbing the status quo, and so may not feel comfortable expressing a refusal. Those who wish to refuse may instead maintain a frustrated (or a confused) silence.

Therefore, considering the circumstances (as we are directed by the courts to do when determining implied consent), it is not reasonable to infer consent from an absence of parental refusal. It is important to be clear that we are not arguing that parents are not able to give a valid consent or refusal or to make an informed decision in the face of medical consensus about newborn screening or in the post-delivery context. Rather, we are arguing that silence is not a sufficient basis for an inference of consent given the circumstances, and

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conversely that a reasonable inference of consent would more properly be based in a situation where the decision has been presented to parents as a need to indicate “yes” or “no,” with neither of those answers characterized as a foregone conclusion. Our position is that in obtaining explicit consent, an emphasis is placed on informing the person with authority to consent as well as ensuring that he or she is aware of his or her authority. In the circumstances of newborn screening, relying on implicit consent (even where the opportunity to dissent is somehow conveyed) risks reducing the informational component and the awareness of authority component of consent to unacceptably low levels.

We conclude that the inferred-from-conduct form of implied consent is not a valid defence of mass newborn screening practices in Canada today. Instituting an opt-out policy for determining consent in a mass screening program risks a mass breach of the law on parental consent. In addition, such a policy leaves little room for sensitivity to particular cases in which, despite parental silence, the inference that consent is intended otherwise appears highly questionable. Given that the law in this area is so uncertain and the reasonableness of the inference in these circumstances is at least debatable, and further, given that there is little reason not to require explicit consent, we take the position that newborn screening programs should err on the side of getting explicit consent. In the alternative, those who oppose this should press for a legislatively-mandated non-voluntary screening program, so as to fit within the legislation exception to the consent requirement.

iii. Routine procedures

A further argument under the heading of “implied consent,” though not aligned with any generally-recognized principles in this area of law, would suggest that consent may be implied where the procedure in issue is recognized as a routine one. That is, it has been suggested that the routine nature of a procedure in itself serves as a justification for not obtaining explicit consent. This form of justification may be easily blurred with the justification from subsumed consent, as indicated in the following passage from the OLRC report:

“[u]nder this approach, the general consent signed upon admission, which covers all routine hospital procedures and practices, would be sufficient. . . . It remains for each jurisdiction to decide which treatable, metabolic disease would be considered routine.”

The question is whether newborn screening (for certain conditions designated by the medical authorities in a jurisdiction) may simply pass into the realm of incontestability on account of its being a form of routine procedure which is deemed advisable by medical authorities. The danger, it seems, in the argument from the routine nature of the treatment is that its efficacy may depend upon the relative invisibility of the practice and the relative agreement of the

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170 Ibid. at 182. The OLRC notes that in Québec, “a by-law of the Health Services and Social Services Act delegates to the Corporation of Physicians and Surgeons the power to decide which tests should be undertaken routinely in health establishments” (ibid. at 182, n. 118, and see note 37, supra).
medical community as to its advisability, without attention to the disposition or values, or potential reasonable disagreement, of the patient (or, where relevant, parent). This is clearly in contrast to statements from the Supreme Court of Canada on the lack of authority on the part of the medical community to unilaterally determine the scope of the duty of disclosure.171 Concerns may be raised, too, about the consequent likely inaccessibility of information about which procedures have been deemed routine (i.e. whether Huntington’s, or cystic fibrosis, or any of a number of other conditions which may not meet the criteria of early-onset, treatable diseases have been included among routine screening tests), and the related inability of the public or individuals to challenge potentially harmful or unjustifiable forms of intervention that may be routinely undertaken.

iv. “Reasonable” consent

Another argument which has been raised in connection with the doctrine of implied consent, though the appropriateness of the connection may be questioned, would suggest that parental consent to newborn screening tests may be inferred where there can be no reasonable disagreement about the propriety of those tests.172 We have challenged a variation on this argument above, in discussing inferred-from-conduct consent and the inference to be drawn from parental silence. There, we suggested that one might question the claim that consent is the most reasonable inference from parental silence because there can be no reasonable disagreement about the innocuous nature (the very low risks and great potential benefits) of established newborn screening tests. We noted that parents may in fact contemplate a variety of risks in connection with newborn screening that could give rise to reasonable disagreement, or in any case, parental dissent, in respect to the propriety of undergoing the tests. Here, in response to a variety of implied consent that would rest the inference of consent merely on the alleged reasonableness of testing, without further attention to circumstances, we would direct the reader back to the legal framework we have set out above, and particularly the section on limitations on parental decision-making authority. There we suggested that while “unreasonable” parental decisions may be overridden by the courts through an exercise of their parens patriae jurisdiction, this jurisdiction is limited to the courts (or alternatively, as also noted above, the state may assume “parental” authority over children through the effect of an Act of the legislature).

171 See Reibl v. Hughes, supra note 103 at 894.

172 For instance, Faden et al. in their 1982 article “Parental Rights, Child Welfare, and Public Health: The Case of PKU Screening” (1982) 72:12 Am. J. of Public Health 1396, argue that parental consent to newborn screening need not be sought, given that there is no room for reasonable disagreement or for an exercise of judgment on the issue of whether or not screening (for such disorders as PKU and hypothyroidism) is in an infant’s best interests (at 1397). In addition, Norman Fost, in “Genetic Diagnosis and Treatment: Ethical Considerations” (1993) 147 Am. J. of Diseases in Children 1190 (ultimately arguing against implied parental consent for newborn screening at 1191-92) poses the conditions for implying consent in terms of whether there is an “obvious” low-risk high-benefit ratio: “[i]mplied consent refers to common, simple, low-risk interventions for which the risks and benefits are so obvious as to not require an explicit agreement” (at 1191). Fost adds: “[t]he discomforts and risks of venipuncture in an adolescent would be an example” (ibid.).
One need only consider the example of the refusal of a non-emergent but life-saving blood transfusion by a Jehovah’s Witness parent on behalf of his or her child to see why a reasonableness standard applied by health care providers cannot be correct in law as the basis for overriding a parental refusal of testing. The Supreme Court of Canada has clearly stated that in such cases, courts should exercise the *pars patris* power and override a parental refusal. However, the presumption of parental authority still applies, and health care professionals faced with a parental refusal of a non-emergent but life-sustaining blood transfusion must still go to court in order to proceed and treat the child in compliance with the law. Given that health care providers may not treat (without first obtaining a court order) even in such situations in which a parent’s refusal would be considered by many or most health care professionals to be clearly unreasonable, we see no valid legal basis for the position that consent to newborn screening should be simply implied, and so not explicitly sought, where a refusal would similarly be deemed unreasonable.

In short, under Canadian law, parents are allowed, at least in the first instance, to make unreasonable decisions about the medical care of their children. However, there are mechanisms for challenging those decisions in court. The reasonableness argument may well have some legal force in a courtroom – but it is in the courtroom, and not in the hands of health care professionals as such, that the force of such an argument must be determined. Consent must be sought despite the fact that it may ultimately be overridden by an exercise of the court’s *pars patris* jurisdiction.

c. Arguments from impracticality

i. Too complex

A further variation on the arguments against requiring informed parental consent before proceeding with newborn screening tests focuses on the complexity and associated impracticality of implementing informed consent practices in this context. In particular, this concern arises in connection with the informational component of obtaining parental consent, given the variety and complexity of disorders that may be targeted in a battery of screening tests.

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174 The informational component of any informed consent process will be key to the adequacy of the consent obtained. One study indicating a failure to communicate the nature or purpose of screening tests arises out of the British experience. A letter to the British Medical Journal from representatives of the Centre for Family Research, Social and Political Sciences Faculty at Cambridge (H. Statham et al., “Mothers’ consent to screening newborn babies for disease” (1993) 306:6881 B.M.J. 858) describes a 1993 Cambridge study which found that most of 1397 women canvassed six weeks after delivery knew that neonatal screening tests had been performed on their infants, and most responded that the nature and purpose of the tests had been explained to them or that they “knew it already.” However, “the extent to which women thought that they were informed was not reflected in the answers to a question about which disorders this blood sample was tested for.” Only 45% of the sample correctly identified PKU as one of the conditions tested for, and only 20% identified hypothyroidism. A majority of the women living in districts where cystic fibrosis was
That is, the objection may be raised that the information that must be transmitted to obtain a significant informed consent in this context is too voluminous and too complex to be transmitted efficiently and with any real hope of achieving understanding on the parent’s part. At least two arguments may be made in response to this objection: first, an argument from data; and second, an argument by analogy.

First, the argument from data. The Maryland precedent suggests that the complexity objection is invalid. In their 1983 article “Effect of Informed Parental Consent on Mothers’ Knowledge of Newborn Screening”, N. Holtzman et al., sought to assess the knowledge of mothers who had been taken through a process of informed consent prior to newborn screening. The study was conducted in seven Maryland hospitals, which had recently included informed consent processes in their newborn screening programs in response to new consent requirements under state regulations respecting genetic screening.

The disclosure statement in issue in that study was a standard one used in all Maryland hospitals with obstetric services and provided by the Maryland Department of Public Health. It had a tenth-grade readability level, and included information on:

(1) the conditions for which screening was available (PKU, hypothyroidism, branched chain ketoaciduria, homocystinuria) and that they caused mental retardation and were usually inherited; (2) the treatments and their ability to usually prevent retardation; (3) the procedure (heel prick) and that it had been performed without complication in more than .5 million infants in Maryland.

included in the screening battery did not identify this as one of the conditions for which their infants were tested. The study therefore suggested that “[m]ost new mothers do not know what the Guthrie test is for: a considerable number incorrectly believe that it will detect more disorders than is the case.” The letter concludes: “[t]hese results clearly challenge any notion that women are giving informed consent for their babies to be tested, even though they believe themselves to have been informed.”

Another example of concerns with respect to informing parents about screening through informed consent practices – this time where no attempts appear to have been made to inform – is provided from Bulgaria, where newborn screening for PKU began in 1978. L. Kalaydjieva & I. Kremensky, (in their article “Screening for phenylketonuria in a totalitarian state” (1992) 29 Journal of Medical Genetics 656) reported of that country’s program (at 657):

The informed consent of parents has never been regarded as a mandatory component of a successful screening program and the laboratory has seen many families where a positive screening result came as an unexpected shock. The lack of public awareness and support also resulted in some parents refusing their permission for a repeat test, in excessive undue concern caused by borderline phenylalanine values or in lack of compliance with dietary treatment. This was often aggravated by the unwillingness or inability of local physicians to provide a reasonable explanation to the families, both because physicians themselves were not sufficiently well informed and because engaging in a dialogue is not part of the traditional authoritative role of the doctor.

176 Ibid. at 807.
Further, “[t]he disclosure cautioned that a positive test did not mean that the baby was affected, but that additional studies were needed to establish a diagnosis.” The brochure also “warned that the test could miss infants with these conditions if they were screened early in life and recommended repeat screening.”

The authors of the study, on reviewing the responses of new mothers about the state’s newborn screening program, concluded that their findings dispelled “doubts expressed by professionals that mothers’ knowledge of an indicated but innocuous procedure can be improved by a consent process that involves only the provision of a simple written explanation.” Rather, “[d]espite its limited nature, the consent intervention was able to increase significantly mothers’ ability to recall spontaneously information in four of seven content areas.”

Consider now the argument by analogy. Imagine that, as part of her reproductive planning, a woman appears at a genetics clinic seeking genetic testing to determine whether she is a carrier of Tay Sachs disease. Despite the complexity of genetic testing, she is told about the potential risks and benefits of testing and her consent is sought prior to the testing. One year later, this same woman appears on the labour and delivery floor of the local hospital. On the grounds of the complexity of genetic testing, she is not told about the potential risks and benefits of testing and her consent is not sought prior to the testing of her newborn. The complexity remained the same and yet the approach taken to consent was different.

The complexity of genetic testing is not used to justify not seeking consent from adults to genetic testing for themselves. It therefore should not be used to justify not seeking consent from adults to genetic testing for their children. The solution is to find ways to convey complex information in such a way that individual decision-makers understand the nature and consequences of the decision they are being asked to make.

ii. Too costly

An additional argument from impracticality may be based in the costliness of instituting a requirement of informed parental consent to newborn screening tests. However, as suggested above, the Maryland model, when evaluated in 1982, deployed a combination of prepared materials and direct nursing attention in a manner that apparently did not make significant time demands on staff.

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177 Ibid. at 807-808.
178 Ibid. at 811, and see Table 3 at 810 for the specific questions and breakdown of responses.
180 “A Survey to Evaluate Parental Consent,” supra note 27 at 1350: “[i]n general, the costs of compliance in terms of staff time were negligible.”
The same study determined that the “cost” of requiring consent did not include decreased numbers of infants tested (with the corresponding threat of increased numbers of undetected disorders).\textsuperscript{181}

We have located no evidence that would indicate that the costs of obtaining informed consents or refusals from parents in this context would be significant or in any case so significant as to outweigh the legal imperatives reviewed above. In the absence of such evidence, such an important principle as respect for autonomy (expressed here through the fostering of informed parental decision-making) should not be breached.

Furthermore, consent cannot be inferred on the basis of efficiency or expediency. As noted by Justice Smith in \textit{Toews (Guardian ad litem of) v. Weisner}:

To some extent the defendants based their argument on efficiency and expediency – on the need for public health officials to be able to conduct immunization programs on children who are sometimes eager to avoid the procedure. I accept that it is necessary to recognize the need for efficiency in carrying out these important public health immunization programs... Nevertheless, health care providers must always respect the fundamental principle that all individuals control access to their own bodies. Individuals may give but then withdraw consent. When the individual is a child, it is the parent who gives or withholds consent.... Inconvenient though it may have been, Ms. Weisner should have checked with a parent before going ahead with the immunization.\textsuperscript{182}

Even if it were very expensive to get informed consent to newborn screening, it is for provincial legislatures, not health care providers, to mandate justified instances of breach of the rule of informed consent. There are many times when health care providers find seeking consent to be very costly and yet we would not want them ignoring the core consent requirement of the law. A widespread practice of breaching the rule of informed consent should only be tolerated where the practice has been subject to the reflection of elected officials and where the resultant policy or legislation can be subject to challenge by the public, for example, through a \textit{Charter} challenge.

D. Conclusion

From the above review of the arguments for and against requiring explicit parental consent to newborn screening, we conclude that the legally defensible way to proceed is to require explicit parental consent, or introduce legislation lifting the consent requirement in these circumstances. We have found no

\textsuperscript{181} \textit{Ibid.}

\textsuperscript{182} \textit{Supra} note 150 at paras. 23-24.
applicable exceptions to the requirement of consent in this context, and no circumstances upon which to base a convincing argument for implied consent.

In sum, informed parental decisions about the propriety of newborn screening cannot be dispensed with or overridden except by court order or by legislation, which would be subject to review under the Charter of Rights and Freedoms. Further, parental consent to newborn screening cannot be implied in or inferred from the circumstances or presumed reasonableness of newborn screening, and specifically cannot be inferred from a parent’s consent to routine newborn care or from the absence of a refusal of the tests.

Therefore, the taking of the heel prick blood sample and screening of that blood sample in the absence of explicit parental consent arguably constitutes a battery of the child. Moreover, even where explicit parental consent is obtained, a further legal duty remains on the part of the health care provider to ensure that the parents’ consent is informed in respect to any material risks (as well as any remote risks of particularly serious or deleterious harm) introduced by the screening tests.

Health care providers should therefore adjust their practices and health care institutions should adjust their policies to be in accord with current Canadian law. Parents should be informed about newborn screening tests and the attendant risks of those tests, and approached for explicit consent to the tests. If they refuse and the health care team believes the screening to be in the best interests of the newborn, then the health care team should seek an order to screen from the court. If health care providers and institutions wish not to have to do this, they should lobby provincial and territorial governments to enact legislation (or regulations under the relevant hospital standards legislation) to exempt a specified set of disorders included in screening batteries from the common law requirement of explicit parental consent. Practice will thereafter be legally defensible, provided the legislation is consistent with the Charter, and approaches to new forms of genetic and metabolic testing made possible by recent technological developments can then be built upon a solid foundation.