

COMPLICATING THE DISTINCTION BETWEEN THE REQUIREMENT AND
RECOMMENDATION-BASED CHILDHOOD VACCINATION PROGRAMS THROUGH
THE LENS OF VOLUNTARINESS

by

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For my parents,
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ABSTRACT

The thesis analyzes the requirement-based childhood vaccination programs of Ontario, New Jersey and the recommendation-based programs of UK and Australia. It complicates the *prima facie* distinction between the requirement and recommendation-based programs by applying the common law requirement of the voluntariness of consent to the vaccination programs. In particular, the voluntariness light is shone on the nature of the “requirement” and “recommendation” to vaccinate distinction; exemptions from the requirement to vaccinate; the choice to refuse vaccination; and financial incentives to doctors and parents. The thesis concludes that on a spectrum of “most voluntary” to “least voluntary,” the aforementioned programs would be located close to each other in terms of actual, practical presence of voluntariness, demonstrating the complexity of the dichotomy between the requirement and recommendation-based vaccination programs.

LIST OF ABBREVIATIONS USED

MIA -- Maternity Immunization Allowance

MMR -- Measles, mumps and rubella vaccine

MMRV-- Measles, mumps, rubella and varicella vaccine

UK -- United Kingdom

WHO -- World Health Organization

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CHAPTER 1. INTRODUCTION

1.1 Introduction

This thesis explores two matters – childhood vaccination programs and consent to treatment. The vaccination programs and the notion of informed consent have been heavily researched in the literature. However, the research in this thesis lies at the intersection of vaccination programs and the voluntariness of consent. In particular, I challenge the dichotomy between the requirement and recommendation based programs. To do this, I look at the childhood vaccination programs implemented in Ontario, New Jersey, United Kingdom (UK) and Australia through the prism of the common law foundations of the voluntariness of consent in Canada.

1.2. General Overview

Routine childhood vaccination is a medical intervention. It has policy, legal, ethical, social and public health implications. The manifold implications of vaccination could be explored via the question posed by the World Health Organization, namely, “why are vaccines so special?”¹ The answer enumerates several reasons. First, vaccines promote health and save lives. Due to vaccination, smallpox, which killed 300 million people in the 20th century alone, has virtually disappeared from the world,² and the incidence of many more infectious diseases has been reduced significantly.³ Every year, childhood vaccination prevents more than 2.5 million

¹ World Health Organization, *Vaccine-Safety Training*, online: WHO <<http://www.vaccine-safety-training.org/Importance-of-immunization-programmes.html>> [WHO].

² Public Health Agency of Canada, *Smallpox*, online: Public Health Agency of Canada <<http://www.phac-aspc.gc.ca/ep-mu/smallpox-eng.php>>.

³ During the last 200 years, vaccination succeeded in controlling a number of major diseases: smallpox, diphtheria, tetanus, yellow fever, polio, measles, mumps and rubella. See Lisa Miller & Joni Reynolds, “Autism and Vaccination-The Current Evidence” (2009) 14 JSPN 166 at 169.

child deaths.⁴ With the exception of safe water, nothing else, not even antibiotics, has had such a major effect on the reduction of mortality (deaths), and morbidity (illness and disability).⁵

Vaccines have an expansive reach and rapid impact.⁶ In other words, vaccination offers immediate protection to communities and nations, especially where strategies are adopted to make it accessible even to hard to reach populations.⁷ Yet, as a public health intervention, vaccination is controversial.⁸ This is first because safety concerns arise in regards to old, as well as newly introduced vaccines. Second, because often times vaccines are mandated, their coercive nature contributes to the “special” status that the programs hold among other public health interventions.⁹

Vaccines are administered as part of vaccination programs. For instance, in Canada, each province has its own childhood vaccination program which includes a set of routine vaccines, such as for measles, mumps, rubella and varicella, diphtheria, polio, and hepatitis B.¹⁰ As a preventative intervention, vaccination programs are implemented under the auspices of public health and, therefore, public health legislation and policy. Thus, the nature of vaccination programs can be partly explained through the notion of public health. But participation in this public health exercise bears on individual consent to do so. These two concepts are basic to the problem this thesis explores, and they are briefly discussed next.

⁴ World Health Organization, United Nations Children's Fund (UNICEF), World Bank, *State of the world's vaccines and immunization*, 3rd ed (Geneva: WHO, 2009), online: <http://whqlibdoc.who.int/publications/2009/9789241563864_eng.pdf>.

⁵ SL Plotkin & SA Plotkin, "A short history of vaccination" in S Plotkin, W Orenstein & PA Offit, *Vaccines*, 5th ed (Philadelphia: Saunders, 2008) at 1-15.

⁶ WHO, *Vaccine-Safety Training*, *supra* note 1.

⁷ World Health Organization, Health Topics, Immunization, online: World Health Organization <<http://www.who.int/topics/immunization/en/>>.

⁸ College of Physicians of Philadelphia, Vaccines and Society, online: History of Vaccines <<http://www.historyofvaccines.org/content/timelines/vaccines-and-society>>.

⁹ *Ibid.*

¹⁰ Alberta Health, Types of Vaccines for Diseases, online: Alberta Health <<http://www.health.alberta.ca/health-info/imm-types-of-vaccines.html>>.

1.3. Underlying Concepts

One of the many definitions of public health regards it “as the science and art of promoting health, preventing disease, prolonging life and improving quality of life through the organized efforts of society”.¹¹ Public health is concerned with promoting the health of a population that “can be achieved only through collective action and not individual endeavour.”¹² Indeed, public health deals with those concerns that individuals would not be able to deal with by themselves, nor organize, nor achieve, since when acting alone, individuals cannot ensure communal health.¹³ For instance, communicable diseases, environmental protection, food and water safety are the concerns that have traditionally come under the umbrella of community efforts.

To accomplish the goal of maintaining the health of a population, public health relies on public health law and policy as its instruments. One of the influential definitions of public health law offered by Lawrence Gostin claims that

Public health law is the study of the legal powers and duties of the state, in collaboration with its partners (e.g. health care, business, the community, the media, and academe), to ensure the conditions for people to be healthy (to identify, prevent and ameliorate risks to health in the population), and of the limitations on the power of the state to constrain for the common good the autonomy, privacy, liberty, proprietary, and other legally protected interests of individuals.¹⁴

In this definition, Lawrence Gostin introduces five essential characteristics of public health law: the responsibility of government; the health of populations; the relationship between

¹¹ National Advisory Committee on SARS and Public Health, *Learning from SARS: Renewal of Public Health in Canada* (Ottawa: Health Canada, 2003) (Chair: Dr. David Naylor) at 66.

¹² Lawrence O Gostin, *Public Health Law: Power, Duty, Restraint* (New York: Milbank Memorial Fund, 2000) at 7.

¹³ LO Gostin & KG Gostin, “A Broader Liberty: J.S. Mill, Paternalism and the Public’s Health” (2009) 123 *Public Health* 214 at 219.

¹⁴ *Public Health Law: Power, Duty, Restraint*, *supra* note 12 at 4.

the government and the populace; services to promote the public's health; and the power to coerce individuals and business for the community's protection.¹⁵

The last characteristic of public health law -- the use of coercive power -- that has been said to cause controversies around vaccination, relates to limiting liberties in order to attain the common good. The use of coercive power is justified by the role and importance of community in the individual's life, and the interrelation between the health of an individual and public health, especially in cases of infectious diseases. Still, a community is composed of individuals who are entitled to values and rights, including the right to choose freely. Consequently, there is a clash between the people as parts of communities versus the premium placed on individual autonomy and thus free, voluntary choice.

In Western countries, it has long been established in law and ethics that individuals should generally be able to make decisions about their health care in accordance with their wishes.¹⁶ In health care, consent is the capacity a person has to exercise autonomy and self-determination by "authorising what happens to them and who touches them".¹⁷ The common law foundations of consent require consent to be given voluntarily by somebody who is capable and informed.¹⁸

Vaccination could be viewed as both a public and individual good. As a public health measure, it could be implemented in response to an emergency or crisis, as well as a routine intervention to prevent an outbreak of infectious diseases.¹⁹ Non-routine vaccinations are outside the scope of this thesis. The problem considered is the intersection of the public health values of

¹⁵ Lawrence O Gostin, "Public Health Law in a New Century – Part I: Law as a Tool to Advance the Community's Health" (2000) 283 *Journal of the American Medical Association* at 2837.

¹⁶ J Leask J, A Braunack-Mayer & I Kerridge, "Consent and public engagement in an era of expanded childhood immunisation" (2011) 47:9 *J Paediatr Child Health* at 603.

¹⁷ *Ibid.*

¹⁸ Patricia Peppin, "Informed Consent" in Jocelyn Downie, Timothy Caulfield & Colleen M Flood eds, *Canadian Health Law and Policy*, 4 ed (Markham: LexisNexis, 2011) at 155.

¹⁹ *Emergencies Act*, RSC 1985, c N-5 s 126. *Quarantine Act*, RSC 1985, c Q-1 s 8.

routine childhood vaccination with the individual values that underlie consent. This problem is now explained.

1.4. Identifying the Problem

The tension between individual and collective values in childhood vaccination programs in Canada arose with their very first implementation at the end of the 19th century.²⁰ Among other reasons, the requirement to be vaccinated for smallpox in order to attend school caused resistance to smallpox vaccination.²¹ Since that time, vaccination programs expanded and have been the most effective weapon for the control of infectious diseases in Canada (and worldwide). But contemporary vaccination programs present a series of challenges to the values of consent.

The mass, routine delivery of the programs carries complications for an individual-oriented notion of consent to vaccination. It is claimed that vaccination programs have a “very dynamic environment”²² for ensuring consent. In particular, the increasing volume of information on vaccinations²³ and the busy atmosphere of public health clinics or family physicians’ offices present difficulties for ensuring that the information aspect of the consent requirement is adequately met for the patient’s benefit.²⁴ According to policy officials and scholars, even more problematic is the obligatory nature of vaccination programs (so-called mandatory programs), which require vaccination and, therefore, eliminate the voluntariness of consent to it.²⁵

To avoid this tension between what is held as both a public and individual good, one commentator suggests that all public health interventions should be exempted from the

²⁰ Katherine Arnup, “Victims of Vaccination? Opposition to Compulsory Immunization in Ontario, 1900-90” (1992) 9:2 *Canadian Bulletin of Medical History* 159 at 160.

²¹ *Ibid.*

²² J Leask et al, *supra* note 16 at 604.

²³ *Ibid.*

²⁴ *Ibid.*

²⁵ This point will be expanded on in Chapter 5.

requirement of consent for the purpose of attaining public health program objectives.²⁶ Onora O’Neill argues that individual choice should not be allowed to undermine public health goals.²⁷ Others see the non-availability of choice in vaccination programs as a given and argue that vaccination policies should focus on the information aspect of consent which, according to Wendy Parmet, will “provide individuals and communities with the respect and knowledge necessary for their acceptance and support of public health procedures”.²⁸ Therefore, increasing emphasis is placed on the information component.²⁹

Finally, some contend that a strong case can be made in law and ethics for implementing only voluntary vaccination programs which recommend vaccination rather than require it.³⁰ Vaccination programs which recommend vaccination (so-called voluntary programs are considered to be in compliance with the common law and ethics foundations of consent, and are inherent in requirement-based programs (so-called mandatory programs).

1.5. Thesis Objective

The views of academics on the compatibility of consent with vaccination programs, which are briefly set out in Section 1.3., are grounded in the theoretical underpinnings of consent and public health. Their analysis has concentrated solely on specific elements of vaccination programs (i.e., the recommendation to vaccinate *per se*) in isolation from the program as a whole.

²⁶ O’Neill, “Some limits of informed consent” (2003) 29 J Med Ethics at 4-5. O’Neill, “Informed Consent and Public Health” (2004) 359: 1447 Philos Trans R Soc Lond B Biol Sci at 1133.

²⁷ *Ibid*

²⁸ Wendy E Parmet, “Informed Consent and Public Health: Are They Compatible When It Comes to Vaccines?” (2005) 8:1 J Health care L & Pol’y 71 at 107.

²⁹ This may necessitate changes both in the content of the disclosures (e.g., inclusion of public health risks and benefits) and the location of the disclosures (e.g., moving from the individual clinical setting to the community level). See Jessica Berg, “All for One and One for All: Informed Consent & Public Health” (2012) 50:1 Houston Law Review at 39.

³⁰ D Isaacs, HA Kilham & H Marshall, “Should routine childhood immunizations be compulsory?” (2004) 40:7 Journal of Paediatrics & Child Health 392-396. Richard Griffith, “Immunisation and the law: Compulsion or parental choice?” (2003) 18:10 Nursing Standard at 39-41. P Bradley, “Should childhood immunisation be compulsory?” (1999) 25:4 Journal of Medical Ethics at 330.

Therefore, proposed solutions to the tensions between consent and vaccination programs have emphasized the value of the information element of consent. Also, some have suggested that vaccination programs that require vaccination and thwart the voluntariness of consent should be replaced by recommendation-based programs which, it is claimed, respect voluntariness.

My research has not identified academic analysis of current requirement or recommendation-based childhood vaccination programs in terms of their correspondence with the voluntariness element of consent, which could be utilized to inform solutions for the tensions between the common and individual good. Therefore, in this thesis, I explore the correspondence between the childhood vaccination programs and consent with a focus on the voluntariness of consent. I aim to complicate the *prima facie* distinction between the requirement and recommendation-based vaccination programs by exploring how voluntariness is exercised in practice in the vaccination programs of the four common law jurisdictions. To do this, I apply the requirement at common law of the voluntariness of consent, to the requirement-based childhood vaccination programs of New Jersey and Ontario, and to the recommendation-based programs of Australia and UK.

The rationale for selecting the four jurisdictions, as well as the vaccine I focus on, is explained next.

1.6. The Selected Vaccination Programs

There are four programs under scrutiny in this thesis. Two programs -- Ontario and New Jersey -- have been selected for being requirement-based and two other programs -- UK and Australia -- for being recommendation based. As well, the vaccination models studied are instituted in common law jurisdictions, where the notion of consent has had similar patterns of development, in comparison to civil law countries where the notion of consent is shaped and

applied differently. In this sense, the criteria I use to analyze the voluntariness of consent in the vaccination programs implemented in the four jurisdictions are essentially similar.

Since I review the programs from the perspective of the Canadian law on consent, vaccination policies in Canada are the point of departure for the choice of vaccination programs. I first consider the requirement-based programs, since they are viewed to be less favorable to the right of consent. Three jurisdictions in Canada legislated the requirement to vaccinate children for school and day care admission and attendance: New Brunswick,³¹ Manitoba³² and Ontario.³³ The vaccination program in Manitoba requires vaccination only against measles for day care and school admission.³⁴ Given that programs worldwide require vaccinations, at least, against measles, mumps and rubella in one vaccine, it is not possible to find programs to compare Manitoba with. For this reason, it is excluded. New Brunswick and Ontario have similar vaccination policies and posit the requirement to vaccinate against the same set of diseases. However, Ontario appears to be more suitable for this review, since more studies have been done on the Ontario vaccination program which provides insights into the way the program works.³⁵

The New Jersey, UK and Australia vaccination policies are selected based on their differences when compared to the program of Ontario. Ontario is a requirement-based vaccination program with exemptions. The vaccination program in New Jersey is also requirement-based, but it differs from Ontario in terms of the exemptions it offers. Both Australia and the UK have recommendation-based programs that implement financial incentives. However, in the UK, the program offers incentives to doctors, whereas in Australia, parents receive

³¹ *Reporting and Diseases Regulation*, NB Reg 2009, 136 ss 12 (1-3).

³² Man Reg 388/88, s 24 (1).

³³ *Day Nurseries Act*, RRO 1990, Reg 262 s 33 (1). *Immunization of School Pupils Act*, RSO 1990, C 1(1) s 6.2 (1).

³⁴ Man Reg 388/88, s 24 (1).

³⁵ New Brunswick, Department of Health, *Policy 2.10 - Required Immunization for Children Attending Daycare* (September 2013), online: The Government of New Brunswick <<http://www2.gnb.ca/content/dam/gnb/Departments/h-s/pdf/en/CDC/HealthProfessionals/NBIPG-policy2-10-e.pdf>>.

immunization-related benefits. Altogether, the four programs represent four different vaccination models that fall under the “recommendation” and “requirement” categories, and this makes them suitable for comparison.

1.7. The Selected Vaccine

A discussion of vaccination programs is based on the Measles, Mumps, and Rubella (MMR) and Measles, Mumps, Rubella and Varicella (MMRV) vaccines. The MMR vaccine is a mixture of the attenuated viruses against three or four diseases administered via one injection. MMR is required or recommended for 12 month old children and a second dose of the MMR plus Varicella vaccine is required/recommended when a child is 4-6 years old.³⁶ In Ontario, MMR was given in two doses. In 2007, the MMRV vaccine was approved and replaced the second dose of the MMR.³⁷ MMRV was also approved and added to the vaccination schedules in Australia and the US.³⁸ This replaced the second dose of the MMR and Varicella vaccines.³⁹ The UK has

³⁶ Ontario, Ministry of Health and Long-term Care, *Publicly Funded Immunization Schedule for Ontario* (August 2011), online: Ministry of Health and Long-term Care

<<http://www.health.gov.on.ca/en/public/programs/immunization/docs/schedule.pdf>>.

³⁷ MMRV was approved for use in Canada in 2007. See Ontario, Ministry of Health and Long-term Care, “Measles-Mumps-Rubella-Varicella Vaccine Programme” (July 2011), online: Ministry of Health and Long-term Care <http://www.health.gov.on.ca/en/pro/programs/immunization/docs/qa_mmr.pdf> at 1.

³⁸ In 2005, MMRV was approved in the US. See US, Centers of Disease Control and Prevention, Vaccine Safety, MMRV, online: Centers of Disease Control and Prevention

<http://www.cdc.gov/vaccinesafety/Vaccines/MMRV/MMRV_qa.html>.

From 1 July 2013, the MMRV vaccine was added to the vaccination schedule in Australia. See Australia, Department of Health, Immunize Australia Program, MMRV, online: Australian Government

<<http://www.health.gov.au/internet/immunise/publishing.nsf/Content/immunise-MMRV-Vaccine>>.

³⁹ In Ontario, only MMR is required but the second dose of the MMR is given only in combination with the varicella vaccine. See *Publicly Funded Immunization Schedule for Ontario*, *supra* note 36.

New Jersey, requires MMR and Varicella. See New Jersey Department of Health and Senior Service, *Age-appropriate Vaccinations for Licensed Child Care Centers/Pre-Schools*, online: New Jersey Department of Health and Senior Service <http://www.state.nj.us/health/cd/documents/age_vac.pdf>. In Australia, MMR/MMRV was included into the schedule for 18 months - 4 years old children. See Australian Government, Department of Human Services, Current Immunisation Schedule, online:

<<http://www.medicareaustralia.gov.au/provider/patients/acir/schedule.jsp>>.

not introduced the MMRV vaccine yet, so the second dose of MMR and Varicella vaccines are administered separately.⁴⁰

The implications of the MMR (V) vaccine for the purpose of this thesis are the following: the discussion of the policies is centered on children who are 12 months – 6 years old. This means that the timeline includes entrance to a day care or school, and the restrictions on school attendance if an immunization record is not updated with the second dose of the MMR (V) vaccine when a child is four-six years old. Moreover, as more fully discussed later in this thesis, children up to six years old lack capacity to consent to treatment. Therefore, the vaccination of children up to six years old implies a discussion of parental consent to vaccination.

1.8. Terminology

In this thesis, I use the terms “immunization” and “vaccination”; and “immunize” and “vaccinate”. Immunization is “the process by which a person or animal becomes protected [immune] against a disease through an enhancement of their immune response.”⁴¹ Vaccination “is a form of immunization”⁴² which is the “introduction into an organism of a material designed to provoke an immune response that will provide protection from a related disease agent”.⁴³ Though the meaning of the terms are not exactly the same, WHO, some policy makers and commentators use them interchangeably.⁴⁴ I too will use the terms “vaccination” and

⁴⁰ United Kingdom, National Health Services, The NHS Vaccination Schedule, online: NHS <<http://www.nhs.uk/Conditions/vaccinations/Pages/vaccination-schedule-age-checklist.aspx>>.

⁴¹ World Health Organization, United Nations Children's Fund (UNICEF), World Bank. State of the world's vaccines and immunization, 3rd ed (Geneva: WHO, 2009)

⁴² *Ibid.*

⁴³ A Project of The College of Physicians of Philadelphia, The History of Vaccines, Glossary of Terms, online: The History of Vaccines <<http://www.historyofvaccines.org/glossary>>.

⁴⁴ World Health Organization, Immunization, online: <<http://www.who.int/topics/immunization/en/Australian/>>. Government, Department of Health, Frequently Asked Question about Immunisation, online: Australian Government <<http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/faq#2>>. Robert M Wolfe & Lisa Sharp, “Vaccination or Immunization? The Impact of Search Terms on the Internet” (2005) 10:6 Journal of Health Communication: International Perspectives at 537.

“immunization”, “vaccinate” and “immunize” interchangeably, in keeping with their prevalence in the sources I relied on.

In addition, since the programs are analyzed in the light of the voluntariness of consent, to avoid confusion in the discussion of the four programs, I differentiate programs that *require* vaccination (so-called mandatory programs), from those that *recommend* vaccination (so-called voluntary programs). The use of the words “voluntary” and “mandatory” in relation to the programs is dropped to avoid confusion when the voluntariness of consent is considered in relation to the vaccination programs.⁴⁵

Also, I avoid the use of the “opt in/opt out programs” terminology that is sometimes employed to refer to vaccination programs. “Opt in” programs recommend a treatment, whereas “opt out” ones require a certain treatment but allow exemptions.⁴⁶ In the literature, “opt out” programs are tied to the notion of presumed consent in the context of organ donation or biobank research. For instance, it is claimed that an “opt out” system is “(t)he system by which consent to donate is presumed unless a person has expressly indicated otherwise during his/her lifetime”.⁴⁷ This link between opt out and presumed consent is not applicable to childhood vaccination programs. In childhood vaccination programs, in general, children will not be vaccinated if parents do not refuse, unlike in the aforementioned example where the failure to refuse equals assent. So, to avoid misperception, I refer to the vaccination programs as *recommendation* and *requirement*-based programs.

⁴⁵ The term is only used in the quotes in Chapter 4.

⁴⁶ This distinction might also cause some confusion, since a recommended/opt in vaccination program I discuss in this thesis has exemptions which make it an opt in/opt out program.

⁴⁷ Ontario, Ministry of Health and Long-Term Care, *Report of the Citizens Panel on Increasing Organ Donations* 2007, online: Legislative Assembly of Ontario <<http://www.ontla.on.ca/library/repository/mon/17000/272129.pdf>> at 34.

1.9. Roadmap

This thesis applies voluntariness as an element of consent to childhood vaccination programs. As children up to six years old are not capable of giving consent, Chapter 2 considers whether parents are the appropriate parties to consent to vaccination. If parents do not have decision-making authority as regards their children in relation to vaccination, the vaccination decision would be taken by the state. The discussion in this chapter is centered on the scope of parental liberty, which is a protected sphere of parental-decision making.

Chapter 2 begins by briefly discussing the capacity to give consent, and then turns to parental liberty as the underlying reason for parents' authority to give consent. This is followed by an exploration of the mechanisms by which the state can intervene to override parental refusal of treatment: the use of *parens patriae*; child in need of protection; and intervention in cases of parental disagreement. A review of cases on state intervention in the exercise of parental liberty leads to the conclusion that parents hold decision-making authority regarding routine vaccination of their children. It follows that this decision-making authority must be exercised on a voluntary basis.

Chapter 3 explores the basis of the voluntariness of consent to set the stage for analysis of the vaccination programs. The first focus of this Chapter relates to battery, followed by a consideration of voluntariness as an element of consent in terms of the availability of choice as well as influences that can infringe the voluntariness of consent. The constraints on choice are discussed under the umbrella of "undue influences". Those examined are coercion; a combination of "power imbalance" relationship and exploitation; psychological compulsion; and the direct and indirect influence of financial incentives for parents and doctors as potentially undue influences.

Chapter 4 examines the childhood vaccination programs of Ontario, New Jersey, UK and Australia. It first reviews the nature of the requirement *versus* recommendation-based programs to provide insights into the nature of the policies. Then follows an examination of the requirement-based vaccination policies in Ontario and New Jersey in terms of a general overview of the policies, the requirement to vaccinate, and exemptions. Then comes a discussion of the recommendation-based programs of UK and Australia in the context of the consequences of leaving a child unimmunized, including the offer of financial incentives to doctors in the UK, and to parents in Australia. The features of these programs are summed up in a table which appears in the appendix to this thesis.

Chapter 5 covers the application of voluntariness of consent to the vaccination programs. It begins by reviewing the nature of the recommendation, and the requirement to vaccinate, in light of the voluntariness of consent. This analysis shows that, *prima facie*, there is correspondence between the recommendation-based programs and voluntariness of consent, and that the programs that require vaccination are involuntary. However, this correspondence proves weaker than initially anticipated due to the fact that exemptions offer some freedom of choice. In particular, exemptions are discussed in light of the exercisability and availability of choice criteria which prove that some parents could exercise the voluntariness of consent in practice. Also, considered is the possible presence of psychological compulsion acting as undue influence on the decision to vaccinate or to claim exemptions from doing so. The consequences of leaving a child unimmunized in the requirement-based programs are viewed through the prism of the necessity to vaccinate, in order to demonstrate the degree of coercion to participate in the program.

Turning to the recommendation-based programs in UK and Australia, the consideration of voluntariness of consent focuses on financial incentives. In regard to doctors, it is examined whether financial incentives could cause undue pressure, coercion, or act as other undue influences that may cause them to push for desired targets or outcomes. The analysis of the impact of the immunization-related benefits for parents employs an ethics framework. The goal is to assess whether such financial benefits amount to exploitation.

Chapter 6 concludes the thesis. Based on my examination of the two types of programs, the Chapter argues that if voluntariness occurs along a spectrum from “the least voluntary” to “the most voluntary”, both the requirement and recommendation-based programs are located close to each other in terms of the actual, practical presence of voluntariness. The spectrum illustrates the complexity of the distinction between the programs at the intersection of public health programs and the voluntariness of consent.

1.10. Limitations

This thesis has several limitations. First, it does not look into consent law in all four jurisdictions whose vaccination programs are discussed. Some variations of the law on this subject exist in common law jurisdictions.⁴⁸ The focus only on Canadian law of consent renders the project manageable. As well, analyzing each program on the same foundations of consent law contributes to the accuracy of the findings.

The discussion of the vaccination programs on the basis of consent is done as case studies. In other words, the programs are utilized as tools to pursue the research objective, rather than to explore specific violations of the law of consent in Australia, UK, and New Jersey in the

⁴⁸ Manitoba Law Reform Commission, *Substitute Consent to Health Care* (October 2004) online: <http://www.manitobalawreform.ca/pubs/pdf/archives/110-full_report.pdf>. Murray Early, “The Future of Informed Consent in British Common Law; Consent – medical and legal issues”, online: Thompsons Law <<http://www.thompsons.law.co.uk/clinical-negligence/consent-for-medical-treatment.htm>>.

administration of their vaccination programs. Even though it is the consent law of Canada that is applied, the work does not seek to reach any specific conclusion on the Canadian law on consent, nor on any merits of Canadian vaccination programs. Also, outside the scope of this thesis is the question of the constitutionality of the requirement-based programs in Canada. This is not considered because whatever conclusions its discussion may yield would not contribute to the attainment of the objectives of this research as set out in Section 1.4 above.

It is acknowledged that it may seem inadequate to utilize only four jurisdictions for the conclusions that this thesis draws. However, as mentioned above, the models of vaccination programs represent models used or that may be used in other jurisdictions. Therefore, the findings of this research might be applicable to more programs than those studied.

Finally, some of the data used in the research to inform assumptions are not the most recent, except that more recent studies could not be located. Also, there is no official data or studies pertaining to some issues on vaccination relevant to this research. However, since vaccination is widely discussed by the media, some parts of this thesis rely on information provided in newspapers and news reports. It is admitted, however, that the reliance on media information may weaken my findings.

Despite these limitations, the thesis provides insights into the complexity of the distinction between the requirement and recommendation-based vaccination programs, which challenges the dichotomy between the vaccination programs.

CHAPTER 2. DECISION-MAKING AUTHORITY OVER ROUTINE CHILDHOOD VACCINATION PROGRAMS

2.1. Introduction

The dependence of children on their parents varies, ranging from extreme dependence to independence.¹ Young children are not autonomous actors and cannot make decisions for themselves. This is why, the right to autonomous decision-making for their benefit is transferred to their parents, unless there are grounds for the state to intervene.² The decision-making authority of parents is included in the notion of parental liberty, which is the focus of this Chapter.

Parental liberty is a broad concept that touches upon various aspects of the parent-child relationship. In this Chapter, it is discussed in the context of health care choices, including routine MMRV vaccination. The Chapter discusses the limits of parental liberty to make medical choices, and determines whether the decision on MMRV vaccination falls within the scope of parental liberty. In other words, the analysis considers whether parents are the ones to decide on the matter of vaccination.

The first issue considered is that of capacity to give consent, vesting decision-making, *prima facie* in parents. The opinion of La Forest J in the Supreme Court of Canada case, *BR v Children's Aid Society*,³ which offers an extensive deliberation on the notion of parental liberty, is discussed in this connection. To illustrate the scope of parental liberty, I first briefly cover the mechanisms the state can use to intervene when parents refuse treatment. These mechanisms

¹ Joan M Gilmour, "Children, Adolescents and Health Care" in Jocelyn Downie, Timothy Caulfield & Colleen Flood eds, *Canadian Health Law and Policy*, 2nd ed (Toronto: Butterworths, 2002) at 205. (*This chapter is not included in the most recent edition of the book*)

² In common law and in some provincial statutes that address consent and health care, parents are recognized as substitute decision-makers for decisionally incapable minors, unless somebody else was appointed as such, or the state exercised *parens patriae* power.

³ *B.R. v Children's Aid Society of Metropolitan Toronto*, [1994] SCJ No 24, [1995] 1 SCR 315 at para 85. [*BR*].

include the *parens patriae* power of the courts to intervene, “child in need of protection” proceedings, and the power of courts to intervene when parents disagree. When using these mechanisms, the courts rely on “the best interest of a child” standard, and this is also discussed.

Next, the discussion shifts to the consideration of case law on state intervention in situations of parental refusal. For the purpose of this Chapter, case law is reviewed to illustrate the pattern of state intervention in these situations, and the factors that are taken into consideration by the courts in determining the best interest of the child. Finally, I discuss the case law on the intrusion of the state into parental liberty in relation to childhood vaccination to shed some light on state interference in cases where parents refuse vaccination for their children.

I conclude that decisions on routine vaccination, such as MMRV, fall within the scope of parental liberty. Therefore, parents are entitled to make decisions on vaccination, and thus, to give consent to MMRV. For the purpose of this thesis, the conclusion implies that parents are entitled to exercise their decision-making authority voluntarily. This conclusion offers the justification for the discussion and application of the voluntariness of consent to analyze childhood vaccination programs in the next Chapters.

2.2. Parental Consent

Capacity to give consent is one of the requirements of a valid consent.⁴ Capacity includes the patient’s ability to understand the nature, purpose, and potential consequences of the intervention being proposed and the consequences of its refusal.⁵ If a doctor has reason to believe

⁴ The requirements of consent are discussed in the next Chapter.

⁵ Erin Nelson, “The Fundamentals of Consent” in Jocelyn Downie, Timothy Caulfield & Colleen Flood eds, *Canadian Health Law and Policy*, 2nd ed (Toronto: Butterworths, 2002) 111 at 122.

the patient lacks the aforementioned ability and understanding, the patient's capacity should be examined, "using expert professional assistance where appropriate."⁶

The test for determining capacity is "functional".⁷ It does not focus on universal capacity and the patient's general ability to understand.⁸ Rather, it requires a patient's understanding of the particular treatment.⁹ A patient may have capacity to manage some financial affairs, but not to consent to a particular treatment. Also, capacity may exist in relation to some treatment options, but not to others.¹⁰ Concerns as to capacity to consent usually arise in relation to children or adults with disabilities or the aging population.¹¹

As mentioned above, in this thesis, I focus on children up to six years old, since it is recommended or required for this category of children to receive the MMRV.¹² Children up to six years old always lack capacity to consent to medical treatment. If a child does not have capacity to make a treatment decision, the child's parents generally have the authority to consent to the treatment. Provincial statutes and common law recognize parents as substitute decision makers, unless there are grounds for the state to intervene.¹³ According to the statutes of some provinces, parents are joint guardians. Therefore, each parent of a child should consent to a proposed treatment for the child.¹⁴ However, if a consent form for immunization is signed by one parent, or if one parent brings a child for medical examination, it is presumed that the other

⁶ Ellen I Picard & Gerald B Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 4th ed (Toronto: Thomson Carswell, 2007) at 68.

⁷ Erin Nelson, *supra* note 5 at 122.

⁸ *Ibid.*

⁹ *Ibid.*

¹⁰ *Ibid.*

¹¹ Ellen I Picard & Gerald B Robertson, *supra* note 6 at 68.

¹² Mature minors' consent is regulated differently than young children's. See generally *Ac v Manitoba (Director of Child and Family Services)*, 2009 SCC 30.

¹³ *Health Care Consent Act*, 1996 RSO, 1996 c 2 s 20.

¹⁴ *Family Law Act*, SA 2003, c F-4, s 21(2) (a). *Family Law Act*, SBC 2011, c 25 39 (1) 40, 41.

parent also consented to it.¹⁵ When the parents disagree, depending on the separation agreement and statutory authorization, treatment cannot be performed and the direction of a court may be sought.¹⁶

Essentially, parental consent to a medical treatment is required if a child is an immature minor.¹⁷ As demonstrated by the B.C. case, *Toews v Weisner*,¹⁸ the vaccination of an 11-year-old girl without parental consent resulted in a charge of battery and \$1,000 in damages. The nurse mistakenly thought that the girl's parents had already agreed to the vaccination. She went ahead to vaccinate the girl though the girl had mentioned that her parents did not give their consent.

Parental consent is, however, subject to emergency exemptions. If parents are not available, and delaying treatment puts a child's life or health under significant risk, the treatment could be provided without parental consent.¹⁹ Considering the nature of preventative vaccination, such as MMRV, the emergency exception is unlikely to apply in the context of interest here.²⁰

The reason parents are given authority to exercise consent regarding their children's medical treatment, and the nature and scope of their authority are considered next.

2.3. Parental liberty: the Rationale behind Parental Consent

It has been recognized by the courts that “the child's welfare conceives it to lie, first within the warmth and security of the home provided by his parents”,²¹ since parents are the people who most likely provide love and the nurturing needed for the child's healthy

¹⁵ Ellen I Picard & Gerald B Robertson, *supra* note 6 at 88. There might be more than two parents, or parents might be separated or divorced.

¹⁶ *Anson v Anson*, (1987) 10 BCLR (2d) 357 at paras 1-2. *Decision Making, Support and Protection of Adults Act*, SY 2003, c 21 Schedule B. *Health Care Consent Act*, SO 1996, s 20 (6).

¹⁷ *Health Care (Consent) and Care Facility (Admission) Act*, RSC 1996 (Supp), c 181 ss 4 (12).

¹⁸ *Toews v Weisner*, 2001 BCSC 15 at paras 31-33.

¹⁹ Ellen I Picard & Gerald B Robertson, *supra* note 6 at 87. *Reibl v Hughes*, (1980) 2 SCR 880, 114 DLR (3d) at para 10. *Malette v Shulman*, (1990) 67 DLR (4th) 321, 72 OR (2d) 417 at 328-329.

²⁰ The nature of the MMRV is discussed in the introduction to the thesis.

²¹ *Hepton v Maat*, [1957] SCR 606 at 608.

development.²² Parents tend to know better what is best for their children and “appreciate the best interests of their children.”²³ Parents have a personal interest in nurturing their children’s growth, since they aim to achieve the greatest good for themselves. Moreover, as claimed by La Forest J in *B.R. v Children’s Aid Society*, (the Supreme Court of Canada decision on a constitutional challenge to child welfare legislation), the state is not “well-equipped” to perform a parenting role.²⁴ Therefore, parents are recognized to be in “the best position to take care of their children, and make all the decisions necessary to ensure their well-being.”²⁵

These reasons foster a presumption that parents act in the best interest of the child, which is the underlying reason for assigning children to their parents and allowing parents to act on behalf of their children, unless they fail in their parenting role. This presumption and the transfer of decision-making from child to parent, create a sphere of parental decision-making which is included in the concept of parental liberty. According to Justice La Forest, in the *BR* case, “the common law has always, in the absence of demonstrated neglect or unsuitability, presumed that parents should make all significant choices affecting their children, and has afforded them a general liberty to do as they choose.”²⁶

La Forest J, writing for three judges in *BR*, claims that “the right to nurture a child, to care for its development, and to make decisions for it in fundamental matters such as medical care, are part of the liberty interest of a parent” protected under s.7 of the *Charter*.²⁷ ²⁸ Whether

²² *Newfoundland (Director of Child Welfare) v CRB*, (1995) 137 Nfld & PEIR 1 (Nfld SCTD) at para 49.

²³ *BR*, *supra* note 3 at para 85.

²⁴ *Ibid*.

²⁵ *Ibid* at para 83.

²⁶ *Ibid* at para 85.

²⁷ Justice Lamer found that the aforementioned right, as well as a broader right to educate and bring up children without undue interference by the state, could not be protected in s. 7. Also, Cory, Iacobucci and Major JJ said that if the survival of the child is at stake, the parents’ right to make health care decisions falls outside the scope of s. 7. *Per Sopinka J.*: “It is unnecessary to determine whether a liberty interest is engaged in this case because the threshold requirement of a breach of the principles of fundamental justice is not met.” In all other respects, La Forest

or not parental liberty is protected under s.7, it is important for my purposes to consider the nature of parental liberty *per se*, which explains the rationale behind, and signifies the considerable leeway parents have in taking decisions as regards their children.

Justice La Forest approached parental liberty from the perspective of children's rights, as well as parents' responsibilities. He claimed that children are protected by the *Charter*, but since children cannot claim these rights by themselves, there is a presumption that parents will exercise rights in the way that does not infringe the children's right.²⁹ In addition, according to La Forest J, parents owe responsibilities to their children, and parents' rights in relation to their children exist in order for parents to discharge those responsibilities.³⁰ However,

this liberty interest is not a parental right tantamount to a right of property in children... The state is now actively involved in a number of areas traditionally conceived of as properly belonging to the private sphere. Nonetheless, our society is far from having repudiated the privileged role parents exercise in the upbringing of their children.³¹

He emphasizes that considering the fact that the parenting role includes taking many decisions daily, only in "exceptional cases" will there be the need for a state to balance children – parents' rights. La Forest J admits that the decisions that parents take might not correspond with the wishes/rights of their children, but the state will interfere only when parental decisions fall "below the socially acceptable threshold"³² which "encompasses situations ... [in which] the

J.'s reasons were agreed with. Justice La Forest went on to find that "the scheme designed by the legislature accords with the principles of fundamental justice." See: *BR, supra* note 23 at paras 52, 83.

²⁸ Cases after *BR* affirmed the broad scope of s. 7, making it sufficient to claim that parental liberty is included in s. 7. See: *Chaoulli v Quebec (Attorney General)*, 2005 SCC 35 [2005] 1 SCR 791 at para 197. *Winnipeg Child and Family Services v K LW*, [2000] SCJ 48 at para 6. *New Brunswick (Minister of Health and Community Services) v G (J)*, [1999] 3 SCR 46 at para 58, 65. *Blencoe v British Columbia (Human Rights Commission)*, [2000] 2 SCR 307, 2000 SCC 44 at paras 42-54.

²⁹ *BR, supra* note 3 at para 86.

³⁰ *Ibid* at para 85.

³¹ *Ibid*.

³² *Ibid* at para 86.

life of the child may be in jeopardy [as well as]...where treatments might be warranted to ensure his or her health or well-being.”³³

Therefore, parental liberty is not an unconstrained freedom, and parents are not absolutely free to refuse medical treatment according to their wishes and beliefs, even when those are conscientiously held. However, as claimed by La Forest J, “state intervention has been tolerated only when necessity was demonstrated.”³⁴ This signifies a policy of minimal intervention which “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.”³⁵

This discussion of the nature of parental liberty does not, however, clarify in which cases socially acceptable threshold is crossed, and whether vaccination is one of these cases. There is no list of health care treatments that parents are not allowed to refuse because refusal is outside the scope of parental liberty. Thus, it is not clear how the policy of “minimal intervention” is applied and how “well equipped” the state is to decide whether to override parental refusal.

To shed some light on these questions, I next review legislation and case law on state intervention in case of parental refusal or disagreements as regards treatment choices. This will also set the stage for the discussion of parental liberty *vs* state intervention in the matter of routine MMRV vaccination.

2.4. When and How the State Intervenes

Parents have a legal duty to ensure that their children receive needed medical care. When they fail to do so, there are mechanisms that could be used to override parental refusal.

³³ *Ibid* at para 88.

³⁴ *Ibid* at para 83.

³⁵ *Ibid*.

First, a court could exercise *parens patriae* jurisdiction over children.³⁶ Second, a parental refusal might result in proceedings that lead to temporary custody of the child by welfare authorities.³⁷ The child may be apprehended by child welfare authorities “as a child in need of protection” under child welfare legislation.³⁸ Also, courts might intervene when there are disagreements between separated or divorced parents as regards health care choices for children. A brief overview of these options follows.

2.4.1. Parens Patriae

Parens patriae, as “parent of the country” doctrine, is an “ancient common law prerogative” which was used to protect those who could not speak for themselves, including children.³⁹ Overall, “its [*parens patriae*] exercise is founded on necessity -- the need to act for the protection of those who cannot care for themselves. The jurisdiction is broad. Its scope cannot be defined. It applies to many and varied situations”.⁴⁰

The courts can intervene “to protect children whose lives are in jeopardy and to promote their well-being, basing such intervention on its *parens patriae* jurisdiction.”⁴¹ Since the scope of the *parens patriae* jurisdiction is “unlimited”⁴² in principle, “[t]he discretion given under this jurisdiction is to be exercised for the benefit of the person in need of protection and not for the benefit of others.”⁴³ Therefore, if the courts use *parens patriae* power to override parental refusal,

³⁶ This mechanism is proscribed in the Northwest Territories and Nunavut Children’s Law Act. See: *Northwest Territories and Nunavut Children’s Law Act*, SNWT 1997, c 14 s 39.

³⁷ *Health Care Consent Act*, SO 1996, s 20(6). *Care Consent Act*, SY 2003, s 14. *Anson v Anson*, (1987) 10 BCLR (2d) at 357.

³⁸ *Child, Youth and Family Enhancement Act*, RSA 2000, c c-2. *Child and Family Services Act*, RSM 1987, c 80.

³⁹ Laura Westra, *Human Rights: The Commons and the Collective* (Vancouver: UBC Press, 2011) at 250.

⁴⁰ *E (Mrs) v Eve*, [1986] 2 SCR 388 at 339.

⁴¹ *BR*, *supra* note 3 at para 88.

⁴² *E (Mrs) v Eve*, *supra* note 40 at 428.

⁴³ *Ibid* at 426.

the best interest of a child standard is applied to determine whether it is in the best interest of a child to authorize a treatment.⁴⁴

2.4.2. Child in Need of Protection

All provinces have provisions in their Child Family and Service Acts that define “a child in need of protection”.⁴⁵ “Child in need of protection” is a broad term which “encompasses many separate headings”⁴⁶ in provincial statutes -- ranging from physical harm and neglect to abandonment. A child is recognized to be in need of protection if a court finds that the circumstances of a child fall under one of the headings.⁴⁷ A child whose parents or guardians have refused to consent to essential or necessary treatment might fall within “a child in need of protection” category.⁴⁸

In Ontario, a child is recognized to be in need of protection when “the child requires medical treatment to cure, prevent or alleviate physical harm or suffering and the child’s parent or the person having charge of the child does not provide, or refuses or is unavailable or unable to consent to, the treatment.”⁴⁹ According to the Alberta *Family Law Act*, “a child is neglected if the guardian is unable or unwilling to obtain for the child, or to permit the child to receive, essential medical, surgical or other remedial treatment that is necessary for the health or well-being of the child.”⁵⁰ British Columbia’s statute claims that a child in need of protection “is

⁴⁴ See generally *Re DS*, [1983] 42 BCLR 153. *Re K, (LD)* (1985) 48 RFL (2d) 164. *Re J*, [1990] 3 All ER 930, (1991) 9 BMLR 10 (CA).

⁴⁵ *Family Law Act*, RSO 1990, c F 3. *Family Law Act*, SA 2003, c F 4 (5). *Family Law Act*, SBC 2011, c 25. *The Child and Family Services Act*, SS 1989, 90 C 7 (2).

⁴⁶ Marvin A Zucker et al, *Children’s Law Handbook*, 2nd ed (Toronto: Carswell, 2009) at 20.

⁴⁷ *Ibid.*

⁴⁸ *Child and Family Services Act*, RSO 1990, c 11 s 37 (2). *Child, Youth and Family Enhancement Act*, RSO 2000, C-12 s 2 (1) b. *Child, Family and Community Service Act*, RSBC 1996, c 46 s 13 (1) f: If the child is deprived of necessary health care.

⁴⁹ *Family Law Act*, RSO 1990, c F 3.

⁵⁰ *Family Law Act*, SA 2003, c F-4.5.

deprived of necessary health care”.⁵¹ The *Child and Family Services Act* of Saskatchewan refers not only to the treatment but also to a health care worker: “medical, surgical or other recognized remedial care or treatment that is considered essential by a duly qualified medical practitioner has not been or is not likely to be provided to the child.”⁵² The constitutional validity of legislation on “child in need of protection” was upheld in the aforementioned *BR v Children’s Aid Society of Metropolitan Toronto*.⁵³

When the court determines that a child is in need of protection, a child becomes a ward of the welfare authorities, who are empowered to consent to the treatment. In child protection proceedings, the court also takes into account the question whether the authorization of essential or necessary treatment is in the best interest of a child.⁵⁴

2.4.3. Disagreements between Parents

When parents disagree over a child’s health care, the direction of the court may be sought. Health care decisions, including consent to treatment, in most cases, are taken by the parent who has decision-making authority on behalf of a child.⁵⁵ However, parents who have joint decision-making authority over children might have different views on how to proceed with health care matters. If they are not in agreement, a parent might make an application to a court for an order regarding the matter of disagreement;⁵⁶ or a parent might apply to change the

⁵¹ *Family Law Act*, SBC 2011, c 25.

⁵² *The Child and Family Services Act*, SS 1989-90, c 7-2.

⁵³ *BR*, *supra* note 3.

⁵⁴ *Child, Youth and Family Enhancement Act*, RSA 2000, c C-12 ss 2, 55 (2), 57 1 (1) b.

⁵⁵ *Divorce Act*, RSC 1985, c 3 s 2 (1). *Children’s Law Reform Act*, RSO 1990, c 12 s 21.1.

⁵⁶ *Children’s Law Reform Act*, *supra* note 55 at s 21.1.

conditions of exercising decision-making authority.⁵⁷ If a court considers an application, the best interest of a child standard, which is central to all custody and access proceedings, is applied.⁵⁸

Therefore, the “child in need of protection” proceedings, parental disagreements as regards health care, or the use of *parens patriae*, are the mechanisms the courts use to intervene. The best interest of a child standard could be applied by courts as a decision-making instrument in case of parental refusal or disagreements. This standard is considered next.

2.4.4. The “Best Interests” Standard

The concept of “the best interests” is derived from family law where “the best interests” test is used to determine a wide range of issues as regards the well-being of a child.

However, the concept of the best interests is also a standard used at common law to make decisions about medical treatment for those who are incapable of making their own health care decisions.⁵⁹ “Best interests” is prescribed in health care legislation as a standard that is used when a patient is not competent and his or her previous wishes are unknown.⁶⁰

The “best interests” is considered to be “the most heralded, derided and relied upon standard in family law today.”⁶¹ It is heralded “because it espouses the best and highest standard; derided because it is necessarily subjective; and relied upon because there is nothing better.”⁶² Family law legislation prescribes universalized “best interests” tests. The tests vary slightly from province to province, but the skeleton remains the same. For instance, according to the BC

⁵⁷ *Divorce Act*, *supra* note 55 at s 17.1. *Children’s Law Reform Act*, *supra* note at ss 21, 24, 28.

⁵⁸ Marvin A Zucker et al, *supra* note 46 at 41.

⁵⁹ Joan M Gilmour, *supra* note 1 at 225.

⁶⁰ *Health Care Consent Act*, RSBC 1996, p 3 s (21) 2.

⁶¹ Lynn Marie Kohm, “Tracing the Foundations of the Best Interests of the Child Standard in American Jurisprudence” (2008) 10 *Journal of Law and Family Studies* at 1.

⁶² *Ibid.*

Family Law Act, in order to determine what is in the “best interests” of a child, all of the child’s needs and circumstances must be considered. Some of them are:

- (a) the child’s health and emotional well-being;
- (b) the child’s views, unless it would be inappropriate to consider them;
- (c) the nature and strength of the relationships between the child and significant persons in the child’s life;
- (d) the history of the child’s care;
- (e) the child’s need for stability, given the child’s age and stage of development;
- (g) the impact of any family violence on the child’s safety, security or well-being, whether the family violence is directed toward the child or another family member.⁶³

In Alberta, in addition to the aforementioned factors, the child’s cultural, linguistic, religious and spiritual upbringing and heritage, and the views of the child’s current guardians are taken into account.⁶⁴ In Saskatchewan, “the best interests” test in the *Child and Family Services Act* also takes into consideration the effect on the child of a delay in making a decision.⁶⁵

Legislation is helpful in defining the factors that should be considered when determining whether it is in the best interests of a child to consent to or refuse a treatment. However, the assessment of benefits, needs, and values is unique in every case. In some of them it is “exceptionally difficult”⁶⁶ because of the sensibility of the circumstances. Therefore, to encompass the application of the best interests test, case law should be considered. These cases illustrate the tendencies of the policy of minimal intervention into parental liberty, assuming parents are in agreement. In other words, they disclose the limited circumstances (i.e. the refusal of certain health care treatments) in which the state actually intervenes and overrides parental decisions.

I cover cases on various health care choices first, and then the discussion shifts to cases on vaccination.

⁶³ *Family Law Act*, SBC 2011, c 25 s 37 (2).

⁶⁴ *Family Law Act*, SA 2003, F 4 (5) s 18 (2).

⁶⁵ *Child and Family Services Act*, SS 1989, c 7-2 s 1(4) (h).

⁶⁶ Ellen I Picard & Gerald B Robertson, *supra* note 6 at 90.

2.5. Parental Liberty Cases

The cases in which the child is apprehended as a child in need of protection and in which *parens patriae* is used arise most often in relation to life and death situations, such as blood transfusions that are needed to preserve the lives of Jehovah's Witnesses children.⁶⁷ However, in some cases, intrusion has been justified not only when the child's life is in imminent risk of harm, but also when the child's health and well-being are at stake.⁶⁸ Some cases arise out of parental objections to the approved therapies that fall within the "health and well-being" category.

For instance, in *Re IB*, the HIV mother lost custody of her two HIV-positive children after refusing to consent to their treatment with an aggressive HIV drug therapy program which had some side effects.⁶⁹ The mother, who did not believe in conventional medicine, considered the drug therapy to be toxic and wanted to continue to treat her children with natural remedies.⁷⁰ The children's immune systems were in rapid decline, and the court found that the refusal to provide them with the HIV drug therapy program was not reasonable but was contrary to the children's best interests.⁷¹ Therefore, the court authorized the therapy for six months with a re-valuation of the effect of the HIV therapy to follow.

⁶⁷ Ellen I Picard & Gerald B Robertson, *supra* note 6 at 90. See generally *VM v British Columbia (Director of Child, Family and Community Service)*, [2008] BCJ 1071, 2008 CarswellBC 1195. *The Children's Aid Society of the Niagara Region v Schram Respondents*, [2011] OJ 3888, 2011 ONSC 4718. *BH (Next friend of) v Alberta (Director of Child Welfare)*, [2002] AJ 518, 2002 ABQB 371. *Children's Aid Society of Toronto v ML*, [2008] OJ 4271, 2008 ONCJ 52.

⁶⁸ *BR*, *supra* note 3 at para 88.

⁶⁹ *Re I B*, [2000] JQ 490 in Canadian Medical Association, Canadian Bioethics Report, Court Decisions (2000), online: <http://www.collectionscanada.gc.ca/eppp-archive/100/201/300/cdn_medical_association/cbr/2000/may00/court.htm>.

⁷⁰ *Ibid.*

⁷¹ *Ibid.*

In the English case, *Re C (HIV test)*,⁷² parents were extremely opposed to the HIV-related procedure testing, and to any medical therapy for their newborn baby who had a 25% chance of being HIV positive.⁷³ Parents did not accept the scientific understanding of HIV and rejected the value of the testing and therapies. The court claimed that the views of parents were very important even when they contradicted established medical knowledge.⁷⁴ Yet, the judge stated that it is crucial for the well-being of the child to find out if she was HIV positive, so that somebody knows how to take care of the baby.⁷⁵ It was established that the child's welfare required consideration of the parents' position, especially when parental objections were in relation to the issues where there is room for debate. But when the parent's position is not supported by medical evidence, it definitely loses some weight.⁷⁶ In this case, the court ordered the test.

Parental refusal also did not stand in *Re Superintendent of Family & Child Service and Dawson*.⁷⁷ In this case, parents did not authorize a surgery to replace a shunt in a severely disabled child. The court intervened using *parens patriae* authority to order the treatment.⁷⁸ The evidence claimed that the child would have a relatively happy life with the replaced shunt.⁷⁹ Without surgery, he would experience pain, but would not necessarily die.⁸⁰ The court established that no matter how low the quality of life is, the life of a disabled child is still worth

⁷² *Re C (HIV test)*, [1999] 2 FLR 1004.

⁷³ *Ibid* at 295.

⁷⁴ *Ibid* at 298.

⁷⁵ *Ibid* at 298.

⁷⁶ Andrew Downie, "Re C HIV test. The limits of parental autonomy" (2000) 12 Child & Fam L Q at 200.

⁷⁷ *Re Superintendent of Family & Child Service and Dawson*, (1983) 145 DLR (3d), [1983] 3 WWR 618, 42 BCLR at 610.

⁷⁸ *Ibid* at para 14.

⁷⁹ *Ibid* at para 40

⁸⁰ *Ibid* at para 31.

continuing. Therefore, it authorized the surgery which was medically recommended to improve the condition of the child.⁸¹

Similarly, in *New Brunswick (Minister of Health & Community Services) v B.R.*,⁸² the parents refused to authorize antibiotics for meningitis for a severely disabled child. However, there was a disagreement among doctors as to whether the child should be treated.⁸³ The court granted the Minister temporary custody of the child and authorized the treatment, holding that the decision not to treat would constitute discrimination against a child based on disability. The court concluded that the treatment would prolong the child's suffering, but her life would be prolonged too, and since the child was entitled to her right to life, the antibiotics were authorized.⁸⁴ However, in cases where the treatment offers only a small chance of success, the court might uphold the parental refusal to the treatment.

For instance, in *Couture-Jacquet v Montreal Children's Hospital*,⁸⁵ the mother and grandmother of a three year old child suffering from cancer refused to consent to the fourth course of chemotherapy. The Superior Court authorized the treatment, but the decision was appealed. The treatment was strongly recommended by the medical professionals since without it the child would die.⁸⁶ However, the chances of her survival after the treatment were less than 20%.⁸⁷ Moreover, the side effects the child had experienced over the last courses of chemotherapy were severe.⁸⁸ Since the chemotherapy offered small chances of improvement and

⁸¹ *Ibid* at paras 40, 44.

⁸² *New Brunswick (Minister of Health & Community Services) v BR*, (1990) 70 DLR (4th) 568 (NBQB).

⁸³ *Ibid* at 2-3.

⁸⁴ *Ibid* at 2-3.

⁸⁵ *Couture-Jacquet v Montreal Children's Hospital*, (1986) 28 DLR (4th) 22 (Que CA).

⁸⁶ *Ibid* at para 17.

⁸⁷ *Ibid*.

⁸⁸ *Ibid*.

brought great suffering to the child, the Quebec Court of Appeal did not recognize the treatment to be in the best interests of the child.⁸⁹ Therefore, the parental refusal was upheld.

In *Saskatchewan (Minister of Social Services) v P (F)*,⁹⁰ parents also decided against a treatment -- liver transplant for their infant son, but in this case, the chances of the child's survival with the transplant were good. After transplantation, the child might suffer side-effects, including life-threatening effects, but without the transplant, the child would die.⁹¹ The court considered the government's application to recognize the child as in need of protection so that the procedure could be authorized.

The parents, who were members of First Nations, assessed the medical burdens caused by the transplant, their ability to take care of the child after the surgery, as well as the spiritual invasion associated with the procedure, and decided against seeking the transplant.⁹² However, the parents' decision was found to be in accordance with medical standards,⁹³ and the values of caring parents of a terminally ill child.⁹⁴ The court emphasized that "the decision to be made cannot be reduced to mere mathematical probabilities",⁹⁵ and this is why it took into account the parents' emotional, psychological and social considerations while determining the best interests

⁸⁹ *Ibid* at para 27.

⁹⁰ *Saskatchewan (Minister of Social Services) v P (F)*, [1990] SJ 708, 1990 69 DLR (4th) 134.

⁹¹ *Ibid* at para 9.

⁹² *Ibid* at paras 62-65.

⁹³ "The Minister has failed to satisfy the court principally because the parents' decision is wholly and completely within the bounds of current medical practice". See: *Saskatchewan (Minister of Social Services) v P (F)*, *supra* note 90 at para 80.

⁹⁴ "Can it be said that this is a clear case of rejection by the parents of the values society expects of thoughtful, caring parents for a terminally ill child? In my opinion, in this case the question must be answered in the negative". See *Saskatchewan (Minister of Social Services) v P (F)*, *supra* note 90 at para 92. "The parents have chosen a course of treatment which they recognize will not avoid the death of the child. This course of treatment is clearly recognized by the medical community as being acceptable in this situation. In fact, the majority of the doctors who testified and proffered expert opinions in evidence in this case are not critical of the parents' choice for reasons that are clearly articulated". See: *Saskatchewan (Minister of Social Services) v P (F)*, *supra* note 90 at 89.

⁹⁵ *Saskatchewan (Minister of Social Services) v P (F)*, *supra* note 90 at para 91.

of the child. Therefore, the court did not interfere with parental liberty and the treatment was not authorized.

To conclude, parental liberty entitles parents to make a range of decisions in regard to the medical treatment of their children, including the withdrawal or withholding of treatment. However, this liberty is not absolute and the state can intervene to override parental decisions even when the life of a child is not at stake. The intervention is based primarily on medical consideration. When the “best interests” test is applied, medical considerations remain to be important, but the courts also take into consideration parents’ opinion even when it is not fully supported with medical evidence. In some cases, they adhere to parents’ wishes, as it was in *Couture-Jacquet v Montreal Children’s Hospital*. Overall, the courts prefer treatment that preserves life. However, “the lower the odds of long term benefit, the more likely will the law accept the legitimacy of the decision to let the infant die.”⁹⁶

Other examples of extreme health care situations in which the court intervened are refusal to consent to the insertion of a feeding tube for a four year old child suffering from cystic fibrosis,⁹⁷ and a refusal to authorize heart surgery for a child with Down’s syndrome.⁹⁸ Obviously, not all health care decisions are taken in such extreme situations. There are routine health care choices, such as consent or refusal to routine vaccination, including MMRV, that every parent takes at some point in time. I turn to the discussion of court intervention in routine vaccination cases. These give a better understanding whether parental liberty would be interfered with if parents refuse consent to the MMRV vaccination.

⁹⁶ Barney Sneiderman, Philip H Osborne & John C Irvine, *Canadian Medical law: An Introduction for Physicians, Nurses and Other Health Care Professionals*, 3d ed (Thomson Carswell, 2003) at 420.

⁹⁷ *Children’s Aid Society (Peel) v B (C)*, (1998) 8 ACWS (3d) Ont Prov Ct 425.

⁹⁸ *Re Goyette: Centre de Services Sociaux du Montreal*, [1983] CS 429 [Que SC].

2.6. Vaccination: Parental liberty and State Intervention

MMRV, as one of the routine vaccinations, is considered to be medically beneficial. However, the question is whether it is within the scope of state intrusion, that is, whether parental refusal to vaccinate a child would be a ground for state interference with parental liberty. There are only a few cases in Canada where courts considered authorization for routine and non-routine childhood vaccination. These cases discuss intrusion in parental decision-making when both parents refused to vaccinate a child, or determined whether immunization was in the best interests of a child when parents disagreed on that matter.

In *Children's Aid Society of Peel (Region) v H. (T.M.C.)*,⁹⁹ the court considered a parental refusal to a non-routine Hepatitis B vaccination. A woman who was a chronic hepatitis B carrier gave birth to a child who, according to medical evidence, needed to be vaccinated within 12 hours of birth to prevent hepatitis B infection and other lifelong complications, such as liver cirrhosis.¹⁰⁰ The parents wanted to delay vaccination for two years, believing that in that way, they would avoid putting the baby at risk. They also thought that vaccination caused the autism of their older child.¹⁰¹ The court recognized that the parents refused vaccination because they believed that it was not in the best interests of the child.¹⁰² But it held that “the medically and professionally uncontradicted evidence presented...clearly and convincingly establishes that a failure to vaccinate this child *almost immediately* will likely result in serious physical and permanent harm.”¹⁰³ Therefore, since the refusal to vaccinate the child might lead to serious and imminent harm, the vaccination was authorized.

⁹⁹ *Children's Aid Society of Peel (Region) v H (TMC)*, [2008] OJ 217, 2008 CarswellOnt 257.

¹⁰⁰ *Ibid* at para 8.

¹⁰¹ *Ibid* at para 5.

¹⁰² *Ibid* at para 13.

¹⁰³ *Ibid* at para 13. Italics added.

In *Di Serio v Di Serio*,¹⁰⁴ the court considered the authorization of routine vaccination. In *Di Serio v Di Serio*, the parents sought the direction of the court, not because of parental refusal, but because of a disagreement between separated parents over the immunization of their five and eight year old children. The mother had sole custody and wanted to vaccinate the children.¹⁰⁵ But the father, who had the right to participate in all major decisions regarding the children, objected to vaccination.¹⁰⁶ Because of this discord in the exercise of the parental liberty of a mother and a father, the judge went straight to the determination of the best interests of the child.

The mother relied on the physician's opinion that vaccination was in the best interests of a child. On his part, the father presented evidence that the judge found to be "improper"¹⁰⁷ since none of it came from firsthand knowledge and had no relation to his religious or conscientious beliefs. As such, the court refused to take into consideration his references to unverified "publications", "books", and "associations" in support of his position.¹⁰⁸ At the end, the father was left with his statement that he "truly believe[s] that it is in the best interest of the children that they do not receive any vaccination/immunization."¹⁰⁹ The court found vaccination to be in the children's best interest, since the medical evidence favoured the mother's decision, which was also in accordance with the public policy of Ontario.¹¹⁰ Therefore, vaccination was authorized.

In an English case on disagreements between parents on the matter of routine vaccination, *Re C & F (Children)*,¹¹¹ the court also decided in favour of vaccination. Vaccination

¹⁰⁴ *Di Serio v Di Serio*, [2002] OJ 5341 (Sup Ct).

¹⁰⁵ *Ibid* at 2.

¹⁰⁶ *Ibid*.

¹⁰⁷ *Ibid* at para 18.

¹⁰⁸ *Ibid* at para 17.

¹⁰⁹ *Ibid* at para 18.

¹¹⁰ *Ibid* at para 24.

¹¹¹ *Re C & F (Children)*, [2003] EWHC 1376 (Fam) at 382. Two unconnected applications were listed together since in both cases, fathers applied in relation to routine vaccination of children who lived with mothers.

was found to be in the best interests of children from a medical perspective. The court emphasized the best interests of a child in the context of harmonious mother-child relationship and considered the liberty of the mother in the face of a conflict over parental liberties. It was claimed that

even if the court was persuaded by the medical evidence that a programme of immunisation was in the girls' best interests, this should not be ordered by the courts. It is not right to impose it against the wishes of a caring mother [as that] would cause them great distress which would affect the children.¹¹²

The rationale behind giving so much weight to the emotional stability within a parent-child relationship lies in the strong psychological ties children have with parents, which are “rooted in the infant’s inability to ensure her own survival”;¹¹³ they are caused by the day to day attention the child needs for “physical care, nourishment, comfort, attention, and stimulation.”¹¹⁴ In *Re C & F*, routine vaccinations were authorized not only because they were medically advisable, but also because the judge concluded that the mothers would accept the vaccination order and it would not affect their care for the children.¹¹⁵ In other words, the judge was persuaded that harmony in the daughter-mother relationship would not be at risk because of vaccinations.¹¹⁶

In a similar case on disagreements between parents, *Chimiliar v Chimiliar*, the court recognized that the child’s well-being largely depends on its emotional and psychological conditions.¹¹⁷ In *Chimiliar*, divorced parents disagreed about vaccination of their children. A 10-

¹¹² *Ibid* at 365.

¹¹³ Joseph Goldstein *et al*, *The best interest of the child* (New York: The New York Free Press, 1996) at 13.

¹¹⁴ *Ibid* at 11.

¹¹⁵ *Re C & F*, *supra* note 111 at 346-352.

¹¹⁶ Based on *Re C & F*, it could be assumed that the courts might give preference to a harmonious children-parent relationship if such will be affected by the authorization or non-authorization of the treatment, especially in those decisions that do not carry serious consequences for a child’s life or health.

¹¹⁷ *Chimiliar v Chimiliar*, [2001] AJ 838 (QL) 2001 ABQB 525 (QC). [*Chimiliar*]

year old boy was ordered to undergo routine vaccination based on medical consideration.¹¹⁸ A 13-year old girl was found to be capable of making decisions as regards vaccination, but because of fears instilled by her mother, she lost the capacity.¹¹⁹ The court claimed that the mother's position on vaccination was unfounded.¹²⁰ Yet the court gave the most weight to the psychological well-being of the child who feared vaccination. It was found that vaccination would harm rather than benefit the child.¹²¹ Moreover, because of the absence of a serious health risk, and given the girl's age, the judge decided that she would be able to make an independent decision soon.¹²² Therefore, vaccination of the girl was not ordered.

A 2010 case, *JP (Re)*,¹²³ is the most recent court decision on immunization of children in Canada. In *JP Re*, unlike in the aforementioned cases, both parents refused vaccination. Five children in the P. family were apprehended by a child welfare caseworker due to concerns with respect to domestic violence, neglect and lack of supervision.¹²⁴ After the children, who were immature minors, were taken to see a paediatrician, it was discovered that two older children's vaccination certificates were not up to date and two younger children had never been vaccinated. Both parents refused to immunize their children and the Director applied for an order authorizing vaccinations.

According to section 22.1 of the *Alberta Child, Youth and Family Enhancement Act*, the judge could consider whether vaccination is in the best interests of a child only if he determines

¹¹⁸ *Ibid* at paras 30-33.

¹¹⁹ *Ibid* at paras 55, 61.

¹²⁰ *Ibid* at paras 20-21.

¹²¹ *Ibid* at para 65.

¹²² *Ibid* at para 65.

¹²³ *JP (Re)*, [2010] AJ 1379, 2010 ABPC 379.

¹²⁴ A six month Temporary Guardianship Order was issued by the court with the consent of the parents. See *JP (Re)* *supra* note 124 at para 6.

that vaccination is “an essential treatment”.¹²⁵ In other words, state intervention is appropriate when the parents refuse to consent to an essential treatment. The court interpreted “essential” to mean an “absolutely necessary, indispensable” treatment without which the health conditions in issue could lead “to serious or permanent impairment”, or that they are indispensable to the preservation of a child’s life.¹²⁶ Even though the judge could not define the time period captured by the word “essential”, he rejected the argument that “essential” had no temporal connection to the event.¹²⁷ As to the matter before him, the judge had no doubt that

the vaccinations proposed by the Doctor are the preferred way to proceed, given the risks [of leaving a child unimmunized as] described by the Doctor in her evidence. A child is at risk in a playground or in crossing the street. When the risk of any adverse reaction to the Vaccines is weighed against the benefit of giving them, I believe the decision to vaccinate to be the preferred alternative.¹²⁸

However, based on the medical evidence on vaccination and the fact that the children in question were healthy and not in imminent risk of harm, he held, in *JP (Re)*, that vaccination did not fall within the scope of essential treatment.¹²⁹ Therefore, parental liberty as regards routine vaccination could not be interfered with in this situation.

In an older, 1995 case, *Newfoundland (Director of Child Welfare) v. C.R.B.*,¹³⁰ both parents also refused vaccination. In this case, the court deliberated on the nature and extent of parental rights and the religious practices of parents in relation to immunization. The temporary custody of three children was awarded to the state since their parents, due to their religious beliefs, preferred to provide home schooling, put their children on a strict dietary regime and

¹²⁵ *Child, Youth and Family Enhancement Act*, RSA 2000, C 12 s 22 (1) (2).

¹²⁶ *JP (Re)*, *supra* note 123 at para 30.

¹²⁷ *Ibid* at para 41.

¹²⁸ *Ibid*.

¹²⁹ *Ibid* at para 49.

¹³⁰ *Newfoundland (Director of Child Welfare) v CRB*, (1995) 137 Nfld & PEIR 1 (Nfld SCTD).

refused to immunize them.¹³¹ On appeal of the Provincial Court decision, Newfoundland Supreme Court found that there was no medical evidence to prove that the parental aversion to immunization and their refusal to allow it for their children was harmful enough to justify state intrusion.¹³² Therefore, it held that “the refusal of immunization was not sufficient grounds for interference in the upbringing of children by the state...No authority has been offered to suggest that refusal of immunization constitute grounds for interference in the upbringing of children by the state”¹³³.

The judge also claimed that the courts intervened when the refusal of treatment was life threatening and “short of this courts have generally preserved the parental right to raise children in the manner that they deem appropriate and consistent with their religious belief.”¹³⁴ However, as evidenced by the review of cases, the courts have intervened not only when the failure to consent to treatment is life threatening. The cases pertaining to the replacement of the shunt, HPV testing, and even necessary immunization are not about preserving life *per se*; these are situations in which the parental refusal falls beyond the “socially acceptable threshold.”¹³⁵

In case of the refusal of routine vaccination, including MMRV, the “socially acceptable threshold” is likely not crossed since the benefit of the treatment, such as routine vaccination, is not “necessary to ensure health and well-being” and as concluded in *JP*, routine vaccination is not “essential treatment.” Moreover, in the aforementioned case *Chimiliar*, the judge also stated that “although the vaccinations may protect them from illness and more serious difficulties later in their lives, it is not open to this court to order vaccinations based solely on the belief that

¹³¹ *Ibid* at paras 1-5.

¹³² *Ibid* at paras 9-10.

¹³³ *Ibid* at para 10.

¹³⁴ *Ibid*.

¹³⁵ *Ibid* at para 86.

vaccinations are good for the children when the parents do not want to vaccinate their children.”¹³⁶

2.6.1. Vaccination and Parental Liberty: Summary

The preceding review shows that the cases in which the courts authorized routine vaccination were in regard to disagreements involving the liberty of a mother versus a father, or child’s life or health, which was in serious danger if the child was not vaccinated with a non-routine vaccination. According to *JP, Newfoundland (Director of Child Welfare) v. C.R.B.*, and *Chimiliar*, parental refusal would not be overridden when both parents object to routine vaccination. Thus, parental liberty in case of routine vaccination would be preserved.

This is not to say that vaccination is not medically preferable. It is just that the parents are given the discretion to decide by themselves if their child should be vaccinated. The sole fact that a treatment is good for a child is not enough to rebut parental objection to it. As mentioned above, non-vaccination with MMRV does not cause serious consequences, and the child is not in the imminent risk of harm. Therefore, the decision taken by parents to not vaccinate a child with routine vaccination, including MMRV, does not cross a socially acceptable threshold to enable intervention. This conclusion is also consistent with the policy of minimal intervention, which signifies an intervention in case of serious risk to a child’s life and health, illustrated by the overview of cases on other health care choices.

Vaccination might not be authorized when parents disagree on the matter of vaccination, as courts take into account the generalized conception of what is good for that individual.

¹³⁶ *Chimiliar*, *supra* note 117 at para 8.

According to *Chimiliar*¹³⁷ and *Re C & F (Children)*¹³⁸, the “best interests” standard includes not only medical consideration, but also harmonious parent-child relationship, as well as the emotional well-being of a child. What is more, according to *Saskatchewan (Minister of Social Services) v P (F)*,¹³⁹ the weight courts give to parents’ considerations as regards a child’s treatment might even weaken the value of medical considerations.

Therefore, it could be concluded that parents have parental liberty regarding routine MMRV vaccination without it being interfered with unless there are disagreements between them.

2.7. Conclusions

To determine whether parents have decision-making authority as regards vaccination of their children, this Chapter first addressed children’s capacity to give consent to treatment. Also, it explained the rationale behind transfer of decision-making authority to parents in light of parental liberty and its underlying presumption that parents act in the best interests of the child. The discussion of the nature and, to some extent, scope of parental liberty was mainly based on La Forest J’s opinion in *BR*. Then I covered a range of legal mechanisms by which the state may intervene where parents refuse to consent to treatment, i.e. “*parens patriae*”, “child in need of protection,” and where parents disagree as regards treatment choices.

Next, I considered a range of cases in which the state intruded in the sphere of parental liberty as regards health care choices, and the case law on parental refusal or disagreements in the matter of vaccination. The analysis of the courts’ decisions in these matters, including their application of the best interest standard, led to the conclusion that the decision to vaccinate a

¹³⁷ *Chimiliar*, *supra* note 117.

¹³⁸ *Re C & F*, *supra* note 111.

¹³⁹ *Saskatchewan (Minister of Social Services) v P (F)*, *supra* note 90 at paras 62-75.

child with routine vaccines is likely to fall within the sphere of parental liberty. Even though the state is equipped with the best interest standard to consider the authorization of treatment if necessary, in case of routine vaccination, such as MMRV, parents have liberty to decide whether to authorize the treatment. Therefore, parents have a decision-making authority as regards MMRV vaccination.

If parents have the decision-making authority, in principle, they should be able to exercise it voluntarily like any other proposed health care intervention. However, the state may, depending on the details of any vaccination program it establishes, interfere, to a greater or lesser extent, with parent's ability to exercise their decision-making authority in a voluntary manner. This is the rationale for discussing the voluntariness of consent in the next Chapter and its application to vaccination programs. The Chapter after that focuses on the legal and ethics foundation of the voluntariness of consent to set the stage for the analysis of vaccination programs.

CHAPTER 3. THE VOLUNTARINESS OF CONSENT

3.1. Introduction

Consent carries fundamental importance at the intersection of medicine and law. Courts have long stated that a patient is provided with a medical treatment only when he or she consented to it, since “with very limited exceptions, every person’s body is inviolate, and, accordingly, every competent adult has the right to be free from unwanted medical treatment.”¹ Therefore, the notion of consent cemented “the right to determine what shall, or shall not be done with one’s own body and to be free from non-consensual medical treatment.”² The underlying idea of consent is the protection of bodily integrity. The safeguarding of the right to be free from unwanted or offensive bodily touching could be traced back to the legal concern for bodily integrity that is manifested in the writ of trespass for assault and battery.³

The legal doctrine of consent has had a long development, influenced by historical events, shifts in the perception of the medical profession, and the emergence of other disciplines that cherish values of autonomy and self-determination in North America. In this Chapter, I trace the emergence of, and elements that comprise, consent in law (in Part 1), and then shift (in Part 2) to focus in greater depth on one element of consent, namely, voluntariness. More specifically, in the second part of the Chapter, I discuss various influences that can infringe the voluntariness of consent: coercion, undue influence caused by a combination of inequality in a power dependency relationship and exploitation, psychological compulsion, pressure via verbal persuasion and the offer of financial incentives.

¹ *Fleming v Reid*, (1991) 82 DLR (4th) 298 (Ont CA) at para 31.

² *Ibid.*

³ Paul S Appelbaum et al, *Informed Consent. Legal Theory and Clinical Practice* (Oxford: Oxford University Press, 2001) at 41.

The findings of this Chapter will therefore set the stage for the next Chapter on the voluntariness of consent in vaccination programs.

3.2. Consent in Law

There are two ways in which the right to make treatment decisions is protected in the law of torts. First, patients protect their bodily integrity by giving consent to treatment or by refusing it.⁴ Second, a doctor has a duty of disclosure which enables a patient to make an informed decision about the proposed treatment.⁵ Therefore, there are two causes of action, battery and negligence that could be brought to protect the patient's right to give consent. The difference between the two causes of action in relation to consent in the health care context was established by *Reibl v Hughes*.⁶ Along with further details on battery this case is discussed next.

I do not focus on negligence as it encompasses the discussion of informed consent which is outside the scope of this thesis.

3.2.1. Elements of Battery

The tort of battery is committed when a person intentionally causes a harmful or offensive contact with another person.⁷ Battery aims to protect bodily integrity from interference by others.⁸ Even when the interference aims to help somebody, it might constitute battery if it is

⁴ Patricia Peppin, "Informed Consent" in Jocelyn Downie, Timothy Caulfield & Colleen M Flood eds, *Canadian Health Law and Policy*, 4 ed (Markham: LexisNexis, 2011) at 153.

⁵ *Ibid.*

⁶ *Reibl v Hughes*, (1980) 114 DLR (3d) 1 (SCC).

⁷ Allen M Linden & Bruce Feldthusen, *Canadian Tort Law*, 9th ed (Toronto: Lexis Nexis, 2011) at 42.

⁸ *Non-Marine Underwriters, Lloyd's of London v Scalera*, [2000] SCJ No 26, [2000] 1 SCR 551, 2000 SCC 24 at para 15. [*Scalera*]

unwelcome by the person.⁹ Harmful or offensive physical interference, directness and intent are the elements of battery.¹⁰

Not every unwelcome physical interference that happens in the course of everyday life amounts to battery, but only those that are offensive or harmful.¹¹ The contact that may constitute battery might cause no physical harm. The contact might have been driven by the desire to compliment a person but “all contact outside the exceptional category of contact that is generally accepted or expected in the course of ordinary life, is *prima facie* offensive.”¹²

To satisfy the element of directness, the plaintiff must prove that interference is “the immediate consequence of a force set in motion by an act of the defendant.”¹³ Also, the act should be intentional, which means that “the actor desires to cause the consequences of his act, or that he believes that the consequences are substantially certain to result from it.”¹⁴

Since the aim of torts is to protect dignity, damages are awarded based on the physical harm and/or offense to the reasonable person’s sense of bodily integrity or dignitary interest.¹⁵

3.2.2. Consent in Battery

Consent is a defence to battery. Prior to the landmark Supreme Court of Canada decision in *Reibl v Hughes*, the plaintiffs who claimed that their consent was impaired sued for battery and/or negligence. However, the court in *Reibl v Hughes* restricted the action for battery and Justice Laskin drew a clear line between cases of negligence and battery:

⁹ Anthony M Dugdale, Michael Jones & Mark Simpson, *Clerk & Lindsell on Torts*, 19th ed (London: Sweet & Maxwell, 2006) at 882.

¹⁰ *Bettel v Yim*, (1978) 20 OR (2d) 617 at 4.

¹¹ *Scalera*, *supra* note 8 at para 19.

¹² *Ibid* at para 18.

¹³ *Ibid* at para 8.

¹⁴ *Bettel v Yim*, *supra* note 10 at 6.

¹⁵ Patricia Peppin, *supra* note 4 at 155.

I do not understand how it can be said that the consent was vitiated by the failure of disclosure so as to make the surgery or other treatment an unprivileged, unconsented to and intentional invasion of the patient's bodily integrity. I can appreciate the temptation to say that the genuineness of consent to medical treatment depends on proper disclosure of the risks which it entails, but in my view, unless there has been misrepresentation or fraud to secure consent to the treatment, a failure to disclose the attendant risks, however serious, should go to negligence rather than to battery. Although such a failure relates to an informed choice of submitting to or refusing recommended and appropriate treatment, it arises as the breach of an anterior duty of due care, comparable in legal obligation to the duty of due care in carrying out the particular treatment to which the patient has consented. It is not a test of the validity of the consent.¹⁶

According to Justice Laskin, who spoke for all the Justices, the action for battery should be restricted only to those cases where there was no consent at all, or where the act went beyond the scope of the consent.¹⁷ Consequently, failure of disclosure about the risks and benefits associated with a proposed medical intervention must be litigated in negligence.

For consent to be valid it must be voluntary and it must be given by somebody who is capable.¹⁸ Consent is absent in case of a refusal or when one of these two elements of valid consent is missing. One of the elements, the capacity to give consent, is an ability to make a treatment decision, which includes “any legal capacity established by statute or common law.”¹⁹

Voluntary consent is free of coercion or other undue influences, which will be discussed in more detail later in this chapter.²⁰ Also, to be voluntary consent must be free of misrepresentation. In case of the misrepresentation of the treatment, an act goes beyond consent,

¹⁶ *Reibl v Hughes*, *supra* note 6 at 891.

¹⁷ *Ibid* at 891.

¹⁸ Patricia Peppin, *supra* note 15 at 156.

¹⁹ *Ibid*.

²⁰ *Norberg v Wynrib*, (1992) 92 DLR (4th), 449 (SCC) at para 26 [*Norberg*]. *Gerula v Flores*, (1995) 126 DLR (4th) 506 (Ont CA) at 72.

such as unauthorized sterilization preceded by a caesarian operation to which consent was given,²¹ or the treatment of a hand for which a patient gave consent, but not an amputation.²²

There is an exception to the requirement to obtain consent before performing treatment in cases of emergency. However, to proceed without consent, some requirements must be met. First, patient must be unable to give consent due to a state of unconsciousness or lack of capacity; and there is nobody who can consent on behalf of a patient.²³ Second, an immediate medical intervention is needed to preserve patient's life and health.²⁴ Third, "under the circumstances, a reasonable person would consent, and the probabilities are that the patient would consent"²⁵ to the treatment.

In *Murray v McMurchy*,²⁶ a doctor tied fallopian tubes after a caesarian section, because he discovered tumors in the patient's uterine wall during the section. He was found liable for battery, because the convenience of tying the tubes did not fall within an emergency situation as the tumors did not present any immediate danger to the patient's life. Canadian courts established a difference between a necessary procedure and a convenient procedure.²⁷ Thus, the emergency exemption does not apply when doctors believe that the patient would not have agreed to treatment, or when the procedure does not need to be performed immediately.

²¹ *Mulloy v Hop Sang*, [1935] 1 WWR 714 in *Reibl v Hughes*, *supra* note 6 at 892.

²² Cases are listed by Justice Laskin. See *Winn v Alexander and the Soldiers' Memorial Hospital*, [1940] OWN 238 at 8.

²³ William Lloyd Prosser et al eds, *Prosser and Keeton on the Law of Torts* (West Pub Co, 1988) at 117-118 in *Malette v Shulman*, (1990) 67, DLR (4th) 321 (Ont) at paras 6-7 [*Malette*].

²⁴ *Malette*, *supra* note 23 at paras 6-7.

²⁵ *Ibid.*

²⁶ *Murray v McMurchy*, [1949] 2 DLR 442 (BC SC) at 444.

²⁷ Ellen I Picard & Gerald B Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 4th ed (Toronto: Thomson Carswell, 2007) at 58.

Since I focus on routine vaccination and the voluntariness of consent, in this thesis, emergency circumstances would not be relevant to this discussion. In the next part of this chapter, I explore on the concept of the voluntariness of consent in more detail.

3.3. Voluntariness

Voluntariness as a component of a valid consent seems to be “straightforward”²⁸ – it presupposes that consent must be given freely. In *Norberg*, La Forest J cites “Salmond and Heuston on the Law of Torts” according to which “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.”²⁹ La Forest J claims that 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.”³⁰ Consent is voluntary when it is not obtained through coercion, undue influence³¹ or misrepresentation as to the treatment provided.³²

For consent to be genuine there first must be a choice available, which puts an individual in position to choose freely. The availability of choice is essential since in terms of health care choices, consent to a certain treatment is an option one selects among alternative treatments; or if there is no alternative to a suggested medical treatment, then a patient has a choice to consent to

²⁸ Erin Nelson, “The Fundamentals of Consent” in Jocelyn Downie, Timothy Caulfield & Colleen M Flood eds, *Canadian Health Law and Policy*, 2nd ed (Markham: LexisNexis, 2002) at 120. (*This Chapter is not included in the most recent edition of the book*)

²⁹ R F V Heuston & R S Chambers, *Salmond and Heuston on the Law of Torts*, 19th ed (London: Sweet & Maxwell, 1987) in *Norberg*, *supra* note 20 at para 27.

³⁰ *Ibid.*

³¹ *Ibid.*

³² *Reibl v Hughes*, *supra* note 6 at 892.

or refuse a proposed treatment. Therefore, the notion of consent as based on an “individual autonomy and free will”³³ is meaningless when the choice to refuse is not even available.

Moreover, the option to decide against the treatment should be present to enable a patient to exercise the right to refuse the treatment recognized by common law to “be fundamental to a person’s dignity and autonomy.”³⁴ In, *Fleming v Reid*, a case on the correspondence of provisions of the Ontario *Mental Health Act*³⁵ with ss 1, 7, 15 of the *Charter*, Justice Robins indicated that

with very limited exceptions, every person’s body is considered inviolate, and, accordingly, every competent adult has the right to be free from unwanted medical treatment. The fact that serious risks or consequences may result from a refusal of medical treatment do not vitiate the right of medical self-determination.³⁶

Therefore, it is “the patient, not the doctor, who ultimately must decide *if treatment --any treatment -- is to be administered.*”³⁷ However, the availability of choice is not enough for consent to be voluntary, since it could be affected by external constraints.

3.3.1. Choice Constraints

As mentioned above, voluntary consent should be free of coercion, undue influence³⁸ or fraudulent misrepresentation as to the nature of the treatment provided.³⁹ This is the terminology courts operate with as regards infringements of the voluntariness of consent in the health care context. Also, this is the categorization that authors in Canada use to discuss the voluntariness of consent.⁴⁰ Fraudulent misrepresentation as to the nature of the treatment provided and coercion

³³ *Ibid.*

³⁴ *Starson v Swayze*, 2003 SCC 32, [2003] 1 SCR 722 at 412.

³⁵ *Mental Health Act*, RSO 1980, c 262, ss 35(2) (b) (ii), 35 a.

³⁶ *Fleming v Reid*, *supra* note 1 at para 31.

³⁷ *Ibid.* Italics added.

³⁸ *Norberg*, *supra* note 20 at para 26.

³⁹ *Reibl v Hughes*, *supra* note 6 at para 11.

⁴⁰ Ellen I Picard & Gerald B Robertson, *supra* note 27 at 62, 65. Erin Nelson, *supra* note 28 at 120.

are long-established to vitiate the voluntariness of consent to the treatment.⁴¹ However, as I will show, the use and the scope of the term “undue influence” as borrowed from contracts law is not clear in relation to consent in torts. Also unclear is the interrelation between undue influence and coercion.

To begin with, as regards the general notion of influence, in *Geffen v Goodman Estate*, a case on trusts and the presumption of undue influence, Wilson J states that

"Influence" refers to the ability of one person to dominate the will of another, whether through manipulation, coercion, or outright but subtle abuse of power. To dominate the will of another simply means to exercise a persuasive influence over him or her. The ability to exercise such influence may arise from a relationship of trust or confidence but it may arise from other relationships as well.⁴²

Therefore, according to this definition, undue influence includes coercion or other factors that can vitiate the voluntariness of consent.

In *Rodriguez*, the Supreme Court of Canada case on the correspondence of the *Criminal Code* prohibition of assisted suicide with ss 7, 12, 15 (1) of the *Charter*, Lamer J., in the discussion of the free choice to terminate one’s life, uses the term “undue influence” and claims that a patient might be “vulnerable to coercion *or other* undue influence”.⁴³ This means that undue influence includes a number of factors that can negate the voluntariness of consent, including coercion. Some cases on wills, in which the notion of undue influence is most often

⁴¹ *Reibl v Hughes*, *supra* note 6 at para 11. Misrepresentation is withholding information about a treatment, or its exaggeration that amounts to fraudulent misrepresentation as to the nature of the treatment. In *Gerula v Flores*, the court held that misrepresentation by omission is sufficient to vitiate consent. In this case, a surgeon mistakenly operated on a fourth vertebra instead of the third vertebra, but later obtained the patient’s consent to the second surgery in which he operated on the third vertebra. The surgeon did not inform the patient that the second operation was needed because of his error in performing the first. The Ontario Court of Appeal held that the misrepresentation was deliberate and this negated the patient’s consent to the second operation. Courts differentiate between the cases in which doctors intentionally mislead the patient, as happened in *Gerula*, and where consent is received as a result of doctor’s error. The latter does not vitiate consent. See generally *Gerula v Flores*, (1995) 126 DLR (4th) 506 (Ont CA). *Kita v Braig*, (1992) 71 BCLR (2d) 135 (CA).

⁴² *Geffen v Goodman Estate*, [1991] 2 SCR 353 at para 40.

⁴³ *Rodriguez v British Columbia (Attorney General)*, [1993] 3 SCR 519 at para 217. Italics added.

considered, differentiate between undue influence and coercion. They claim that coercion/duress⁴⁴ or undue influence vitiates consent.⁴⁵

In *Norberg*, Justice La Forest did not indicate that undue influence *per se* infringed consent in tort law. However, the term appears in *Norberg*, when Justice La Forest draws on the voluntariness of consent in the law of contracts. He claims that “the doctrines of duress, undue influence, and unconscionability have arisen to protect the vulnerable when they are in a relationship of unequal power.”⁴⁶ Moreover, La Forest J states:

Professor Klippert in his book *Unjust Enrichment* refers to the doctrines of duress, undue influence, and unconscionability as "justice factors". He lumps these together under the general term "coercion". If the "justice factor" of unconscionability is used to address the issue of voluntariness in the law of contract, it seems reasonable that it be examined to address the issue of voluntariness in the law of tort. This provides insight into the issue of consent: for consent to be genuine, it must be voluntary.⁴⁷

Since Justice La Forest pointed to the aforementioned principles and concluded that “the principles that have been developed in the area of unconscionable transactions to negate the legal effectiveness of certain contracts provide a useful framework for this evaluation”,⁴⁸ it could be assumed that coercion included all influences that infringe consent in the health care context too. Moreover, in some cases on wills, courts cite the English case *Wingrove v. Wingrove*, in which all undue influences were included under the broader concept of coercion.

In contrast to the approach in *Wingrove*, I rely on the approach in *Geffen* and *Rodriquez*, in which undue influence includes coercion as “the action or practice of persuading someone to

⁴⁴ “Coercion” and “duress” are used by Canadian courts interchangeably.

⁴⁵ See *Fennell v Fennell*, [2012] NJ No 63 at para 37 (wills, estate and trusts law). *Kenyon v Kenyon*, [2011] BCJ No 1005 at paras 35-37 (family law). *Brooks v Alker et al.*, (1976), 9 OR (2d) 409 at 5 (contracts, sale of land). *Carter v Canada*, [2012] BCJ No 119 at para 10 (assisted suicide). *Kaulp v Colman*, [2003] AJ No 1426 at para 2. *Kennedy v McNamara*, [1997] NSJ No 596 at para 13 (family law).

⁴⁶ *Norberg*, *supra* note 20 at para 28.

⁴⁷ *Ibid.*

⁴⁸ *Ibid* at para 29.

do something by using force or threat”⁴⁹ and other external influences that infringe consent. I apply the term undue influence to the health care context since it was factored into the analysis in *Norberg* as a concept from the law of contracts that could be helpful to analyze the voluntariness of consent in the law of torts. Moreover, scholars discuss undue influence as related to the law of torts and consent in the health care context.⁵⁰ In this Chapter, the infringements of consent are discussed under the umbrella of undue influence.

3.3.2. Undue Influences and Influences that could Become Undue

A person is always under some type of influence because external influences are hardly avoidable. It will be true to say that an individual is embedded in society and our choices are always a result of our “values, attitudes, characteristic motivations, and life plans that the individual personally accepts”,⁵¹ which are formed in the society under the influence of others including parents, friends, colleagues, teachers or doctors. For instance, “an anxious, ill person, often with a concerned family hovering and advising”,⁵² might be unable to make a decision free of some degree of external influence. Moreover, to some extent a decision to undergo a surgery is the result of a doctor’s advice to opt for the surgery.⁵³ Therefore, it could be either the advice of the family, the influence of the doctor or financial incentives that encourage individuals to submit to a certain treatment or a clinical research.

If a physician orders a patient to undergo a surgery under the threat of being dismissed as a patient, the influence of the physician controls the patient’s choice via coercion.⁵⁴ On the contrary, when a physician simply identifies reasons to undergo a treatment, he or she influences

⁴⁹ The Oxford English Dictionary, *sub verbo* “coercion” online: Oxford Dictionaries <<http://oxforddictionaries.com>>.

⁵⁰ Ellen I Picard & Gerald B Robertson, *supra* note 27 at 62, 65. Erin Nelson, *supra* note 28 at 120.

⁵¹ Robert L Nelson et al, “The concept of Voluntary Consent” (2011) 8 *The American Journal of Bioethics* at 11.

⁵² Ellen I Picard & Gerald B Robertson, *supra* note 27 at 62.

⁵³ *Re T*, [1992] ALL ER 649, 1992 9 BMLR at 662.

⁵⁴ Robert L Nelson et al, *supra* note 51 at 7.

a patient but this influence is not necessarily controlling.⁵⁵ The line between the voluntariness and non-voluntariness of consent is not always as apparent as it is with the use of force or threat in case of coercion. When it is not so apparent, voluntariness “should be regarded as a matter of degree, rather than a quality that is wholly present or not present in some cases.”⁵⁶

So, it could be claimed that voluntariness “occurs along a spectrum”.⁵⁷ The question is when the external influences as regards the treatment choice might be said to have crossed the line and become incompatible with voluntariness. According to *Re T*, an English case on the refusal of blood transfusion, for the voluntariness of consent to be infringed “there must be such a degree of external influence as to [cause] the patient to depart from her own wishes”.⁵⁸ In other words, “a [patient] may be led but not driven”.⁵⁹

In this section, I consider (1) coercion; (2) undue influences that occur under the combination of inequality in a power dependency relationship and exploitation; and (3) psychological compulsion. Also, (4) pressure via verbal persuasion, and (5) the offer of financial incentives are discussed as influences that could become undue. The first three types of influence render choice involuntary, whereas pressure via persuasion and the offer of financial incentives are influences that could amount to undue influences.

It should be noted that some influences might overlap or occur in a combination with other external influences if analyzed in a certain context. For instance, voluntariness could be vitiated by a combination of verbal pressure and the offer of financial incentives.

⁵⁵ *Ibid.*

⁵⁶ President’s Commission for the Study of Ethical Problems in Medicine, *Making Healthcare Decisions: The Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship* (October 1982), online: <http://bioethics.georgetown.edu/pcbe/reports/past_commissions/making_health_care_decisions.pdf> at 62.

⁵⁷ Paul S Appelbaum, Charles W Lidz & Robert Klitzman, "Voluntariness of Consent to Research: A Conceptual Model" (2009) 1 *Hastings Center Report* 30 at 37.

⁵⁸ *Re T*, *supra* note 53 at 669.

⁵⁹ *Hall v Hall*, (1868) LR 1 P & D 481 at 482.

However, in the following sections, influences that could be viewed as undue are discussed as categorized above to ensure the clarity of concepts which would be applied to consent in vaccination programs in Chapter 5. I focus on the common law foundation of the voluntariness of consent; however, the discussion shifts to ethics to fully comprehend some concepts that were not touched upon by the courts.

The discussion starts with the notion of coercion, which is the strongest form of undue influence.

3.3.2.1. Coercion

Coercion results in either compelling someone to do something that he or she does not want to do, or in preventing somebody from pursuing what she or he wants.⁶⁰ In *R v Big M Drug Mart Ltd*, when discussing the notion of “freedom”, Dickson J provided a definition of coercion, which could be applicable to the notion of coercion in the health care context. Dickson J stated that “coercion includes not only such blatant forms of compulsion as direct commands to act or refrain from acting on pain of sanction, coercion includes indirect forms of control which determine or limit alternative courses of conduct available to others.”⁶¹

A direct form of coercion includes the use of force or threat.⁶² Even though the meaning of threat relates to the threat to use force, in the health care context, patients could be threatened with the potential loss of health care benefits or withdrawal of any privileges. And when “the threat is tied to the request to accede to the demands, [t]his interferes with the ... freedom of

⁶⁰ *Ibid* at 339.

⁶¹ *R v Big M Drug Mart Ltd*, [1985] 1 SCR 295 at para 95 [*Big M*].

⁶² Robert L Nelson, *supra* note 51 at 7.

choice, as the [patient] may be coerced into doing something he or she would otherwise have chosen not to do.”⁶³

“Indirect forms of control” is a vague category. As an example of indirect coercion, two Supreme Court of Canada cases on the right to silence and against self-incrimination, *White* and *Fitzpatrick*, could be used to depict indirect forms of control. According to a later decision, *Choy*, which interpreted *Fitzpatrick* and *White*, the Supreme Court of Canada identified “the degree to which a person was required to participate in the legislative scheme” as a form of coercion.⁶⁴ Even though in these cases voluntariness was discussed outside the health care context, it could be applied to consent to treatment to enrich the concept of the degree of voluntariness of consent to treatment.⁶⁵

In both cases, the court touched upon the voluntariness of choice while considering how voluntary the choices to engage in certain activities were. In *Fitzpatrick*, La Forest J claimed that there was free choice to get involved in the commercial fishery since “no one is compelled to participate in the groundfish fishery [as the captain of a vessel], they do so purely as the result of their own free decision.”⁶⁶

In *White*, Iacobucci J commented on the freedom of choice to drive. In this case, the Crown claimed that the choice to drive a vehicle was a voluntary choice. However, Iacobucci J stated that

⁶³ *R v Davis*, [1999] 3 SCR 759 at para 45.

⁶⁴ *R v Choy*, [2008] AJ No 1320, 2008 ABQB 737 at para 24.

In *Fitzpatrick*, a fisherman was charged with overfishing. The issue was “whether admission in evidence of hail report and fishing logs infringes the fisherman’s right against self-incrimination under s. 7 of Canadian Charter of Rights and Freedoms”. “All fishermen are required under s. 61 of the Fisheries Act to provide these documents and failure to do so constitutes an offence under the Act”. See *R v Fitzpatrick*, [1995] 4 SCR 154 at 1. In *White*, “The primary issue... is whether the admission into evidence in a criminal trial of statements made by the accused under compulsion of the *Motor Vehicles Act* offends the principle against self-incrimination embodied in s. 7 of the Charter.” See *R v White*, [1999] 2 SCR 417 at para 32.

⁶⁵ *R v Fitzpatrick*, [1995] 4 SCR 154 at para 38. *R v White*, [1999] 2 SCR 417 at para 55.

⁶⁶ *R v Fitzpatrick*, *supra* note 65 at para 38.

Driving is not freely undertaken in precisely the same way as one is free to participate in a regulated industry such as the commercial fishery. Driving is often a necessity of life, particularly in rural areas...When a person needs to drive in order to function meaningfully in society, the choice of whether to drive is not truly as free as the choice of whether to enter into an industry.⁶⁷

Consequently, the degree of voluntariness in case of driving is much lower than in choosing a “profession”⁶⁸ as in *Fitzpatrick*. Even though, in *White*, Iacobucci J did not conclude that the choice to drive is coerced, the “necessity” to submit to the activity that allowed an individual to “function...in society” was viewed as a factor that affected the voluntariness of choice.

Therefore, there are two forms of coercion: direct control, which implies the use of force or threat; and indirect forms of control – a vague category that includes some types of control that undermine other potentially available alternatives. As the meaning of indirect forms of control is broad, the following sections explore a number of indirect forms of control.

3.3.2.2. A Combination of Inequality in a Power Dependency Relationship and Exploitation that Give Rise to Undue Influence

The doctor’s authority in a doctor-patient relationship causes some concerns about the voluntariness of a patient’s consent for two reasons. First, the doctor’s knowledge and power could be used to control a patient’s consent, which might lead to the impairment of the voluntariness of the patient’s decision. Second, “patients seek the help of doctors when they are in a vulnerable state -- when they are sick, when they are needy, when they are uncertain about what needs to be done”,⁶⁹ which makes them more prone to influence.

⁶⁷ *R v White*, *supra* note 65 at para 55.

⁶⁸ *R v Choy*, *supra* note 64 at para 24.

⁶⁹ The Final Report of the Task Force on Sexual Abuse of Patients, An Independent Task Force Commissioned by The College of Physicians and Surgeons of Ontario (November 1991) at 11 in *Norberg*, *supra* note 20 at para 43.

This issue emerged in *Norberg v Wynrib*,⁷⁰ where a physician who was aware of the patient's drug addiction prescribed a drug in exchange for sexual favours. The patient sued the physician for battery, negligence and a breach of fiduciary duty and the physician raised the defence of consent. Three out of six judges found that the patient's consent was influenced by the combination of the inequality of power between the doctor and patient, and the exploitative nature of the relationship.⁷¹

In *Norberg*, Justice La Forest described the inequality in a power dependency relationship and exploitation as elements of a "two-step process"⁷² for determining "whether or not there has been legally effective consent".⁷³ *Norberg* considered consent to a sexual relationship; still, it could be applicable to consent to treatment, as the opinion delivered by La Forest J on behalf of Gonthier and Cory JJ focuses on the law of torts and a power dependency relationship.⁷⁴

To begin with, the common characteristic of a power dependency relationship "is an underlying personal or professional association which creates a significant power imbalance between the parties",⁷⁵ including such relationships as "parent-child, psychotherapist-patient, physician-patient, clergy-penitent, professor-student, attorney-client, and employer-employee."⁷⁶ In *Guerin v The Queen*,⁷⁷ a Supreme Court of Canada case on fiduciary duties of the Crown towards the First Nations of Canada, Dickson J claimed that a power dependency relationship occurred "in any situation where one party, by statute, agreement, a particular course of conduct,

⁷⁰ *Norberg*, *supra* note 20.

⁷¹ *Ibid* at para 40.

⁷² *Ibid*.

⁷³ *Ibid*.

⁷⁴ Per L'Heureux-Dubé and McLachlin JJ. The fiduciary duty which existed in a patient-doctor relationship was breached; since I focus on torts, fiduciary duties are outside the scope of my thesis. See *Norberg*, *supra* note 20.

⁷⁵ Phyllis Coleman, "Sex in Power Dependency Relationships: Taking Unfair Advantage of the 'Fair' Sex", (1988) 53 Albany L Rev in *Norberg*, *supra* note 20 at 255.

⁷⁶ *Norberg*, *supra* note 20 at para 39.

⁷⁷ *Guerin v The Queen*, [1984] 2 SCR 335 at 384.

or by unilateral undertaking, gains a position of overriding *power or influence* over another party.”⁷⁸

Justice La Forest, in *Norberg*, stated that the mere existence of a power dependency relationship does not automatically mean that there is such power imbalance that infringes consent and “the factual context of each case must, of course, be evaluated to determine if there has been genuine consent.”⁷⁹ Sopinka J., who disagreed with La Forest J on the application of the law to the facts⁸⁰ also stated that “the question of consent in relation to a battery claim is ultimately a factual one that must be determined on the basis of all the circumstances of a particular case.”⁸¹ Therefore, as concluded by Sopinka J., “these factors must be applied on a case-by-case basis rather than by establishing categories of individuals or relationships with respect to which apparent consent will never or rarely be considered valid.”⁸²

An inequality between the parties must be proved first. Even though La Forest J noted that because of the nature of the doctor-patient relationship the inequality “will ordinarily occur within the context of a special "power dependency" relationship”,⁸³ the marked inequality in the respective powers in *Norberg* was obvious. On the one side in this relationship was Laura Norberg, an appellant with limited education, who had an addiction to a pain killer, Fiorinal; on the other side, there was a doctor with knowledge of the patient’s addiction and the authority to prescribe medications.

⁷⁸ *Hodgkinson v Simm*, [1994] 3 SCR 377 at para 34 in *Guerin v The Queen*, *supra* note 77 at 384

⁷⁹ *Norberg*, *supra* note 20 at para 29. Italics added.

⁸⁰ Sopinka J claimed that “Importing the principles of unconscionability into the context of a battery claim has the potential to obscure the real question of whether, in all the circumstances, the plaintiff actually consented to the touching which constituted the alleged battery. The facts of this case are more accurately reflected by acknowledging that the appellant consented to the sexual contact and by considering the respondent's conduct in light of his professional duty towards the appellant.” See *Norberg*, *supra* note 20 at 234.

⁸¹ *Norberg*, *supra* note 20 at para 123.

⁸² *Ibid* at para 123.

⁸³ *Ibid* at para 40.

As regards the second element, exploitation, it occurs when a person who has an authority, takes advantage of that powerful position to use a person for his or her own needs. According to La Forest J., the type of relationship and the community standards of conduct in certain relationships could be relied on to determine whether there was exploitation.⁸⁴ For instance, in *Norberg*, La Forest J claimed that patients reasonably expected to receive professional health care and not to be exploited by the physician since “the Hippocratic Oath reflects this universal concern that physicians not exploit their patients for their own ends, and in particular, not for their own sexual end.”⁸⁵

The respondent claimed that it was the plaintiff who exploited “the weakness and loneliness of an elderly man to obtain drugs”.⁸⁶ Justice La Forest agreed with the fact that the doctor had his vulnerabilities but, in that relationship, it was the doctor who suggested the sex-for-drugs arrangement.⁸⁷ Dr. Wynrib did not stop prescribing pills and never advised counselling. Instead, he used his “power and knowledge to initiate the arrangement and to exploit [the patient’s] vulnerability”.⁸⁸ Despite the patient’s wish not to engage in the sexual relationship, she was “overwhelmed by the driving force of her addiction and the unsettling prospect of a painful, unsupervised chemical withdrawal” which undermined her ability to make a real choice.⁸⁹ Thus, in *Norberg*, a patient was induced into a sexual relationship.⁹⁰

Therefore, for the analysis of La Forest J analysis to apply, there must be a combination of inequality of power in relationship and exploitation for consent to be non-voluntary.

⁸⁴ *Ibid* at para 73.

⁸⁵ *Ibid* at paras 45-46.

⁸⁶ *Ibid* at para 46.

⁸⁷ *Ibid* at para 46.

⁸⁸ *Ibid* at para 49.

⁸⁹ Andrew Grubb, Judith Laing & Jean McHale eds, *Medical Law*, 3d ed (Oxford: Oxford University Press, 2010) at 759.

⁹⁰ *Norberg*, *supra* note 20 at para 39.

3.3.2.3. Psychological Compulsion

Also applicable to treatment choices could be the notion of psychological compulsion that courts operate with in criminal cases that engage constitutional analysis.⁹¹ Under psychological compulsion, a patient's choice is influenced by state power. In *R v Therens*, the term "psychological compulsion" was used to discuss freedom of choice in the context of defining "detention" within the meaning of s.10 of the *Charter*. It was established that "the element of psychological compulsion, in the form of a reasonable perception of suspension of freedom of choice, is enough to make the restraint of liberty involuntary."⁹² According to Justice Le Dain, the underlying idea of psychological compulsion lies in the fact that

it is not realistic, as a general rule, to regard compliance with a demand or direction by a police officer as truly voluntary, in the sense that a citizen feels that he or she has the choice to obey or not even where there is in fact a lack of statutory or common law authority for the demand or direction and therefore an absence of criminal liability for failure to comply with it.⁹³

Overall, the notion of psychological compulsion was used by courts mostly in relation to detention.⁹⁴ In *Morgentaler*, the court drew on psychological compulsion to show "state-imposed psychological trauma" as the effect of a state action which could infringe s. 7 of the *Charter*.⁹⁵ Therefore, as psychological compulsion touches upon freedom of choice, its application might be extended to the health care context.

For psychological compulsion to be established, there should be a "demand or direction" in response to which "the person concerned submits or acquiesces in the deprivation of liberty

⁹¹ *R v Abbey*, [2006] OJ No 4689 at para 46. *R v Holt*, [2012] BCJ No 1581 at para 40. *R v Therens*, [1985] 1 SCR 613 at para 53.

⁹² *R v Therens*, [1985] 1 SCR 613 at para 53.

⁹³ *Ibid.*

⁹⁴ *R v Abbey*, *R v Therrien*, *R v Holt*, *supra* note 91.

⁹⁵ *R v Morgentaler*, [1988] SCJ No 1 at paras 19-20.

and reasonably believes that the choice to do otherwise does not exist.”⁹⁶ In *Thereens*, the request or direction came from a police officer, who unlike a doctor, has a state authorized capacity to coerce. However, in the health care context, it is the power dependency doctor-patient relationship that could lead to psychological compulsion.

A patient hears an offer in a doctor-patient relationship. In a doctor-patient relationship, according to McLachlin J in *Norberg*, a doctor has authority over patients which could be exercised to affect the interests of the patient.⁹⁷ A doctor’s authority, as mentioned above, also makes patients vulnerable to external influences. Therefore, considering the vulnerable position of patients in a doctor-patient relationship, the mere offer could be interpreted by a patient as a “direction” to submit to treatment. In other words, a doctor’s authority in a doctor-patient relationship could strengthen the offer and escalate it to the level of “direction”, which might make patients believe that the choice to say no is not available as such.

What is more, it could be assumed that psychological compulsion could occur when a doctor “offers” a routine clinical intervention, that is, for instance, a part of a public health program. The existence of the program *per se* and the involvement of state “direction” to submit to treatment announced by a doctor might also contribute to psychological compulsion, especially in combination with a power dependency relationship.

Therefore, if psychological compulsion is applicable to health care consent, a doctor’s authority in a doctor-patient relationship and the involvement of the state could lead to the perception that the choice to refuse treatment does not exist and, therefore, vitiate consent.

Two types of influence discussed next are less strong than the ones discussed above, and their occurrence is less likely to infringe consent.

⁹⁶ *R v Bazinet*, (1986) 25 CCC (3d) 273 at paras 34-35. *Toronto (City) v Bednarski*, [2009] OJ No 2955 at para 73.

⁹⁷ *Norberg*, *supra* note 20 at paras 69-70.

3.3.2.4. Undue Pressure by Verbal Persuasion

In *Norberg*, Justice La Forest quotes a book “Unjust Enrichment”, which claims that “unlawful pressure ...vitiates a person's freedom of choice”.⁹⁸ However, it is not clear what types of pressure are unlawful. In this section, I discuss pressure via verbal persuasion that does not necessarily need to occur within a doctor-patient power dependency relationship to become undue. Moreover, the category of pressure via verbal persuasion is not intertwined with exploitation -- using a patient for a doctor’s private purpose, as it was in *Norberg*. Therefore, this is a type of undue influence that arises out of verbal persuasion *per se*.

A concern as regards “the degree of pressure to turn persuasion or appeals to affection into undue influence”⁹⁹ was raised in the English case, *Re T*. In *Re T*, the 21 year old woman, at her 34th week of pregnancy, was brought to the hospital by her mother who was a Jehovah’s Witness. Miss T, the patient, was not a member of that faith herself, but after a conversation with her mother, she indicated that she would not consent to a blood transfusion in case it would be necessary. Miss T claimed that she had some of the beliefs of a Jehovah’s Witness.¹⁰⁰ When the patient needed blood transfusion, Miss T’s father applied to the court to allow him to authorize the transfusion. The order was granted and the judge found that the refusal of the transfusion was due to undue pressure via persuasion from her mother.

On appeal of the decision, Lord Donaldson said that

Doctors have to consider whether the decision is really that of the patient. It is wholly acceptable that the patient should have been persuaded by others of the merits of such decision and have decided accordingly. It does not matter how strong the persuasion was, so long as it did not overbear the independence of the patient’s decision.¹⁰¹

⁹⁸ *Norberg*, *supra* note 20 at para 39.

⁹⁹ *Re T*, *supra* note 53 at 662.

¹⁰⁰ *Ibid* at 662.

¹⁰¹ *Ibid*.

Consequently, not all types of pressure via persuasion are incompatible with consent, but a patient should not be overwhelmed with influence, and he or she should not consent to treatment “because the advice and persuasion to which he has been subjected is such that he can no longer think and decide for himself.”¹⁰²

The court held that “the strength of the will of the patient”¹⁰³ and the existence of the relationship of “the 'persuader' to the patient may be of crucial importance”¹⁰⁴ to determine the extent of the external pressure. More specifically, Lord Donaldson reaffirmed that “patients that are suffering from pain or depression are more likely to be less resistant to the influences than people who are not suffering”.¹⁰⁵ He also emphasized the strength of the relationship, claiming that “the influence of parents on their children or of one spouse on the other can be, but is by no means necessarily, much stronger than would be the case in other relationships”.¹⁰⁶

To sum up, pressure via verbal persuasion is acceptable as long as it does not overbear the independence of the decision.

3.3.2.5. The Offer of Financial Incentives

The offer of financial incentives might give rise to undue influence. I consider two types of financial incentives: the offer of financial incentives to patients and the offer of financial incentives to doctors. Later in this thesis, incentives to patients are referred to as “benefits to patients”. The offer of incentives to patients could influence choice by inducing the patient to do something that he or she would not have done if it was not for the offer. The offer of financial incentives to doctors might give rise to undue influences that they exert on patients. In other words, it can trigger undue influences and infringe consent indirectly.

¹⁰² *Ibid.*

¹⁰³ *Ibid.*

¹⁰⁴ *Ibid.*

¹⁰⁵ *Ibid.*

¹⁰⁶ *Ibid.*

Even though so far the discussion of the voluntariness of consent was based on relevant case law, the discussion of financial incentives differs. I rely on ethics to see whether the offer of financial incentives can cross the line and become undue. As regards the influence of the offer of financial incentives on doctors, the section illustrates the rationale behind the concern that financial incentives could entail undue influences that doctors impose on patients.

3.3.2.5.1. Financial Incentives to Patients

Offering financial incentives to patients is a common way to attract people to participate in studies. This is why concerns about financial incentives are usually discussed in the context of participation in clinical trials and research. It is well known that an offer of money can persuade people to do things that they do not want to do, or that they consider wrong.¹⁰⁷ Therefore, potentially, money “can impair an individual’s judgment regarding what is at stake in the research or blind him or her to the potential risk of research participation.”¹⁰⁸ Courts have not deliberated on the impact of financial incentives on the voluntariness of consent to treatment.¹⁰⁹

In Canada, the Tri-Council Policy Statement, “Ethical Conduct for Research Involving Humans”, touches upon financial incentives.¹¹⁰ It claims that since “incentives are used to encourage participation in a research project, they are an important consideration in assessing voluntariness”.¹¹¹ More specifically, since “financial [incentives] is a way for [participants] to

¹⁰⁷ Christine Grady, “Money for research participation: does it jeopardize consent” (2001) 1:2 AJOB 40 at 42.

¹⁰⁸ *Ibid.*

¹⁰⁹ Financial incentives are often referred to as inducements in the literature. *Carter v Canada* uses the word “inducement” to identify undue influences which might also be related to those financial incentives which amount to undue influences. In *Carter v Canada*, the Supreme Court of British Columbia case on the *Charter* said that “a patient’s request for an assisted death is voluntary, when it is free of...*undue inducement*” [italics added]. See *Carter v Canada*, (2013) BCCA 435 at 750.

¹¹⁰ Government of Canada, Panel on Research Ethics, *TCPS 2 - Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, online: Panel on Research Ethics <<http://www.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/>>.

¹¹¹ *Ibid* at 29.

gain favour or improve their situation”,¹¹² incentives can amount to undue inducement, which negates the voluntariness of consent.¹¹³

At the same time, it is not clear whether money is “uniquely capable of distorting judgment about the risks and benefits of research”.¹¹⁴ People have different motivations to participate in research, including altruistic ones, and money might be one of the reasons. Moreover, since not every degree of influence undermines consent, the offer of financial incentive does not automatically obviate consent. For instance, according to a framework offered by Nelson, Beauchamp, Miller, Reynolds, Ittenbach and Luce [Nelson/Beauchamp framework], it is claimed that if financial incentives are welcomed, subjects do not want to refuse it, and if the risks related to participation in research are not high, incentives might have a minimal impact on consent.¹¹⁵

However, financial incentives become morally problematic when risks entailed by participation in research are very high, a large amount of money is offered to a potential participant who lacks resources or alternatives, and when “more attractive inducements” are introduced.¹¹⁶ In other words, it is the combination of the high risk and the offer which is hard to resist that might affect voluntariness. Nelson et al claim that when, at least, one of the aforementioned factors in the framework is not present, the problem of undue influence weakens but does not vanish.¹¹⁷ If all factors are present, then voluntariness shifts to “exploitation” and incentives amount to undue influences.¹¹⁸

¹¹² *Ibid.*

¹¹³ *Norberg, supra* note 20 at para 26.

¹¹⁴ Christine Grady, *supra* note 107 at 43.

¹¹⁵ Robert L Nelson et al, *supra* note 51 at 9.

¹¹⁶ *Ibid*

¹¹⁷ *Ibid.*

¹¹⁸ *Ibid.*

In relation to the large amounts of money as a criterion in the Nelson/Beauchamp framework, it could be claimed that, indeed, oftentimes, it is the amount of money offered that constitutes a problem. Many commentators have addressed this concern; the most common suggestion is to limit the amount of money offered, and to establish a locally acceptable standard for the payments per day/visit which is less likely to affect judgments than the payments designed to attract participants.¹¹⁹

However, it is the irresistibility of the offer which complicates the solution to decrease the value of the offer as it is unclear where to place the threshold for irresistible offer and what the standards of irresistibility are.¹²⁰ For one person, the offer of a small amount might be very attractive but resistible. Yet, the same offer might induce somebody else into participation in the trial.¹²¹ Therefore, to examine and address irresistibility, the circumstances, such as an income or overall financial needs of individuals who accept an offer should be available.

To conclude, financial incentives for patients could, in some cases, infringe the voluntariness of consent. In particular, as suggested by the Nelson/Beauchamp framework, which could be applied to examine the offer of financial incentives, financial incentives might amount to exploitation. Next examined is the financial incentives offered to doctors.

3.3.2.5.2. Financial Incentives: Indirect Influences

Not only patients are targeted by the offer of financial incentives, health care workers receive financial incentives too, which also gives rise to some concerns as regards the voluntariness of patients' consent. Overall, all payments to doctors, which vary in terms of the

¹¹⁹ N Dickert, "What is the price of a research subject. Approaches to payment for research participation" (1999) 341:3 N Engl J Med at 198.

¹²⁰ *Ibid.*

¹²¹ *Ibid.*

behavior payments aim to motivate, create some sort of incentives to health care workers.¹²² These concerns are partly directed towards the system of payments to doctors since “each major method of paying physicians has the potential to put physicians’ primary interest in promoting the best interests of their patients at odds with their secondary financial interests.”¹²³ However, I focus on incentives that primarily aim to encourage some type of behaviour rather than purely remunerate a doctor, as, for instance, a fee-per-service method of payment does. Thus, in relation to indirect influence on consent, I consider those payments that are motivational *per se*.

One type of such “motivational” incentives is target payments or performance-based incentives, which “reward the provision of a specified percentage of the population with a particular clinical intervention, e.g. screening”.¹²⁴ Apart from a desired outcome, target payments linked to the quantity of the outcome are claimed to lead to unwelcome results related to the quality of the treatment as well as the process of consent.¹²⁵ Motivational also are incentives from commercial health care companies, such as payments physicians receive from pharmaceutical companies for the recruitment of patients for research studies; gifts from the companies that encourage health care workers to practice medicine in a way favourable to the company; and private firms’ incentives for the referral of patients.¹²⁶

The nature of these incentives is controversial in the light of the competing interests to act in the best interest of patients and doctors’ own financial interest.¹²⁷ Financial incentives

¹²² Marc A Rodwin, “Financial incentives to doctors” (2004) 328 BMJ at 1328.

¹²³ Bernard Lo & Marilyn J Field, *Conflict of Interest in Medical Research, Education, and Practice* (Washington: National Academies Press, 2009) at 168.

¹²⁴ Mirelle Kingma, “Can Financial Incentive Influence Medical Practice?” online: WHO <http://www.who.int/hrh/en/HRDJ_3_2_05.pdf> at 3.

¹²⁵ *Ibid.*

¹²⁶ Marc A Rodwin, *supra* note 122.

¹²⁷ United Kingdom, General Medical Service, *Financial and Commercial Arrangements and Conflicts of Interest* (2013), online: GMS <http://www.gmc.uk.org/guidance/ethical_guidance/21161.asp>.

could compromise doctors' ability to exercise independent judgment¹²⁸ as regards prescribing, advising, treating, referring or commissioning services for patients.¹²⁹ A possible manifestation of the competing interest can constitute an undue influence on a patient. In other words, doctors might promote their own interest through coercion, persuasion or exploitation.

Therefore, it could be assumed that the offer of financial incentives to health care workers could indirectly affect the voluntariness of patients' consent.

3.4. Conclusion

In this Chapter, I focused on voluntariness as one of the elements of consent. First, covered was consent in law. Its discussion showed that patients can sue for battery or negligence if their bodily integrity is infringed. According to *Reibl v Hughes* and *Hopp v Lepp*, battery claims are restricted only to those cases where there was no consent at all, or where the act went beyond the scope of the consent. Then, the chapter examined the voluntariness of consent based on the consideration of many variations of influence that could become undue. It was concluded that coercion as a threat and the use of force negates voluntariness. However, coercion can manifest as an indirect form of control that undermines the alternatives. Two Supreme Court of Canada cases, *White* and *Fitzgerald* were used to depict the "necessity" to participate in certain activity as a factor that signifies the absence of the voluntariness of consent.

According to *Norberg*, the combination of inequality of a power dependency relationship and exploitation infringe the voluntariness of consent. It was also noted that consent is especially vulnerable in a power dependency relationship. Also, psychological compulsion as a result of a state-imposed influence and a doctor's authority could infringe consent in a health care context.

¹²⁸ Marc A Rodwin, *supra* note 122.

¹²⁹ *Financial and Commercial Arrangements and Conflicts of Interest* (2013), *supra* note 127 at 128.

Pressure via verbal persuasion could affect the voluntariness of consent, provided it overbears the independence of the decision. Financial incentives could become undue influences. I have not been able to locate cases, in which courts discussed financial incentives. In terms of guidance from bioethics, according to the Nelson/Beauchamp framework, the influence of financial incentives offered to patients on the voluntariness of consent could be measured, provided some more details on the offer and a group of individuals who accept or refuse the offer are available. Financial incentives to health care workers could trigger undue influences and infringe consent indirectly.

The forms of influence discussed above require careful consideration since they present dangers to voluntary choice, and they could be fully considered only within the context in which they occur. Moreover, according to *Norberg*, the voluntariness of consent should be analyzed on a case-by-case basis. The consideration of the context can open up new aspects of the voluntariness of consent, and allow for determining whether certain conditions would present danger to voluntary choice.

Next, in Chapter 4, I examine childhood vaccination policies in Ontario, New Jersey, UK and Australia in order to apply the findings on the voluntariness of consent to the vaccination programs. Chapter 4 considers the nature of vaccination programs, as well as aspects of the programs relevant to an analysis of the correspondence of vaccination programs to the voluntariness of consent that will be undertaken in Chapter 5.

CHAPTER 4. CHILDHOOD VACCINATION PROGRAMS IN ONTARIO, NEW JERSEY, UK AND AUSTRALIA

4.1. Introduction

In this Chapter, I examine the Ontario, New Jersey, UK and Australia vaccination programs. The Chapter first gives some insights into two categories of vaccination programs: requirement and recommendation-based programs. Then, it provides a detailed overview of the various aspects of the vaccination programs that I focus on. This sets the stage for the application of the concept of the voluntariness of consent to participation in the vaccination program discussed in Chapter 5.

Childhood vaccines are delivered through vaccination programs, and these vary between jurisdictions. In attempts to achieve and maintain herd immunity against infectious diseases, vaccination programs legislate requirements for vaccination, introduce incentives to parents and physicians or focus on education or awareness raising.¹ For the purposes of this thesis, the most relevant distinction between the programs is their requirement or recommendation-based nature.

Requirement-based programs are implemented via school or day care entry vaccination regulations. They require vaccination, and non-compliance with the requirement might result in a fine, or some restrictions as regards admission to, and attendance of day care or school. Some authors define requirement-based programs as “based on laws that require a population -- or a population segment -- to be vaccinated in order to have the right to reside in a jurisdiction or to receive an entitlement”.² Also, it is suggested that the program is requirement-based if it meets two criteria:

¹ Alvin Nelson & El Amin et al, "Ethical issues Concerning Immunization Requirement" (2009) 34:1 Public Health Reviews at 35.

² DA Salmon, “Compulsory vaccination and conscientious or philosophical exemptions: past, present, and future” (2006) 367:9508 Lancet at 436.

First, opting out of the mandate [requirement] should require some action beyond simply saying no. Second, there should be some enforcement mechanism to encourage compliance, that is, there should be a penalty, however mild, for opting out. In short, a mandate [requirement] is not the same as a mere recommendation.³

A recommendation to vaccinate is what recommendation-based programs are built on. Within these programs, an unimmunized status does not entail fines or day care and school entrance or attendance restrictions. Still, in the policies that recommend vaccination, parents might need to submit an immunization record prior to school admission.⁴ This does not mean that a child must be immunized, but an immunization record, even if blank, must be submitted.

Conventionally, recommendation-based vaccination programs are less controversial than requirement-based programs. The latter are seen as coercive, whereas the former preserve freedom of choice. In other words, recommended vaccination is perceived as more consistent with commitments to consent, as they explicitly allow parents to decide whether to consent to vaccination.

The Australia and the UK programs are considered to be recommendation-based as parents do not have to vaccinate or claim exemptions in order to secure daycare or school admission. The governments of New Jersey and Ontario legislated the requirement to vaccinate a child; therefore, they are requirement-based. The appendix to this thesis provides a table summarizing the basics of these four programs. In the next sections I identify specifics regarding the vaccination programs of these jurisdictions.

³ MK Wynia, "Mandating Vaccination: What Counts as a "Mandate" in Public Health and When Should they be Used?" (2007) 7:12 AJOB at 2.

⁴ The requirement to submit immunization forms is legislated in the Public Health Acts of some states and territories in Australia. See *Public Health Act 1997*, (Tas) Division 2 s 58. *Public Health and Wellbeing Act 2008* (Vic), Division 7 ss 145-146. *Public Health Regulations 2000* (ACT), Division 2(2) s 8.

4.2. Vaccination Program in Ontario

In Canada, provinces have jurisdiction over routine childhood vaccination.⁵ Vaccination policies among the provinces and territories vary. Further, the Public Health Agency of Canada states that “some provinces require certain vaccines to be given before a child can enter school, but these are not mandatory in the usual sense of the term” as they allow for exemptions.⁶ Despite this, policy makers, doctors and scholars refer to the vaccination program in Ontario as “mandatory” (i.e., requirement-based) as it is one of three jurisdictions in Canada that requires vaccination for day care entrance and school attendance.⁷ Requirement-based vaccination in Ontario takes its roots in the *Vaccination Act*, 1887, that prescribed the foundations for requiring smallpox vaccination for pupils.⁸ Today, two Acts, the *Day Nurseries Act*, and the *Immunization of School Pupils Act* require vaccination against diphtheria, tetanus, polio, measles, mumps, and rubella for day care and school admission and attendance.⁹ These and other vaccines that are included in the childhood vaccination schedule, are publicly funded by the province. They are delivered mainly by physicians, but also by public health nurses in public health clinics.¹⁰

⁵ Erin Walkinshaw, “Mandatory Vaccinations: The Canadian Picture” (2011) 183: 16 CMAJ at E1165.

⁶ Public Health Agency of Canada, Immunization & Vaccines, Frequently Asked Questions, “Is immunization compulsory in Canada? Does my child have to be immunized?” online: Public Health Agency of Canada <<http://www.phac-aspc.gc.ca/im/vs-sv/vs-faq16-eng.php>>.

⁷ CL Mah, “Compulsory School-Entry Vaccination Laws and Exemptions: Who Is Opting Out in Ontario and Why Does It Matter?” (2010) 5:4 Health Policy at 37. Patricia Peppin, “Vaccines and Emerging Challenges for Public Health” in Jocelyn Downie, Timothy Caulfield, & Colleen Flood eds., *Canadian Health Law and Policy*, 2nd ed (Toronto: Butterworths, 2002) at 149. Law Reform Commission of Saskatchewan, Report to the Minister of Justice, *Vaccination and the Law* (December 2009) online: Law Reform Commission of Saskatchewan <<http://lawreformcommission.sk.ca/vaccinationfinal.pdf>>. Brendan Kennedy, “Toronto seeks more mandatory vaccinations” (20 January 2012) *The Star* online: [The Star](http://www.thestar.com) <<http://www.thestar.com>>.

⁸ Revised Statutes of Ontario 1887, Volume 2, *An Act Respecting Vaccination and Inoculation* s 15.

⁹ *Immunization of School Pupils Act*, RSO 1990, C 1(1). Public Health Agency of Canada, *Publicly funded Immunization Programs in Canada - Routine Schedule for Infants and Children including special programs and catch-up programs* (March 2013), online: Public Health Agency of Canada <<http://www.phac-aspc.gc.ca/im/ptimprog-progimpt/table-1-eng.php>>.

¹⁰ Sandra Romain, “Childhood immunization. Availability of primary care providers in Ontario” (2009) 55: 11 *Canadian Family Physician* at 1104.

The Ontario *Day Nurseries Act* requires “every operator [to] ensure that before a child is admitted to a day nursery operated by the operator or to a location where private-home day care is provided by the operator, and from time to time thereafter, the child is immunized”.¹¹

Therefore, compliance with immunization schedule is required in order to be admitted to a day care. However, the vaccination requirement does not apply to children who are exempted from vaccination.

Though an immunization record should be submitted for registration in school, the law does not say that a child cannot be registered for school in Ontario without an up-to-date immunization record. According to the *Immunization of School Pupils Act*, the immunization certificate (or exemptions) of children is required to attend school.¹² This means that the child could be registered if his or her record is not up-to-date, but a suspension might be imposed when immunization records are reviewed.¹³

If the records are incomplete, parents/guardians will be notified by the department and requested to update them.¹⁴ When immunization records are not updated after proper notification, Public Health has the authority to direct a school to suspend a student until the

¹¹ *Day Nurseries Act*, RRO 1990, Reg 262 s 33 (1).

¹² *Immunization of School Pupils Act*, RSO 1990, C 1(1) s 6.2 (1).

¹³ As a public health measure, suspension from school is enforced annually. For instance, in Ottawa, according to the data, in November 2012, letters were sent to the parents of 18,000 students who had not provided proof of updated vaccination certificates by November 2012. A second batch of reminder letters was sent in February 2013, to 8,000 students. Then, parents of 5,000 students received a third letter saying that time was running out for them to contact the city health unit. In the week of April 25th, 2013, around 900 students were informed they were suspended from school. See: Angela Mulholland, “Ottawa students facing suspension over out-of-date vaccination records” *CTV news* (24 April 2013), online: <://www.ctvnews.ca/health/ottawa-students-facing-suspension-over-out-of-date-vaccination-records-1.1253457>. Toronto Public Health studied 850 schools and board records of 350,000 students per year. Based on this, it has been estimated that approximately 70,000 letters are mailed annually and if the public health authorities do not receive any information within three weeks, a final notice is mailed to about 40,000 students. The suspension orders are issued three weeks after the last notice is sent out. See Kristin Rushowy, “Missed shots spur kids' suspension” *The Star* (02 January 2009), online: The Star <<http://www.thestar.com>>.

¹⁴ *Immunization of School Pupils Act*, RSO 1990, C 1(1) s 8 (1).

immunization information is obtained.¹⁵ Students can be suspended for a period of 20 school days if they don't have the required vaccinations.¹⁶ In case parents do not comply with the requirement (either catching up with the immunization schedule or claiming exemptions), they are guilty of an offence and subject to a fine of not more than \$1,000.¹⁷

4.2.1 Exemptions

According to the *Day Nurseries Act* and the *Immunization of School Pupils Act*, a child could be exempted from the vaccination requirement based on medical condition, religious or beliefs of conscience.¹⁸ The *Immunization of School Pupils Act* lists required vaccines and provides for exemption forms that are also applicable under the *Day Nurseries Act*.

A medical exemption is allowed when the vaccination against an infectious disease is not necessary, such as when a child has already had the disease. Also, a child is exempted when vaccination is detrimental to health in cases of contraindications, such as incompatibility of a live vaccine with a congenital immunodeficiency state.¹⁹ To claim medical exemption, parents must present with a statement of exemption signed by a medical professional that indicates the evidence of the immunity or contraindication.²⁰ A medical exemption could be temporary or permanent.²¹ Also, a medical exemption applies to the administration of one vaccine, such as MMRV or a whole vaccination schedule if necessary.²²

¹⁵ *Ibid* at s 6 (1).

¹⁶ *Ibid* at s 7.

¹⁷ *Ibid* at s 4.

¹⁸ *Ibid* at s 6.2 (2) (3). *Day Nurseries Act*, RRO 1990, Reg 262 s 33 (2).

¹⁹ Public Health Agency of Canada, Canadian Immunization Guide, MMR, online: Public Health Agency of Canada <<http://www.phac-aspc.gc.ca/publicat/cig-gci/p04-meas-roug-eng.php>>.

²⁰ *Immunization of School Pupils Act*, RSO 1990, C 1 (1) s 5. *Day Nurseries Act*, RRO 1990, Reg 262 s 33 (1).

²¹ *Immunization of School Pupils Act*, RRO 1990, Reg 645 Form 1, Form 2. The same forms are used for exemptions prescribed in the *Immunization of School Pupils Act* and *Day Nurseries Act* RRO 1990, Reg 262.

²² *Ibid*.

Religious and conscientious exemptions do not require proof of the sincerity of beliefs, such as a letter from a church, or a statement explaining the essence of beliefs written by parents. To be granted the exemption, the program requires a notarized form declaring that “the requirement of the immunization of the *Immunization of School Pupils Act* conflicts with my sincerely held convictions based on my religion or conscience.”²³ Exemptions do not have to be renewed.²⁴ According to the exemption form, parents could not claim exceptions from one or two vaccines based on religious or conscientious beliefs, but only from the whole program.²⁵

4.3. Vaccination Program in New Jersey

To understand the details of the vaccination program in New Jersey, it is first necessary to provide some background details about vaccination in the US more generally. Vaccination programs in all the US states are requirement-based.²⁶ The legal foundation for the requirement-based vaccination programs in the US was laid by a landmark US case, *Jacobson v Massachusetts*.²⁷ In 1905, *Jacobson v Massachusetts* confirmed that the vaccination requirement is a legitimate use of police powers.²⁸ It also established that the protection of public health outweighs individual interests. The constitutionality of the school-based vaccination requirement was upheld by the Supreme Court in 1922.²⁹

In the US, the federal government gives recommendations as to immunization policies, such as requirements for school and day care registration.³⁰ The control of infectious diseases, including routine vaccination, is the prerogative of the states. In 1970, the Center for Disease

²³ *Ibid.*

²⁴ *Ibid.*

²⁵ *Ibid.*

²⁶ Centre for Disease Control and Prevention, State Vaccination Requirements, online: CDC <<http://www.cdc.gov/vaccines/imz-managers/laws/state-reqs.html>>.

²⁷ *Jacobson v Massachusetts*, 197 US 11 (1905) at 12-13.

²⁸ *Ibid.*

²⁹ *Zucht v King*, 260 US 174 (1922).

³⁰ National Network for Immunization Information, Immunization Policy, online: National Network for Immunization Information <<http://www.immunizationinfo.org/issues/immunization-policy>>.

Control and Prevention (CDC) lobbied for requirement-based vaccination and asked states to review their laws as part of the program to request federal funds to purchase vaccines.³¹ By 1980, all 50 states had laws that linked vaccination with school entrance.³² Consequently, vaccination programs in the US became requirement-based. However, their enforcement varies. New Jersey's program is considered to be among the strictest because it allows for a limited number of exemptions.³³ Vaccines included in the vaccination schedule are publicly funded, and physicians are the vaccination providers for the majority of children.³⁴

In New Jersey, the childhood vaccination program is regulated by the *New Jersey Administrative Code*,³⁵ which prescribes the requirement to vaccinate children. According to the *New Jersey Administrative Code*, “a principal, director or other person in charge of a school, preschool, or child care facility shall not knowingly admit or retain any child whose parent or guardian has not submitted acceptable evidence of the child's immunization”.³⁶ Therefore, the New Jersey program does not allow a day care or school enrollment without an up-to-date immunization record unless parents claim exemptions from the immunization requirement. This is discussed next.

4.3.1. Exemptions

The *New Jersey Administrative Code* allows solely for medical and religious exemptions. Therefore, parents cannot claim exemptions based on philosophical, moral, secular, or more

³¹ David A Salmon et al, “Compulsory vaccination and conscientious or philosophical exemptions: past, present, and future” (2006) 367:9508 *Lancet* 436 at 439.

³² *Ibid.*

³³ *New Jersey Administrative Code*, NJ tit 8, §57 s 4.4.

³⁴ Charles W LeBaron et al, “Childhood Vaccination Providers in the United States” (2002) 92:2 *Am J Public Health* at 266–270.

³⁵ Mandatory participation is stipulated in the New Jersey Administrative Code. See *Administrative Code*, NJ tit 8, §57 s 4.4. State of New Jersey, Department of Health, Communicable Disease Service, online: Department of Health <<http://www.state.nj.us/health/cd/imm.shtml>>. National Vaccine Information Centre, New Jersey, State Vaccine Requirement, online: National Vaccine Information Centre <<http://www.nvic.org/newjersey.aspx>>.

³⁶ *New Jersey Administrative Code*, NJ tit 8 § 8:57-4.2.

general grounds in New Jersey.³⁷ There is no standardized form for the exemptions.³⁸ As regards medical exemption, a licensed medical professional must send a letter “to the school or a day care indicating that an immunization is medically contraindicated for a specific period of time and the reasons for medical contraindication must be based upon valid medical reasons.”³⁹

Depending on the medical condition, medical exemptions may apply to one or many vaccines.

There is no standard religious exemption form in New Jersey. Parents must write a letter to declare their religious beliefs.⁴⁰ The vaccination program in New Jersey prohibits requesting parents to present with a proof of belief.⁴¹ It says that

when a parent or guardian submits their written religious exemptions that contain some religious reference, those persons charged with implementing administrative rules at N.J.A.C. 8:57 – 4.4, should not question whether the parent’s professed religious statement or stated belief is reasonable, acceptable, sincere and bona fide.

Moreover, as long as “the written statement contains the word “religion” or “religious” or some reference thereto, then the statement should be accepted and the religious exemption of mandatory [required] immunizations granted.”⁴²

Even though the *New Jersey Administrative Code* does not indicate that exemptions from specific vaccines are unacceptable, in practice, parents cannot exempt their child from a specific

³⁷ *New Jersey Administrative Code*, NJ tit 8 § 8:57-4.2. *New Jersey Statute*, Pub Law 2002, c 58 § 18A:61D-10, Exemption from vaccination. State of New Jersey, Department of Health, *Required Immunizations for Day Care/Preschool and Sixth Grade*, online: State of New Jersey, Department of Health <http://www.state.nj.us/health/cd/req_imm.shtml#mre>.

³⁸ *New Jersey Statute*, Pub Law 2002, c 58 § 18A:61D-10, Exemption from vaccination.

³⁹ *Ibid.* Reasons are indicated in the Advisory Committee on Immunization Practices or the American Academy of Pediatrics (AAP) guidelines. See Centers for Disease Control and Prevention, *Advisory Committee on Immunization Practices*, online: Centers for Disease Control and Prevention <<http://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-acip-color-office.pdf>>.

⁴⁰ *Ibid.*

⁴¹ State of New Jersey, Department of Health and Senior Services, *NJAC 8:57-4.3 and 4.4 Immunization of Pupils in Schools rule, Religious and Medical Exemption* (1 December 2008), online: State of New Jersey Department of Health <http://www.state.nj.us/health/cd/documents/religious_exemption.pdf>.

⁴² *Ibid.*

vaccine on religious grounds.⁴³ A religious objection to one vaccine leads to exemption from participation in the vaccination program.

4.4. The UK Vaccination Program

The UK vaccination program has a long history of requirement-based smallpox vaccination, as well as a long history of opposition to the requirement-based nature of the program. Its requirement-based vaccination law was repealed in 1946, as there was an overall increase in vaccination rates, despite the fact that many parents claimed conscientious exemptions.⁴⁴ Since 1946, childhood vaccination in the UK has been recommended but not required.

The issue of whether vaccination programs should be requirement-based was revisited in 2004 by the British Medical Association (BMA). It concluded that “such a policy [requirement-based vaccination] is not consistent with key elements of the frameworks or principles for immunisation policy...more substantively it runs counter to the...core principle that vaccines should be administered on a voluntary [recommendation-based] basis.”⁴⁵ The Chairman of the BMA stated that “the BMA does not think [that requirement-based vaccination programs] would be right for the United Kingdom” and that “the doctor-patient relationship is based on trust, choice and openness and we think introducing compulsory [requirement-based] vaccination may be harmful to this.”⁴⁶ As such, childhood vaccination in the UK remains recommendation-based.

The vaccination program is implemented via national immunization policies. All recommended vaccines are included in the vaccination schedule by the Ministers who take

⁴³ Steve P Calandrillo, “Vanishing Vaccinations: Why are so many Americans Opting Out?” (2004) 37:2 Univ Mich J Law Reform 353 at 429.

⁴⁴ *Ibid* at 438.

⁴⁵ The Scottish Government, *Report of the MMR Expert Group* (April 2002), online: The Scottish Government <<http://www.scotland.gov.uk/Publications/2002/04/14619/3779>>.

⁴⁶ “Doctor Say No to Compulsory Vaccine” *The Daily Mail* (29 June 2003), online: Mail Online <<http://www.dailymail.co.uk/news/article-186604/Doctors-say-compulsory-vaccines.html>>.

decisions on the most appropriate use of vaccines on the basis of advice from the UK Joint Committee on Vaccination and Immunization (JCVI).⁴⁷ Government-recommended vaccines are provided for free.⁴⁸ National childhood vaccination policies in the UK are not legislated. The “Giving all Children a Healthy Start in Life” policy stipulates its aim to be “protecting children from serious diseases, through screening and immunisation”.⁴⁹ The issues pertaining to the delivery of vaccination are regulated by the Green Book issued annually by the National Health Services to health care professionals.⁵⁰ Immunization-related financial incentives, which are paid to doctors depending on vaccination rates, are regulated by General Medical Services (GMS) contract.⁵¹

There is no requirement to vaccinate children, and no consequences for leaving them unimmunized. Therefore, soon after childbirth, doctors or health visitors, who are nurses with further training in child health, ask parents whether they want their child to participate in the vaccination programs.⁵² Vaccinations could be administered by doctors or health visitors.⁵³ However in each case, doctors are responsible for obtaining consent prior to the administration

⁴⁷ Government UK, National Health Services, *The NHS Vaccination Schedule* (April 2012), online: NHS <<http://www.nhs.uk/Conditions/vaccinations/Pages/vaccination-schedule-age-checklist.aspx>>.

⁴⁸ *Ibid.*

⁴⁹ Government UK, Department of Health, *Giving All Children a Health Start in Life* (25 March 2013), online: Government UK <<https://www.gov.uk/government/policies/giving-all-children-a-healthy-start-in-life>>.

⁵⁰ Government UK, Public Health England, *Immunisation against infectious disease: the green book* (11 September 2013), online: Government UK <<https://www.gov.uk/government/organisations/public-health-england/series/immunisation>>.

⁵¹ Government UK, National Health Services, *General Medical Services Contract*, online: NHS <<http://www.nhsemployers.org/PayAndContracts/GeneralMedicalServicesContract/Pages/Contract.aspx>>.

⁵² GL Freed, “Vaccine Policies across the Pond: Looking at the U.K. And U.S. Systems” (2005) 24:3 *Health Affairs* 755 at 756. Government UK, National Health Services, *The NHS Vaccination Schedule* (April 2012), online: NHS <<http://www.nhs.uk/Conditions/vaccinations/Pages/vaccination-schedule-age-checklist.aspx>>.

⁵³ Sarah A Redsell et al, “Health visitors’ role in the universal childhood immunisation programme” (2010) 11: 51 *Primary Health Care Research & Development* at 54. Sarah Cowley et al, “Why health visiting” (2013), online: National Nursing Research Unit <<http://www.kcl.ac.uk/nursing/research/nuru/publications/Reports/Why-Health-Visiting-NNRU-report-12-02-2013.pdf>> at 54. United Kingdom, National Health Services, What do health visitors do, online: NHS <<http://www.nhs.uk/explore-by-career/nursing/careers-in-nursing/health-visiting/what-do-health-visitors-do/>>.

of each vaccine.⁵⁴ As part of the vaccination program, doctors receive financial incentives for achieving certain vaccination rates. Immunization-related financial incentives are discussed next.

4.4.1 Financial Incentives to Doctors

Immunization-related target payments to doctors were implemented as part of a General Medical Service (GMS) contract in 1990.⁵⁵ According to the policy, for a doctor to receive a target payment, 70% of the children attending that doctor's practice must be immunized.⁵⁶ For instance, if the practice reaches 70 % of two and five year olds fully vaccinated, a physician receives £955. Doctors receive £2,865 if the vaccination coverage reaches 90 %.⁵⁷ The payments are received quarterly.⁵⁸ The vaccination coverage of children, who are two or five year olds on the first day of the quarter, is calculated. Not all vaccinations included in the schedule are required for the calculation of the vaccination coverage. Only diphtheria, tetanus, poliomyelitis, pertussis and Haemophilus influenza type B (HiB), measles/mumps/rubella and Meningitis C count for the coverage.⁵⁹

In 2003, a new GMS contract came into force, which maintained in modified version childhood immunization-related target payments.⁶⁰ According to the 2003 GMS contract, immunization-related incentives are issued for the vaccination rates of two and five year old children separately. Also, the value of target payments increased significantly. If 70-89% or 90%

⁵⁴ *Ibid.*

⁵⁵ Mireille Kingma, "Can Financial Incentive Influence Medical Practice?" online: WHO <http://www.who.int/hrh/en/HRDJ_3_2_05.pdf>.

⁵⁶ Government UK, National Health Services, *General Medical Services of Financial Entitlements Directions 2013*, online: Government UK

<https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213225/GMS-Statement-of-Financial-Entitlements-2013.pdf> at 9-10.

⁵⁷ Mark Dusheiko et al, "Incentivising prevention by general practitioners: some research possibilities", online: Academia.Edu <<http://www.york.ac.uk/che/pdf/primcareprevgp incentives040506.doc>> at 2.

⁵⁸ *Ibid* at 38.

⁵⁹ *General Medical Services of Financial Entitlements Directions 2013*, *supra* note 56 at 38.

⁶⁰ National Health Service, New GMS Contract 2003/2004, online: NHS <<http://www.nhsemployers.org/PayAndContracts/GeneralMedicalServicesContract/GMSContractChanges/gmscontract200304/Pages/NewGMSContract200304.aspx>>.

of two year old children attending the practice are vaccinated, doctors receive an average of £2,655 and £7,965 each quarter respectively.⁶¹ Also, doctors receive £822 or £2465 for achieving 70% or 90% vaccination rates among five year old children quarterly.⁶² A new contract in 2014 did not include any changes to childhood vaccination target payments.⁶³

4.5. The Australian Vaccination Program

The requirement-based smallpox vaccination program that was the point of departure for the development of childhood vaccination policies in the other common law jurisdictions under review was never part of the law in Australia.⁶⁴ In 1997, due to low vaccination rates, the Immunize Australia program was launched. It was later stated that “none of the successes [of the immunization program after the introduction of the Immunize Australia program] is due to compulsory vaccination [requirement-based program]. Immunisation is not and has never been compulsory [required] in Australia.”⁶⁵

Indeed, the Public Health Acts of the states and territories do not generally require vaccination for school registration.⁶⁶ In some states and territories in Australia, such as Victoria, Tasmania and the Australian Capital Territory, parents must submit a school entry immunization

⁶¹ “The maximum sums payable to a practice under each programme will depend on the number of children on the practice list at the first day of each quarter compared with the average UK number of children per 5000 population.” See National Health Services, Specification for a Directed Enhanced Service, online: NHS <http://www.nhsemployers.org/SiteCollectionDocuments/Childhood_immunisations_DES_ja220413.pdf> at 3.

⁶² Government UK, National Health Service, General Medical Statement of Financial Entitlements Directions 2013, online: Government UK <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213225/GMS-Statement-of-Financial-Entitlements-2013.pdf> at 27 section 11.

⁶³ Government UK, National Health Services, Enhanced Services, online: NHS <<http://www.nhsemployers.org/PayAndContracts/GeneralMedicalServicesContract/DirectedEnhancedServices/Page/EnhancedServices.aspx>>.

⁶⁴ Carolyn Smith, “Vaccination in Australia” (2006) 367:9522 *The Lancet* at 1575.

⁶⁵ *Ibid.*

⁶⁶ One exception is New South Wales which, as of 2014, will require a certificate with age-appropriate immunizations or a statement of exemptions for day care entrance. In other words, unlike other states in Australia, childhood vaccination is requirement-based. Therefore, the shift towards the requirement to vaccinate happened, but vaccination in Australia is still under the auspices of the Immunize Australia program. In this Chapter, I will not consider vaccination policy in NSW to avoid confusion between the recommendation and required-oriented jurisdictions. See *Public Health Act 2010*, (NSW) s 87.

status certificate before a child starts primary school.⁶⁷ The certificate must show whether or not they have been vaccinated against a range of diseases.⁶⁸ As proof, the immunization record from the Australian Childhood Immunization Register, or a letter issued by a local council or doctor could be provided.⁶⁹ Still, children are entitled to enroll even when their vaccination certificate is blank, or is not up to date, but they must leave if there is an outbreak of one of the immunizable diseases.⁷⁰ Therefore, the childhood vaccination program in Australia is primarily recommendation-based.

Immunization-related financial benefits to parents and incentives to doctors were the main components introduced by the “Immunize Australia” program in 1997. The General Practitioners Immunization Incentive was cancelled in 2013.⁷¹ However, the immunization-related benefits to parents are still in place. The legislation underpinning parental benefits is the federal *Family Assistance Act*. Even though the federal government in Australia does not have jurisdiction over public health other than quarantine, the immunization clause was prescribed via

⁶⁷ *Public Health Act 1997* (Tas), division 2 s 58. *Public Health and Wellbeing Act 2008* (Vic), ss 145-146. *Public Health Regulations 2000* (ACT), division 2.2 s 8.

⁶⁸ *Ibid.*

⁶⁹ *Ibid.*

⁷⁰ *Ibid.*

⁷¹ A year before the financial benefits for parents were introduced, the federal policy implemented incentives for family doctors who are the main providers of vaccination in Australia.⁷¹ The General Practitioners Immunisation Incentive (GPII) provided incentives for monitoring, promoting and providing appropriate immunisation services to children less than seven years old. Payments were made to the eligible practices that achieved 90% vaccination coverage of children that had been attending the practice for, at least, the preceding 12 months. \$20 million went into 5600 GP practices via the immunization incentive scheme annually. Practices received an average of \$3640 annually. However, in 2013, the budget eliminated the funding for the GPII and, therefore, the immunization payments for practitioners ceased. It is claimed that this decision was motivated by the achievement of high vaccination rates in Australia. See Australian Government, Department of Health, *Department of Human Services Budget 2012-2013*, online:

<<http://www.humanservices.gov.au/corporate/publications-and-resources/budget/1213/>>. Jo Hartley, “How will the end of PIP affect immunisation rates?” *Australian Doctor* (15 May 2012), online: Australian Doctor

<<http://www.australiandoctor.com.au/news/polls/how-will-the-end-of-pip-affect-immunisation-rates>>. Australian Government, Medicare Australia, *General Practice Immunisation Incentive Guidelines* (April 2010), online: Australian Government

<<http://www.medicareaustralia.gov.au/provider/incentives/gpii/files/gpii-guidelines.pdf>>.

the *Family Assistance Act* in the context of eligibility criteria for family assistance.⁷² According to the *Family Assistance Act*, parents who want to leave children unimmunized but aim to receive benefits can claim conscientious or medical exemptions. A federal exemption form was created to be used by the territories and states.⁷³ Public Health Acts duplicate the exemptions included in the *Family Assistance Act* to regulate the submission of immunization certificates prior to school or day care entrance.⁷⁴

Financial benefits to parents are discussed next, followed by exemptions.

4.5.1. Financial Benefits to Parents

As mentioned above, the *Family Assistance Act*⁷⁵ regulates a nationwide immunization benefits scheme. When the scheme was first introduced, parents were required to provide evidence that their children were fully age-appropriately immunized or exempted in order to receive maternity immunization allowance (MIA) and child care benefit. The payments of the maternity immunization allowance were linked to the baby bonus money. Before the initiative was introduced, a baby bonus amount of \$882 was paid on the birth of a child.⁷⁶ When the MIA component was added, the baby bonus increased to \$950.⁷⁷ However, eligible mothers received only \$750 on the birth, and an additional \$200 was paid when a child received all recommended vaccines before 18 months of age unless a child was exempted.⁷⁸

⁷² *A New Tax System (Family Assistance) Act 1999* (Cth), division 2 ss 4-7.

⁷³ Department of Human Services, *Australian Childhood Immunisation Register, Immunisation Exemption, Conscientious Objection Form*, online: Australian Government <<http://www.humanservices.gov.au/spw/customer/forms/resources/immu12-1302en.pdf>>.

⁷⁴ *Public Health Act 1997* (Tas), division 2 s 58. *Public Health and Wellbeing Act 2008* (Vic), ss 145-146, *Public Health Regulations 2000* (ACT), division 2.2 s 8.

⁷⁵ *A New Tax System (Family Assistance) Act 1999*, (Cth).

⁷⁶ Marie Swain, "Childhood Immunisation: The Legal Dimensions" (Master of Policy, University of New South Wales, 1997) [unpublished] at 20-21.

⁷⁷ *Ibid.*

⁷⁸ *Ibid.*

In 2008, concerns about low vaccination rates of children older than 2 years peaked.⁷⁹ To address this issue, the MIA was split into two payments to remind parents to vaccinate children who are two years old and older.⁸⁰ Therefore, since 2009, the MIA allowance has been paid in two installments of \$129 to parents whose children have received all vaccinations recommended for 18 month and four year old children or are exempted.⁸¹

In June 2012, the policy changed again and the immunization payments are now linked to the family tax benefit.⁸² A total of \$2100 is paid for each child who is fully vaccinated.⁸³ The amount of \$726 is paid at one, two, and five years of age per a fully immunized or exempted child. This means that the current policy offers financial benefits that are six times higher than in 2007.

Also, fulfillment of the immunization requirements is one of the eligibility criteria for child care benefits.⁸⁴ The approved care rate, which means the cost of care in an approved day care for a non-school-aged child up to 50 hours per week, is \$199.50.⁸⁵ The payment rate for school-aged children is \$169 per week.⁸⁶ Also, parents can claim registered care benefits, which

⁷⁹ BP Hull, CR MacIntre CR & PB MacIntre, "Immunization Coverage in Australia corrected for underreporting to the Australian Childhood Immunisation Register" (2003) 27 Aus NZ Public Health at 533.

⁸⁰ Australian Government, Department of Health, *Immunisation Related Payments for Parents. Immunize Australia Program*, online: Australian Government <<http://www.health.gov.au/internet/immunise/publishing.nsf/Content/related-payments>>.

⁸¹ *Ibid.*

⁸² *A New Tax System (Family Assistance) Act 1999* (Cth), p 2 division 2 s 6 (1) b. p 3 div 1 subdiv A. Australian Government, Department of Human Services, *Payment rates for Family Tax Benefit Part A*, online: Australia Government <<http://www.humanservices.gov.au/customer/enablers/centrelink/family-tax-benefit-part-a-part-b/ftb-a-payment-rates>>.

⁸³ *Ibid.*

⁸⁴ *A New Tax System (Family Assistance) Act 1999* (Cth), p 2 division 2 s 6 (1) a.

⁸⁵ Australian Government, Department of Human Services, *Child Care Benefit*, online: Australian Government <<http://www.humanservices.gov.au/customer/services/centrelink/child-care-benefit>>.

⁸⁶ *Ibid.*

is care outside of child care. The rate for this type of care is lower than for an approved child care, but equals \$33 per week.⁸⁷

4.5.2. Exemptions

The *Family Assistance Act* allows parents who do not want to have their children vaccinated to remain eligible for benefits by claiming medical exemption, or an exemption based on conscientious beliefs.⁸⁸ There is a standardized form for a medical exemption.⁸⁹ Medical exemptions in Australia could be temporary or permanent.⁹⁰ Also, the form includes a list of vaccines that a child could be exempted from, which means that an exemption could be claimed for one, as well as for many vaccines.⁹¹

If claiming conscientious exemption, the process is more complicated than just declaring the belief since, according to the vaccination certificate form, parents must discuss the benefits and risks of immunization with a provider prior to claiming exemptions.⁹² Therefore, parents must sign a document declaring that they were given an opportunity to discuss any concerns about immunization with a health care provider.⁹³ In other words, parents must sign an informed refusal.

In the same form, a medical professional must declare that he or she “explained the benefits and risks associated with immunization to the parent or guardian of the child named,

⁸⁷ *Ibid.*

⁸⁸ *A New Tax System (Family Assistance) Act 1999* (Cth), p 2 division 2 s 5.

⁸⁹ Australian Government, Department of Human Services, *Australian Childhood Immunisation Register, Immunisation Exemption, Medical Contraindication*, online: Australian Government <<http://www.medicareaustralia.gov.au/provider/pubs/forms/files/ma-medical-contraindication-form.pdf>>.

⁹⁰ *Ibid.*

⁹¹ *Ibid.*

⁹² *A New Tax System (Family Assistance) Act 1999* (Cth), p 2 division 2 ss 2-4. Australian Government, Department of Human Services, *Australian Childhood Immunisation Register, Immunisation Exemption, Conscientious Objection Form*, online: Australian Government <<http://www.humanservices.gov.au/spw/customer/forms/resources/immu12-1302en.pdf>>.

⁹³ *Ibid.*

and...informed him/her of the potential dangers if a child is not immunised.”⁹⁴ The conscientious belief exemption form does not allow selection of a particular vaccine; rather, one must refuse all vaccines in the vaccination schedule.

4.6. Conclusions

In this Chapter, I examined the vaccination policies of Ontario, New Jersey, UK and Australia. Following a brief overview of the two types of vaccination programs, I focused on some aspects of the vaccination programs of two requirement-based and recommendation-based programs. The requirement-based vaccination programs in Ontario and New Jersey were considered in the context of the requirement to vaccinate, and exemptions. In both programs, childhood vaccination is required for day care and school admission/attendance. It was shown that the vaccination program in Ontario allows for religious, conscientious and medical exemptions; however, the New Jersey vaccination program offers only religious and medical exemptions. To receive exemptions, parents in Ontario must notarize an exemption form; in New Jersey, it is sufficient to send a letter which includes the word “religion”.

The recommendation-based programs in the UK and Australia were considered mainly in relation to the immunization-related financial incentives. In the UK, doctors receive financial incentives if they reach certain immunization rates among children attending their practice. In Australia, financial benefits are paid to parents whose children are vaccinated or exempted. Leaving a child unimmunized in the UK and Australia does not lead to any restrictions on day care or school admission.

⁹⁴ Australian Government, Department of Human Services, *Australian Childhood Immunisation Register, Immunisation Exemption, Conscientious Objection Form*, online: Australian Government <<http://www.humanservices.gov.au/spw/customer/forms/resources/immu12-1302en.pdf>>.

The requirement and recommendation-based vaccination programs discussed in this Chapter are analyzed in light of the voluntariness of consent in the next Chapter. In particular, the following Chapter is centered on the requirement or recommendation to vaccinate, exemptions, and financial incentives and benefits.

CHAPTER 5. EXPLORING THE DISTINCTION BETWEEN THE PROGRAMS VIA THE VOLUNTRINESS OF CONSENT

5.1. Introduction

Childhood vaccination programs are commonplace preventative measures. The public health achievements of vaccination programs in eradication or control of infectious diseases are well recognized. However, vaccines are claimed to be “victims of their own success”¹. Further, some childhood vaccination programs are claimed to undermine or eliminate parents’ right to exercise voluntariness as regards vaccination decisions.

Voluntariness of consent is one of the necessary elements of a valid consent. As discussed in Chapter 3, for consent to be voluntary, an individual should have options to choose from, or, at least, an option to refuse treatment. Also, consent should be free of fraudulent misrepresentation as to the nature of treatment provided. It should also be free of undue influence, such as coercion which “involves the use of credible threat of harm to compel a potential subject to [consent to treatment]”,² and other external influences that are viewed in law as undue.³

In this Chapter, I apply the voluntariness requirement of consent to the childhood vaccination programs in Ontario, New Jersey, Australia and the UK. I first determine the correspondence between the recommendation and requirement-based programs, and voluntariness of consent. Then, I reconsider the consistency of the programs with the voluntariness of consent criterion by examining whether parents could, in practice, exercise voluntariness of consent in the four jurisdictions studied. This analysis enables a demonstration

¹ Ricki Lewis, “Vaccines: Victims of their Own Success”, *The Scientist* (July 2004), online: The Scientist <<http://www.the-scientist.com/?articles.view/articleNo/15802/title/Vaccines--Victims-of-Their-Own-Success-/>>.

² RM Nelson et al, “The Concept of Voluntary Consent” (2011) 11:8 Am J Bioeth 6 at 9.

³ *Norberg v Wynrib*, (1992) 92 DLR (4th) 449 at 457 [*Norberg*].

of the complexity of the distinction between the requirement and recommendation-based programs.

5.2. Vaccination Programs: Requirement v Recommendation

As discussed in Chapter 4, “the right to determine what shall, or shall not, be done with one’s own body, and to be free from non-consensual medical treatment, is a right deeply rooted in our common law.”⁴ Clearly, “the right to refuse treatment is fundamental to a person’s dignity and autonomy”.⁵ According to *Malette v Shulman*,

the doctrine of informed consent is plainly intended to ensure the freedom of individuals to make choices concerning their medical care. For this freedom to be meaningful, people must have the right to make choices that accord with their own values regardless of how unwise or foolish those choices may appear to others.⁶

The discussion of voluntariness as one of the necessary elements of consent revolves around the concept of freedom of choice. As mentioned in Chapter 3, in a landmark Supreme Court of Canada case, *Norberg*, when discussing the voluntariness of consent, La Forest J quoted “Salmond and Heuston on the Law of Torts” according to which “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.”⁷ He claimed that “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.”⁸

Justice La Forest stated in *Norberg* that “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

⁴ *Fleming v Reid*, 48 OAC 46, 4 OR (3d) 74, 82 DLR (4th) at 298.

⁵ *Starson v Swayze*, [2003] 1 SCR 722, 2003 SCC 32 at 75.

⁶ *Malette v Shulman*, [1987] OJ 1180, 67 DLR (4th) 321 at para 6.

⁷ R F V Heuston & R S Chambers, *Salmond and Heuston on the Law of Torts*, 19th ed (London: Sweet & Maxwell, 1987) at 564-65 in *Norberg*, *supra* note 3 at 247.

⁸ *Norberg*, *supra* note 3 at 247.

individual *has freedom to consent or not to consent*”,⁹ which means that apart from the absence of controlling influences there must be a choice available. Therefore, the discussion of voluntariness of consent in the vaccination programs should begin with the consideration of whether there is a choice to “consent or not to consent” to the participation in the vaccination programs.

With this distinction in mind, the vaccination programs under scrutiny here can be divided into two categories: those that require vaccination (Ontario and New Jersey), and programs that recommend vaccination (UK and Australia). To begin with, even the word “requirement” as a “direct command to act or refrain from acting”¹⁰ points to a conflict between the requirement to vaccinate, and voluntariness of consent, since the requirement does not provide options to consent or not to consent. When a person submits to the requirement, “[the] person is compelled by the state or the will of another to a course of action or inaction which he [might] not otherwise have chosen; he is not acting of his own volition and he cannot be said to be truly free.”¹¹ In contrast, a recommendation to be vaccinated constitutes “a suggestion or proposal as to the best course of action.”¹² It gives guidance as to advisable course of actions and theoretically puts a parent in “a position to choose freely”.¹³

Therefore, the requirement to vaccinate does not promote freedom of choice since it does not offer an option “to not consent” and, subsequently, eliminates voluntariness of consent. To the contrary, consent to vaccination in a recommendation-based program equals consent to an elective treatment in a clinical medicine setting that a parent might choose or not. This initial

⁹ *Ibid.* Italics added.

¹⁰ *R v Big M Drug Mart Ltd*, [1985] 1 SCR 295 at para 95 [*Big M*].

¹¹ *Ibid.*

¹² The Oxford English Dictionary, *sub verbo* “recommendation” online: Oxford Dictionaries <<http://oxforddictionaries.com>>.

¹³ *Norberg*, *supra* note 3 at 247.

analysis shows that the recommendation-based vaccination programs are consistent with voluntariness of consent, whereas the programs that require vaccination are not.

In the following sections, I complicate this conclusion on the distinction between the programs. I do this on the basis of the following assumptions. First, even though the requirement-based vaccination programs are *prima facie* involuntary, in practice, parents might exercise voluntariness of consent. This assumption is grounded in the availability of exemptions from the requirement, and the choice of leaving a child unimmunized as alternatives to the requirement. Secondly, the recommendation-based programs widely use financial incentives to increase vaccination rates. Since the offer of financial incentives was discussed in the previous chapter as one of the influences that could become undue, it leads to the question whether parents can, in practice, exercise voluntariness of consent in the recommendation-based programs.

The discussion that follows first examines the requirement-based programs, and then moves on to the programs that recommend vaccination.

5.3. Requirement to Vaccinate a Child: Vaccination Programs in Ontario and New Jersey

Childhood vaccination programs in Ontario and New Jersey legislated the requirement to vaccinate children. As discussed above, the requirement to submit to any medical procedure does not correspond with the voluntariness of consent. However, the description of the requirement-based vaccination programs in Chapter 4 shows that the vaccination programs in Ontario and New Jersey allow for medical, religious or conscientious exemptions. The availability of exemptions means that parents can vaccinate a child or claim exemptions in certain circumstances prescribed by law. Also, parents can decide against claiming exemptions and leave a child unimmunized, which, depending on the consequences of non-compliance, might

provide alternatives to the requirement. Therefore, the discussion of the programs in Ontario and New Jersey is centered on exemptions from vaccination requirement, and the choice to refuse vaccination without claiming exemptions. The goal is to determine whether exemptions or refusal to vaccinate allow parents to exercise voluntariness of consent in practice.

The nature of vaccination exemptions and the interrelation between exemptions in both jurisdictions and the voluntariness of consent is discussed next. The fundamental question asked is whether exemptions amount to choice.

5.3.1. Exemptions

An exemption is “the action of freeing or the state of being free from an obligation imposed on others.”¹⁴ This “implies special privilege or freedom from imposed requirements”.¹⁵ These characteristics do not create or amount to a choice to say “no”, which is inherent in the right to refuse treatment, because normally, the choice to refuse treatment is not burdened by any conditions or processes. The process or the privilege of being free from the requirement impacts voluntariness. This raises the issue of the interrelation between exemptions and voluntariness, which is generally discussed in the next subsections, and then specifically applied to discuss the voluntariness of consent and exemptions in the Ontario and New Jersey vaccination programs.

5.3.1.1. The Scope of Exemptions

Parents have been claiming exemptions from vaccine requirements as long as exemptions have been offered by vaccination policies.¹⁶ Overall, there are three types of exemptions parents can take advantage of: medical, religious and conscientious. The number of exemptions varies

¹⁴ The Oxford English Dictionary, *sub verbo* “exemption”, online: The Oxford English Dictionary <<http://www.oxforddictionaries.com>>.

¹⁵ Dictionary Reference, *sub verbo* “exemption”, online: Dictionary Reference <<http://dictionary.reference.com/browse/exemptions>>.

¹⁶ Vincent Ianelli, “Religious Exemptions to Vaccines” (August 2013) *Pediatrics*, online: Pediatrics <<http://pediatrics.about.com/od/immunizations/a/religious-vaccine-exemptions.htm>>.

between vaccination programs. It ranges from allowing only medical exemption, to offering all three types of exemptions. For those parents who wish to use an exemption clause, an exemption is granted only if they meet certain requirements. The discussion here of the vaccination exemptions is in the context of their scope in order to illustrate the breadth of objections that fall within the exemptions. The exemption processes are also analyzed for insights into the obstacles to the use of exemptions.

5.3.1.1.1. Medical Exemptions

The medical exemption could be utilized when vaccines are contraindicated, or when a child has immunity to a certain infectious disease.¹⁷ Medical exemptions are obtained when health care professionals determine that a child has a reason to be exempted. A discussion of the breadth of this exemption is not necessary for the purpose of this chapter as a parent is not the one to decide whether a child should be exempted. This instance is therefore irrelevant to the issue of the voluntariness of consent.

5.3.1.1.2. Religious Objections

Religious exemptions are “based on the tenets of an organized religion that prohibits [totally or partially] vaccinating its members”.¹⁸ The members of religious organizations who believe in faith healing over medical care or have ethical concerns related to the use of human tissue cells to produce vaccines rely on these reasons to claim objections to vaccinations.¹⁹ However, the scope of objections depends on the religious organization one belongs to. For instance, if parents are members of an unrecognized and unestablished church or denomination,

¹⁷ *Ibid.* Ontario, Guidelines for Completing the Statement of Medical Exemption Form (2006), online: Region of Waterloo Public Health <http://chd.region.waterloo.on.ca/en/healthyLivingHealthProtection/resources/CCC_FormC2.pdf>.

¹⁸ Vincent Ianelli, *supra* note 16.

¹⁹ College of Physicians of Philadelphia, “Cultural Perspectives on Vaccination” (16 January 2014), online: The History of Vaccines <<http://www.historyofvaccines.org/content/articles/cultural-perspectives-vaccination>>.

their religious objections to vaccination could be rejected.²⁰ Therefore, religious objections do not necessarily encompass all objections based on religious beliefs.

5.3.1.1.3. Conscientious Exemption

If the scope of medical and religious exemptions is clear in terms of the grounds for claiming exemptions, the scope of conscientious objections is ambiguous, and vaccination laws have not expanded on it.²¹ Moreover, the meaning of conscience *per se* is vague. There are many variations of the definition of conscience, but generally, it could be described as “a person’s moral sense of right and wrong, viewed as acting as a guide to one’s behavior.”²² It is also said to be a factor that “alerts a moral agent to his or her desires, but does not reveal anything that is universally good or normative for another person.”²³

As regards the nature of conscience, Dickson J claimed that “the values that underlie our political and philosophic traditions demand that every individual be free to hold and to manifest whatever beliefs and opinions his or her conscience dictates”.²⁴ Conscientious objections include religious beliefs, but “freedom of conscience necessarily includes the right not to have a religious basis for one’s conduct.”²⁵ Therefore, as claimed by Wilson J., “freedom of conscience and

²⁰ Alicia Novak, “The religious and philosophical exemptions to state-compelled vaccination: constitutional and other challenges” (2005) 7:4 U Pa J Const L 1101 at 1113.

“Recognized” religion language in the statutes. See Ariz Rev Stat (2000) § 36-883(c). Haw Rev Stat Ann § 325-34 (Michie 2002). Iowa Code (2002) § 139a 8(4) (b). Neb Rev Stat (2002) § 79-221(2) 25. *Texas Administrative Code* § 97.62(2) (West 2001).

²¹ *Immunization of School Pupils Act*, RSO 1990, 6.2 (2) (3). *New Jersey Statute*, Pub Law 2002, c 58 § 18A:61D-10.

²² The Oxford English Dictionary, *sub verbo* “conscience” online: Oxford Dictionaries <<http://oxforddictionaries.com>>.

²³ Ryan E Lawrence & Farr A Curlin, “Clash of Definitions: Controversies About Conscience in Medicine” (2007) 12: 10 Am J Bioeth at 10.

²⁴ *Big M*, *supra* note 10 at para 121.

²⁵ *R v Edwards Books & Art*, [1868] 2 SCR 713 at para 19.

religion should be broadly construed to extend to conscientiously held beliefs, whether grounded in religion or in a secular morality.”²⁶

It is difficult to determine the particulars of conscience based on the nature of belief as discussed above, but it is clear that they “extend beyond faith-based interpretations”.²⁷ Commentators claim that “appeals to conscience may stem from a variety of cultural, religious, philosophical and moral frameworks”.²⁸ As regards the underlying groundings of the objections, some academic commentators argue that “appeals to conscience might not be grounded in the *recognized* [italics added] philosophical... moral tradition”, and that conscientious objection “would have moral weight even if [parents] were unable to ground those beliefs in a foundational ethical theory”.²⁹ What is more, it is claimed that “a genuine conscientious objection, even if misinformed, is an expression of a commitment to acting morally.”³⁰ Therefore, objections could be viewed as conscientious even if misinformed or supported by unrecognized philosophies, as long as somebody is “acting morally”.

The idea of conscience has been used in various ways. For example, some forms of alternative medicine have been discussed in relation to conscience in the context of vaccination programs. They include the objections of some members of the chiropractic community, homeopaths, and naturopaths to vaccination that are based on their philosophies.³¹

²⁶ *R v Morgentaler*, [1988] 1 SCR 30 at 496.

²⁷ E J Sutton & R E G Upshur, “Are there different spheres of conscience?” (2010) 16 *International Journal of Public Health Policy and Health Services* 338 at 339.

²⁸ *Ibid.*

²⁹ F A Curlin et al, “Caution: conscience is the limb on which medical ethics sits” (2007) 7:6 *The American Journal of Bioethics* 30 at 31. It is not clear what types of objections would not fall within conscientious vaccination exemptions, but the parallel could be drawn with health care workers’ conscientious objection which most likely does not include “practitioner convenience, irrational fear, prejudice or reluctance to treat patients perceived to be making unhealthy lifestyle choices.” See Jocelyn Shaw & Jocelyn Downie, “Welcome to the Wild, Wild North: Conscientious Objection Policies Governing Canada’s Medical, Nursing, Pharmacy, and Dental Professions” (2013) 28:1 *Bioethics* 33 at 35.

³⁰ F A Curlin, *supra* note 29 at 31.

³¹ Simon Singh & Edzard Ernst, *Trick or Treatment: The Undeniable Facts about Alternative Medicine* (London: Bantam Press, 2008) at 185.

Libertarianism as an opposition to the vaccination mandate is also indicated as a reason for conscientious objections.³²

However, to shed more light on the scope of conscientious objections vis-à-vis vaccination, it is necessary to indicate the reasons that parents most often use to claim conscientious exemption. For instance, a study of non-medical exemptions in the US shows that the most common objections for not vaccinating a child were related to vaccine safety (68%) and “the immune system overload” (49.1%).³³ Also, the study indicated that objections based on religious beliefs equaled 9.0%.³⁴ It was not specified whether or not “vaccine safety” and “the immune system overload” were used as reasons to claim conscientious objections; however, since in the US only conscientious and religious non-medical exemptions are available, these reasons were probably used as bases for conscientious exemption.

Similar results were obtained in Ontario. According to secondary findings of research on vaccination in Ontario, safety concerns and the lack of confidence in vaccine efficacy were the most frequently indicated reasons for opting to use the non-medical exemptions clause.³⁵ However, in the Ontario study, researchers did not distinguish between conscientious and religious objections. Therefore, it is not clear whether Ontarians use safety or efficacy concerns to claim conscientious beliefs. However, based on the US study in which safety concerns was the top reason for conscientious objections, it could be assumed that, at least, some parents in Ontario might use safety concerns to claim conscientious exemptions.

³² J Shaw & J Downie, *supra* note 29 at 30.

³³ Daniel A Salmon et al, “Factors Associated With Refusal of Childhood Vaccines Among Parents of School-aged Children a Case-Control Study” (2005)159:5 Arch Pediatr Adolesc Med at 470.

³⁴ *Ibid.*

³⁵ Kumanan Wilson, “Parental Views on pediatric vaccination: the impact of competing advocacy coalitions” (2008) 17:2 Public Underst Sci 231 at 234. James B Campbell, Jason W Busse & H Stephen Injeyan, “Chiropractors and Vaccination: A Historical Perspective” (2000) 105:4 *Pediatrics* at e43.

Based on the aforementioned definitions of conscience, safety concerns *per se* would likely not fall within the scope of conscientious objections. For instance, safety objections might not be viewed as conscientious in terms of “a person’s moral sense of right and wrong” unless they are based on some type of belief, such as religious, chiropractic or naturopathic philosophies.³⁶ Some authors claim that parents use conscientious objections since they “have strong personal beliefs about the dangers of vaccines, in particular, the belief that childhood vaccines are linked to rising rates of autism.”³⁷ However, these could be seen as safety *concerns* that, for instance, are grounded on Andrew Wakefield’s³⁸ fraudulent study on the link between autism and vaccination, rather than beliefs grounded in religion, a secular morality, or even an unrecognized ethical theory.

On the other hand, the underlying reason for parents’ safety concerns resides in the belief that they should act in the “best interest” of a child, and not expose their children to the risks of vaccination. The studies on vaccination show that parents who refuse to vaccinate children, link objections grounded in safety concerns with the best interest of their children.³⁹ Also, in relation to vaccination, “not wanting to harm...loved ones”⁴⁰ is indicated in the literature as one of the standards by which individuals live and take health care decisions.

Health care decisions, such as refusal of vaccination because of safety reasons, when taken by parents who believe that their decision is in the best interest of a child, are grounded in

³⁷ Nancy Berlinger, “Parental Resistance to Childhood Immunizations: Clinical, Ethical, and Policy Considerations” (2006) 8:10 *Virtual Mentor* at 681-684.

³⁸ Fiona Godlee, “Wakefield’s article linking MMR vaccine and autism was fraudulent” (2011)342: c7452 *BMJ* at 637.

³⁹ Irene A Harmsen et al, “Why parents refuse childhood vaccination: a qualitative study using online focus groups” (2013) 13 *BMC Public Health* at 1183.

⁴⁰ E J Sutton & R E G Upshur, *supra* note 27 at 340.jep_13

the “parenting philosophy”⁴¹ or parental liberty;⁴² by virtue of it being a philosophy, parents’ reasoning could fall within the meaning of conscientious objections. Moreover, as indicated above, even if parents are misinformed, for instance, about the safety of vaccines, it does not undermine their commitment to act morally according to what they think the best interest of a child is. Consequently, their misinformed objections might still fall within the scope of conscientious objections. However, the inclusion of safety concerns within the scope of conscientious objection depends on, and could be clarified by way the objection is shaped in the vaccination policy.

For instance, in Texas, one of the last states in the US that adopted conscientious objection, the introduction of exemption was tied to safety concerns which was claimed to be based on parental beliefs to act in the best interest of a child.⁴³ Even though the legislation does not specify the link, the draft of the amendment offered “conscientious objection in cases where an applicant’s sibling had experienced an adverse reaction.”⁴⁴ This construction pointed to the link between medical choices and the liberty to act in what the parents thought was in the best interests of their child, as one of the children in the situation had suffered adverse reaction. The “sibling adverse effects” requirement was eliminated to broaden the scope of exemption, but the draft implied a link between safety considerations and best interests.⁴⁵

⁴¹ Courts refer to approaches parents use in child rearing and taking decisions related to life choices of their children as “parenting philosophies”. See *Robinson v Filyk*, [1996] BCJ No 2519 at para 26. *CME v CAL*, 2002 BCSC 1536 at para 31.

⁴² The link between parental liberty and the “best interest of a child” standard are discussed in Chapter 2.

⁴³ House Research Organization, Interim News, Texas House of Representatives, “Public Health. Conscientious Objections” (2003) 17:1, online: HRO <<http://www.hro.house.state.tx.us/interim/int78-1.pdf>> at 3. This is the position of the advocates for the exemptions, those who were in opposition were against the inclusion of the exemptions as such.

⁴⁴ *Ibid.*

⁴⁵ *Administrative Code*, TX tit 25 C-97 B Rule 97.62 (2005).

There is a vast literature on conscientious objections that provide details on the aforementioned arguments on the scope of conscientious exemptions.⁴⁶ However, this is beyond the scope of my thesis. The brief review above shows that conscientious objection to vaccination might be viewed as grounded or not grounded in deeply held beliefs pertaining to the role and responsibilities of a parent in society or as the reasons which guide a moral agent. Still, its scope will most likely depend on how the vaccination policy would define it.

5.3.1.1.4. Number of Vaccines Covered by Exemption

The final part of the overview of exemption applicable to the scope of exemptions relates to the number of vaccines covered by exemption. Based on his or her medical condition, a child could be exempted from one or two vaccines, or from a whole program, depending on contraindications or a child's immunity.⁴⁷ In some jurisdictions, conscientious and religious objections could cover either one vaccine or a set of vaccines offered by the vaccination program.⁴⁸ In other jurisdictions, parental objections to one vaccine, for instance, MMRV, could lead to exclusion from the childhood vaccination program.⁴⁹ Therefore, an exemption claim could cover a single vaccine or a whole panel of vaccines required by the vaccination schedule.

This examination of the scope of exemptions shows the types of beliefs that could be put forward in order to receive exemption, particularly, conscience-based exemptions. However, to have reasons that could fit within the scope of an exemption is not the same thing as actually obtaining exemptions from vaccination. The exemption process presents obstacles to the use of

⁴⁶ See Jocelyn Shaw & Jocelyn Downie, *supra* note 29; Claudia I Emerson & Abdallah S Daar, "Defining Conscience and Acting Conscientiously" (2007) 12 AJOB. BM Dickens & R Cook, "The scope and limits of conscientious objection" (2000) 71:1 International Journal of Gynecology and Obstetrics at 71-7.

⁴⁷ Guidelines for Completing the Statement of Medical Exemption Form, *supra* note 17.

⁴⁸ Texas Department of State Health Services, Immunization Requirement, online: Texas Department of State Health Services <<http://www.dshs.state.tx.us/IMMUNIZE/school/default.shtm>>.

⁴⁹ *New Jersey Statute*, Pub Law 2002, c 58 § 18A: 61D-10. Exemption from vaccination.

exemptions and indicates that there is an interrelation between the use of exemptions and the complexity of the exemption process. This is now discussed.

5.3.1.2. The Exemption Process

Vaccination policies implement exemption processes which could be categorized as more or less complex. The complexities of the exemption process are viewed as ways to prevent a high frequency of exemptions of convenience, and to ensure that a claim of exemption is the result of serious deliberation and sincerity of beliefs.⁵⁰ The rationale behind imposing these requirements lies in the fact that the process makes it less likely that “a parent would make the exemption choice simply because it is easier”.⁵¹

The requirements of the exemption process that is implemented in some jurisdictions, or suggested in the literature, indicate that to obtain exemptions, parents could be asked for proof of attendance at their health department for counselling, or to produce a signed informed refusal form.⁵² Also required might be proof of the sincerity of religious belief in the form of a letter from a religious organization, or a written explanation of the foundations of the religious belief.⁵³ In some cases, exemptions must be renewed annually or upon change of school.⁵⁴ A “memorialized or standardized”⁵⁵ requirement of informed refusal, as well as written and formal

⁵⁰ Daniel A Salmon, “Mandatory Immunization Laws and the Role of medical, religious and philosophical exemptions” [unpublished], online: Vaccine Safety <<http://www.vaccinesafety.edu/exemptreview101503.pdf>> at 3. Daniel A Salmon & Andrew W Siegel, “Religious and Philosophical Exemptions from Vaccination Requirements and Lessons Learned from Conscientious Objectors from Conscription” (2001) 116 Public Health Reports 289 at 293.

⁵¹ Daniel A Salmon & Andrew W Siegel, *supra* note 50 at 294.

⁵² M Wharton, R Hogan & P Segal-Freeman, “Childhood Immunization: Exemptions and Vaccine Safety” (2005) 334 J Law Med Ethics 34 at 34-35.

⁵³ *Ibid.*

⁵⁴ *Ibid.*

⁵⁵ RD Silverman, “No more kidding around: restructuring non-medical childhood immunization exemptions to ensure public health protection” (2003) 12:2 Ann Health Law 277 at 294.

instructions on the exemption process, are also measures which can make the exemption process complex.⁵⁶

It is claimed that though the aforementioned requirements present some difficulties, they are not overly complicated requirements for parents to meet.⁵⁷ However, there is a difference between submitting an exemption form which must be notarized, and a form which just requires parents' signature.⁵⁸ Obviously, notarization of a form "adds a degree of effort and formality to the process",⁵⁹ as well as expenses which influence the accessibility of the choice. Indeed, the correlation between the complexity of obtaining exemptions and the frequency of exemptions being claimed has been established by several studies.

In one of the studies, the difficulties of the "paperwork or effort" parents needed to put into the exemption process were inversely related to the number of exemptions in a jurisdiction.⁶⁰ In other words, parents are discouraged to claim exemptions when they need to put effort into the process. A more recent study researched the interrelation between the complexity of vaccination policies in different US states, and the rates of non-medical exemption.⁶¹

Exemption processes were categorized as easy, medium and difficult, based on the following factors:

whether completion of a standardized form was permissible, as opposed to a letter from a parent; whether the parent obtained the form (i.e., school vs. health department); whether the form had to be notarized; and whether a letter from a parent, if required, needed to be worded in a specific way, resulting in extra effort on the part of the parent.⁶²

⁵⁶ M Wharton, R Hogan & Segal-Freeman P, *supra* note 52 at 34-35.

⁵⁷ Jeniffer S Rota, "Processes for obtaining nonmedical exemptions to state immunization laws" (2001) 91:4 Am J Public Health 645 at 647.

⁵⁸ *Ibid.*

⁵⁹ *Ibid.*

⁶⁰ *Ibid.*

⁶¹ SB Omer et al, "Vaccination policies and rates of exemption from immunization, 2005- 2011" (2012) 367:12 N Engl J Med at 1170.

⁶² *Ibid.*

The data says that the exemption rates for easy, medium and difficult policies in 2011 were 4.8%, 3.1%, 1.3%, respectively.⁶³ The rates of the use of “non-medical” exemptions are lower for the “difficult” policies than for “easy” policies. However, as shown by the data, parents still use exemption clauses in jurisdictions where the exemption processes are the most complex. Therefore, notwithstanding obstacles posed by exemption process, some parents appear to exercise the available exemptions.

It could be concluded that the scope of exemption could be more or less broad, and exemption process less or more complex. This sets the stage to consider the voluntariness of consent to the exemptions in the Ontario and New Jersey vaccination programs, which are discussed next.

5.3.1.3. Analysis

In this section, I apply freedom of choice theory to the exemptions in the vaccination programs in Ontario and New Jersey. Freedom of choice theory provides a lens through which to analyze exemptions in the requirement-based vaccination programs. In particular, it offers two criteria, availability and exercisability, by which to evaluate freedom of choice. Availability and exercisability of exemptions are useful to determine whether exemptions constitute indirect forms of control as asserted by Dickson J in *R v Big M*.⁶⁴

In *R v Big M*, the Supreme Court of Canada case on s. 2 of the *Charter* on freedom of conscience and religion, Dickson J claims that coercion manifests not only via direct forms of control, such as commands to “act or refrain from acting on pain of sanction”,⁶⁵ but also via “indirect forms of control”⁶⁶ that can undermine the choices that an individual could have opted

⁶³ *Ibid.*

⁶⁴ *Big M*, supra note 10.

⁶⁵ *Ibid* at 95.

⁶⁶ *Ibid.*

for. Consequently, to have an exemption from the requirement might not be enough to put parents in a position to choose freely, since there might be forms of control that indirectly undermine alternatives.

Below, with the help of the concepts of availability and exercisability encompassed under freedom of choice theory, I determine if indirect forms of control are hidden behind the alternatives, i.e., exemptions, to the vaccination requirement. The analysis of the availability and exercisability of exemptions contained in the requirement-based vaccination programs overlaps to some extent, since exercisability depends on whether exemptions are available, and some elements of the availability of exemptions also point to their exercisability. However, to bring clarity to the conclusions, availability and exercisability are discussed separately. Then, I examine whether there are any direct undue influences on the decision to vaccinate or claim exemptions.⁶⁷

5.3.1.3.1. Availability of Exemptions

According to freedom of choice theory, the availability of choice is evaluated on the basis of the range of options available.⁶⁸ In the context of vaccination programs, the availability criterion could be linked to the scope of exemptions discussed above. The scope of exemptions underscores whether parents have options to choose from in terms of the range of exemptions, as well as the breadth or scope of certain types of exemptions which fulfill the availability criterion in content. Therefore, the variations in the scope of exemptions are useful for measuring freedom of choice via the availability criterion.

⁶⁷ Amartya Sen, *Rationality and Freedom* (Cambridge: The Belknap Press of Harvard University Press, 2002) at 10; Gerald Dworkin, *The Theory and Practice of Autonomy* (Cambridge: Cambridge University Press, 1988) at 65.

⁶⁸ *Ibid* at 10.

In light of the availability criterion, between the New Jersey and Ontario vaccination policies, the vaccination policy in New Jersey is the more restrictive in terms of making choices available, since it offers only religious and medical exemptions. As mentioned in Chapter 4, the New Jersey authorities state that exemptions “which are of a philosophical, moral, secular, or more general nature continue to be unacceptable.”⁶⁹ Consequently, there is no option for parents who have beliefs grounded in secular morality to refuse vaccination. However, in Ontario, parents’ choice is not restricted to religious beliefs and medical contraindications.⁷⁰ The Ontario vaccination policy includes exemptions based on conscientious beliefs, which increases their availability, in comparison to New Jersey.

As regards the objections which fall within religious exemptions, in both jurisdictions, parents who have religious objections to vaccinations are not required to be members of recognized organizations to qualify for the exemption. To receive a religious exemption in New Jersey, it is sufficient to write a letter which includes the word “religion”.⁷¹ Moreover, in New Jersey, public health authorities do not “question whether the parent’s professed religious statement or stated belief is reasonable, acceptable, sincere and *bona fide*”.⁷² Likewise, in Ontario, the statement of religious and conscientious beliefs does not contain any fields to indicate the substance of beliefs.⁷³ Therefore, religious exemptions could be claimed by individuals with different religious beliefs, and this adds to the availability of exemptions.

⁶⁹ State of New Jersey, Department of Health and Senior Services, *NJAC 8:57-4.3 and 4.4 Immunization of Pupils in Schools rule, Religious and Medical Exemption* (1 December 2008), online: State of New Jersey Department of Health <http://www.state.nj.us/health/cd/documents/religious_exemption.pdf>.

⁷⁰ *New Jersey Statute*, Pub Law 2002, c 58 § 18A: 61D-10.

⁷¹ State of New Jersey, Department of Health, Required Immunizations for Day Care/Preschool and Sixth Grade, online: State of New Jersey, Department of Health <http://www.state.nj.us/health/cd/req_imm.shtml#mre>.

⁷² *NJAC 8:57-4.3 and 4.4 Immunization of Pupils in Schools rule, Religious and Medical Exemption*, *supra* note at 66.

⁷³ *Immunization of School Pupils Act*, RRO 1990, Reg 645, Form 2. It is also applicable to the *Day Nurseries Act*, RRO 1990, Reg 262.

As regards conscientious exemptions in Ontario, based on the analogy between Ontario and the US study mentioned in a previous section,⁷⁴ it may be assumed that some parents in Ontario might use safety concerns to claim conscientious objections to vaccination.⁷⁵ If parents actually use safety concerns, there are arguments they can invoke to justify inclusion of their safety concerns within the scope of conscientious objection. However, the scope of conscientious objection in Ontario is unclear. So, even if safety concerns are subsumed within the conscience exemption, the lack of clarity limits the availability of exemption for those parents who might not be aware of this flexibility.

Vaccination schedules include many vaccines. However, neither of the programs allows parents to use the religious or conscientious exemption clause to claim exemptions from certain vaccinations they are opposed to.⁷⁶ The programs have an “all or nothing” approach, except for medical reasons; a non-medical exemption claim is applicable to all vaccines in the vaccination programs. Obviously, this limits the freedom of choice of many parents who object to one or two vaccines, since the exemption clause is automatically unavailable, unless parents interrupt the vaccination schedule after their children have received some vaccines, in order to avoid the administration of other vaccines they are opposed to.

To sum up, some exemptions are available in both jurisdictions, but the availability of a conscience-based exemption in Ontario suggests greater freedom of choice in that jurisdiction than in New Jersey. However, both programs adopt the “all or nothing” approach in terms of the number of vaccines covered by exemptions, which limits freedom of choice.

⁷⁴ Daniel A Salmon et al, *supra* note 33 at 470

⁷⁵ Kumanan Wilson, *supra* note 35 at 234.

⁷⁶ *Immunization of School Pupils Act*, RRO 1990, Reg 645, Form 2. Steve P Calandrillo, “Vanishing Vaccinations: Why are so many Americans Opting Out” (2004) 37:2 Univ Mich J Law Reform 353 at 429.

The second criterion offered by the freedom of choice theory is the exercisability of choice to exemptions. This criterion is now applied to the Ontario and New Jersey programs.

5.3.1.3.2. Exercisability of Exemptions

Freedom of choice theory does not provide any criteria to measure the exercisability of choice. However, one way to analyze exercisability is to focus on the complexities of the exemption process. The complexities signify the obstacles parents face in the process of obtaining exemptions, which demonstrates how much of voluntariness is offered or taken away by the exemption process. Therefore, the application of the exercisability criterion is interrelated with the above discussion on the obstacles to the use of exemptions, which could be used as a benchmark to measure freedom of choice.

Based on the discussion of obstacles that are implemented in different jurisdictions, it could be concluded that the New Jersey policy on the exercisability of religious exemptions is an “easy policy”. Firstly, it does not require any proof of the sincerity of belief, but a parent’s letter which claims that the parent’s religious beliefs do not allow vaccination.⁷⁷ Secondly, the letter should be written only once, as the exemption does not need to be renewed.⁷⁸ Thirdly, there are no formal instructions as regards the format of the letter.⁷⁹ It is only required to use the word “religion”. This signifies an easy process for claiming exemptions, compared to the requirement in other jurisdictions to submit written statements from the religious organization stating the

⁷⁷ *Immunization of Pupils in Schools rule, Religious and Medical Exemption*, *supra* note 68.

⁷⁸ *Ibid.*

⁷⁹ *Ibid.*

conflict with vaccination and confirming the parent's membership in the organization to affirm the sincerity of the beliefs.⁸⁰

In Ontario, to claim religious and conscientious exemptions, parents do not need to present any proof of the sincerity of the beliefs, but, unlike in New Jersey, there is a standard exemption form that must be filled out and notarized.⁸¹ The existence of the form, which is accessible online and available at doctors' offices and public health clinics, adds to the burden of paperwork. Notarization also contributes to the degree of effort and formality of the exemption process, but, most importantly, it generates expenses. For instance, the cost of notarization in Toronto varies between \$10 and \$40.⁸² The cost might present a substantial obstacle to parents, especially for low income families, and families who have two or more children. However, exemptions do not need to be renewed in Ontario, and, therefore, parents pay for notarization only once.⁸³ Overall, the requirements of the exemption process in Ontario signify that its policy has a higher level of complexity than that of New Jersey.

To sum up, the Ontario vaccination program offers freedom of choice in terms of the availability of choice, but the exemption process in Ontario complicates its exercisability. The New Jersey vaccination program can be categorized as an easily exercisable policy which offers freedom of choice as regards the exercisability criterion. At the same time, the New Jersey policy limits choice in terms of the availability of exemptions. Thus, there are indirect forms of control behind exemptions which might affect the voluntariness of consent. However, overall,

⁸⁰ Daniel A Salmon et al, "Public Health and the Politics of School Immunization Requirements" *American Journal of Public Health* May (2005) 95:5 at 780.

⁸¹ *Immunization of School Pupils Act*, RRO 1990, Reg 645, Form 2.

⁸² Toronto Notary Public, Notarization Fees, online: Toronto Notary Public, <<http://www.toronto-notary-public.com/>>. Red Seal Notary Public, Walk in Fees, Appointment Fees, online: <<http://www.redsealnotary.com/notary-fees.html>>. Document Services, Document Legalization, online: <<http://www.documentservices.ca/notary/>>.

⁸³ *Immunization of School Pupils Act*, RRO 1990, Reg 645, Form 2.

exemptions are still available and exercisable to a greater or lesser extent in New Jersey and Ontario, which, according to freedom of choice theory, means that exemptions allow some degree of voluntariness.

Since exemptions offer some freedom of choice, it could be assumed that the decision to vaccinate or claim exemptions, if one has reasons to claim exemptions, might be unduly influenced. This assumption is probed next.

5.3.1.3.3. Undue Influences

Coercion, undue pressure, the combination of exploitation and inequality in a power dependency relationship or other controlling influences, could unduly influence a parent's decision to vaccinate or claim exemptions. These influences could potentially occur in combination or separately in case of vaccination, though they might not be triggered by the design of the program. For the purpose of this thesis, I focus only on those undue influences on the decision to claim exemptions that could be caused by the vaccination programs *per se*. For instance, some commentators suggest that the fact that the program is designed as "routine" and "required" "implicitly sends the message"⁸⁴ that vaccination should be accepted disregarding the fact that there are exemptions, and this could undermine any freedom of choice a parent has as regards exemptions. To probe this claim, I use the notion of psychological compulsion that might be applicable to the voluntariness of consent in vaccination programs.

As mentioned in Chapter 3, courts operate with the concept of psychological compulsion to assess whether a state action infringes *Charter* rights.⁸⁵ For instance, in *R v Therens*, Justice

⁸⁴ Bennett discusses the nature of the requirement-based HIV testing programs (opt out programs) that could be associated with the requirement-based vaccination programs since both are based on the requirement to submit to the medical intervention. See R Bennett, "Routine antenatal HIV testing and informed consent: an unworkable marriage?" (2007) 33 J Med Ethics 446 at 446.

⁸⁵ *R v Morgentaler*, *supra* note 26 at para 20.

Le Dain held that “the element of psychological compulsion, in the form of a reasonable perception of suspension of freedom of choice, is enough to make the restraint of liberty involuntary.”⁸⁶ He also said that he did not see compliance with the demand of a police officer as voluntary, since as a general rule, an individual who was subjected to the demand could feel that he or she had no option but to obey, even when there was no criminal liability in case of non-compliance.⁸⁷

A parallel could be drawn between the police officer’s direction, and the requirement to vaccinate, that a patient hears from a doctor. Certainly, the role of a doctor is different than the role of a police officer, at least, because the doctor does not have a state authorized capability to coerce. In the case of vaccination, the doctor is not enforcing the law, but only announcing the state-imposed requirement to vaccinate within a doctor-patient relationship. Yet, the elements of psychological compulsion or “the psychological effect”⁸⁸ of the state’s requirement could be applied to vaccination to see if it leads to infringement of voluntariness.

To establish psychological compulsion, there should be a “demand or direction” in response to which an individual agrees to submit to a proposed course of action and believes that there is no other choice.⁸⁹ The legislated requirement to vaccinate in Ontario and New Jersey sustains the direction to submit to vaccination. If a patient hears about the direction to vaccinate from a doctor, then it occurs within a doctor-patient relationship. In this relationship, a doctor is in position of power vis-à-vis a patient, whereas a patient is vulnerable to external influences.⁹⁰ Therefore, it could be assumed that in some circumstances, doctor’s authority could strengthen

⁸⁶ “A compulsion of a psychological or mental nature which inhibits the will as effectively as the application, or threat of application, of physical force.” See *R v Therens*, [1985] 1 SCR 613 at para 53.

⁸⁷ *Ibid* at 642-643.

⁸⁸ *Morgentaler*, *supra* note 26 at para 20.

⁸⁹ *R v Bazinet*, (1986), 54 OR (2d) 129, 25 CCC (3d) 273 at paras 34-35. *Toronto (City) v Bednarski*, [2009] OJ No 2955 at para 73.

⁹⁰ *Norberg*, *supra* note 3 at para 70.

the direction to vaccinate, and this might compel a parent to comply with the state's requirement without considering exemptions. In other words, the requirement to vaccinate in a combination with doctor's authority could forge a reasonable perception that leaves a parent with no choice but to comply with the vaccination requirement.

Moreover, psychological compulsion could occur even when parents know that some exemptions exist as, according to *Therens*, the awareness of the option to refuse to comply does not prevent the perception of suspension of freedom of choice.⁹¹

Thus, if psychological compulsion is applicable in the health care context, the freedom of choice offered by exemptions to vaccination in the vaccination programs in Ontario and New Jersey could be affected by psychological compulsion.

5.3.1.3.4. Summary: Exemptions and the Voluntariness of Choice

To sum up my analysis of the two requirement-based programs, even though the requirement to vaccinate does not correspond with the voluntariness of consent, exemptions appear to offer some freedom of choice in practice. The Ontario vaccination program promotes the availability of choice, whereas in New Jersey, the vaccination program offers more freedom as regards the exercisability of exemption. Still, vaccination exemptions in Ontario and New Jersey trigger some indirect forms of control, which, in some circumstances, affect voluntariness. Moreover, voluntariness offered by exemptions could be infringed by direct controlling influences, such as psychological compulsion.

Besides using an exemption clause, parents could also refuse to vaccinate a child without claiming exemptions. In the section below, I discuss the voluntariness of choice to refuse

⁹¹ In *Therens*, Justice Le Dain was leaning towards Justice Tallis' position in *Currie* according to which even when an individual was given an option of not accompanying the police, the choice to comply with the demand was not free. See *R v Therens, supra* note 86 at para 51.

vaccination via the consequences of leaving a child unimmunized in the requirement-based programs.

5.3.2. Leaving a Child Unimmunized in the Requirement-based Programs

A child up to six years old would not receive childhood vaccines if parents do not bring him or her for a vaccination appointment. Since parents could decide against scheduling vaccination appointments and claiming exemptions, it could be assumed that the refusal to immunize a child could be added to the choice set. However, the choice to leave a child unimmunized has its consequences, which could show whether it is possible for parents to exercise the choice in practice. The consequences of leaving a child unimmunized without claiming exemptions might constitute “indirect forms of coercion”⁹² and, therefore, eliminate a choice of leaving a child unimmunized.

Relevant to this discussion are two Supreme Court of Canada cases, *White* and *Fitzpatrick*. As interpreted in the later case of *Choy*, the Supreme Court, in these cases, identified one of the forms of coercion as “a degree to which a person was required to participate in the legislative scheme”.⁹³ In *White*, Iacobucci J compared the voluntariness of choice to drive, and to choose a profession; the latter was discussed in *Fitzpatrick*.⁹⁴ Iacobucci J concluded that since driving is a necessity of life, particularly in rural areas where driving allows a person to “function...in society”, the choice to drive is less free than to choose a profession.⁹⁵ Therefore, the level of necessity that leads a person to participate in the activity could undermine the voluntariness of choice to some degree. Similarly, the necessity to vaccinate, or the graveness of

⁹² *R v Choy*, [2008] AJ No 1320, 2008 ABQB 737 at para 24.

⁹³ *Ibid.*

⁹⁴ In *R v Fitzpatrick*, [1995] 4 SCR 154, the appellant was the captain of a vessel engaged in a licensed and regulated commercial groundfish fishery in British Columbia. In *R v White*, Iacobucci J claimed that nobody forced an individual to participate in the commercial fishery and such decision was the manifestation of one’s free choice. See *R v White*, [1999] 2 SCR 417 at para 55.

⁹⁵ *R v White*, [1999] 2 SCR 417 at para 55.

the consequences of leaving a child unimmunized without claiming exemptions, could point to the degree of coercion involved in making a vaccination decision in practice.

There are two types of consequences entailed by the decision to refuse to vaccinate a child. They relate to day care or/and school entry or school attendance. For instance, in New Jersey, vaccination policies restrict admission to a day care or school if the child is not immunized or exempted from the vaccination requirement.⁹⁶ In Ontario, only day care entry is prohibited when parents do not submit a certificate or an exemption form.⁹⁷ A child could be enrolled in a school in Ontario without an up-to-date immunization record or exemption. However, up-to-date records will be required for school attendance, since suspension from school might and probably will follow.⁹⁸ Therefore, the attendance of a daycare or school, which is of high importance to functioning in society for parents and children, depends on vaccination.

Even though a child should be vaccinated in order to attend school or a day care, a choice, “albeit a limited and difficult one”⁹⁹ remains, since parents can home school a child and never send them to a day care. Yet, as stated by Wendy Parmet, “in both a formal and a practical sense, this is not much of a choice.”¹⁰⁰ The reality is that the prevailing majority is not able to educate children at home, and some parents cannot afford not to send them to a day care.¹⁰¹ In relation to that, in the US case, *Allison v Merk*,¹⁰² a judge commented that

⁹⁶ *Administrative Code*, NJ tit 8 § 8:57-4.2.

⁹⁷ *Day Nurseries Act*, RRO 1990, Reg 262 s 33 (1).

⁹⁸ *Immunization of School Pupils Act*, *supra* note at ss 6.2 (1), 8.

⁹⁹ Wendy Parmet, “Informed Consent and Public Health. Are they Compatible When it comes to Vaccines” (2005) 8:1 *Journal of Public Health Law and Policy* 71 at 102-103.

¹⁰⁰ *Ibid.*

¹⁰¹ Many home educating parents do not register with local school officials, so an exact number is not known. However, it is estimated that approximately 1% to 2% of all school-age children are homeschooled in North America, which translates to around 20,000 children in Ontario. The number for Canada as a whole is estimated at approximately 60,000 homeschooled children. See The Ontario Federation of Teaching Parents, *Homeschooling Frequently Asked Questions*, online: The Ontario Federation of Teaching Parents <<http://ontariohomeschool.org/faq.shtml#howmany>>.

¹⁰² *Allison v Merk*, 878 P 2d 948 110 Nev 762, 63 USLW 2091 in Wendy Parmet, *supra* note 100 at 102-103.

Ms. Allison never had any real choice as to whether her son was to receive the vaccine in question...she was faced with the Hobson's choice of either having the vaccine administered or not having the privilege of sending her son to private or public school.¹⁰³

Thus, according to *Allison v Merk*, the choice to not vaccinate, which eliminates the privilege to attend a school, is not even qualified as a choice. Similarly, in the New Jersey and Ontario vaccination programs, the choice of leaving a child unimmunized without claiming exemptions could not be viewed as a “real choice” since it undermines the privilege of school and day care attendance. Indeed, to apply *White*, in which the necessity to participate in the activity undermined voluntariness, it could be concluded that the necessity to attend school and day care which is of high importance to “function meaningfully in society”, can coerce parents into the decision to vaccinate. Consequently, the choice to leave children unimmunized without claiming exemptions is eliminated.

Therefore, the consequences of non-vaccination could be viewed as indirect forms of coercion which eliminate the choice of leaving a child unimmunized in the requirement-based vaccination programs in Ontario and New Jersey.

5.3.3. Conclusion

To sum up the foregoing analysis of the requirement-based vaccination programs parents could, in practice, exercise the voluntariness of consent in the requirement-based programs in some circumstances. The availability and exercisability of exemptions prove that exemptions offer some voluntariness. However, they also show that there are indirect influences which infringe the voluntariness of consent related to the range of exemptions and obstacles to their use. Therefore, the degree of voluntariness parents could exercise is limited. Moreover, psychological compulsion, if applicable to the health care context, could unduly influence the

¹⁰³ *Ibid.*

voluntariness of the decision to vaccinate or claim exemption. In addition, the consequences of leaving a child unimmunized without claiming exemptions does not offer any freedom of choice.

Thus, the requirement-based vaccination programs do not allow much freedom of choice in practice; exemptions are limited and the choice to refuse vaccination is eliminated. However, the conclusion on the *prima facie* non-consistency of the requirement-based vaccination program with the voluntariness of consent is made more complex by the possibility to exercise exemptions in some circumstances. To further examine and potentially complicate the distinction between the requirement and recommendation-based programs, I next consider whether parents could, in practice, exercise the voluntariness of consent in the UK and the Australian recommendation-based programs.

5.4. Recommendation to Vaccinate a Child: Vaccination Programs in the UK and Australia

In the UK and Australia recommendation-based vaccination programs, parents have options to consent or refuse vaccination. Therefore, the vaccination programs are *prima facie* consistent with the voluntariness of consent. In these two programs, parents can exercise their right to refuse vaccination without any restrictions. For instance, in the UK vaccination programs, parents are asked to consent to participation in the immunization program after the birth of a child as part of the health visitors' first visit to the child's home.¹⁰⁴ If they refuse to consent to participation in the vaccination program, they encounter no obstacles, such as the non-admission of an unimmunized child to a day care and school, or any other formal requirement to present an immunization record.

¹⁰⁴ The child's details are then entered into the system and the call-recall mechanism is activated in time for the first appointment to be scheduled at 3 months. See DM Salisbury, "Vaccine programmes and policies" (2002) 62:1 *Br Med Bull* 201 at 202.

However, in the UK, doctors face consequences when children are left unimmunized. When vaccination coverage of two and five-year-olds in their practice falls below 70%, general practitioners are not eligible for immunization-related incentives payable at the end of every quarter.¹⁰⁵ Doctors receive higher payments for 90% vaccination coverage than for 70%, and this motivates them to vaccinate as much as 90% of children attending their practice.¹⁰⁶

In Australian territories and states, a blank immunization certificate is not an obstacle to a school or day care registration. However, parents would not receive financial benefits if they do not meet the conditions of the vaccination clause prescribed in the *Family Assistance Act*.¹⁰⁷ The vaccination clause states that parents can claim medical or conscientious exemptions and remain eligible for benefits. Therefore, to apply for the benefits, a child does not have to be vaccinated.

To receive conscientious or medical exemptions in Australia, parents must discuss the matter of vaccination with a health care professional and sign a form.¹⁰⁸ In other words, informed refusal is required. According to the discussion of the availability and exercisability of exemptions in the previous section, the requirement of informed refusal is one of the obstacles to obtaining exemptions. No proof of sincerity of beliefs is required; parents just need to receive a doctor's signature on the standard exemption form.¹⁰⁹ It was concluded in the previous part that even a complicated exemption process does not eliminate the choice to opt for exemptions,

¹⁰⁵ United Kingdom, National Health Services, General Medical Services Contract, online: NHS <http://www.nhsemployers.org/SiteCollectionDocuments/Childhood_immunisations_DES_ja220413.pdf>. United Kingdom, National Health Services, Enhanced Services, online: NHS <<http://www.nhsemployers.org/PayAndContracts/GeneralMedicalServicesContract/DirectedEnhancedServices/Pages/EnhancedServices.aspx>>.

¹⁰⁶ *Ibid.*

¹⁰⁷ *A New Tax System (Family Assistance) Act 1999* (Cth), division 2 s 6 (1) b; p 3 div 1 subdiv A; Australian Government, Department of Health, *Immunisation Related Payments for Parents. Immunize Australia Program*, online: Australian Government <<http://www.health.gov.au/internet/immunise/publishing.nsf/Content/related-payments>>.

¹⁰⁸ Australian Government, Department of Human Services, *Immunisation exemption conscientious objection form (IMMU12)* online: Australian Government, <<http://www.humanservices.gov.au/customer/forms/immu12>>.

¹⁰⁹ *Ibid.*

though it limits freedom of choice. Exemptions will be discussed later in this Chapter in more detail, but it could be said that according to the policy in Australia, parents who do not wish to vaccinate their children have an option to leave the child unimmunized and they will not receive financial benefits, and an option to exempt a child and obtain benefits.

To sum up, even though there are no restrictions as regards school and day care attendance, the choice of leaving a child unimmunized in the UK and Australia triggers the consideration of loss of immunization-related financial incentives in both jurisdictions as the consequences of non-vaccination. In Chapter 4, financial incentives were discussed as potential undue influences. It was argued that financial incentives could be the underlying reason for doctors to exert undue influence to procure the immunization of a child.¹¹⁰ Therefore, immunization-related incentives to doctors could indirectly influence the voluntariness of consent via doctors' motivation to reach vaccination targets. Incentives to parents could amount to undue influence that infringes directly on consent.

It was also emphasized that financial incentives do not necessarily infringe the voluntariness of consent when compared to coercion and psychological compulsion. Thus, further consideration of the notion of immunization-related financial incentives is necessary to determine whether there are any other influences from financial incentives, and whether they amount to undue influence. The discussion offers insights into whether voluntariness is unduly influenced in practice in the vaccination programs of both jurisdictions.

¹¹⁰ There are different systems of delivery of vaccines in the UK. In some cases, it might be delivered by health care visitors, or other health care workers. However, doctors are the ones responsible for taking consent. See Sarah A Redsell et al, "Health visitors' role in the universal childhood immunisation programme" (2010) 11: 51 Primary Health Care Research & Development at 54. Sarah Cowley et al, "Why health visiting" (2013), online: National Nursing Research Unit <<http://www.kcl.ac.uk/nursing/research/nnru/publications/Reports/Why-Health-Visiting-NNRU-report-12-02-2013.pdf>> at 54. United Kingdom, National Health Services, What do health visitors do, online: NHS <<http://www.nhs.uk/explore-by-career/nursing/careers-in-nursing/health-visiting/what-do-health-visitors-do/>>.

5.4.1. Immunization-Related Financial Incentives

In this section, I consider two types of financial incentives: immunization-related payments to doctors in the UK, and benefits to parents in Australia. I examine the details of the offer of immunization-related financial incentives, and its interrelation with the voluntariness of consent. In both cases, as discussed in Chapter 3, financial incentives might have some direct or indirect impact on the voluntariness of consent.

5.4.1.1. Financial Incentives to Doctors in the UK

Immunization related financial incentives to doctors were introduced in 1990 in the General Medical Services (GMS) Contract.¹¹¹ According to the 1990 contract, in the UK, financial incentives were paid to practices which achieved at least 70% vaccination rates among two and five year old children. The payment depended on the vaccination rates; a lower rate equals 70-89%, and a higher rate stands for 90%. The eligible practices receive target payments quarterly.¹¹² A 2003 GMS Contract also included a provision on childhood immunization target payments.¹¹³ In the 2003 Contract, the system changed slightly and the value of the target payments increased. The rate of payment for the high vaccination coverage for the children two years old was approximately £7,965, and for the low rate, it was £2,655 paid quarterly.¹¹⁴ For the vaccination of children five years old, the practice received £822 and £2465 for achieving 70%

¹¹¹ Physicians in the UK are eligible for payments of 955 and 2,865 pounds quarterly when the vaccination rates of children attending the practice are as high as 70-89%, or 90% respectively; Under this contract, in 1991, GPs who achieved a high (90%) or low (70-89%) target level were eligible for payments of 1,800 and 600 pounds respectively. See Mark Dusheiko et al, "Incentivising prevention by general practitioners: some research possibilities", online: Academia.Edu <<http://www.york.ac.uk/che/pdf/primcareprevgp incentives040506.doc>> at 2.

¹¹² British Medical Association, "Model offer letter for the employment of a salaried general practitioner by a practice to provide primary medical services" at Annex. Target payment specifications, online: NHS <http://www.nhsemployers.org/SiteCollectionDocuments/sal_contracts_offer_gp_gms_cd_110209.pdf>.

¹¹³ United Kingdom, National Health Service, New GMS Contract 2003/2004, online: NHS <<http://www.nhsemployers.org/PayAndContracts/GeneralMedicalServicesContract/GMSContractChanges/gmscontract200304/Pages/NewGMSContract200304.aspx>>.

¹¹⁴ *National Health Services, General Medical Services Contract, Enhanced Services*, *supra* note 105.

and 90% vaccination rates respectively.¹¹⁵ In 2014, the contract did not include any changes to childhood vaccination target payments.¹¹⁶

During the first three quarters of 1990, when the payments were first introduced, the immunization rates increased significantly. For instance, a number of practices that achieved 95% vaccination coverage increased from 31% to 81% for primary immunization (two years old), and from 23% to 64% (five years old) for preschool vaccinations annually.¹¹⁷ The reasons for the increase were not clear. However, financial payments were recognized to play an important role.¹¹⁸ Therefore, the dramatic rise of vaccination rates might point to the fact that financial incentives could have served as motivation to vaccinate children.

Some doctors stated that receiving financial incentives for immunization was important for their practice.¹¹⁹ Also, there is evidence that doctors were opposed to the payments in 2002-2003, claiming that vaccination incentives undermined parents' confidence in vaccine and doctor-patient relationship.¹²⁰ However, as stated above, vaccination incentives were continued in a 2003 Contract and the value of the payments increased.¹²¹ In a 2010 study, health care

¹¹⁵ United Kingdom, National Health Service, General medical services statement of financial entitlements directions 2013, online: UK Government <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213225/GMS-Statement-of-Financial-Entitlements-2013.pdf> at 27 section 11.

¹¹⁶ *National Health Services, Enhanced Services*, *supra* note 105.

¹¹⁷ LD Ritchie, D Russell & Leslie V Thomson, "Primary and preschool immunisation in Grampian: progress and the 1990 contract" (1992) 304:8 *Br Med J* 16 at 19.

¹¹⁸ Jon Christianso, Sheila Leatherman & Kim Sutherland, "Financial incentives, healthcare providers and quality improvements" (London: The Health Foundation, 2007) at 27.

¹¹⁹ Doctors claim that immunization-related payments is "quite serious finance". See "Children without MMR jab struck off GPs' list" (17 Nov 2002) *The Telegraph*, online: The Telegraph

<<http://www.telegraph.co.uk/news/uknews/1413425/Children-without-MMR-jab-struck-off-GPs-list.html>>.

"Children Whose Parents Refuse the MMR Jabs are being Dropped by their GPs" *Daily Mail*, online:

<<http://www.dailymail.co.uk/health/article-156664/Children-parents-refuse-MMR-jab-dropped-GPs.html>>.

¹²⁰ Linda Beecham, "CMOs criticised over target payments for MMR" (2003) 327 *BMJ* at 72. Cecilia Hall, "Doctors Abandon Bonus Scheme for MMR Jabs", *The Telegraph* (03 July 2002) online: The Telegraph

<<http://www.telegraph.co.uk/news/uknews/1399087/Doctors-abandon-bonus-scheme-for-MMR-jabs.html>>.

¹²¹ *National Health Services, Enhanced Services*, *supra* note 105.

visitors who were involved in the practice of immunization claimed that doctors “are under pressure to reach targets” in order to receive financial incentives.¹²²

Thus, the rocketing increase in vaccination, some doctors’ motivation to reach targets, and the lack of any restrictions such as school or day care attendance for non-immunized children in the UK, suggest that doctors may be influencing parents’ consent to childhood vaccinations. Indeed, there is some evidence that some parents in the UK experienced verbal pressure to submit to vaccinations.¹²³ Also, it was reported that families were threatened with dismissal from the practice, or were re-registered as temporary patients.¹²⁴

These facts and their interrelation with the voluntariness of consent are considered next in more detail. In particular, I examine pressure via verbal persuasion as influence which could become undue, and the implications of the refusal to vaccinate as the rationale behind the claims that parents could be threatened if they decide against vaccination in the UK vaccination program.

5.4.1.1.1. Pressure via Verbal Persuasion as Caused by Immunization-Related Incentives

There is evidence that parents’ vaccination decisions are influenced by pressure. For instance, studies reveal that in the UK, parents reported “unwelcome pressure from professionals to accept immunization and many immunizers had accepted MMR¹²⁵ because of this pressure...feeling that it was easier to comply than to refuse.”¹²⁶ Another study found that parents agreed to vaccination since they were “not wanting to upset their personal relationship

¹²² SA Redsell, “Health visitors’ perception of their role in the universal childhood immunisation programme and their communication strategies with parents?” (2010) 11: 51 Primary Health Care Research & Development at 54.

¹²³ M Evans et al, “Parents’ perspectives on the MMR immunisation: a focus group study” (2001) 51:472 Br J Gen Pract 904 at 907.

¹²⁴ C Johnston, “Parental autonomy and Immunization: a true choice” (2002) 175 Bulletin of Medical Ethics at 13.

¹²⁵ MMRV is not approved in the UK. See Chapter 1.

¹²⁶ M Evans et al, *supra* note 123 at 907.

with the GP.”¹²⁷ Also, the Daily Mail tells the stories of parents who faced persuasion from doctors. Some of them resisted the pressure, and some consented to the vaccinations.¹²⁸ One of the mothers claimed that “I caved into pressure from the doctors to start ...vaccinations ...even though I wasn't happy about it and he [a son] had the ones for diphtheria, tetanus and Hib.”¹²⁹ The Daily Mail offers, at best, anecdotal evidence, yet parents’ claims in the Daily Mail correspond with the findings of the two studies discussed above.

In relation to pressure via verbal persuasion, it was discussed in Chapter 3 that not all influences are undue.¹³⁰ Therefore, even if parents think that they were pressured by doctors in the process of decision-making, it does not mean that this pressure necessarily constitutes undue influence and undermines parents’ consent. According to *Re T*, only pressure that “overbears[s] the independence of the patient’s decision” amounts to undue influence.¹³¹ In other words, there should be such “a degree of external influence as to persuade the patient to depart from her own wishes”.¹³² In the light of the parents’ stories, if parents consented to vaccination to avoid conflicts with their doctors, or because to vaccinate was easier than to disagree with a doctor, it could be assumed that they consented to vaccination since there was some degree of external influence.¹³³ However, it is not clear whether the pressure fully overbears the independence of their decision.

¹²⁷ Rohers A Pilgrim, “Rational non-compliance with childhood immunization: personal accounts of parents and primary health care professional” in Rachel K Sporton & Sally-Anne Francis, “Choosing not to immunize a child: are parents making informed decisions” (2001) 18:2 Family Practice at 182.

¹²⁸ Kristy Robinson, “Vaccines are like Russian roulette - we'd rather take a chance with the diseases, say parents who refuse to give their babies jabs” *The Daily Mail* (06 April 2008), online: The Daily Mail <<http://www.dailymail.co.uk/health/article-557442/Vaccines-like-Russian-roulette--wed-chance-diseases-say-parents-refuse-babies-jabs.html>>.

¹²⁹ *Ibid*; Rachel K Sporton & Sally-Anne Francis, *supra* note 127 at 182.

¹³⁰ *Hall v Hall*, (1868) LR 1 P & D 481 at 482.

¹³¹ *Re T*, [1992] ALL ER 649, 1992 9 BMLR at 649.

¹³² *Ibid* at 669.

¹³³ *Ibid*.

According to Lord Donaldson in *Re T*, important factors to consider in relation to the degree of pressure are the strength of the will of the patient that could be affected by pain and stress, as well as the relationship between a persuader and a patient.¹³⁴ Most likely, parents and children taken by parents to a doctor are healthy; at least, they are not in pain as a result of a disease. So the strength of the parents' will is not undermined by their or their child's illness when it comes to participating in vaccinations. However, parents agree to vaccination to avoid adverse future implications for their relationship with their doctor. This signifies that some aspects of a doctor's authority might affect the strength of the will of a parent, and this could add to the strength of persuasion from the doctor. It is not known whether any of the parent-physician relationships can be characterized as one in which there is power-imbalance, as not all doctor-patient relationships are power unbalanced.¹³⁵ However, it is obvious that parents agree to vaccination to continue a harmonious patient-doctor relationship.

Based on the evidence available, it is not clear that pressure from doctors amounted to undue influence. However, pressure took place. It could be assumed that in some cases, pressure could be weaker or stronger than considered here. This is why there are some risks that parents' decision to vaccinate has been unduly influenced by pressure from doctors.

5.4.1.1.2 Implications of Leaving a Child Unimmunized

It was claimed that parents who refused vaccination were threatened with dismissal from practice and re-registered as temporary patients. There is no official data to support this claim. However, if parents agree to vaccinate a child as a result of verbal persuasion by a doctor in order to save a harmonious patient-doctor relationship, there might be other reasons that compel

¹³⁴ *Ibid* at 662.

¹³⁵ Details and the circumstances of the relationship should be available to determine whether a doctor-patient relationship is a power-imbalance relationship. According to La Forest J "the factual context of each case must, of course, be evaluated to determine if there has been genuine consent". See *Norberg*, *supra* note 3 at 29.

parents to submit to vaccination. Those reasons relate to the negative implications of leaving a child unimmunized or, more specifically, scenarios that doctors might use to overcome parental refusal in order to receive incentives for their practice. The discussion of the implications of vaccination refusal related to temporarily dropping patients from lists, moving patients to the lists of temporary patients, or dismissing them from the practice, shows the rationale behind the concerns that vaccination refusers might face, which might cause them to submit to the threat.

5.4.1.1.2.1. LEAVING A CHILD UNIMMUNIZED: TEMPORARY PATIENTS/PATIENTS DROPPED TEMPORARILY

At the end of every quarter, the vaccination rates of two and five year olds are calculated to determine whether a practice reached a 70% or 90% benchmark. If a practice reaches any of these targets, it receives financial incentives, and obviously, when the rate is lower than 70%, it does not qualify for any incentives. Interestingly, when the targets are not reached, an option of excluding unvaccinated patients from the calculation could be pursued. When children are being put on the temporary patients' lists, or dropped temporarily, they are excluded when the vaccination rates are calculated.

In 2003, an article in the Daily Mail said that “family doctors are dropping children who have not had the MMR vaccine from their patient lists.”¹³⁶ It was claimed that out of 27 practices in Tunbridge Wells, three practices had removed 24 children from their lists,¹³⁷ but officials reassured that the children continued to receive care from their doctors but only as temporary patients.¹³⁸ According to the Tunbridge Wells Community Health Council in Kent, “they [doctors] feared failing to meet official targets on vaccination [which] would mean a loss of income that could have a serious impact on their practices”, and therefore removed unvaccinated

¹³⁶ “Children Whose Parents Refuse the MMR Jabs are being Dropped by their GPs”, *supra* note 119.

¹³⁷ *Ibid.*

¹³⁸ *Ibid.*

children from the lists of patients.¹³⁹ There are news reports of the same tactic in the Canbury Medical Centre in Kingston, Surrey, and in one of the London practices in 2002.¹⁴⁰

Even though I have been unable to locate the official data, the practice of moving unvaccinated children to the temporary patient lists, or “dropping them temporarily” might not be far from the reality. In 2003, the General Medical Council issued an official advice: “*Target Payments for Preventive Health Measures*”.¹⁴¹ This statement addressed the following question: “can GPs remove some children from their lists, temporarily, for the purpose of calculating the MMR target payment?”¹⁴² The General Medical Council responded that “this must not be done without the parents' agreement. Parents must be given a full explanation of what was proposed and why, their child's rights as a National Health Service's patient, and the implications for their child's future care.”¹⁴³ The General Medical Council advice was withdrawn in November 2006, but it was published at the General Medical Council's website without any indication of withdrawal until October 7th 2007.¹⁴⁴

The negative consequences of temporarily removing children from the lists were listed in the advice. It was claimed that “temporarily removing a child from a GP's list must not adversely affect their care, for example in accessing secondary care and out-of-hours services, or in providing relevant information to ensure continuity of care and allow effective working with

¹³⁹ *Ibid.*

¹⁴⁰ “Children without MMR jab struck off GPs' list” (17 Nov 2002) *The Telegraph*, online: The Telegraph <<http://www.telegraph.co.uk/news/uknews/1413425/Children-without-MMR-jab-struck-off-GPs-list.html>>. “Child dropped as patient over MMR” (6 February 2002) *BBC News*, online: BBC <http://news.bbc.co.uk/2/hi/uk_news/england/1803893.stm>.

¹⁴¹ United Kingdom, General Medical Council, *Target Payments for Preventive Health Measures* (2003), online: General Medical Council <http://www.gmcuk.org/Target_payments_for_preventative_health_measures_2003.pdf_25416533.pdf>.

¹⁴² *Ibid.*

¹⁴³ *Target Payments for Preventive Health Measures* (2003), *supra* note 141.

¹⁴⁴ ChildHealthSafety, “UK General Medical Council Told Docs “Commit Fraud for MMR Vaccine Bonuses” (13 February 2013), online: Child Health Safety <<http://childhealthsafety.wordpress.com/2010/02/13/gmc-fraud-for-bonuses/>>.

other agencies.”¹⁴⁵ Though there are no grave consequences for being moved to the temporary lists, as happened with children in Tunbridge Wells, patients cannot be registered as temporary patients for more than 3 months.¹⁴⁶

According to the UK National Health Services, individuals are registered as temporary patients when they move to a different area for a short period of time. Thus, the lists of temporary patients are not for those who have been excluded from the lists because physicians want to reach targets. To be registered as a temporary patient, an individual must fill the form and indicate his or her permanent physician. This means that parents must refill the form several times per year since vaccination coverage is calculated every quarter for two and five year old patients. This definitely imposes a burden of paperwork, which might be problematic for some parents. For instance, according to the studies, some children in the UK did not receive all vaccines since parents, who work full time, did not have time to visit a doctor regularly to meet the vaccination schedule.¹⁴⁷ Therefore, if even vaccinations are skipped for a lack of time, paperwork would not be very welcome by busy parents.

Moreover, vaccination is an emotional matter for parents; oftentimes non-vaccinators are concerned about the implications of their decision to not vaccinate, such as the contraction and transmission of infectious diseases in light of their parenting responsibilities.¹⁴⁸ Thus, moving a child to the list of temporary patients might impose some stress on parents since a child’s status as a permanent patient changes solely because parents decided against vaccination.

¹⁴⁵ *Target Payments for Preventive Health Measures*, *supra* note 141.

¹⁴⁶ United Kingdom, National Health Services, How Do I register with a GP, online: NHS <<http://www.nhs.uk/chq/Pages/1095.aspx?CategoryID=68&SubCategoryID=158>>.

¹⁴⁷ RK Sporton & SA Francis, *supra* note 127 at 184.

¹⁴⁸ *Ibid* at 186.

Therefore, if parents consider the scenarios set out here, they might fear the negative consequences of their children being moved to lists of temporary patients, or being dropped temporarily.

Another way for physicians to reach their targets is to dismiss a family from the practice; this option and its negative consequences are discussed next.

5.4.1.1.2.2. LEAVING A CHILD UNIMMUNIZED: DISMISSAL FROM THE PRACTICE

Dismissal from the practice was also touched upon in the General Medical Council's letter. The letter claimed that "GPs must not unilaterally end a relationship with a patient, solely because of the financial implications of keeping them on their list."¹⁴⁹ This answer does not directly prohibit the dismissal of families, but there might be other reasons for the termination of a doctor-patient relationship entailed by the vaccination refusal, such as the loss of trust or safety concerns.¹⁵⁰

It is claimed that the dismissal from practice caused by parents' objections to vaccination entails parents' mistrust in vaccination, their choice to opt out of conventional health care, or their inability to find a new physician.¹⁵¹ Also, dismissal might lead to lack of access to health care, and this increases health inequalities.¹⁵² Moreover, studies from the UK show that "removal is a negative and distressing experience for patients".¹⁵³ Consequently, dismissal does not bring any benefits to public health, as children are most likely to continue to be unvaccinated after they

¹⁴⁹ *Ibid.*

¹⁵⁰ Julie Brownlie & Alexandra Howson, "Leap of faith and MMR: An Empirical Study of Trust" (2005) 39:2 *Sociology* 232 at 235.

¹⁵¹ Beth Halperin, "When is it permissible to dismiss a family who refuses vaccines? Legal, ethical and public health perspectives" (2007) 12:10 *Paediatr Child Health* 843 at 845.

¹⁵² Erin A Flanagan- Klygis, Lisa Sharp & Joel E Frader, "Dismissing the families who refuses vaccines" (2005) 159 *Arch Pediatr Adolesc Med* 929 at 931.

¹⁵³ Tim Stokes et al, "Patients' accounts of being removed from their general practitioner's list: qualitative study" (2003) 326: 1316 *BMJ* at 4.

are dismissed, unless parents change their mind and consent to vaccination. Otherwise, dismissal does not benefit the physical and mental well-being of an individual.

5.4.1.1.2.3. THE INTERRELATION BETWEEN THE IMPLICATIONS OF LEAVING A CHILD UNIMMUNIZED AND COERCION

Based on the foregoing, there is some evidence to suggest that if parents do not consent to participation in the vaccination program in the UK, they might face consequences related to being dismissed, dropped from the lists, or moved to the temporary lists. All of these options carry negative consequences for parents. Assuming that when doctors discuss childhood vaccination with parents they bring up the aforementioned consequences, or, accordingly, send a letter to inform parents who refuse to vaccinate a child, it would most likely sound as a threat. As discussed in Chapter 3, where I discussed Canadian law regarding consent and the element of voluntariness, a person can be threatened not only by the use of force, but with the loss of some health care privileges. The negative consequences of being dismissed from a practice, dropped temporarily, or moved to a temporary list, might be the instruments of the threat.

In the case of childhood vaccinations, threat is tied to the request to vaccinate and “when threats are coupled with [doctors’] demands, there is an inducement to accede to the demands. This interferes with the ...freedom of choice, as the [parent] may be coerced into doing something he or she would otherwise have chosen not to do.”¹⁵⁴ Threat is a classic example of coercion, which vitiates consent.¹⁵⁵ Therefore, if parents respond to the threat by consenting to vaccination, consent might not be valid since threat amounts to coercion, which negates consent.¹⁵⁶

¹⁵⁴ *Her Majesty the Queen v DGS*, [2004] OJ No 3440, 72 OR (3d) 223 at paras 53-54.

¹⁵⁵ *Big M*, *supra* note 10 at para 95.

¹⁵⁶ *Norberg*, *supra* note 3 at 247.

Since there is a risk that parents experience pressure and threats from doctors in the UK vaccination programs, it could be assumed that there are other undue influences triggered by doctors' motivation to vaccinate. The occurrence of psychological compulsion, which is explored next, might be one of them.

5.4.1.1.3. Psychological Compulsion

As discussed in Chapter 4, the concept of psychological compulsion which applied in *Therens*, involved the direction of the police officer which led to a perception that a choice to disagree did not exist as such and, therefore, consent was infringed.¹⁵⁷ The analogy was made between the requirement-based vaccination programs and psychological compulsion. It was noted that the role of a police officer is different than the role of a doctor who does not have a state given capacity to coerce, but only announces to the parent the requirement to vaccinate. Yet, a doctor's authority and a patient's vulnerability to external influences in a doctor-patient relationship could lead to psychological compulsion.

Certainly, in the recommendation-based programs, there is no requirement to vaccinate. However, if the recommendation to vaccinate is part of a state-implemented public health program with incentives, it might be used as a stronger form of offering clinical intervention than just "a suggestion or proposal as to the best course of action".¹⁵⁸ In other words, if interpreted as routine and highly recommended, the recommendation to vaccinate might lead to the perception of the suspension of freedom of choice which contributes to the occurrence of psychological compulsion.

¹⁵⁷ *Therens*, *supra* note 86 at para 53.

¹⁵⁸ The Oxford Dictionary, *sub verbo*, "recommendation", online: The Oxford Dictionary <<http://www.oxforddictionaries.com/definition/english/recommendation>>.

To sum up, undue pressure via verbal persuasion, threat and psychological compulsion triggered by the offer of financial incentives could vitiate the voluntariness of consent in the UK recommendation-based vaccination program. It shows that in practice, a recommendation-based program with incentives for doctors could undermine the voluntariness of consent. Another type of immunization related payment, namely, benefits to parents, is implemented in Australia. It is now addressed whether such payments unduly influence the voluntariness of consent to vaccinate children.

5.4.1.2. The Offer of Immunization-related Benefits in Australia

Australia's vaccination programs introduced immunization-related benefits for parents. Concerns pertaining to financial incentives arise in the context of consent to participate in the research. As discussed in Chapter 3, the notion of financial benefits has not been considered by courts as regards the voluntariness of consent. However, in Canada, the issue of financial benefits is addressed by the Tri-Council Policy Statement (TCPS), "Ethical Conduct for Research Involving Humans".¹⁵⁹ The TCPS claims that financial incentives are not "encouraged or discouraged"¹⁶⁰ but since incentives motivate people to participate, they should be regarded when the voluntariness of decision is assessed.¹⁶¹

Contrary to financial incentives to doctors in the UK, I have not been able to locate direct evidence, such as claims by parents in Australia, which points to infringements of the voluntariness of consent because of the offer of financial benefits. In other words, there is no direct evidence to sustain a claim that the offer of financial benefits to parents in Australia

¹⁵⁹ Government of Canada, Panel on Research Ethics, *TCPS 2 - Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (2010) 2nd ed online: Panel on Research Ethics <<http://www.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/>>.

¹⁶⁰ *Ibid* at 29.

¹⁶¹ *Ibid* at 29.

impacts voluntariness. Therefore, I focus on the nature of financial benefits in Australia *per se* to determine whether they could amount to undue influence.

5.4.1.2.1. Immunization Clause and Benefits

Since 1998, parents in Australia have been receiving maternity immunization allowance and child care benefits if they met the requirement of the immunization clause. In 2013-2014, immunization allowance in the amount of \$2100, divided into three payments, is provided when a child is immunized or exempted at the milestone ages of one, two and five years of age.¹⁶² Also, parents whose children are in a registered care, receive child care benefits which equal \$199 per week.¹⁶³ Parents of non-school aged children receive \$169 per week if the children are in a registered care.¹⁶⁴ If a child is not in a registered care, a parent can still claim \$33 per week.¹⁶⁵ The value of the benefits has increased significantly since 1998.¹⁶⁶

As mentioned above, to receive the aforementioned financial benefits, children must be vaccinated according to the vaccination schedule, or parents must present an exemption form signed by a doctor. In other words, in Australia, if a parent does not want to vaccinate a child, but still wants to claim benefits, he or she can use the exemption clause. Consequently, financial benefits do not necessarily influence the voluntariness of a vaccination decision, given that

¹⁶² *A New Tax System (Family Assistance) Act 1999* (Cth), division 2 s 6 (1) b, p 3 div 1 subdiv A. Australian Government, Department of Health, *Immunisation Related Payments for Parents. Immunize Australia Program*, online: Australian Government <<http://www.health.gov.au/internet/immunise/publishing.nsf/Content/related-payments>>.

¹⁶³ *A New Tax System (Family Assistance) Act 1999* (Cth), division 2 s 6 (1) a. Australian Government, Department of Human Services, Child Care Benefit, online: Australian Government <<http://www.humanservices.gov.au/customer/services/centrelink/child-care-benefit>>.

¹⁶⁴ The law refers to it as immunization requirement, but to avoid confusion between the requirement-based and recommendation-based programs, I drop the use of the requirement.

¹⁶⁵ Australian Government, Department of Human Services, Child Care Benefit, online: Australian Government <<http://www.humanservices.gov.au/customer/services/centrelink/child-care-benefit>>.

¹⁶⁶ *Ibid.*

parents can decide against vaccination and still receive benefits.¹⁶⁷ More particularly, if a child is exempted from vaccination and, therefore, consent to vaccination does not take place, immunization-related benefits are still granted. Consequently, the consideration of financial benefits and their impact on the voluntariness of consent to vaccination could be unnecessary, since parents are not left with a choice to immunize and receive exemptions or not to immunize and lose exemptions. But it is still necessary to consider how viable the option to claim exemption is in practice, in light of the current situation in Australia.

5.4.1.2.1.1. EXEMPTIONS: ARE THEY EXERCISABLE?

To recap, in Australia, the program allows for medical and conscientious objections, which point to availability of exemptions. Also, as discussed above, to obtain exemption, parents must receive the signature of a physician and sign a standard informed refusal/exemption form, though no explanation or proof of the sincerity of belief is required. It was concluded that the Australia exemption process, even if categorized as complex, does not prevent a parent from exercising an exemption. Therefore, according to the vaccination policy, exemptions are available and exercisable.

However, in practice, exemptions could have been freely exercised by parents in Australia if all doctors were willing to sign the exemption forms. The Department of Health expressed concerns that “some vaccine refusers are having trouble obtaining an exemption”.¹⁶⁸

¹⁶⁷ Antonio Bradley, “GPs unwilling to sign vax refuser forms”, *Australian Doctor* (17 June 2013), online: *Australian Doctor* <<http://www.australiandoctor.com.au>>.

¹⁶⁸ These concerns were expressed during the legislative debates on the amendments to the *NSW Public Health Act*, when considering whether nurses should be allowed to sign exemptions form. However, an amended *Public Health Act* does not contain provisions on doctors’ obligation to sign exemptions. See Parliament of New South Wales, *Public Health Amendment (Vaccination of Children Attending Child Care Facilities) Bill 2013* (20 June 2013), online: Parliament of NSW <http://www.parliament.nsw.gov.au/Prod/parlment/hansart.nsf/V3Key/LC20130620006?open&refNavID=HA8_1>.

The fact that doctors refuse to sign exemption forms has been widely discussed by the Australian media and anti-vaccination groups, especially when the amount of benefits increased.¹⁶⁹

One of the studies revealed that, in 2008, 2% of GPs refused to treat children whose parents objected to vaccination, and 18% never signed the exemption forms.¹⁷⁰ An online poll that was held in the *Australian Doctor* magazine in June 2013, says that 54% of doctors would refuse to sign an exemption form for non-medical exemptions because they only sign vaccine exemption forms on medical grounds, and 8% would refer a family to a different practitioner.¹⁷¹ 27% stated that they would sign the form only after counselling parents on the benefits of vaccination.¹⁷²

The Department of Health confirmed that there are no legal obligations on doctors to sign exemptions. Moreover, vaccination forms cannot be signed by other health care workers, as the *Family Assistance Act* that addresses the issue of immunization requires that parents must present with an exemption signed by a doctor.¹⁷³ Therefore, the fact that 54% of doctors refuse to sign exemption forms for non-medical reasons, to some extent, signifies the depth of the Department of Health concern as regards difficulties parents might face in order to receive exemptions. Even if the percentage of doctors who refuse to sign forms is lower than 54%, it still points to a significant number of parents who might have difficulties with obtaining exemptions in practice.

¹⁶⁹ “Do you sign vax exemption forms?” *Australian Doctor* (10 June 2013), online: Australian Doctor <<http://www.australiandoctor.com.au/news/polls/do-you-sign-vax-exemption-forms> therefusers.com/refusers-newsroom/most-doctors-wont-sign-vaccine-education-forms/#.UsrtmbSBVqU>.

¹⁷⁰ Julie Leask et al, “Immunisation attitudes, knowledge and practices of health professionals in regional NSW” (2008) 32:3 *Aust N Z J Public Health* 224 at 226.

¹⁷¹ Antonio Bradley, *supra* note 167.

¹⁷² *Ibid.*

¹⁷³ *A New Tax System (Family Assistance) Act 1999* (Cth), Division 2 s 4-7.

Therefore, in many cases, parents might not have any choice but to consent to vaccination in order to receive the immunization-related benefits. This is why the impact of the immunization-related payment on the voluntariness of consent should be considered.

5.4.1.2.2. The Impact of Financial Benefits on the Voluntariness of Consent. Exploitation

Since courts do not give guidance as to the types of financial benefits that constitute undue influences, in this discussion, I apply the Nelson/Beauchamp framework used in bioethics to measure the influence of benefits on voluntariness. According to the framework, if the offer is irresistible, and if it encourages submission to increased risks of research or treatment of individuals who lack resources, it amounts to exploitation.¹⁷⁴

Even though the framework was developed in bioethics, the rationale for its application in this thesis lies in the impact exploitation has on consent, according to La Forest J in *Norberg*. Justice La Forest held that the combination of inequality in a power dependency relationship, and exploitation, infringe consent.¹⁷⁵ In the case of vaccination-related payments in Australia, the offer of the financial benefits is outside the scope of a doctor-patient relationship, since it is the state that offers and grants the payments. However, the state-citizen relationship is also a power-imbalance relationship, which points to the dramatic inequality evident in the states' economic power over its citizens. So, a parallel of the impact of a power imbalance relationship on voluntariness of consent, could be drawn between a doctor-patient relationship as in *Norberg*, and a state-citizen relationship.

As regards the second element, exploitation occurs when somebody who is in a powerful position uses his or her authority to induce a “dependent” person into doing something for the

¹⁷⁴ Robert L Nelson et al, *supra* note 2 at 9.

¹⁷⁵ *Norberg*, *supra* note 3 at para 40.

benefit of the “powerful” person’s.¹⁷⁶ In the case of vaccination-related financial benefits, the state offers benefits in order to achieve high vaccination rates and to prevent the outbreak of infectious diseases. It is not clear whether preventing infectious diseases could be viewed as beneficial to the state only, since it also benefits individuals. However, the offer of the benefits is how the state ensures compliance with its recommendation-based public health program. By using financial benefits to make sure the program succeeds means the incentive procures the state’s “own benefits”. To prove exploitation, Justice La Forest took into account the type of relationship and community standards of conduct as indicators which fit within the context of the case.¹⁷⁷ Indicators of exploitation would certainly vary depending on the nature of each case. In regard to vaccination, the elements of the Nelson/Beauchamp framework could be applied as indicators of exploitation to examine if the offer of financial benefits for parents is exploitative.¹⁷⁸

This is applied to the immunization-related payments to parents in Australia.

5.4.1.2.2.1. NELSON/BEAUCHAMP FRAMEWORK

According to the Nelson/Beauchamp framework, an offer is exploitative if it meets the following conditions. First, the offer should be irresistible. Second, an individual should lack resources.¹⁷⁹ Third, it should motivate an individual to subject themselves to an increased risk situation.¹⁸⁰ Fourth, the offer could be exploitative if “more attractive inducements are introduced”.¹⁸¹

¹⁷⁶ *Ibid.*

¹⁷⁷ *Ibid.*

¹⁷⁸ Robert L Nelson et al, *supra* note 2 at 9.

¹⁷⁹ *Ibid.*

¹⁸⁰ *Ibid.*

¹⁸¹ *Ibid.*

The first criterion, the irresistibility of an offer, is a complex concept as it requires knowledge of many details related to an individual, in order to determine whether the offer is irresistible for him or her.¹⁸² The irresistibility of an offer is intertwined with the second criterion – the lack of resources – which makes the offer more irresistible than not. The discussion below combines these two criteria and applies them to vaccination in Australia.

The third condition, namely, increased risk, is said to include “a risk of harm of sufficient seriousness that the person’s welfare interest is negatively affected by assuming it”.¹⁸³ There are potential serious side effects of the MMRV vaccination, such as seizures, but their occurrence is not high.¹⁸⁴ Still, parents are negatively affected when they think about the low occurrence of seizures since, as discussed earlier, many parents refuse vaccination because of safety concerns. Thus, it could be said that the MMRV vaccination meets the third condition.

Lastly, as mentioned above and discussed in Chapter 3, in Australia, the value of benefits increased significantly since 1998. As such, it could be claimed that “more attractive” benefits were introduced. Therefore, the offer of benefits in Australia meets the fourth condition.

The first and second conditions of the Nelson/Beauchamp framework are discussed under the umbrella of irresistibility next.

5.4.1.2.2.1.1. IS THE OFFER OF FINANCIAL BENEFITS IRRESISTIBLE?

Irresistibility depends on the subjective responses of those who receive the offer.

Therefore, it is hard to locate the threshold of irresistibility of the offer when guided only by the

¹⁸² *Ibid.*

¹⁸³ *Ibid.*

¹⁸⁴ Ontario Ministry of Health and Long Term Care, *MMR, Varicella and MMRV Eligibility and Schedules Questions and Answers for Health Care Providers*, online: Ontario Government <http://www.health.gov.on.ca/en/pro/programs/immunization/docs/mmr_v_eligible.pdf>. Ministry of Health and Long-term Care, *Publicly Funded Immunization Schedules for Ontario*, (2011) online: Ministry of Health and Long-term Care <<http://www.health.gov.on.ca/en/public/programs/immunization/docs/schedule.pdf>>.

amount of money offered. Yet, it might be possible to make assumptions about the irresistibility of the immunization payments to determine whether parents are dependent on them. To do that, I review the data on the effectiveness of financial payments as a motivation to vaccinate a child.

There are two types of payments included in the immunization related benefits: maternity immunization allowance and child care benefits. According to one study, in 2003, only 4.4 % of parents of fully immunized children reported that maternity immunization allowance was the most important factor in their decision. It could be assumed that the 4.4% of parents who consented to vaccination primarily because of financial benefits, could not or did not want to refuse the offer. It's possible that some of them would have found the offer irresistible. Among parents who use child care benefits, only 0.7% claimed that the child care benefit was the single most important factor that influenced their immunization decisions.¹⁸⁵ Overall, 70% claimed that they had applied for and received the payment.¹⁸⁶ According to the conclusions of the study, immunization-related benefits encouraged parents to vaccinate a child.¹⁸⁷ However, only 4.4% and 0.7% of parents can be said to be dependent on the maternity allowance and child care benefits.

Despite the fact that the majority claim that the immunization-related payment is not the most important factor that made them decide for vaccination, it does not mean that parents found the benefits easy to resist. The researchers claim that the influence of financial benefits on immunization rates is likely to be greater than shown by the report.¹⁸⁸ Indeed, only 31% of respondents answered that they could afford day care without child care benefits. Therefore, it

¹⁸⁵ *Ibid.*

¹⁸⁶ Glenda L Lawrence et al, "Effectiveness of the linkage of child care and maternity payments to childhood immunisation" (2004) 22 Vaccine 2345 at 2349.

¹⁸⁷ *Ibid.*

¹⁸⁸ *Ibid.*

could be assumed that the offer should be of immense importance to the rest (69% of parents) who cannot afford day care costs if they are not provided with child care benefits.

The assumption that many parents depend on the immunization payments is strengthened by the fact that 83% of four-year-old children attend day care.¹⁸⁹ Thus, given the percentage of parents who cannot afford to send their children to a daycare without immunization-related payments, and the data as regards parents who claim that they vaccinated their children primarily because of the immunization-related payment, an offer could be considered as irresistible for many parents. According to the Nelson/Beauchamp framework, the irresistibility of an offer means that the immunization-related payment in Australia may be exploitative in its impact upon a portion of the population who lack sufficient financial resources and, therefore, find the offer irresistible. This elevates financial benefits to undue influences.

Therefore, if parents could not claim exemptions, and the evidence says that some of them have difficulty obtaining a doctor's signature on exemptions forms, there are reasons to claim that financial benefits unduly influence some parents' consent to vaccination. Consequently, financial benefits for parents introduced by the vaccination policy in Australia which was primarily designed to increase immunization rates based on free choice, affect the voluntariness of the consent of many parents in practice.

5.4.2. Summary

The recommendation-based vaccination policies in the UK and Australia are *prima facie* consistent with the voluntariness of consent, as the recommendation to vaccinate allows parents to consent to, or refuse vaccination. However, in practice, the voluntariness of consent to

¹⁸⁹ In 2008, 3 and 4 years old child attendance in the formal care is within the range between 60% and 70%. See Australian Bureau of Statistics, Australian Social Trends. Childcare (June 2010), online: Australian Bureau of Statistics <Statistics <http://www.abs.gov.au/AUSSTATS/abs@.nsf/Lookup/4102.0Main+Features50Jun+2010>>.

vaccinate is influenced directly or indirectly by the immunization-related incentives offered to parents or doctors. For instance, an immunization-related financial incentive for doctors is one of the reasons for pressure and coercion from them. The discussion of the financial benefits for parents concluded that immunization-related payments amount to exploitation in their impact on some and, therefore, infringe on the voluntariness of consent.

Therefore, the conclusion that the recommendation-based vaccination programs in the UK and Australia are committed to voluntariness of consent, is rendered more complex by the fact that the design of these programs also triggers infringements of voluntariness. More particularly, the implementation of the financial incentives throws doubt on the possibility to exercise the voluntariness of consent in the recommendation-based vaccination programs.

In the next, concluding Chapter, I summarize the findings of the analysis of vaccination programs to underscore the complexity of the distinction between the requirement and recommendation programs in Ontario, New Jersey, Australia and the UK.

CHAPTER 6. CONCLUSION

6.1. Introduction

The analysis in this thesis points out that the distinction between the requirement and recommendation-based vaccination programs is more complex than one would assume. To highlight the complex distinction between the recommendation and requirement-based programs, this Chapter summarizes the analysis of the vaccination programs in light of the voluntariness of consent.

6.2. Requirement v Recommendation-based Vaccination Programs

In Chapter 5 I considered the nature of the *requirement* and the *recommendation* to vaccinate. The requirement to vaccinate was found to be inconsistent with the principle of autonomy and free will because it does not allow parents to refuse vaccination. In contrast, the recommendation to vaccinate is recognized to respect the voluntariness of consent; it allows parents to decide whether to submit to, or refuse routine childhood vaccinations. Therefore, the requirement-based vaccination programs are *prima facie* inconsistent with the voluntariness of consent, whereas the recommendation-based programs are compliant with the element of voluntariness. However, this conclusion was challenged by examining, in particular, whether, and how voluntariness of consent could be exercised in practice in the requirement and recommendation-based vaccination programs of the four jurisdictions.

The discussion of the requirement-based programs focused on the exemptions in the Ontario and New Jersey vaccination programs in terms of the scope of exemptions and exemption process, and the findings were used to measure the availability and exercisability of exemptions in the two vaccination programs. Two aspects of freedom of choice, namely, the availability and exercisability of choice, underscore indirect forms of control which, according to

Dickson J in the Supreme Court of Canada case of *R v Big M Drug Mart Ltd*,¹ violate voluntariness. From the findings, it was concluded that the New Jersey vaccination policy was more restrictive than the vaccination policy in Ontario in terms of the availability of choice. However, the New Jersey exemption process was easier to exercise than the vaccination process in Ontario. Therefore, exemptions in both jurisdictions limited freedom of choice, but they did not fully undermine it. Thus, some parents could enjoy the voluntariness of consent in practice.

Since some parents can exercise voluntariness in the requirement-based vaccination programs, their decision to vaccinate or claim exemptions could be affected by undue influences triggered by the design of the program *per se*. It was argued that psychological compulsion, as arose in *R v Therens*,² where freedom of choice was discussed in the context of defining “detention” within the meaning of s.10 of the *Charter*, could infringe the voluntariness of decision. If psychological compulsion applies to vaccinations, it could be nurtured by a combination of the requirement to vaccinate announced by a doctor, and the doctor’s authority in the doctor-patient relationship.

Also considered is the choice of leaving a child unimmunized without claiming exemptions in the context of the necessity to submit to treatment. Based on two Supreme Court of Canada cases on the right to silence and the right against self-incrimination *R v White*³ and *R v Fitzpatrick*,⁴ the degree of necessity to participate in the activity is viewed as a factor that influences the degree of voluntariness. Since the choice of leaving a child unimmunized in New Jersey and Ontario entails restrictions on daycare or school entrance, it was concluded that vaccination refusal without claiming exemptions is not a “real choice”.

¹ *R v Big M Drug Mart Ltd*, [1985] 1 SCR 295.

² *R v Therens*, [1985] 1 SCR 613 at para 53.

³ *R v White*, [1999] 2 SCR 417 at para 55.

⁴ *R v Fitzpatrick*, [1995] 4 SCR 154 at para 38.

Thus, the discussion of the Ontario and New Jersey vaccination programs illustrates that even though the requirement-based programs are inconsistent with voluntariness, some voluntariness could be exercised in practice. This complicates the *prima facie* distinction between the requirement and recommendation programs as discussed.

The recommendation-based vaccination programs in Australia and UK are *prima facie* committed to the voluntariness of consent. However, the discussion of the choice to vaccinate in the recommendation-based programs in both jurisdictions entailed a consideration of the immunization-related financial incentives offered to doctors in the UK, and to parents in Australia. Consequently, the discussion of choice shifted to a consideration of the direct or indirect influences of financial incentives on the voluntariness of consent.

As regards the payments to doctors, it was concluded that some doctors in the UK might be motivated by financial incentives to push for high vaccination rates. Therefore, they might unduly influence parents' decision to vaccinate. For instance, some doctors might pressure parents to decide for vaccination. Also, it was argued that UK parents might have faced the threat of being dismissed from a doctor's practice, to be dropped temporarily, or re-registered as temporary patients in case of non-vaccination. It was assumed that the negative consequences of these implications could serve as the instrument of the threat. In addition, it was argued that voluntariness could be infringed by psychological compulsion, which, according to *Therens*, violates consent. What is more, the combination of the recommendation to participate in the public health program, and a doctor's authority might have amounted to psychological compulsion.

As regards financial benefits, in the Australia vaccination program, parents receive benefits if they vaccinate a child or claim exemptions. It was argued that exemptions might be

difficult to obtain for many parents. Consequently, some parents were left with the choice to vaccinate and receive exemptions, or to refuse vaccination and lose financial benefits. Thus, these benefits have a direct influence on voluntariness. To determine whether the offer of financial benefits amounted to undue influence, I applied the Nelson/Beauchamp⁵ framework which considers whether benefits are exploitative in nature. According to La Forest J, in *Norberg v Wynrib*,⁶ the combination of a power-imbalance relationship and exploitation amounts to undue influence. The main criterion of the framework – irresistibility of an offer – was satisfied in relation to some parents in the vaccination program in Australia. Therefore, the offer of financial benefits for parents might amount to undue influence.

Overall, it was concluded that immunization-related financial payments in the UK and Australia could infringe the voluntariness of consent in practice. This conclusion, in addition to the previous finding on the requirement-based programs, complicates the *prima facie* correspondence of the programs with the voluntariness of consent.

To sum up, if the voluntariness of consent to vaccination which could be exercised in practice occurs along a spectrum, the recommendation and requirement-based vaccination policies would be located close to each other. However, the spectrum based on the *prima facie* correspondence between the requirement and recommendation-based programs and voluntariness of consent would look different, as the requirement and recommendation-based programs would be located on opposite sides of the spectrum. These two spectrums demonstrate that programs are not black and white. In other words, the recommendation-based program (i.e., voluntary vaccination), does not necessarily signify the voluntariness of consent, and the requirement-based program (i.e., mandatory vaccination), does not always stand for the non-voluntariness of

⁵ Robert L Nelson et al, “The concept of Voluntary Consent” (2011) 8 The American Journal of Bioethics at 11.

⁶ *Norberg v Wynrib*, (1992) 92 DLR (4th), 449 (SCC) at para 26.

consent. Therefore, infringements of the voluntariness of consent in practice are entailed by the design of the requirement and recommendation-based vaccination programs. This conclusion demonstrates the complexity of the distinction between the two types of programs.

Appendix A. Tables

Table 1. Exemptions

Jurisdiction	Availability of exemptions	Exemption form	Proof of sincerity of belief	Exclusion from one vaccine or all vaccines in the vaccination schedule
Ontario	Medical Religious Conscientious	A medical statement/ A notarized form	NA	Medical: One vaccine or all vaccines in the schedule Non-medical: all vaccines in the schedule
New Jersey	Medical Religious	A letter from a doctor/a letter from a parent	NA	Medical: One vaccine or all vaccines in the schedule Non-medical: all vaccines in the schedule
UK	NA	NA	NA	NA
Australia⁷	Medical Conscientious	Federal Exemptions Informed refusal	NA	Medical: One vaccine or all vaccines in the schedule Non-medical: all vaccines in the schedule

⁷ Exemption from the vaccination requirement in Australia are linked to eligibility for immunization-related benefits.

Table 2. Consequences of Leaving a Child Unimmunized

Non-immunized status as an obstacle for:	Admission to a Day Care	Admission to School/School Attendance	Eligibility for Financial Incentives
Ontario	Yes	Yes/A suspension order is issued when the immunization records are reviewed and records are not up to date	NA
New Jersey	Yes	Yes/NA	NA
UK	NA	NA	Yes (immunization-related payments for physicians)
Australia	NA	NA	Yes (immunization-related payments for parents)

Table 3. Financial Incentives/Benefits

Financial incentives/benefits	Doctors	Parents	Amount
UK	Yes	NA	Two years old: £2,655 (70%) and £7,965 (90%) paid quarterly. Five years old, £822 (70%) and £2465 (90%) paid quarterly.
Australia	NA	Yes	Tax benefits, overall \$2100. Paid at one, two, three years of age); Child Care Benefits (\$199 per week/\$165/\$33)

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- Day Nurseries Act*, RRO 1990, Reg 262.
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