Informed Consent for Chiropractic Care: Comparing Patients’ Perceptions to the Legal Requirements

by

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A thesis submitted in conformity with the requirements for the degree of Master of Science

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Abstract

Purpose: Patients’ perspectives of informed consent for chiropractic care have not been investigated. This study explored how patients of chiropractors perceived the exchange of risk information during informed consent.

Methods: Interviews were conducted with 26 participants, recruited from chiropractic clinics. Interview transcripts were analyzed using a constant comparative method of analysis.

Findings: Participants experienced informed consent as an ongoing process where risk perceptions were shaped throughout four distinct stages. In the first stage information acquired prior to arriving at the clinic for treatment shaped perceptions of risk. In the second stage participants assessed the perceived competence of the practitioners. Participants then signed the consent form and discussed the risks with their practitioner. Finally, they communicated with their practitioners during treatment to ensure their pain threshold was not crossed.

Conclusion: These findings suggest that patients perceive informed consent as a social process involving ongoing communication with their practitioners.
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Chapter 1: Introduction

Spinal Manipulation Therapy

Spinal manipulation therapy (SMT), performed most commonly by chiropractors, is a non-invasive, manual procedure that is applied to specific body tissues with therapeutic intent (Canadian Chiropractic Association, 2012). SMT is most commonly used to treat musculoskeletal symptoms of the low back and neck (Hurwitz, 2012). Although SMT is a non-invasive procedure, unintended consequences have been reported in the literature following treatment (Erikson, Rochester & Hurwitz, 2011); the scope and frequency of these consequences is currently unclear. In 2002, the World Health Organization called for an international effort to understand and prevent adverse events related to health care interventions (World Health Organization, 2005), yet the nature and frequency of the adverse events associated with SMT remain largely unknown. This gap in knowledge presents a challenge for practitioners when explaining SMT related risks to patients during the informed consent process.

Informed Consent to Receive Medical Care

The process of informed consent is intended to provide an opportunity for practitioners and patients to communicate about the nature of treatment, alternative treatment options, and the potential benefits and risks. The doctrine of informed consent states that prior to initiating treatment, practitioners have a legal and ethical obligation to disclose all information that a reasonable patient would consider important when making informed health care decisions (Bulen, 2003). Risk disclosure may be the most challenging element of informed consent as practitioners must determine what risks a reasonable patient would consider important, and research from other areas of health care demonstrates that practitioners and patients often have different interpretations of risk (Quick, 2009).

Legally, chiropractors are required to disclose all known effects, material risks, discomforts and side effects and their likelihood of occurrence prior to providing treatment (Dickens & Cook, 2004). Chiropractors in Ontario are also required to obtain written consent; written consent is recommended by legal experts as evidence in the event of a dispute legal dispute over consent (College of Chiropractors of Ontario, 2004). However, it is unclear whether information
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presented for legal purposes can also accomplish the goal of patient education and shared decision making (Daigenais, Brady, & Haldeman, 2012). Currently, no one has investigated whether the legal aspects of informed consent are appropriate to ensure patient comprehension from the perspectives of chiropractic patients.

Nature of the Problem

The legal doctrine of informed consent is intended to protect the rights of individuals and to mitigate risks of lawsuits arising out of consent (Dickens & Cook, 2004). Patients have a right to make an informed decision about their health care treatments and health care practitioners have a duty to disclose all material information about a treatment to their patients, including areas of uncertainty. Moreover, this information must be disclosed in a manner that is comprehensible to the patients. Disclosure of risk may be particularly challenging with respect to spinal manipulation therapy because evidence surrounding adverse events is limited and risk estimates are contested. If the validity of informed consent is contested in a court of law, the objective patient standard is used to judge whether a patient was adequately consented. The objective patient standard states that all information that a reasonable patient would require to make an informed decision must be disclosed (Bulen, 2003). Since the validity of informed consent is determined from the perspective of a reasonable patient, it is necessary to explore patients’ perspectives of this process. Yet, a systematic literature search revealed a complete absence of information regarding chiropractic patients’ perspectives of informed consent.

Purpose and Scope of the Study

This study employed a qualitative descriptive methodology, to investigate patients’ views of consenting to chiropractic care. The focus of this investigation was on risk communication, since evidence suggests that risk disclosure may be the most complicated aspect of the informed consent process (Quick, 2009). The aim was to illuminate patients’ current understanding of informed consent, and to compare and contrast that with legal definitions and requirements for informed consent. Therefore, the research question for this thesis project was: how do chiropractic patients’ perceptions of exchanging risk information during informed consent compare with the legal requirements of informed consent for chiropractors? The following chapter provides an overview of the risks associated with SMT and describes the legal doctrine
of informed consent in Canada, focusing on the aspect of risk disclosure. Subsequently, the literature on informed consent for medical treatment and chiropractic care is reviewed and areas requiring further inquiry as well as the specific research objectives that aimed to address these deficits are revealed. The qualitative methods used to address these objectives will then be discussed, including the use of interviews for data collection and the constant comparative method used to analyze the data. The findings: a description of how participants experienced the exchange of risk information during informed consent, are presented in Chapter 5, followed by a discussion of their clinical and legal implications.
Chapter 2: Review of the Literature

Informed consent has been studied across many disciplines in the health care field and a number of arguments in the literature support the view of informed consent as a dialogic process that occurs between patients and practitioners (Brenner, Brenner & Horowitz, 2009; Giuseppe & D’Angio 2010). Alternatively, informed consent can be perceived simply as the single event of signing a form. With respect to SMT, the literature has focused on informed consent from the perspectives of clinicians, particularly the perceptions of the chiropractic profession. A number of publications suggest that omission of important information may occur in relation to risk disclosure during the informed consent process and chiropractors may treat informed consent as a static event rather than a dynamic process (Langworthy & Cambron, 2007; Lehman, Conwell, & Sherman, 2008). Studies directly and indirectly relating to informed consent, risk disclosure, and risk communication as they pertain to spinal manipulation therapy were reviewed and are discussed in this chapter.

Adverse Events Associated with Spinal Manipulation Therapy

Adverse events associated with SMT have been reported in the literature and the media. They include worsening of pain, bruising, dizziness, numbness, dislocation, fracture, breathing difficulties, and stroke (Oppenheim, 2005; Spitzer & Segal, 2005). Although most research in this area has focused on the risk of stroke, estimates have also been calculated for the frequencies of cauda equina syndrome, disc herniation, transient neurological symptoms, and increased neck pain following cervical manipulation (Carlesso, 2010; Oliphant, 2004) (Table 1). Unfortunately, these risk estimates vary greatly between studies as most estimates are derived from observational and case report studies. Furthermore, there is no formal surveillance system in Canada to facilitate the identification and quantification of the adverse events associated with SMT. Thus, precise risk estimates have not been determined for any of the adverse events associated with SMT and despite the mounting evidence regarding SMT and adverse events, the nature and frequency of these events remain unclear.
Table 1 Current Risk Estimates for Adverse Events Associated with SMT

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Risk Estimate (manipulations)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke following cervical manipulation</td>
<td>1 in 100 000 to 1 in several million (Carlesso, 2010) OR: 1.5 to OR: 12.7 (Haynes, 2012)</td>
</tr>
<tr>
<td>Transient Neurological Symptoms</td>
<td>99 in 1000 (Carlesso, 2010)</td>
</tr>
<tr>
<td>Increased Neck Pain following cervical manipulation</td>
<td>253 in 1000 (Carlesso, 2010)</td>
</tr>
<tr>
<td>Cauda Equina Syndrome</td>
<td>1 in 3.72 million (Oliphant, 2004)</td>
</tr>
<tr>
<td>Herniated Disc</td>
<td>1 in 1 million to 1 in 3.72 million (Oliphant, 2004)</td>
</tr>
</tbody>
</table>

A note about terminology

The term adverse event, in this thesis, refers to ‘any untoward medical occurrence that may present during treatment but which does not necessarily have a causal relationship with this treatment’ (Edwards & Aronson, 2000). Currently there are no standardized definitions for types and severities of adverse events associated with spinal manipulation therapy and adverse events have been poorly defined in much of the available studies (Carlesso, 2010). This lack of standardized terminology is an obstacle for researchers attempting to pool data and calculate risk estimates for these adverse events. Carnes et al (2010) developed a taxonomy to classify these adverse events into three distinct categories including major, moderate, and minor severity; however boundaries between these categories have not been fully distinguished. For simplicity, adverse events discussed in this thesis will be referred to as serious if they result in death, initial or extended hospitalization, and/or a significant disability (Nebekar et al, 2001). Adverse events that do not result in any of those outcomes will be referred to as non-serious.

Evidence of adverse events associated with spinal manipulation therapy

Stroke following cervical manipulation is the most widely studied of all adverse events associated with SMT. A number of studies have attempted to quantify the risk estimates and they
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vary widely across studies. Two large systematic reviews by Carlesso et al. (2010) and Haynes et al. (2012) have investigated the nature and frequency of this adverse event. Haynes et al. examined 5 retrospective case control studies to quantify the risk of cranio-cervical artery dissection while, Carlesso et al. reviewed 3 prospective studies and 14 randomized controlled trials investigating all potential harms associated with cervical manipulation. Neither of these reviews were able to calculate pooled risk estimates due to variability between studies. By including RCTs in their review, Carlesso et al (2010) found that non-serious adverse events such as increased neck pain and transient neurological symptoms occur much more frequently than serious ones. Risk estimates were pooled from two randomized controlled trials and were 253 in 1000 and 99 in 1000, respectively. The precision of the calculated risk estimates remains uncertain due to potential biases and confounding variables (Carlesso, 2010; Haynes, 2012).

In addition, two large retrospective studies were conducted using Ontario hospital records to determine the association between hospitalisation for vertebrobasilar artery (VBA) stroke and visits to a chiropractor. Using a population-based, case control study design, both of these studies found that cases under the age of 45 were more likely to have visited a chiropractor prior to their VBA stroke than controls, suggesting an increased risk of stroke associated with chiropractic care (Rothwell et al. 2001; Cassidy et al. 2008). However, Cassidy et al. (2008) also investigated the association between VBA stroke and visits to a primary care practitioner and found a similar association. They concluded that patients with undiagnosed vertebral artery dissection seek care for their symptoms from both chiropractors and primary care practitioners prior to having a VBA stroke (Cassidy et al., 2008).

Both lumbar disc herniation and CES have also been investigated in the academic literature. In 2004, Oliphant conducted a systematic review of all retrospective studies, prospective studies, and review articles regarding adverse events associated with the lumbar spine. Data was pooled from 11 different studies and the greatest risk of experiencing lumbar disc herniation or CES was calculated to be 1 in 3.72 million manipulations. A more current review (Rubinstein, 2008) found consistent results for the frequency of CES but suggested that risk estimates for lumbar disc herniation may be as low as 1 in 1 million. Although it is clear that these adverse events are rare, it is that rarity combined with a paucity of surveillance tools that brings into question the accuracy of these risk estimates.
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Both serious and non-serious adverse events are associated with manipulation of the spine. Although the precise frequencies at which these events are occurring remains elusive, it is clear that serious adverse events are rare and non-serious adverse events occur more frequently. More evidence with clear and consistent outcome measures is needed for accurate risk estimates to be determined. Due to the rarity of the serious adverse events associated with SMT and the lack of surveillance tools for SMT, we must rely on observational studies to investigate risk. Therefore, some uncertainty with respect to rare outcomes is inevitable and practitioners are expected to acknowledge the possibility of these risks and educate patients accordingly.

Legal Foundations of Informed Consent

The doctrine of informed consent outlines a practitioner’s duty to disclose all information about a given medical procedure that is relevant to a patient’s decision to receive treatment. This doctrine is founded in the basic common law rule that medical intervention may only be provided where the consent of the individual has been obtained (Dickens, 2002). The modern Canadian doctrine of informed consent is based on 2 decisions made by the Supreme Court of Canada in 1980 in the cases of Hopp v. Lepp and Reibl v. Hughes.

In the case of Hopp v. Lepp the court ruled that “a physician has a duty to, without being asked, reveal the nature of a proposed operation or treatment, its gravity, and any special or unusual risks involved” (McNally, n.d.). In the case of Reibl v. Hughes the plaintiff consented to surgery for the removal of a blockage in the carotid artery and suffered a massive stroke during the surgery that left him paralyzed and unable to work; he was less than two years away from earning pension benefits if he continued at his job. The Supreme Court of Canada ruled the plaintiff was not adequately informed prior to consenting to treatment because the defendant neglected to disclose material information- the patient could have safely postponed the surgery until his pension entitlements were complete (Dickens, 2002). Finally, the case of Mason v Forgie in 1984 shaped the standard of disclosure for the chiropractic profession. The plaintiff sued for negligent disclosure when the chiropractor failed to disclose the risk of stroke associated with treatment. The court ruled that risks which are a mere possibility, such as stroke, must be disclosed if they result in serious consequences (CCA, 2012).
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Similar to the case of *Reibl v. Hughes*, most lawsuits that arise from issues related to informed consent are due to negligent disclosure of material information, rather than a lack of consent. In light of this, the court decided that lawsuits arising out of informed consent would be brought as actions in negligence (failure to satisfy a standard of care) rather than battery (harmful or offensive contact). Since negligence is defined as a failure to satisfy a standard of care, the courts decided on a standard for disclosure of material information during informed consent.

In the ruling of *Reible v. Hughes*, the Supreme Court of Canada rejected the traditional standard of disclosure - what a medical professional would disclose, and decided on the modified objective patient standard - what a reasonable patient would want to know (McNally, n.d.). Thus, in court the materiality of information is determined by what a reasonable patient would require in similar circumstances. Information that must be disclosed to satisfy this standard includes special and unusual circumstances that are relevant to the patient, as well as any concerns to which the patient specifically enquires (Dickens, 2002). To understand what material information a patient might require with regards to SMT, it is important to understand how patients perceive the risks associated with this procedure.

Disclosure of Serious Adverse Events

The current scientific evidence about risk perception and risk disclosure in relation to SMT explores how clinicians perceive these risks and their own experiences with the disclosure of these risks. Practitioners have identified concerns about the disclosure of serious adverse events associated with SMT and have admitted to omitting discussion of serious adverse events during informed consent. Some practitioners have reported feeling that discussion of serious adverse events associated with SMT is unnecessary due to the rarity of events and lack of convincing evidence (Langworthy & Cambron, 2007), while others explained that they avoided discussion of risk out of fear of confusing the patient with inconclusive evidence (Langworthy & Fleming, 2005). The most common reason for omitting information was a fear of increasing patient anxiety and withdrawal rates as a consequence of disclosure of serious risks (Langworthy & Cambron, 2007).

To address this concern, Langworthy & Forrest (2010) surveyed chiropractors to determine how often withdrawal from treatment occurred as a direct consequence of disclosure of serious
adverse events. They found that withdrawal from treatment as a direct consequence of risk disclosure rarely occurs. However, this study relied on practitioner recall of patient withdrawal and practitioners cannot be sure of a patient’s motivation for choosing to withdraw from treatment. Carlesso, Cairney, Dolovich & Hoogenes (2011) interviewed patients about the adverse events associated with SMT and found that most patients were aware of serious adverse events such as stroke and death, yet they had no expectation of serious harm. These results further suggest that patients are not likely to withdraw from treatment as a result of disclosure of serious adverse events associated with SMT. There is currently no research that explores how chiropractic patients understand the serious risks that are disclosed to them prior to initiating SMT or how the disclosure of these risks contributes to their decision making process.

Disclosure of Non-serious Adverse Events

The literature suggests that practitioners are more likely to disclose non-serious adverse events than serious risks. Most practitioners that were surveyed by Langworthy et al. (2005, 2007) stated that they always disclosed all of the non-serious risks associated with SMT. However; these surveys did not define non-serious adverse events. There is little consensus amongst professionals on this topic (Carnes, 2009) and even less consensus between patients and clinicians (Carlesso et al, 2011). Worsening of symptoms is one example of a controversial non-serious adverse event, as a threshold determining at what point a symptom becomes an adverse event has not been established (Carlesso, Macdermid & Santaguida, 2010). A clear definition of what constitutes a non-serious adverse event is required to determine whether non-serious risks are being disclosed.

Some practitioners did report non-disclosure of non-serious risks to patients because they believed patients who received treatment already knew what to expect and that disclosing this information was not necessary (Langworthy & Cambron, 2007). Carlesso et al (2011) conducted interviews with patients receiving SMT to explore how patients defined and classified SMT related adverse events. They found that receiving information about both serious and non-serious post-treatment responses was important to most patients. Patients were generally more accepting of non-serious adverse events if they were previously explained by their practitioner. These findings emphasized the importance of the patient practitioner relationship, and patient education of post-treatment responses. Since the focus of this research was on classification of adverse
events rather than risk disclosure and informed consent, further details were not obtained regarding the extent to which patients feel risk information should be discussed. A systematic review of the literature revealed no further information about the patients’ perspectives of risks associated with SMT.

Informed Consent as a Social Process

There are limited data about chiropractors’ perceptions of informed consent; however, the research that is available suggests that chiropractors may view informed consent as a single event rather than as a continuous process. For example, a survey of chiropractors in the UK and the US found that only 3% of the US sample of chiropractors and 11% of the UK chiropractors discussed major risk with patients after their first visit. Also 45% of the chiropractors from the US and 20% of the chiropractors from the UK obtain written consent from patients in the waiting room (Langworthy & Cambron, 2007). The results of this study are not generalizable to a larger population due to the small sample size that represented less than 1% of chiropractors in the UK and the US. An extensive literature did not identify any studies investigating whether patients perceive informed consent as a process or a single event.

Researchers who study informed consent in a clinical context advocate for informed consent to be treated as a continuous process of dialogue between a practitioner and a patient throughout the course of a given treatment, rather than a single event such as signing a form (Giuseppe & D’Angio, 2010; Brenner, Brenner, & Hurowitz, 2009; Langworthy & Cambron, 2007). Concerns have been raised that simply having patients sign a form prior to initiating treatment may detract from the educational component of informed consent, and that this form may be used primarily as a waiver to protect practitioners from litigation rather than an educational tool to enhance patient autonomy (Brenner, Brenner & Horowitz, 2009). Alternatively, treating informed consent as a process of ongoing communication may enable practitioners to remain alert to any concerns of the patient as they arise and to ensure patient competence in making health care decisions (Langworthy & Cambron, 2007).

Despite support for informed consent to be treated as a process of communication between the patient and the practitioner, there is very little information available explaining what that process should look like. Corbin and Strauss (1990) define a process as ‘changes that are made in
response to prevailing conditions’. In the context of informed consent changes in health status, mental capacity or treatment modalities may warrant further discussion about the risks, benefits, and alternative treatments. This is particularly important when practitioners are faced with uncertainty regarding risks and benefits of treatment, because it allows for the inclusion of new information as new evidence is developed (Crowson, Therneau, Matteson and Gabriel, 2007). It is also unclear if, and to what extent, the process of informed consent should be patient driven, though research suggests that the desired level of involvement in the decision making processes will vary between patients and include patient-based decision making, shared decision making, and practitioner-based decision making (Neeraj et al, 2000).

After reviewing the relevant literature it is clear that informed consent to receive medical treatment serves two possibly conflicting purposes- to preserve patients’ rights to autonomous decision making while simultaneously decreasing the risk of malpractice lawsuits for practitioners. While both of these goals are necessary and important it is unclear if a single means, such as informed consent, can adequately accomplish both of these ends. Sociological research that explores the educational aspects of informed consent is often directed towards the goal of protecting and enhancing patient autonomy. Alternatively, the legal literature about informed consent is frequently concerned with decreasing the risk of malpractice lawsuits for practitioners. Research on informed consent within the chiropractic profession suggests that chiropractors may treat informed consent as a means to protect themselves against litigation, rather than an educational process to enhance informed decision making for patients. Currently, there is no research within the chiropractic profession that explores how these two distinct goals intersect within a clinical setting. Therefore this study will explore informed consent for chiropractic care, from the perspective of patients’ who have recently consented to treatment.

Research Objectives

Specific aims of my thesis are to:

1. Interpret how patients perceive informed consent for chiropractic care – as a process or a single event
2. Explore similarities and differences between patients’ views of informed consent and the legal requirements of informed consent, with respect to risk information.

3. Describe how patients who receive treatment from chiropractors perceive and understand the associated risks.

In summary, there is a paucity of information about patients’ understanding and interpretation of the risks associated with chiropractic care and it is unclear whether patients perceive informed consent as a process or as a single event. Moreover, the literature on informed consent for chiropractic care suggests that chiropractors may not disclose all material risks to patients prior to treatment. While some studies have investigated chiropractors’ experiences of informed consent and risk disclosure, literature on risk communication demonstrates that patients and practitioners often have different perceptions of risk. Finally, the purpose of informed consent is to educate patients about the risks, benefits and nature of treatment so they can make an informed decision about whether or not to receive treatment it is important to understand patients’ perspective. Therefore, in this qualitative descriptive study I investigated how patients perceive informed consent and how the exchange of risk information compares to the legal criteria of disclosing risk information for chiropractors.
Chapter 3: Methods

Study Design

I used a qualitative descriptive methodology to investigate participants’ perceptions of consenting to chiropractic care, with a focus on risk information. Their views of informed consent and a comparison of these views to the legal conceptualization are presented in the findings (Sandelowski, 2000). Participant recruitment, data collection and data analysis occurred in an iterative manner, such that emerging themes and concepts influenced the direction of inquiry. Elements of grounded theory, as described by Charmaz (2003) were used to guide the development of the interview guide and the analysis of interview transcripts. The findings presented in my thesis, contribute to the SAFETYNET research team that aims to support a culture of safety for SMT.

Theoretical Orientation

My study is based on assumptions of the interpretive perspective of reality and how knowledge about reality is created. The interpretive perspective assumes that the human social world is different from the natural physical world because the social world is conceived through human perception and is shaped by cultural and linguistic concepts (Lincoln & Guba, 1989). When creating knowledge about human experiences and social processes the goal is not to discover an objective truth, rather it is to explore different perceptions of a particular reality. Thus, knowledge about the social world is created discursively through dialogue and observation to reach an informed consensus about a given reality, such as the social process of informed consent (Patton, 2001). In this thesis I seek to capture varying patient perceptions risk information and consent to chiropractic care and to illuminate similarities and differences across the diversity of patients.

Although a specific social theory was not employed to guide the inquiry of my study, interview questions and analysis were influenced by the legal definitions and requirements for obtaining informed consent. Interview guides were constructed to probe patients’ perceptions and investigate how they were similar or different from the legal standards that govern practitioners’
practices. Throughout this process, I remained open to participants’ stories, allowing them to discuss what they believed was important, as it related to specific objectives that were developed based on gaps in the literature. Allowing participants to discuss what was important to them rather than sticking solely to the interview guide, helped me to stay grounded in the data. In this way, the participants and I developed findings that were relevant to the field of informed consent, specifically for chiropractic care.

Sample Population

The sample population for my study consisted of patients who were receiving chiropractic care from regulated chiropractors and/or chiropractic students in Ontario. To be included in this study, participants had to be new to the practice from which they were recruited. ‘New patients’ were defined as: patients who had their first visit with their practitioners within three weeks of contacting the researcher team. New patients were chosen based on the assumption that they would be more likely to recall any informed consent documents that were signed prior to their first visit as well as the accompanying risk discussion. Eligible participants were also over the age of 18 and able to provide free and informed consent to treatment. Patients who were health care workers or who were in school to become health care professionals were excluded from the study due to their specialized knowledge about health care related risks and informed consent.

Participant Recruitment

I purposively recruited a sample of participants who met the inclusion criteria for the study from chiropractic teaching clinics and from 1 private chiropractor’s office. I contacted the teaching clinics and 6 private chiropractors by email and provided a brief statement about the aims and implementation of the study (Appendix A). After receiving permission to recruit and interview new patients from each clinic, I sent them a detailed information sheet about the study (Appendix B). Initially, participants were recruited from a teaching clinic associated with a chiropractic college in Ontario and from one satellite teaching clinic. Approximately half-way through data collection, participants were recruited from two additional satellite teaching clinics to increase the variation in demographic characteristics among the study participants – including age, gender, ethnicity and level of education. Towards the end of data collection and analysis,
participants were recruited from one private practice to explore the transferability of the findings outside of a teaching clinic environment.

Two of the teaching clinics were located in neighbourhoods of low socio-economic status at health centers that provided community support services, while two were in suburban neighbourhoods of higher socioeconomic status. Participants were recruited from each of these clinics to enhance the diversity of the sample population by increasing the range of ethnicities and education levels. Ethnicity and education level may influence the participants’ interpretations of complementary medicine and their understanding of risk information, respectively. Finally, a private chiropractor with over 30 years of experience was included to see if there were any differences in patients’ experiences based on the level of experience of the chiropractors. Enhancing the diversity of the sample population and including practitioners with different levels of experience allowed for further understanding of the breadth and depth of patients’ experiences.

At each of the participating chiropractors’ offices, I provided receptionists with an information sheet explaining the study and the inclusion and exclusion criteria and asked them to facilitate the recruitment process (Appendix C). Receptionists at two of the teaching clinics were asked to provide patients with packages containing information about the study. The receptionists received these packages for distribution in blocks of twenty-five to fifty allowing for adaptations to the inclusion criteria. Inclusion criteria were adapted once: initially participants were required to have received SMT during treatment. However, this did not permit the investigation of participants who chose not to consent to that treatment modality. Thus, this criterion was removed from the protocol. Receptionists were compensated with a confectionary gift basket valued at approximately $50 for distributing study information to patients.

The information packages that were distributed to participants contained a letter describing the purpose of the study and what participation in the study would entail (Appendix D), a detailed instruction sheet containing information about how to proceed if they are interested in the study and contact information for the research team (Appendix E), and a written letter of informed consent (Appendix F). In addition, a recruitment poster was hung in the office waiting rooms (Appendix G). Patients who were interested in participating in the study were asked to contact
me by email to state their interest and provide their contact information. I then contacted the patient and asked a series of screening questions to determine if they were eligible to participate in my study. Screening questions were as follows:

- Are you currently receiving treatment from a chiropractor?
- On what date did you receive your first treatment from your current practitioner?
- Are you over the age of 18?
- Are you currently, or were you ever, employed as a health care professional?

Patients who met all of the inclusion criteria were eligible to participate in the study and were asked to participate in an interview, either in person or over the phone. I arranged a date and time for the interview and asked participants to sign and fax or email the informed consent document that was enclosed in their information package prior to the interview. A twenty-five dollar gift card incentive was mailed to participants after interviews were conducted; options for Tim Hortons, Starbucks, ITunes, or a local grocer were presented. Finally, I asked participants if they were willing consent to follow-up interviews if clarification or further information was required as emerging concepts and categories were refined. No follow-up interviews were conducted.

Data Collection

I conducted in-depth, semi-structured interviews as the primary method of data collection. In-depth, interviewing was appropriate for the aims of this research because it enabled me to explore the diversity and similarities of participants’ experiences of exchanging risk information during informed consent. The use of interviews also allowed me to explore unexpected areas of inquiry that were related to the research question. Interviews were between thirty and sixty minutes and took place over the phone and face-to-face from a private room at the University of Toronto, after an informed consent document was signed by the participant. Immediately prior to each interview I briefly discussed the purpose of the interview and reminded each participant of his/her right to withdraw. This conversation also served to develop rapport with the participant prior to the interview. To determine basic contextual information that may influence the patient’s experiences of informed consent, I conducted a brief demographic survey after each interview (Appendix H).
I developed an interview guide (Appendix I), based on the background literature presented in this proposal and Charmaz’s (2003) suggestions for qualitative interview questions, to facilitate the interview process. This interview guided was intended to help me remain focused on the research objectives while also providing the flexibility to remain open to the participants’ stories (Charmaz, 2003). Questions on the interview guide were intended to spark discussion about topics that were relevant to the study objectives. These questions evolved in response to emerging concepts within the data and the interview guide was revised a total of six times. Interviews were audio recorded and subsequently transcribed by an assistant. Questions for further interviews were adapted to focus on emerging theory throughout data collection and analysis.

Data Analysis

Data analysis and data collection was an ongoing, iterative process. Throughout this process I read each of the transcripts and analyzed them using constant comparative analysis. Constant comparative analysis is a technique for analyzing data where events are compared to other events for similarities and differences, until the data can be separated into different categories and eventually into themes that represent major concepts in the data (Corbin & Strauss, 1990). During data analysis I paid attention to the content of the interview, as well as the context and unspoken meanings embedded in the conversation.

In the initial stages of data analysis the data were explored, looking for processes, meanings, actions, and interactions to answer the question “what is happening in the data?” (Charmaz, 2003). Both my research supervisor and I read each of the transcripts, searching for recurring concepts and ideas that were relevant to the research question and objectives. Relevant, recurring, ideas and concepts were given descriptive labels called codes. For example, the code ‘waiver’ was used to label parts of the data where the participants referred to the consent form as a legal document and the code ‘taking time’ was used to label parts of transcripts where participants spoke of the amount of time that their chiropractors spent with them. Codes and definitions were recorded in a coding table (appendix J) so that they could be compared within and across interviews.
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I used the initial codes to search for patterns and relationships that spoke to participants’ stories by comparing and contrasting them against one another to sort the data into conceptual categories. Categories were developed to cut across multiple interviews and represent recurring themes in the data. For example, the code ‘taking time’ was grouped with ‘building trust’ and other similar codes to form a category called ‘general impressions of clinicians’. I explored each category searching for indications of contextual factors, such as age or education; and social conditions, including relationships with chiropractors, family, and friends. I then explored how these factors and conditions shaped individual perceptions of risk and perceptions of consenting to treatment. Finally, I developed hypotheses about relationships between categories.

Throughout the process of data collection and analysis, the codes and categories that were developed provided leads that I pursued in subsequent interviews. In this way, I tested the hypotheses that were developed about relationships between categories against the data from ongoing interviews. When a hypothesis about relationships was not supported by the data it was discarded or revised. Furthermore, I clarified these categories through discussion with my research supervisor and thesis advisory committee members.

Towards the end of the coding process, categories were integrated to develop four themes that represented distinct phases of the main phenomena present in the data, ‘the process of informed consent’. Each of these themes described a stage where risk information influenced their process of informed consent for chiropractic care. The themes were achieved by analyzing codes, defining relationships between categories and specifying conditions under which theoretical relationships emerged, changed, or were maintained, and by comparing categories to the literature about risk disclosure and informed consent. The together these themes represented an abstract process, describing how participants experienced informed consent to receive care from their chiropractors.

Chapter Summary

I designed a qualitative descriptive study to address a gap in the literature regarding patients’ perspectives of informed consent, particularly with respect to chiropractic care. A purposive sampling method was used to recruit participants who had recently consented to receive chiropractic care. I conducted semi-structured interviews as the primary form of data collection
and interview transcripts were analyzed using a constant comparative method of analysis. The findings are presented in the following chapter including a description of participants’ perceptions of the process of informed consent and the four themes that describe how this process was shaped by risk information.
Chapter 4: Findings

Both the interviews and interpretation of the data were guided by the research question for this study how do chiropractic patients’ perceptions of exchanging risk information during informed consent compare with the legal requirements of informed consent for chiropractors?? Following a description of the study participants, their experiences are described. The overarching theme constructed from the findings was informed consent, as participants described their perceptions of consenting to treatment. The analysis revealed that participants’ perceptions of informed consent involved weighing the potential risks against the potential benefits of treatment to decide whether or not to proceed with treatment. Analysis of the data focused on how the process described by patients was similar or different to legal standards of informed consent.

Demographic characteristics were recorded for each participant, when permission was granted, including gender, ethnicity, highest level of education, clinic where treatment was received and year of birth (Table 2). Of the 26 participants who were interviewed, 14 were female and 12 were male. Highest level of education ranged from high school diploma to PhD; 13 participants had completed a bachelor’s degree. Approximately half the participants described their ethnicity as North American, while approximately one-quarter identified themselves as being European or Asian. 85% of the participants interviewed were receiving treatment from teaching clinics and 15% received treatment at a private clinic. Ages ranged from 19-82 years, most of the participants fell between the ranges of 19-29 and 50-59. No differences were observed between participants who were recruited from teaching clinics and those who were recruited from private clinics.
Table 2: Participant Characteristics (n=26)

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* Category does not add up to n=26 or 100% because participants did not disclose information

A description of the process of informed consent was derived through the analysis of interview data from the participants described above. The fact that participants in this study experienced informed consent as a social process is the main finding of my research. This process consisted of on-going information exchange with their practitioners, family, friends, and the media. For participants, the informed consent process began prior to arriving for their visit at the clinic, and continued throughout the course of treatment.
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The four themes presented in this chapter represent four stages where participants incorporated risk information into their decision making process. These subthemes include: 1) Preconceived ideas of safety and risk; 2) Perceived practitioner competence; 3) Risk disclosure; and 4) Patient/practitioner feedback loop. These sub-themes explain how contextual factors influenced participants’ perceptions of risks and informed their decisions to receive treatment. Since these factors informed decision making for participants in this study, they were conceptualized as stages of the participants’ informed consent process. The themes are described in the chronological order in which they were experienced by participants throughout their treatment (Figure 1).

Figure 1: Four stages where risk information shaped participants experiences of consenting to treatment

Preconceived Ideas about Risk

Upon arrival at their first visit with the chiropractor, each participant brought with them a preconceived notion about the safety or risk of receiving chiropractic treatment. Participants’ stories demonstrated that these preconceptions came from information that they received from various sources prior to seeking treatment for their current concerns. The most frequently discussed sources of information were the influence of past personal experiences with chiropractors, members of their social networks, and the media. Information from these sources often influenced their decisions to consent to treatment.

Although the chances of experiencing harm do not necessarily decrease with experience receiving treatment, past experience often led participants to perceive the treatment as safe. This was particularly true when those experiences resulted in positive outcomes:
INFORMED CONSENT FOR CHIROPRACTIC CARE

I had the chiropractic treatment like about ten years earlier, I kind of was aware and I had successful chiropractic treatments, I came from past experience so I just kind of, my concerns were minimal- Bill

Uh, it doesn’t scare me because I know how it works. I mean if it was someone who is brand new to it, they might feel a little bit skeptical but like I’ve had my ribs adjusted before. – Jade

Participants who heard stories of people being harmed from chiropractic treatment or those who experienced harm themselves were more likely arrive at the treatment feeling apprehensive about the risks:

It’s funny, my dad actually when he heard about me going to the chiropractor he was very insistent. So I probably went in there very nervous about neck manipulations. Uh you know, oh well with the neck ones there’s a risk of nicking arteries and you could have a stroke and die in terrible ways!- VioletGrumple

I’ve heard of people, because the central nervous system is so important that, um, again, I don’t have any proof for this but it’s kind of, in my family and in my social circle of people…there are these alleged stories of people who have gone and they have had their spine manipulated and then not been able to walk or they’ve, um, lost the ability to use certain limbs. So I was a little bit leery of that, obviously, having heard that.- Hannah

When I went in for a second visit, I remember because she was unable to crack me the first time I was more resistant to her cracking me the second time because it was very painful when she was unable to crack me. - Silver

Information from sources in the media such as the news, movies and the internet also raised concerns among some participants, specifically about the risks associated with cervical manipulation:

Just reading about, you know, probably some people that are not so keen on chiropractors that do this because of the risks or reading about actual instances where someone was, um, injured because of this, because of the neck manipulation, so you know it made me informed and a little concerned.- John Sunshine

You always hear in the press, just the horror stories of they crack your neck and you’re going to die. People die from getting their necks cracked, so probably just preconceived notions and things like that… The actual risk is very, very, small, but the headlines kind of stick with you no matter how small the risks are. So in my mind I know the risk is extremely small, but sometimes
what your mind knows and the way you act are completely different things.- Logan

For some participants these preconceptions about risk informed their decisions about whether or not to receive treatment. For example, when Janis arrived at her treatment, she had already decided that she would not receive spinal manipulation because family members had informed her that the procedure was risky. Alternatively, the positive experiences of Christine and Hannah’s friends’ and family informed their decisions to receive chiropractic care:

I do remember before I went to the clinic and I must have discussed it with family members and the strong advice I got from at least two people was, don’t let them touch your spine! And I said, okay, I won’t. So I had that, I remember, that was the first time I had gone to a chiropractor and I remember I went in chanting that, don’t let them touch your spine! Don’t let them touch your spine! - Janis

Like I know people who went to chiros before and I haven’t heard of anybody having a problem, so I know that it’s more like a precautionary thing with the consent form. I don’t think that it [risks on consent form] affected my decision at all. – Christine

How I made the decision? I think, well, I knew that my neck and my upper back’s been hurting me so I, I put aside my reservations and I had some friends who go to the chiropractic college as well and have just had a lot of success. So I, I just kind of put it in the back of my mind and I agreed to it and I decided to prioritize the potential gains and, um, that that was greater than the potential risks. - Hannah

Other participants received conflicting information about the safety of treatment prior to arriving at their chiropractor’s office. In these instances they often weighed the positive stories and experiences from their past against the negative ones when deciding whether or not to receive treatment. For example, Theodore arrived at treatment with perceptions that were shaped by both positive and negative experiences. He heard one story from his co-worker that emphasized the risk of pain associated with treatment and another from a family friend that described a positive treatment experience. According to his account, he weighed positive and negative information within these stories and decided to proceed with treatment:

Well I actually have a co-worker that had a chiropractic person do an adjustment on his neck and he said he would never go back because the whole thing was very painful and he doesn’t recommend it…so I was aware from co-
workers about how negative the profession is from their perspective and I was also aware how positive it is from a friend of my wife’s right? So I had already made up my mind as to have the treatment [before arriving at the clinic]. – Theodore

Gerry also drew on his preconceived ideas about the safety/risk of treatment to inform his decision to receive treatment. Although he heard about the possibility of severe risks occurring after treatment, he weighed those risks against his own previous successful experiences and decided to proceed with treatment:

I’ve you know, you read the odd article in the paper where someone has a stroke or someone’s paralyzed by chiropractic treatment…but I’ve, I’ve had enough treatments that have been successful that I’ll, I’ll take the risk. - Gerry

The data presented in this section suggest that preconceived ideas about safety and risk may inform some participants’ decisions to consent to treatment. Participants who received positive information or had successful treatments were more likely to perceive the treatment as safe than those who experienced or heard stories of harm. These preconceived notions were often incorporated into their decisions to consent to treatment. Therefore, participants’ preconceived ideas about risk may be considered the first stage in their experiences of the informed consent process. For participants in this study, the second stage of incorporating risk information to their decision to receive or continue with treatment began when participants arrived at the clinic for treatment and met their practitioners.

Perceived Practitioner Competence

Participants and practitioners usually have an opportunity to develop rapport during initial introductions and the medical history taking process. Participants in this study described how they assessed the competence of their practitioners during this time. Perceived competence was influenced by the nature and disposition of the practitioner; practitioners who took their time with participants and explained what they were doing were more likely to be perceived as competent. For example, Sterling and Joe described how they believed that their current practitioners were better at treating patients than their previous practitioners because they took the time to explain what they were doing:
They were more personal, they actually let you know what was going on and made sure you knew what was going on. They were being social but they were professional about it so when they were asking you to do stuff, they were explaining what movements you had to do. – Sterling

I felt like he really spent a lot of time with me, whereas I’ve gone to chiropractors in the past and you’re in and out in five minutes and you feel like it is very fast food kind of, whereas this gentleman is very thorough and I appreciate that… I was at another one [chiropractor] and I found him to be, he was thorough but he didn’t really talk you through it and I felt worse after treatment - Joe

Likewise, Amanda described how her chiropractor’s use of orientation language enhanced her confidence in his ability to safely perform the procedure. Orienting language refers to explanations provided by practitioners to their patients about what they were doing and why, through the treatment process. Sweet pea attributed the confidence she had in her practitioner to his willingness to spend time with her and make her feel heard:

When I asked questions about things, when I asked a lot he would explain it to me very well and in detail. Yah, just willing to take the time to explain things, and explaining things as he does them. So like, oh, you have this um, trigger point here and it’s travelling along here and I’m just going to rub it upwards or whatever it is. He did a good job of explaining everything he was doing…so you could sort of, um, tell just cause he was like talking out his process and I thought he knew what he was doing, so I felt confident about him giving me treatment. – Amanda

The young man that I met, he is absolutely amazing because he took the time to listen to me, and then went and did an assessment and went right away to the doctor that he works under, he sat and assessed and came back and told me what he was going to do. And like I do, I have complete confidence in this young man.- Sweetpea

Many participants in this study perceived the level of risk involved in treatment as directly related to the perceived competence of the practitioner. Some participants felt that it was safe to proceed with treatment if they perceived their practitioners as competent and capable of performing the procedures:

Yah, things can go wrong but I know that she’s doing what she can to minimize the risks and she’s a competent professional, so I shouldn’t have anything to worry about. – John Sunshine
I also know they get a lot of, these guys get a lot of training and these students get a lot of training in the various disorders, so I wasn’t too concerned…I mean it [level of training] influences [safety of treatment] in the sense that, you know, if they only take, say, I don’t know, uh, you know, a three week course in how to treat backs and, you know, they’re treating, they’re treating some, you know, potentially severe problems, there would be concern.” - ComputerGuy

With this man his whole manner is so kindly, there’s something very solid and grounded about him and so that genders a feeling of safety. You know what I mean?...I think it’s very important. It really begins as soon as you meet them. It’s not like just what happens in the treatment room, it’s the person. It’s how they conduct themselves, whether they look you right in the eye and make you feel safe and welcome and that you’re being paid attention to and you’re not just another person going through and getting your thing for ten minutes. - Carissa

When deciding whether or not to consent to treatment, the level of trust that some participants had in their practitioners to perform the treatment safely, influenced their decisions. For example, Sarah described how she felt unsafe after her previous chiropractor refused to listen to her and she decided not to return to him for treatment:

I felt it was necessary to let him [previous chiropractor] go, right, because he wasn’t paying attention…I got the warning, this young, this guy that I was seeing, because he’s pushing you too hard and he’s not listening to you, that’s a warning sign. –Sarah

Furthermore, Janis felt safe proceeding with cervical manipulation, only after she had developed trust in her chiropractor, and the trust that Hannah had in her practitioner contributed to her decision to proceed with treatment despite the associated risks:

At the intake I didn’t want any spinal manipulation if I recall, and you know, okay, they’re cool with that… but as I built up a rapport with Darlene, she’s a lovely person, um, I began to trust her a little bit, you know, and so we kind of talked about it and she said there’s something I can do to help your headaches. Cause she just wasn’t interested in the arm and the leg. She’d ask, how are you doing in general and like, so it came, the agreement for her, my agreement for her to try this thing was after I’d seen her for a long time. -Janis

I can see how it [risk] would influence some people…but no, in my case I knew that, um, I felt really strongly that I needed the treatment and I had a good experience and I trusted her and the chiropractor college.– Hannah
Therefore, the experience of developing rapport with their practitioners appears to be an important aspect of participants’ experiences of the informed consent process, and comprises the second stage in their process of informed consent. Participants in this study had the opportunity to develop rapport with their practitioners. Those who took their time and explained what they were doing to participants were more likely to be perceived as competent professionals. According to some participants’ accounts they were more likely to consent to treatment if they trusted their practitioner to safely conduct the treatment. The third stage of this process of informed consent occurred prior to receiving treatment and involved discussing the risks with practitioners and signing a consent form.

Risk Discussion and Consent Form

Most participants in this study described their experiences of risk disclosure during the informed consent process. According to their descriptions, this process consisted of two parts: 1) signing what most described as a waiver and 2) discussing the risks that were listed on the consent form with their practitioners. Participants appeared to place a higher value on the discussion that accompanied the informed consent form than they did on the form itself. In fact, many patients felt that the act of signing the informed consent form was a formality and some even described it as an inconvenience. Logan, Sweetpea, and Carissa all described how the act of signing consent forms had become such a common occurrence in their lives that it was no longer meaningful to them. Carissa appeared to perceive signing the form as more of an inconvenience than an asset:

I am in a sort of resigned, fatigued way, used to signing things because society has become increasingly litigious... You know, it's tiresome but it's like, oh gosh, you just want to get on with whatever and here's the freakin’ form, and like oh right, I'll sign it, you know? – Carissa

I feel bad, I didn’t really read it [consent form] that much but I assume it’s just that I’m not going to sue them for anything… ‘Cause, like society now, so many times we sign consent forms online and things like that, it’s just a natural thing. So I think it was just like yeah, okay I’ll sign it and hopefully it’s not saying that I’ll owe a lot more money or something like that. - Logan

I have to sign something. You always do. So I take it as part and parcel of being treated…With anything, I mean, if you go to the dentist and you’re going
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to have a tooth out and you’re going, he’s going to give you gas, he makes you sign something… I don’t think about it when I sign it. I do it as a matter of rote. You’re supposed to do it and that’s it. And forget about it! – Sweetpea

Like Carissa, Sarah Burnheart also perceived the act of signing the consent form as an inconvenience:

The consent form was a mere formality. It was kind of like, okay you’ve got to do this to get past go, and not go to prison, you know. It’s a stupid thing to do. – Sarah Burnheart

Logan, Carissa, Silver, Sweetpea, and Sarah Burnheart all seemed to perceived treatment as a low-risk activity which may account for their lack of interest in the consent form. Participants who did not perceive the treatment as entirely safe did not describe the informed consent document as a formality or an inconvenience, yet they did believe that the form was more beneficial for their practitioners than for themselves. In fact, all of the participants in this study perceived the primary purpose of signing the consent forms as protection for practitioners from litigation:

Well in my opinion I think it’s just like basically to, to cover their own asses, just in case like something does happen, that you agreed that everything’s going to be fine, that you understand there are sometimes, something could go wrong. I mean in any situation there’s the possibility of something going wrong and so they just, I guess they have to protect themselves too. – Christine

Um, I imagine it’s so that if they do, do something wrong um and if I tried to sue them then they’d be like well you signed this form saying you were aware of the risks so. Uh, definitely covering their asses, that’s probably the intention of that form um, it does also inform the patient that there are risks associated which is nice, but when it comes down to it, it is um to cover their asses, let’s be honest. – Violet Grumple

I imagine it’s to do with liability. I think that, and also, um, to explain what the chances are and, um, but number one for sure for me would be the liability aspect. I think it’s probably mutually beneficial but at the time I certainly thought it was more to cover their own butts than to really benefit me. – Hannah

The risk discussion that took place between participants and their chiropractors seemed to be more significant to participants’ decisions to receive or continue with treatment than the
informed consent document. Many participants valued the discussion that they had with their chiropractors about the risks disclosed on the consent form. When chiropractors discussed these risks with participants in an open and approachable manner, some were more comfortable proceeding with treatment:

It actually put me at ease, having that discussion actually put me at ease and made me comfortable. I mean get it out in the open and lay it, lay it on the table and then I was able to make a decision that I wanted to continue with treatment, or proceed with treatment actually. – Bill

Um, it definitely put me at ease to understand that like she knew more about the risks then what was um in writing in front of me. Yeah it’s just good to know that when you ask a follow up question, someone is going to be able to answer it. Um, and, yeah it put me at ease that she didn’t down play it. So, so if she had not you know, if she had down played or if she had not been able to answer the question then I think I might have changed my course of treatment. – John Smith

We talked about that [risk of stroke]. That’s where I got the whole thing about like millions of, like so many adjustments and it’s only one or two stories and so, yah, he was, it was good cause he was open about that and that probably made me more relaxed with him…it gave me a better understanding of the situation, like cause when you read it in the paper it’s like, oh, everybody is having a problem and it’s going to be a big one, but just putting the risks into perspective cause, I guess as individuals you always, uh, you don’t really have a rational view of risk. You either over-inflate it or under-inflate it, so just talking to someone who knew a little bit better and was kind of educated about it kind of helped educate me and it makes it easier to make the decisions when you actually know what’s going on. – Logan

Participants in this study felt that there was value in being informed about the risks associated with treatment. Some had trouble articulating why they valued this knowledge; however, many of them concluded that it helped to make an informed decision about whether or not to receive treatment. Whether this knowledge actually influenced their decisions to consent to treatment appeared to be related to their preconceived ideas about the safety of the treatment that were discussed in Stage 1. Participants who were concerned about the risks involved in treatment before they arrived at the clinic seemed to be more likely to be influence by the risk disclosure process when consenting to treatment. For example, both Christine and Sterling perceived the treatment as safe because they had previous successful experience with chiropractors. Although
they theorized that the purpose of risk disclosure was to inform decision making they both
conceded that risk disclosure had no influence on their decisions to consent to treatment:

Oh, yah, of course there’s purpose to that because sometimes things can
happen that are unexpected, it just gives you a heads up that this could happen
and it’s normal. I mean, other than like, the basic things, like bruising,
tenderness, like very minor things, but then it’s good to be informed that
something more serious can happen too and just to make sure that you’re okay
to go ahead with the treatment based on that information.

Interviewer: Do you think that learning about those risks actually influenced
your decision of whether or not to receive treatment?

Um, I don’t think so because going into it realistically like I’m pretty young, I
don’t expect there to be any serious complications. - Christine

Well, it’s good to know the risks cause if you think that the risks are worth
getting it done well then you have the choice then whether or not to get
treatment…It didn’t really influence the [his] choice. It was, I already know
that I needed some work done so I was going in to get the treatment regardless.
- Sterling

Alternatively, John Sunshine was concerned about the risk of stroke associated with cervical
manipulations when he arrived at treatment because he heard “horror stories” about this in the
media. He used the risk disclosure process as an opportunity to address these concerns with his
practitioner and to work together to come up with a treatment plan that he felt comfortable
consenting to:

I think I got into a discussion with her that, you know, I read that it’s pretty
much only people with a certain kind of artery configuration in their brain [that
are at risk of stroke] and uh, she said yes, but they don’t need to do a traditional
manipulation. [There are] other ones for the neck that can be done that would
have less, that wouldn’t have that risk, so I think that’s what she ended up
doing anyway… I think she sensed, I wasn’t so keen on doing that, uh, the kind
that you twist your neck around, rotatently, and there was one that involved
more of a pressing sideways kind of motion, when you lay on your side and
they press, they press sideways, that way. So that, yah, it was kind of like
mutual decision it’s like, this is fine. – John Sunshine

Regardless of how safe or risky participants perceived the treatment, most participants were
unable to recall all of the risks that were disclosed by their practitioner on the consent form.
Stroke and worsening of pain were discussed most frequently but very few participants were able
to recall moderate risks such as rib and disc injuries. The data suggest that they were likely to
dismiss risks that were non-severe and/or perceived as not relevant to their individual situations.
Thus, risk disclosure did not appear to be about trying to understand and remember all of the
disclosed risks; rather it was an opportunity for participants to address concerns that they had
prior to seeking treatment and to discuss the risks that they felt were relevant to their unique
situations:

Um, he may have mentioned it [risk of fractured rib] but I wasn’t concerned
about my ribs because it was, the manipulation was in the neck area. So I don’t
think, I don’t think that information stuck in my brain, just because of the
location of my muscle strain. - Bill

I don’t know, now I remember the rib part because I did get a little worried
about that but then it, I guess it quickly jumped out of my mind and I focussed
more on the stroke aspect of it, just cause, well I feel like, if you get a stroke it
affects your, it’s more fatal than a fractured rib so I guess I put that more as a
priority in terms of most dangerous risk. – Amanda

No I don’t [remember the risks] so I guess I should have paid more attention. I
think I did read them but none of them really stood out to me, so I probably just
dismissed them, uh, yah, in one ear and out the other, I guess…I’m sure if
there’s something, a risk that kind of stood out to me, maybe I would have
flagged it or I would have, I guess, second thoughts I can guess what I was
doing but like I say none of the risks seemed severe enough for me to
remember now or at the time. – Logan

When asked about the risks associated with treatment most participants described them as
minimal, and rare. They believed that these risks are simply a product of being treated for a
medical condition as they were perceived as no worse than risks associated with other medical
treatments and day to day activities:

It did concern me but like I also knew that like there is always a level of risk
that you need to take on… even if you’re at the dentist or even if you’re going
in for a simple surgery um there are inherent risks with letting a doctor work on
your body. – John Smith

Participants were aware of the risk of stroke and understood the severity of this risk; however
most dismissed it because they did not consider the strength of the association between the two
events to be significant. The nature of this association was explained to participants verbally by
their practitioners and in writing on the consent form. It seems that participants interpreted the
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uncertain relationship between cervical manipulation and stroke to mean that the risk of stroke only applies to specific patients who are predisposed to this outcome:

The form, when you read the form it makes it sound like really serious, but when they explain it to you and you’re like, well see with the stroke it’s more like sometimes with the elderly it could happen, things like that. Like it clarifies a little better so I appreciated they could explain it verbally. Um, because I just know that it doesn’t apply to me. – Christine

He told me there weren’t any real risks except for, uh, some stroke…because of the, um, adjustment but this was only with patients who already had a stroke and they were coming in for treatment, so they would get a stroke after because of the pressure that the discs were pushing out to their blood vessels. But otherwise there wasn’t, there wasn’t any real concern. – Amanda

Participants in this study interpreted the uncertainty surrounding the association between cervical manipulation and stroke as an indication that this risk was unlikely to affect them personally. They seemed to categorize the treatment as safe for themselves, though potentially dangerous for others.

Although participants seemed to view the informed consent document as a formality or a waiver, they valued the risk information that was disclosed to them. The discussion that accompanied the informed consent document was more significant to the participants’ decision to receive or continue with treatment than the consent form. At times, this discussion shaped participants decisions about whether or not to receive certain treatments, particularly those who arrived at their treatments with concerns about the risks.

Patient/Practitioner Feed-back Loop

This stage consisted of verbal and non-verbal communication between participants and their practitioners while participants were receiving treatment. For most participants, treatment began after they signed the informed consent form and continued throughout multiple visits. Participants and their practitioners provided feed-back to each other about the location and the amount of force being applied and the resulting level of comfort or discomfort during treatment. Many participants were willing to accept pain that was perceived as therapeutic and ensured that their pain threshold was not crossed:
I’m expecting pain because I’m showing signs of it and I know that they’re aware of it and that’s my main concern if, you know, that they’re just not doing things willy nilly without being aware that, you know, I’m here experiencing something, feelings, so I feel good that they’re aware of that… I could tell [they were aware of the pain], you know, by just the way that she handled me and her verbalizations…, she’s aware of, you know, the amount of, how much I can handle, I would say, that she isn’t overdoing it or under doing it, but just, yah, applying therapeutic levels of stress. - JohnSunshine

Well, you know, it’s up to me to gage whether it’s the normal [pain], okay, this is tight, we’ve got to just push it a little bit as opposed to, this is extreme agony, you know, and I am in tune enough with myself to know that, you know, when it’s not going to do, of any good to push this, right. So I would just say to him, you know, he said, no actually he’s the one who’s been staying on top of that. He’s been saying to me, you let me know if it’s too much. You let me know, and I say, yes I will. And then we just work through it, right. – Sarah Burnheart

It was just kind of wince in pain, they see that it hurts, so they changed over to a different, trying to work the muscles differently until they got one that didn’t cause pain. - Sterling

The practitioner’s ability to engage in this feedback loop, seemed to influence the participants’ perceived safety of the treatment. Participants often felt safe with practitioner’s who were able to adjust the treatment in response to verbal and non-verbal feedback. John Sunshine and Jade described how they felt safe because their practitioners were engaging in this feed-back loop:

She’s doing what she can to minimize the risks…like asking if, uh, you know, sensing when you know she’s gone as far as she can go with say a certain motion, uh, reducing the amount of stress on, you know, torques, say doing some kind of twisting so that it’s not, uh, so she’s kind of in the feedback loop for experiencing what I’m experiencing and adjusting her degree of effort accordingly so that she’s maybe bending but not breaking. - John Sunshine

Just like the way that they were doing everything, I mean, if you were to go there and get adjusted yourself you would see that they are very careful. It’s not like they just go through the motions and do whatever. They really do know their stuff and they check over and if something, is hurting, cause like with my ribs, it hurt in some places and like I was expecting that but she would change tactics and not follow through with that one adjustment to make sure that I didn’t get hurt.-Jade

Moreover, when asked what can be done to make the treatment safer both Logan and Sterling described this concept of providing feed-back about pain or discomfort to avoid injury:
Interviewer: Is there anything you or the chiropractor can do to make the treatment safer?

Just communication and, um, responding to the needs or whatever of the patient, like adjusting the treatment based on the patient’s reactions and things like that and he seems to do that. You know like if it’s, like we talked about, um, pain before and just have, instead of them keep on doing the same thing kind of moving around that area, finding a different way to crack or whatever he does. - Logan

Interviewer: Do you think that there’s anything that either you or the chiropractor can do, um, to make the treatment safer? If it’s causing pain just let them know and that’s what I think can be done, really. - Sterling

Some participants explained that the feedback loop was beneficial for their safety because it provided them with opportunities to withdraw consent if they felt that they were in danger of being harmed. Most participants did not find themselves in a position where they needed to stop treatment; however, some speculated that they would feel comfortable doing so if they did find themselves in that situation.

Well I would be comfortable telling anyone to stop! If I felt threatened, I mean this is my body, if I, you know, I know some personalities might not because they give up their power too much to someone who has the name doctor. I know that there’s all that psychology going on which is unfortunate. The people give up their power and feel like the doctor knows best. But, I would not. If I felt threatened by anybody or felt like they are causing me pain and this isn’t good, I would immediately say, stop! I know I would. I know I would. But I, I didn’t need to, well with any of them, I never was in that position of needing to say stop. – Carissa

Interviewer: Would you feel comfortable telling him to stop if it was causing too much pain?

Yes, it is your body you know. - Joe

Although Joe speculated that he would feel comfortable telling his practitioner to stop if the treatment was too painful, he subsequently recalled a time when he found himself in that situation and did not ask his practitioner to stop. Instead he decided not to return to his chiropractor for further treatments. Sarah reacted in a similar manner when her chiropractor failed to respond to the pain that she perceived as harmful:
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I just didn’t feel comfortable with his adjustment it didn’t feel very good, to be quite honest…No I didn’t [tell him], I just basically didn’t show up for any more of his treatments. – Joe

The chiropractor that I was seeing regularly, I don’t know if he’s, he’s just old school or what his take is, but he was pushing me too hard, trying to get the shoulder mobilized and he was actually causing pain and I’m not a big believer that more [pain] is actually going to solve the situation… I felt it was necessary to let him go, right, because he wasn’t paying attention. – Sarah

Conversely, when Logan experienced pain during his treatment he withdrew his consent by asking his chiropractor to stop treatment because his pain threshold had been reached. His chiropractor listened to his feedback and Logan returned to him for future treatments.

Yah, just once [he experienced excessive pain], especially at the beginning when it was more sore. I just let him know that my tolerance or my threshold had been reached for the day. And then when I did that he kind of went on from like the putting a heating pad on it and things like that and let me lie with the heating pad. – Logan

It seems that a feedback loop occurred between the participants and their practitioners during treatment. Many participants believed that this feedback loop facilitates the avoidance of risk during chiropractic treatment. For some, this feedback loop presented opportunities to withdraw consent if they felt that they were in danger of being harmed. Thus, the ability of the practitioner to receive and provide feedback to and from participants during treatment may inform the participants’ decisions to return to treatment and this feedback loop may represent the last stage in the participants’ processes of informed consent.

Summary of Findings

Participants experienced informed consent as a process. This process began prior to arriving at their first treatment, as information from past experience and non-clinical sources shaped their perceptions of risk. Ultimately, these perceptions informed many of their decisions to receive treatment. Their experiences of informed consent continued as they assessed the competence of their practitioners, determining whether or not it was safe to proceed with treatment. Risk discussion followed and was often perceived as an opportunity to address specific concerns that participants had and to discuss severe and relevant risks. Finally, participants engaged in a feedback loop during treatment that some perceived as an opportunity to mitigate risk and/or
withdraw consent if they felt they were in danger. It seems that for participants in this study, risk information influenced their experiences of informed consent through the four stages described in this chapter. Information about the benefits of receiving treatment also appeared to inform their decisions to consent. However, this study focused on risk and did not directly explore how information about the benefits of treatment influenced participants’ experiences of informed consent.
Chapter 5: Discussion and Conclusion

My findings contribute to the literature about informed consent within the chiropractic profession by demonstrating that some chiropractic patients in Ontario view informed consent as an on-going process of communication with their practitioners, and by describing that process from the perspective of patients receiving chiropractic care. This process included four different stages where risk information influenced participants’ decisions to receive or continue with treatment. Furthermore, my findings suggest that, through this process, it may be possible for chiropractors to educate patients’ about risks associated with care while satisfying the legal criteria for informed consent. This conceptualization of how chiropractic patients view risk information may enhance the informed consent process for patients receiving medical care and reduce the risk of litigation if harm occurs. In this chapter, I will describe how these findings contribute the literature and discuss their clinical and legal implications. Limitations and strengths of the study along with areas of inquiry for future research will also be discussed.

Informed Consent as a Process

My study was the first qualitative descriptive study to explore the meaning of informed consent from the perspective of chiropractic patients. A report on informed consent, in the Journal of Medical Ethics, suggests that informed consent for medical treatment should be treated as a process, where patients are given control over the information that they receive, to avoid coercion and deception (O’Neill, 2003). My findings demonstrate that patients in this study view informed consent as a social process consisting of ongoing communication with their practitioners throughout introductions, medical history taking, risk disclosure, and treatment. My findings are not consistent with other research in this area which suggests that informed consent in the chiropractic profession may be treated as a static procedure consisting only of signing a consent form (Langworthy & Cambron, 2007; Lehman, 2008; Ernst, 2004). The findings presented in my thesis provide a detailed account of what the informed consent process looks like for the chiropractic patients in the study, by describing specific stages where risk information is incorporated into their decisions about whether or not to consent to treatment. To ensure that informed consent is treated as a process within the chiropractic profession, it is
necessary to conceptualize what that process looks like, as this can help practitioners to understand how it can be implemented in a clinical context. To date, no other studies have provided a description of the informed consent process within the chiropractic profession. However, researchers who study informed consent for surgery have conceptualized the informed consent process as ‘consisting of repeated risk disclosure throughout treatment and subsequent testing of patient recall’ (Tebbetts & Tebbets, 2001; Wu, Nishimi, Page-Lopez, & Kizer, 2005).

Research on risk communication demonstrates that information can be used in one moment during decision-making and then forgotten the next (Waisel, 2011). Likewise, very few participants in my study were able to retain all of the risks that were disclosed to them prior to receiving treatment. Most participants only retained information they perceived as significant to their decision making process, suggesting that improved recall does not necessarily lead to improved comprehension or consent. If this is true, then researchers and clinicians may want to consider using qualitative methods to evaluate patient comprehension, in addition to measuring patients abilities to recall individual risks.

Understanding how patients perceive the informed consent process may facilitate chiropractors and researchers in developing standards of practice for informed consent that meet the needs of individuals’ decision making processes. If chiropractors address the four stages of informed consent described in this study, patients may be empowered to decide their preferred level of involvement in the informed consent process. By enhancing patient comprehension and autonomous decision making, engaging in this process may also help protect practitioners from lawsuits arising from inadequate consent. Each of the stages in this process may represent distinct opportunities for practitioners to tailor the information they disclose to the specific needs of each patient. For example, practitioners can inquire about patients preconceptions of risk, present themselves in a manner which makes them appear competent and makes the patient feel safe, focus on conversation rather than the consent form during risk disclosure and engage in the patient/practitioner feed-back loop during treatment. Each of these examples is discussed in the following sections.
Patients’ Preconceptions of Risk

The findings from my study demonstrate that for the chiropractic patients in this study, preconceived ideas about risk influence their decisions to receive treatment, often to a greater extent than risk disclosure. Likewise, Crowson et al. (2007) conducted a review of the literature on risk communication and found that risk perceptions stem not only from risk disclosure but from external sources as well, such as personal experiences, family history, and cultural beliefs. They also found that, to successfully assist with patients’ individual decision making processes, practitioners must communicate with patients with the intent to understand their individual perceptions (Crowson et al, 2007). Since participants preconceived ideas about risk often come from non-clinical sources, the information was at times conflicting, confusing, and/or inaccurate. Thus, if chiropractors ask patients what they already know about the associated risks prior to disclosure, it may enhance the informed consent process by providing an opportunity to clarify conflicting information, correct any misconceptions about the risks associated with treatment and address individual concerns.

Determining information about patients’ preconceived ideas of risk may also help chiropractors to satisfy the legal requirements of informed consent in Canada, as practitioners must seek to understand individual patients’ positions, and tailor disclosed information to their unique circumstances. The more specific the information that chiropractors receive about their patients’ positions, the more they may approach the reasonable patient standard of informed consent outlined by the Supreme Court of Canada (Dickens, 2002). Therefore, understanding this stage of the informed consent process may enhance patient education and help chiropractors to fulfil the legal criteria of informed consent.

Perceived practitioner competence

Participants in this study often developed trust in chiropractors who took the time to listen to their concerns and who explained what they were doing throughout treatment. Although it is unclear if establishing trust between the patient and the practitioner enhanced patient education and autonomous decision making, it had other benefits including making patients feel comfortable and safe proceeding with treatment. For example, when participants trusted their chiropractors, they were perceived as competent which made participants feel safe proceeding
with treatment. Chiropractors who were open and honest during risk disclosure also made patients feel more comfortable consenting to treatment. Yet, studies have demonstrated that chiropractors may be hesitant to disclose severe risks due to a fear of increasing patient anxiety and withdrawal from treatment (Langworthy & Cambron, 2007). My study suggests that being open and honest about severe risks may have the opposite effect, increasing the likelihood that patients will consent to treatment and return for future treatments.

Taking time with patients and explaining the treatment process as it is carried out may also reduce the risk of malpractice lawsuits for practitioners. For example, a negative correlation between patient satisfaction with his/her physician, and malpractice risk was demonstrated in two surveys studies (Cydulka, R., Tamayo-Sarver, J., Gage, A., & Bagnoli, D., 2011; Stelfox, H., Gandhi, T., Orav, J & Gustafson, M., 2005). Criteria used to measure patient satisfaction included amount of time spent with their practitioner. This suggests that when practitioners take time to address patients concerns, it will not only enhance rapport with their patients but may decrease the chance of litigation if harm occurs. Similarly, a study explored differences in communication between physicians who had been sued multiple times and those who had never been sued by recording conversations with their patients. The findings demonstrated that practitioners who had never been sued spent an average of three extra minutes with each patient, made “orienting comments” explaining what they were doing, and were more likely to engage in active listening compared to practitioners who had been sued multiple times (Levinson, Roter, Mullooly, Dull, & Frankel, 1997). Thus, spending time with patients, using orienting language, and being open and honest about risk disclosure may benefit practitioners by enhancing patient retention and reducing risk of litigation. However, more research is required to determine how trust influences patient comprehension and the validity of informed consent.

Risk Discussion and Consent Form

In this study many participants did not read the consent form, and no one appeared to use it to inform their decision to receive treatment. Participants perceived the form as more beneficial for their practitioners than for themselves. While it is important to obtain written consent from a legal perspective, a signature on a consent form alone does not constitute proof of consent (Dickens, 2004). Brenner et al.’s (2009) review of the informed consent literature demonstrated that consent forms alone cannot verify patients’ comprehension and that consent forms may
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detract from patient education, if their primary use is to protect practitioners from litigation. Since participants in this study perceived the consent form as a tool to protect practitioners from litigation, these findings lend support to the notion that the informed consent form is not particularly useful for facilitating informed decision making within the chiropractic profession.

Despite research suggesting that the informed consent form may not be useful for patient education, the chiropractic profession has placed a great emphasis on the consent form compared to other practitioners who perform spinal manipulation. For example, physiotherapists in Ontario who practice SMT are required to obtain verbal consent whereas the standard of practice for chiropractors requires them to obtain written consent (College of Chiropractors of Ontario, 2004). In addition the Canadian Chiropractic Protective Association has designed an informed consent form and recommends that chiropractors use this particular form when obtaining consent from patients. However, if patients view the form primarily as a waiver to protect practitioners from litigation, the chiropractic profession may benefit by also treating that form as a waiver to simply document that the patient has given permission to receive treatment. My findings question the validity of the use of a form to educate patients suggesting that this may be better accomplished through ongoing discussion.

The emphasis on the consent form is also reflected in the literature; a recent article by Daigenais et al (2012) suggested that chiropractors should include more information on their consent forms to adequately inform decision making for management of lower back pain. Yet, if patients are not reading the consent form, as my findings suggest, it may be more beneficial to include these elements in the verbal discussion that accompanies the form rather than on the form itself. Moreover, chiropractors have expressed concern over the language used to describe serious risks that are disclosed on consent forms. Their concern is that the use of aggressive language such as ‘death’ may scare away patients and/or research participants (Langworthy & Forest, 2010). However, my findings demonstrate that participants were not affected by the language on the consent form and they valued open and honest discussion about the risks associated with treatment.
Patient/Practitioner Feedback Loop

Participants in this study experienced a communication feedback loop with their practitioners to ensure that the amount of force being applied did not cause a level of discomfort that was perceived as harmful. Some participants in this study perceived this feedback loop as an opportunity to withdraw their consent to treatment if they felt that they were in danger of being harmed. According to the Ontario Patients’ Bill of Rights Act, patients have the right to ``make complaints, raise concerns, and recommend changes without fear of interference, coercion, discrimination or reprisal” (Smith, 2002). This includes their right to withdraw consent during treatment if they feel they are in danger of harm. The law has recognized this right to withdraw permission to receive treatment at any point in order to enforce the notion that consent is a process (Dickens, 2004). Therefore, this feedback loop has been conceptualized a part of the informed consent process because participants recognized it as an opportunity to withdraw consent.

For some participants, engaging in this communication feedback loop was perceived to mitigate risk. Research published in Canada (Ford, Rolfe, & Kirkpatrick, 2011), Australia (Jorme, Dunbar, Sudano, & Travaglia, 2009), and America (Hovey et al. 2011), encourages the implementation of a health care safety culture that is patient-centered. While these studies suggest action areas for the implementation of patient-centered patient safety measures, open communication about discomfort resulting from treatment is not discussed. This could be because current research in this area focuses on hospital settings, and there is no research available on a patient-safety approach to manual therapy. If this feedback loop does have the potential to mitigate harm, it may be incorporated into the safety culture as a potential method for patient involvement in patient safety.

The Agency for Health Care Research and Quality has recommended informed consent as 1 of 22 patient safety strategies that are encouraged for adoption (Skekelle et al., 2013). Yet, it is unclear how informing patients of risks associated with a treatment could mitigate those risks. If this feedback loop is in fact part of the informed consent process, it could represent a direct link between informed consent and patient safety. This stage of the informed consent process was not
fully explored in this study because patients rarely experienced a level of pain that they perceived as harmful.

Limitations, Strengths, & Future Directions

The full process of informed consent was not explored in this thesis; I was unable to explore how participants weighed the risk information they received against the benefits of treatment while making a decision about whether to proceed with treatment. Moreover, there were some areas of inquiry, regarding the ‘patient-practitioner feedback loop’ that I was unable to investigate. For example, at the end of data analysis it remained unclear to what extent participants perceived the patient/practitioner feed-back loop as an opportunity to withdraw consent. In the future researchers may consider exploring these areas of inquiry, using purposive sampling to recruit patients who chose to withdraw from treatment.

Strengths of the study included the concurrent collection and analysis of the interview data and the diversity of participants in the sample population. The iterative collection and analysis of data allowed participants’ stories and emerging concepts to drive the area of inquiry. This helped the researcher remain grounded in participants’ stories, thereby developing themes that spoke directly to their experiences. Furthermore, the sample population was diverse with respect to education, gender, age, and ethnicity and no major differences were observed between participants with different characteristics. The diversity of the sample enhanced the depth and breadth of the findings since they are explored across a range of demographic characteristics. However, the range of ages was predominately younger than the average population attending chiropractic care and participants in this age range may have unique views about risk and informed consent that could have contributed further to the findings. Moreover, it is unclear if these findings can be extrapolated to other chiropractic patients at private clinics. Further research could be conducted to determine if the level of experience a chiropractor has, influences patients’ perceptions of informed consent.

Conclusion

The 26 participants interviewed in this study, explained their perceptions of consenting to chiropractic care, and how risk information influenced their decisions. The most significant
finding from this research is that informed consent was perceived by participants as a social process. This process was conceptualized as four stages, during which risk information shaped participants’ decisions to receive or continue with treatment. These stages include: 1) preconceptions of risk, 2) perceived practitioner competence, 3) risk discussion and consent form, and 4) patient/practitioner feedback loop. Understanding how patients experience this process may facilitate clinicians and researchers in developing standards of practice for informed consent that meet the needs of individuals’ decision-making processes. For example, clinicians can ask participants about their preconceived understanding of associated risks, explain the treatment process as it is carried out, discuss the risk in an open and honest manner, and pay attention to patients verbal and non-verbal feedback during treatment. In doing this, practitioners can allow patients to drive the informed consent process, by focusing on the risks that are most pertinent to each patient’s unique situation. Furthermore, these findings suggest that it may be possible to educate chiropractic patients about the risks associated with treatment while satisfying the legal requirements of informed consent. However, the informed consent form does not appear to be the most appropriate tool for patient education and may be more useful as a legal waiver. Future research can expand on this process by investigating the influence of the informed consent form on patient education and by exploring how patients weigh the risk information against the potential benefits of treatment, to make an informed decision about whether or not to consent to treatment.
References


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Wassersug, R. J., (2013) Consent forms for clinical trials are too aggressive. *BMJ* doi: 10.1136/bmj.f4879


Appendix A: Letter to Practitioners Requesting Assistance with Participant Recruitment
Leslie Dan Faculty of Pharmacy, University of Toronto letterhead

**Research Study:**

**Exchanging Information about Spinal Manipulation Therapy:**

**A Qualitative Descriptive Investigation of The Patient’s Experience**

Dear ______________

I am a graduate student at the University of Toronto and I am currently conducting a research project with the SAFETYNET research team. This project is a requirement for my master’s thesis and I am writing to ask for your assistance recruiting participants for this study.

**What is this study about?**

This is a qualitative study about spinal manipulation therapy and patients’ experiences of exchanging information with their practitioners prior to receiving treatment. The goal of this project is to explore the process of informed consent and the meaning of this experience for patients.

**How can I help?**

I am writing to request your permission to recruit participants from your office. Eligible participants will be patients who are new to your practice, receiving spinal manipulation therapy, are over the age of 18, and are not employed as health care professionals. I am hoping to recruit patients who are new to your practice, having received their first treatments no longer than three weeks prior to contacting the research team, so that they are able to recall the consent process. If you agree to assist with participant recruitment for this research project, receptionists at your office will be asked to provide eligible participants with information packages about the study and the researchers contact information. A research assistant may also be hired to recruit patients from the waiting room of your office.

**What if I am unable to help?**

I fully acknowledge that you are already doing a lot to facilitate the SAFETYNET research team and I want to thank you for this. Your assistance with this study is completely voluntary and if you choose to participate you will have the right to withdraw the use of your office for recruitment purposes at any point during participant recruitment. Participant recruitment is expected to take place from October 2012 through to March 2013. If you are unable to help but know of any other chiropractors or physiotherapists who practice spinal manipulation therapy
and may be interested in assisting with this project, it would be greatly appreciated if you would forward this information to them.

**What will my patients’ participation in this study involve?**

Patients of chiropractors and physiotherapists who are interested in participating in the study will be asked to participate in a telephone interview lasting approximately 45 minutes to an hour. All interviews with participants will be audio recorded and transcribed into an electronic document and stored on a password protected computer. Questions will be about their experiences communicating with their practitioners about spinal manipulation therapy. I will be conducting the interviews and my research supervisor Dr. Heather Boon will be present during some of the interviews to provide guidance and feedback.

**How will you protect my confidentiality and the confidentiality of my patients?**

All identifying information including the name and location of your practice and the name and location of residence of your patients will be removed from all transcripts. Quotes from the interview will be used in the final thesis document; however a pseudonym will be used to protect patient identity. You will not know which, if any, of your patients decide to participate in this study and we will not disclose which practitioners helped recruit patients. All participants will have the right to withdraw their information from the study at any point prior to the completion of data analysis (May 2013). At that point I will be in the final stages of writing and will be unable to make significant changes to the document.

I appreciate you taking time to consider assisting with this research that will help me learn more about patients’ experiences of exchanging information about spinal manipulation therapy. Please contact me or my faculty supervisor if you are able to assist with this research or if you have any questions or concerns about the study (see below for contact information)

With kind regards,

Melissa Winterbottom (Researcher): melissa.winterbottom@mail.utoronto.ca

Dr. Heather Boon (Supervisor): heather.boon@utoronto.ca

Tel: 416-946-5859

Fax: 416-978-1833
Appendix B: Informed Consent: Use of Practitioner’s Office for Recruitment Purposes

Leslie Dan Faculty of Pharmacy, University of Toronto letterhead

Research Study:
Exchanging Information about Spinal Manipulation Therapy:
A Qualitative Descriptive Investigation of The Patient’s Experience

Consent to Use of Office for Recruitment Purposes

I have read and understood the letter of invitation describing the purpose of this research project that is part of a thesis for a Master of Science degree and I understand how I will be assisting with participant recruitment. I have had the opportunity to ask questions and raise concerns about the study.

I understand that new patients at my office will be approached and asked to participate in this study if they have received their first spinal manipulation treatment within three weeks prior to contacting the researcher.

I am aware that I will my patients’ decisions to participate in the study will not be disclosed to me. All identifying information including the name and location of my practice and all information about my patients will remain confidential and my involvement with the study will not be disclosed.

I understand that my assistance with participant recruitment is completely voluntary and that I have the right to withdraw the use of my office for recruitment purposes at any point during the process of participant recruitment.

I give permission for the receptionists at my office to approach new patients who are receiving spinal manipulation therapy and provide them with information about the study.

I give permission for a research assistant to approach patients in the waiting room, ask them when they received their first treatment at my office, and offer new patients information about the study.

Name:__________________________________________________________

Date:_______________________

Signature:______________________________________________________

Please Scan and Email or Fax this form to:
Principal Investigator: Melissa Winterbottom email: melissa.winterbottom@mail.utoronto.ca OR
INFORMED CONSENT FOR CHIROPRACTIC CARE

Faculty Supervisor: Heather Boon email: heather.boon@utoronto.ca; FAX: 416-978-1833

Appendix C: Information Sheet for Receptions to Facilitate Recruitment Process

Leslie Dan Faculty of Pharmacy, University of Toronto letterhead

Research Study:

Exchanging Information about Spinal Manipulation Therapy:
A Qualitative Descriptive Investigation of The Patient’s Experience

Dear ____________________

I am a graduate student at the University of Toronto and I am currently conducting a research project with the SAFETYNET research team. This project is a requirement for my master’s thesis and I am writing to ask for your assistance recruiting participants for this study.

What is this study about?

This is a qualitative study about spinal manipulation therapy and patients’ experiences of exchanging information with their practitioners prior to receiving treatment. The goal of this project is to explore the process of informed consent and the meaning of this experience for patients.

How can I help?

I am requesting your assistance recruiting participants for this study from your office of employment. I would like to provide you with packages containing information about the study and ask that you hand out these packages to all patients who are new to your office of employment. You will receive 10 packages at a time and asked to contact the research team when all 10 have been distributed to receive more. Your assistance with this study is completely voluntary and if you do agree to facilitate the recruitment process you will able to withdraw your assistance at any point in time should you find it to be too burdensome. Patients who are eligible to participate in this study will be asked to participate in a telephone interview lasting from 45-60 minutes where I will ask them questions about their experiences communicating with their practitioners about spinal manipulation therapy. Patients will be eligible to participate in the study if the following inclusion criteria are met:

- The patient is receiving spinal manipulation therapy
- The patient has received their first treatment at this office less than 3 weeks prior to contacting the researcher
- The patient is over the age of 18
- The patient is not currently employed as a health care professional.
INFORMED CONSENT FOR CHIROPRACTIC CARE

The information packages that will be handed out to the patients will include instructions on how to proceed if they are interested in participating, contact information for the research team, and a consent document.

Will I be compensated?

I recognize that your time and energy are extremely valuable and would like to demonstrate my gratitude for your assistance. For every 10 information packages that are handed out to new patients, one ballot will be entered into a draw from your office to win one of two $100 gift certificate to your choice of either a local spa of your choice or a local grocery chain.

I appreciate you taking time to consider assisting with this research that will help me learn more about patients’ experiences of exchanging information about spinal manipulation therapy. Please contact me or my faculty supervisor if you are able to assist with this research or if you have any questions or concerns about the study (see below for contact information)

With kind regards,

Melissa Winterbottom (Researcher): melissa.winterbottom@mail.utoronto.ca
Dr. Heather Boon (Supervisor): heather.boon@utoronto.ca
Tel: 416-946-5859
Fax: 416-978-1833
INFORMED CONSENT FOR CHIROPRACTIC CARE

Appendix D: Letter of Invitation/Information Sheet for Potential Patient Participants

Leslie Dan Faculty of Pharmacy, University of Toronto letterhead

Research Study:

Exchanging Information about Spinal Manipulation Therapy:

A Qualitative Descriptive Investigation of The Patient’s Experience

Dear Patient of (Dr. _______) or (____________________ Clinic),

Thank you for taking the time to read the information provided to you about this study. My name is Melissa Winterbottom and I am a graduate student at the University of Toronto. I am currently working towards a Master of Science degree in the department of pharmaceutical sciences. I would like to invite you to participate in this study that is a requirement for my degree and part of my master’s thesis.

What is this study about?

This is a qualitative study about spinal manipulation therapy and patients’ experiences of exchanging information with their practitioners prior to receiving treatment. I am interested in investigating your experiences of communicating with your practitioner about the nature and potential outcomes of this treatment.

What will my participation involve?

Your participation in this study will involve an interview that will last approximately 45 minutes to an hour. The interview will consist of questions about your experience of your first visit and first treatment with your practitioner and you do not have to answer any questions that you do not wish to. The interview will be conducted by me (the researcher) and will take place over the telephone; my research supervisor may also be present during the interview to assist with the interview process and you will be informed if this is the case. I will be conducting interviews from a private office located at the University of Toronto. All interviews will be audio-recorded so that I can accurately reflect on what has been discussed. Audio recordings will be immediately transcribed into an electronic document for analysis. You may be asked to participate in a second interview at a later date for clarification or further information however you are not obligated to do so.

Your participation in this study is completely voluntary. If you choose to participate you will have the right to withdraw from the study at any point during or after the interview, until data analysis is near completion in March 2013. If you withdraw from the study you do not need to provide a reason and the audio recording and transcript will be destroyed. All data collected during your interview will be destroyed and will not be included in the analysis.
How will my confidentiality be protected?

Your participation in this study will be completely confidential. Your practitioner will not be informed of your decision to participate or not. You will choose a pseudonym that will be used to identify your transcript and for any quotes or information from your interview that will be used in the final thesis document or any publications.

The recordings and transcripts will only be viewed by the researcher and members of the research team for the purpose of data analysis. All information that could identify yourself or your practitioner including names of people and locations will be removed from your interview transcript. All data will be kept in a secure location at the University of Toronto so that no one except for members of the research team will have access to it. The results of the study may be published or presented at professional meetings, but your identity will not be revealed.

Will I be compensated for my time?

Following the interview you will receive a $25 gift card for your choice of Tim Hortons, Starbucks, Best Buy, ITunes, or Sobeys as compensation for your participation in this study. Should you choose to withdraw from the study at any point during or following the interview but before the final stages of the writing process (March, 2013) you will still be entitled to your compensation.

I appreciate you taking time to consider participating in this study that will help me learn more about patients’ experiences of exchanging information about spinal manipulation therapy. Taking part in this study is your decision. You may also quit being in the study at any time or decide not to answer any question you are not comfortable answering. If you decide to participate in this research project detailed instructions can be found on the following page.

With kind regards,

Melissa Winterbottom (Researcher): melissa.winterbottom@mail.utoronto.ca

Dr. Heather Boon (Supervisor): heather.boon@utoronto.ca

Tel: 416-946-5859 / Fax: 416-978-1833
INFORMED CONSENT FOR CHIROPRACTIC CARE

Appendix E: Instruction Sheet for Patient Participants

Leslie Dan Faculty of Pharmacy, University of Toronto letterhead

Research Study:
Exchanging Information about Spinal Manipulation Therapy:
A Qualitative Descriptive Investigation of The Patient’s Experience

Thank you for your interest in participating in this study of patients’ experiences of exchanging information with their practitioners prior to receiving treatment.

To determine if you are eligible to participate in this study please contact me (the researcher) by email at melissa.winterbottom@mail.utoronto.ca, or my research supervisor, Dr. Heather Boon (heather.boon@utoronto.ca), by email or telephone at ________________ (will provide 1-800 number to avoid long distance fees). If you choose to contact me by email please write “RESEARCH STUDY PARTICIPATION” in the subject line and provide a brief paragraph stating your interest in the study and a phone number where you can be reached, or if you prefer we can continue to correspond through email until the interview is conducted. You may also include any questions that you may have about the study in this email.

After your email has been received you will be contacted and asked a series of screening questions to determine if you are eligible to participate in this study. You do not have to answer any questions that you are not comfortable with. If you meet the requirements to participate in this study I will review the information provided to you about the study and the informed consent document with you. Once this information has been discussed you will be asked to sign the informed consent document that is contained within your information package. (If this document has been misplaced another copy of the consent form will be emailed to you.) The signed informed consent document can be returned to the researcher through email at melissa.winterbottom@mail.utoronto.ca or can be faxed to Dr. Heather Boon (research supervisor) at 416-978-1833.

Once the informed consent form has been received by the researcher a date and time that is convenient for you will be arranged to conduct a telephone interview, lasting approximately an hour. The researcher will contact you by telephone at the arranged time and date, or if you prefer we will provide you with a telephone number to contact us. We will review the purpose of the study and your rights as a participant and then the interview will take place. You have the right to stop the interview at any time. With your permission your contact information will be retained in a safe and private location in case a follow up interview is required. If that is the case you will be contacted and a date and time for a second interview will be arranged. You have the right to say no to a follow up interview. After the interview a gift card that you choose will be mailed to you.

Thank you again for your interest in this research project that will help us to learn about patients experiences of receiving SMT. Should you have any questions please feel free to contact myself or my research supervisor at the contact information provided below.
INFORMED CONSENT FOR CHIROPRACTIC CARE

With kind regards,

Melissa Winterbottom (Researcher): melissa.winterbottom@mail.utoronto.ca.
Dr. Heather Boon (Supervisor): heather.boon@utoronto.ca
Tel: 416-946-5859 / Fax: 416-978-1833
Appendix F: Informed Consent Form for Patient Participants

Leslie Dan Faculty of Pharmacy, University of Toronto letterhead

Research Study:
Exchanging Information about Spinal Manipulation Therapy:
A Qualitative Descriptive Investigation of The Patient’s Experience

Consent to Participate in a Research Interview

I have read and understood the letter of invitation describing the purpose of this research project that is part of a thesis for a Master of Science degree and I understand what my participation in this study will involve. I have had the opportunity to ask questions and raise concerns about the study.

I understand that my interview will be audio-recorded and analyzed by members of the research team and that extracts from my interview may be anonymously used in a thesis document, academic publications, and presentations.

I am aware that I will my practitioner will not be informed of my decision to participate in the study and that my participation in the study will be completely confidential

I understand that my participation in this study is completely voluntary and that I have the right to withdraw at any point during or after the interview up until March 2013.

I agree to participate in an interview

Name:____________________________________________________

Date:__________________________________________

Signature:______________________________________________

If you have any questions or concerns about your rights as a research participant you may contact the Office of Research Ethics at ethics.review@utoronto.ca

Please Scan and Email or Fax this form to:
Principal Investigator: Melissa Winterbottom email: melissa.winterbottom@mail.utoronto.ca OR
Faculty Supervisor: Heather Boon email:heather.boon@utoronto.ca ; FAX:416-978-1833
Take part in an important research study...

**Are you a new patient at this office?**

**Would you like an opportunity to share your opinion about your treatment experience?**

If you answered YES to these questions you may be eligible to participate in an interview as part of a research study about patients’ experiences of exchanging information with their chiropractor (physiotherapist).

Participants will receive a gift card valued at $25 dollars for your choice of Sobeys, Tim Hortons, Starbucks or ITunes.

**Please see the receptionist for detailed information or contact the research team at the phone number or email address provided below:**

*melissa.winterbottom@mail.utoronto.ca* (principal investigator)

*heather.boon@utoronto.ca* (research supervisor)

Phone Number_________________
Appendix H: Demographic Survey

1. Gender: M/F

2. What is the profession of your Practitioner?

3. What is your date of birth?

4. What is the population of your city or the nearest town?
Appendix I: Interview Guide

1. What brought you into the chiropractor/physiotherapist’s office on your first day of treatment?
   - How long were you feeling that way?
   - How was it interfering with your life?
   - Was this the first chiropractor that you saw?

2. What else have you tried for your (back pain/neck pain etc.)?
   - If yes: Are you still taking that/ seeing them/doing that?
   - If no: Did you consider trying other options than the chiropractor/physiotherapist?
   - How did you decide to that the chiropractor/physiotherapist was the best option?

3. Before you had your first visit what were you expecting it to be like?
   - Did you have any concerns about seeing the chiropractor/physiotherapist?

4. What happened at your first visit with the chiropractor/physiotherapist?
   - What did you talk about with them?
   - How did this compare with what you were expecting?
   - Did they perform a physical exam before treating you?

5. What did you and the chiropractor/physiotherapist talk about during your first visit?
   - Did they explain how the treatment was going to help you?
   - Did they discuss any downsides of the treatment?
   - Did you ask any questions/what were they/ how were they answered?

6. Were you asked to sign any forms at this visit?
   - Did you have an opportunity to read the forms?
   - Do you remember anything that was on them?
   - Did anyone talk to you about them/ Who?/ What was discussed?
   - Where were you given them/ where did you sign them?
   - What do you think the purpose of these forms was?

7. How could your chiropractor/physiotherapist have better prepared you?
   - Was there anything that happened that you weren’t expecting?
   - After talking to your chiropractor/physiotherapist did you feel like you knew what you were getting into?

8. What advice would you give to someone else who was thinking of going to see a chiropractor/physiotherapist?

9. Is there anything you would like to talk about that we haven’t discussed yet?

10. Is there anything that you would like to ask me?
## Appendix J: Coding Table

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asking Questions</td>
<td>Asking the practitioner questions about their treatment or their health that are not related to risk</td>
</tr>
<tr>
<td>Cost</td>
<td>Any discussion of the cost of treatment, means of paying for treatment, and/or participants financial situation</td>
</tr>
<tr>
<td>Disclosure</td>
<td>Any mention of telling other health care providers about receiving chiropractic care</td>
</tr>
<tr>
<td>Efficacy</td>
<td>Progress or improvements in outcomes that they believe are related to the treatment.</td>
</tr>
<tr>
<td>General Impressions of Clinicians</td>
<td></td>
</tr>
<tr>
<td>Being Heard</td>
<td>Mention of Being listened to by the practitioner</td>
</tr>
<tr>
<td>Confidence/Trust</td>
<td>Believing that the practitioner will help them, feeling comfortable around their practitioner</td>
</tr>
<tr>
<td>Clinician Other</td>
<td>Overall experience and perception of the clinician not already coded for</td>
</tr>
<tr>
<td>Taking Time</td>
<td>Discussion of the amount of time that the practitioner spent with the patient</td>
</tr>
<tr>
<td>Competence</td>
<td>Any mention of the practitioners ability to perform the treatment safely/effectively</td>
</tr>
<tr>
<td>Other Forms</td>
<td>Any forms related to treatment aside from the informed consent form</td>
</tr>
<tr>
<td>Motivation</td>
<td>Explanation for seeing chiropractor including: people who influence the decision, symptoms, medical history, and referral from other practitioners</td>
</tr>
<tr>
<td>Risk</td>
<td>Adverse Event</td>
</tr>
<tr>
<td></td>
<td>Personal experiences with negative, unintended consequences or events that occur during or after treatment that directly related to the treatment</td>
</tr>
</tbody>
</table>

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INFORMED CONSENT FOR CHIROPRACTIC CARE
<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparison</td>
<td>Comparing the risk of spinal manipulation to other procedures</td>
</tr>
<tr>
<td>Concerns</td>
<td>Any emotive language used to describe worries, fears, or issues expressed about the treatment</td>
</tr>
<tr>
<td>Denial</td>
<td>Any mention of not wanting to know about the risks</td>
</tr>
<tr>
<td>Direct Risk Description</td>
<td>Listing and explaining potential risks- not including risks that are listed on the form.</td>
</tr>
<tr>
<td>Discussion</td>
<td>Between the patient and the practitioner about the risks that are directly associated with the treatment. Includes discussion about the informed consent document.</td>
</tr>
<tr>
<td>Downplaying</td>
<td>Any mention of the practitioner avoiding risk discussion or brushing off the importance of risks or making the patient feel uncomfortable talking about it.</td>
</tr>
<tr>
<td>Family/Friend Influence</td>
<td>On the participants perception of risk</td>
</tr>
<tr>
<td>“I didn’t want her to go easy on me”</td>
<td>Anticipation that discussion of risk may lead to more gentle treatment</td>
</tr>
<tr>
<td>Informed Consent Choice</td>
<td>Making a decision about whether to receive treatment based on the risk information</td>
</tr>
<tr>
<td>Content</td>
<td>What’s on the form</td>
</tr>
<tr>
<td>Copy</td>
<td>Whether or not they kept a copy of the informed consent form.</td>
</tr>
<tr>
<td>I don’t remember</td>
<td>Any mention of not being able to recall signing the form or the accompanying discussion.</td>
</tr>
<tr>
<td>Location</td>
<td>That the consent form was signed</td>
</tr>
<tr>
<td>Non-discussion</td>
<td>Mention of not discussing the informed consent document with the practitioner</td>
</tr>
<tr>
<td>Other</td>
<td>All other mention of the informed consent document</td>
</tr>
<tr>
<td></td>
<td>Perceptions</td>
</tr>
<tr>
<td>----------------</td>
<td>-------------</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Perceived</td>
<td>To inform</td>
</tr>
<tr>
<td>Purpose</td>
<td>Waiver</td>
</tr>
</tbody>
</table>

**Media Influence**

On the perception of risks that are directly related to the treatment

**Mitigating Risk**

Patients perceptions of how risks can be mitigated: includes actions that patients and practitioners can take

**Logical**

The patient knew about a risk because it seemed logical or obvious.

**Openness**

Any mention of how upfront the practitioner was about the risks involved in treatment

**Part and Parcel**

The idea that you just have to sign something for any procedure or that there are always risk involved in treatment, “it’s just what you’re supposed to do,” “I don’t think about it.”

**Past Experience**

Experience visiting the chiropractor, prior to the first visit at the teaching clinic

**Predisposed**

Some people are more likely to experience adverse events than others, predisposed to certain risks

**Versus benefit**

Weighing the benefits and the risks of treatment, discounting risk because of pain

**Indirect Risk**

Risks associated with the visit to the chiropractor that are not directly associated with treatment such as falling off the table,
Appendix K: Informed Consent Document for Chiropractic College

CANADIAN CHIROPRACTIC PROTECTIVE ASSOCIATION

Informed Consent to Chiropractic Treatment FORM L

There are risks and possible risks associated with manual therapy techniques used by doctors of chiropractic. In particular you should note:

a) While rare, some patients may experience short term aggravation of symptoms or muscle and ligament strains or sprains as a result of manual therapy techniques. Although uncommon, rib fractures have also been known to occur following certain manual therapy procedures;

b) There are reported cases of stroke associated with visits to medical doctors and chiropractors. Research and scientific evidence does not establish a cause and effect relationship between chiropractic treatment and the occurrence of stroke. Recent studies suggest that patients may be consulting medical doctors and chiropractors when they are in the early stages of a stroke. In essence, there is a stroke already in progress. However, you are being informed of this reported association because a stroke may cause serious neurological impairment or even death. The possibility of such injuries occurring in association with upper cervical adjustment is extremely remote;

c) There are rare reported cases of disc injuries identified following cervical and lumbar spinal adjustment, although no scientific evidence has demonstrated such injuries are caused, or may be caused, by spinal adjustments or other chiropractic treatment;

d) There are infrequent reported cases of burns or skin irritation in association with the use of some types of electrical therapy offered by some doctors of chiropractic.

I acknowledge I have read this consent and I have discussed, or have been offered the opportunity to discuss, with my chiropractor the nature and purpose of chiropractic treatment in general, (including spinal adjustment), the treatment options and recommendations for my condition, and the contents of this Consent.

I consent to the chiropractic treatment recommended to me by my chiropractor including any recommended spinal adjustments.

I intend this consent to apply to all my present and future chiropractic care.

Dated this __________ day of ____________________, 20 __________

Patient Signature (Legal Guardian)  Witness of Signature

Name: ____________________________  Name: ____________________________
(please print)  (please print)  COPA12.08 (ENGLISH)