REPORTING ADVERSE DRUG REACTIONS ASSOCIATED WITH HERBAL PRODUCTS: CONSUMER, HEALTH FOOD STORE PERSONNEL AND PHARMACIST PERSPECTIVES

by

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A thesis submitted in conformity with the requirements for the degree of Doctor of Philosophy
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ABSTRACT

Reporting adverse drug reactions associated with herbal products: consumer, health food store personnel and pharmacist perspectives.

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Background: Natural health products (NHPs) are sold over-the-counter and are often perceived to be safe, despite potential risks. The current Canadian reporting system collects information on suspected adverse drug reactions (ADRs) and suffers from severe under-reporting. As retailers, pharmacists and health food store personnel may be in a position to facilitate collection of herbal ADR reports because of their accessibility to consumers.

Objective: To investigate retailer and consumer responses to herbal ADRs.

Methods: In-depth interviews were conducted with retailers and consumers across Toronto until theoretical saturation was achieved (n=36). Participants were purposefully selected to ensure diverse backgrounds and experiences. Interviews were transcribed and coded for key emerging themes.

Results: Consumers tended to self-prescribe NHPs and were only likely to discuss their NHP use with people they trusted – usually health food store personnel, family and friends. Many consumers did not have good relationships with their conventional health providers, which inhibited discussions about NHP-related ADRs. When consumers did disclose suspected ADRs to retailers, the retailers generally did not report these NHP-related ADRs to Health Canada. Most pharmacists found workplace challenges insurmountable, although pharmacist approaches to herbal ADRs tended to vary depending on their professional disposition. Pharmacists who saw themselves as knowledge generators were more likely to report. Health food store personnel offered generous product return policies and actively returned NHPs
suspected of causing an ADR to the manufacturer. However, they had no knowledge of the Canadian ADR reporting system and thus did not submit any reports.

Conclusion: Consumers tended to disclose suspected NHP-related ADRs only rarely and to retailers with whom they had developed previous good relationships. This highlights the importance of improving patient-practitioner (or retailer) communication. Pharmacists generally did not report ADRs due to workplace challenges, unless they had a very strong professional disposition. These results have important implications with respect to pharmacy education. Health food store return policies resulted in suspected ADR reports to the manufacturers. Manufacturers are mandated to report ADRs to Health Canada, so this finding may have important implications within industry for the future of ADR reporting systems involving herbal products and public health.
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A. THESIS PUBLICATIONS

1. **Walji, R:** Boon, H; Barnes, J; Austin, Z; Welsh, S; Baker, G.R. Consumers and Herbal Product Related Adverse Drug Reactions. *Patient Education and Counseling.* (Submitted June 27 2008)

2. **Walji, R:** Boon, H; Welsh, S; Austin, Z; Barnes, J; Baker, G.R. Pharmacists and reporting of herbal product adverse effects: Whose responsibility is it? *Social Science and Medicine.* (In preparation, to be submitted in Sept 2008).

3. **Walji, R:** Boon, H; Barnes, J; Austin, Z; Welsh, S; Baker, G.R. Adverse effect reporting for herbal medicines: A result of market forces. *Healthcare Policy.* (In press).

B. OTHER PUBLICATIONS


<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADR</td>
<td>Adverse drug reaction</td>
</tr>
<tr>
<td>CAM</td>
<td>Complementary and alternative medicine</td>
</tr>
<tr>
<td>d/c</td>
<td>Discontinue</td>
</tr>
<tr>
<td>F/f</td>
<td>Friends and family</td>
</tr>
<tr>
<td>HFS</td>
<td>Health food store</td>
</tr>
<tr>
<td>MD</td>
<td>Medical doctor</td>
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<td>NHP</td>
<td>Natural health product</td>
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<td>PHM</td>
<td>Pharmacist</td>
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CHAPTER 1. INTRODUCTION

Despite the popular belief that herbs and other natural health products (NHPs) are safe, these products are pharmacologically active and therefore have inherent risk. The topic of adverse drug reactions (ADRs) associated with herbs is increasing in importance now that almost seven in ten Canadians have used an NHP at some time in their lives. Seventy-seven percent agree that NHPs can be used to maintain or promote health, while sixty-eight percent consent that NHPs can be used to treat illness. (NHPD, 2005b) Adverse drug reactions (ADRs) are defined as unintended consequences suspected to be related to the use of medicinal products, including herbal medicines. (World Health Organization, 1995) Herbal supplements are complex products where synergistic pharmacokinetic and/or pharmacodynamic interactions are of relevance. (Spinella, 2002; Williamson, 2001) The lack of systematically collected safety information about herbal medicines results in deficiencies in our understanding of the potential risks of herbs and herb-drug interactions.

Due to some concerns about herbal product quality Health Canada increased quality assurance in 2004 by regulating the manufacturing processes of NHPs. (NHPD, 2003) Although the NHP Regulations may increase the quality of herbal products themselves, ADRs can still occur as a result of the products’ pharmacological properties, drug-herb interactions, allergy or inappropriate dosage. ADRs are only identified when reported to appropriate channels such as the Canadian Vigilance Program (CVP) (formerly the Canadian Adverse Drug Reaction Monitoring Program – CADRMP). In Canada, the CVP is a spontaneous voluntary adverse drug reactions reporting program. Under-reporting is the major limitation associated with such spontaneous reporting systems. (Alvarez-Requejo, Carvajal, Begaud, Moride, Vega, & Arias, 1998; Fletcher, 1991a) Several reasons for under-reporting of ADRs associated with herbal
products have been postulated. It is likely that practitioners may not be aware of the reporting system procedures for herbal products or they may have difficulty in obtaining information about ADRs filed by other practitioners. It is also possible that health care providers do not have the time or resources to dedicate to a voluntary task in the face of their other duties. (Green, Mottram, Rowe, & Pirmohamed, 2001; Herdiero, Polonia, Gestal-Otero, & Figueiras, 2004)

One key issue with respect to herbal product ADR reporting appears to be the widespread perception among the public that NHPs are completely safe and thus have no inherent adverse effects. (Boon, Brown, Gavin, Kennard, & Stewart, 1999; Drew & Myers, 1997a; McNeill, 1999; Montbriand, 1993) This is complicated by the fact that many patients who use herbal products do not disclose this use to conventional health care providers. (Boon, Stewart, Kennard, Gray, Sawka, & Brown, 2000; Eisenberg, Davis, & Ettner, 1998; Frank, Godwin, Verma, Kelly, Birenbaum, & Seguin, 2001; Verhoef, Sutherland, & Brkich, 1990) When patients experience symptoms that may be the result of herbal product use or herb-drug or herb-herb interaction, these may never be investigated if the patient does not identify these are ADRs associated with the herbal product or if health care providers are not aware of the NHPs the patient is taking. Patients have been shown to be less likely to report ADRs with NHPs to health care providers than they are to report similar events associated with drugs. (Barnes, Mills, Abbot, Willoughby, & Ernst, 1998) The incidence of herbal ADRs is difficult to determine because they are available over-the-counter (OTC) and are thus often used without direction from a health care practitioner. When a consumer experiences an ADR, they make judgments about whether they think it is related to the herbal product that they have taken. They then decide whether they want to report that event. It is therefore important to examine how consumers identify their adverse drug reactions and how they respond to this situation.
This thesis focuses on real life experiences of consumers who believe they have experienced an ADR to a herbal product and some of the people with whom consumers share their ADR experiences. It will explore in-depth, consumers’ perceptions and experiences as well as investigate pharmacist and health food store personnel responses to consumers who have had ADRs.

1.1 Statement of the problem

It is difficult to estimate the incidence of ADRs associated with herbal products because of under-reporting by health care providers and the fact that consumers’ use of herbal products is often not monitored by a health care provider. In order to understand the risks of herbal products and possible interactions, it is necessary to improve current reporting systems. Literature on ADR reporting primarily focuses on reasons for health provider under-reporting related to pharmaceutical medications, with very little information on NHP ADR reporting. There is also a lack of information that explores consumers’ role in identifying and reporting ADRs. Understanding how consumers and retailers experience and respond to ADRs, and how they make decisions regarding reporting their experiences may aid in the understanding of everyday herbal product use and risk as well as contribute to improvements in current data collection methods.

1.2 Purpose of the research

The purpose of this research was to contribute to an evolving understanding of safety issues associated with herbal products, and more specifically how they are addressed by retailers and consumers. These groups were chosen because NHPs are often self-prescribed so consumer perspectives and reactions to ADRs are considered key to understanding communication about these safety issues. In addition, retailers such as pharmacists and health food store personnel
have access to consumers at the point of sale and therefore are well placed to have exposure to ADR information. To address that purpose and gain an in-depth understanding, qualitative methods of inquiry were employed.

1.3 Objectives

The specific objectives of this study were to:

1. Explore and describe the perceptions about safety issues and reporting of ADRs of pharmacists and health food store personnel at the point-of-sale; and

2. Explore and describe the behaviours and beliefs of consumers with respect to herbal product related ADRs.

Following from the purpose of the research, underlying generative mechanisms that will be explored include: How do patients/consumers respond to an ADR? What makes them decide how to handle the situation and who to talk to? What are the barriers and facilitators to communicating about their ADR? How do pharmacists respond to ADRs? What triggers them to report? What barriers exist to reporting? How do health food store personnel respond to ADRs? What motivates them to respond?

1.4 Structure of thesis

The individual phases of this work, that is, the qualitative components examining consumer and retailer experiences and perspectives, addressed different, but related, aspects of the overall research purpose. When combined, those components form an integrated whole, resulting in an overall thesis that consists of seven chapters. The structure of this thesis is paper-based, which means that papers from each of the three populations studied have been drafted for publication in scientific journals. They will be added to the thesis as submitted and therefore
will repeat methods and some background details. This repetition is a function of the particular type of thesis structure. Details of each chapter are discussed below.

Chapter 1 presents an overall introduction to the research topic. It justifies the need for the research and the approach taken to achieve the stated objectives. Chapter 2 presents a review of the relevant literature, introduces the theoretical perspectives and provides details and justification of the methods used to address the objectives of the research. Chapter 3 presents a comprehensive discussion of the qualitative methodology used for analysis, including a description of the theoretical paradigm and selected key methodological challenges.

Chapters 4, 5, and 6 present the results of the research. Each chapter is written as a complete paper and includes an abstract, research questions, background/introduction specific to the chapter, methods, results, discussion, and/or conclusion. Chapter 4 provides the results of the phase of research conducted with consumers. Chapter 5 presents the phase of research conducted with health food store personnel. Chapter 6 documents the results of research conducted with pharmacists.

By integrating the findings of each of the individual papers, Chapter 7 provides a discussion that addresses and answers the goals of the research. This chapter also makes recommendations for further research as they apply to the findings and discusses limitations of the research. Lastly, it presents the conclusions of the thesis.
1.5 References


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CHAPTER 2. LITERATURE REVIEW

The purpose of this chapter is to critically review the published literature on herbal adverse drug reactions (ADRs) and provide context for the study. Current understandings of adverse drug reactions have been derived from research on pharmaceutical products, both prescription and over-the-counter. Thus, the literature was reviewed with the purpose of providing a framework through which to understand the occurrence of adverse drug reactions, how they are managed by patients and practitioners, and the unique environment around herbal and other natural health products. There is also a discussion of the theoretical framework used for this study.

2.1 Adverse Drug Reactions

ADRs are defined as unintended consequences suspected to be related to the use of medicinal products, including herbal medicines. (World Health Organization, 1995) Spontaneous reporting systems, such as the Canada Vigilance Program (previously named the Canadian ADR Monitoring Program), are used by many countries as a way of collecting information about suspected ADRs. Voluntary reports of suspected serious or unexpected ADRs, and those associated with recently marketed products are particularly encouraged. (Fletcher, 1991b) The reports typically contain information about the symptoms associated with the reaction, the dose of the drug or product used, any concomitant medications and other relevant information related to the reaction. For a copy of the ADR reporting form, refer to Appendix L. Health Canada accepts all reports of suspected ADRs, with an emphasized priority on serious and undocumented reactions.

Reporting of ADRs to spontaneous reporting systems is estimated at under 10% of ADRs that occur. (Hazell, 2006) In contrast to Canada’s voluntary system, compulsory ADR reporting
exists in countries such as France and Sweden. However, it is not clear how this requirement is enforced (Wilholm, 2002) and these systems also suffer from severe under-reporting. (Hazell, 2006; Backstrom, 2004)

In Canada, physicians, pharmacists, other healthcare providers and consumers are encouraged to submit reports which are assessed by Health Canada to identify product safety concerns that require action. The goal of the preliminary evaluation is to assess the likelihood of an association between the reaction and the health product. Typical information which must be taken into account includes the frequency, severity, plausibility, quality of the information contained in the ADR reports, amount of product used, time needed for appearance of the reaction, underlying diseases, simultaneous use of other medications, and evidence of disappearance or reappearance of the reaction once the product was discontinued or reintroduced. Additional investigative studies and consultations with other regulatory agencies are often necessary to confirm the health product-ADR relationship. If action is needed, Health Canada may require changes/additions to product labelling, dosing, or removal of products from the market.

Although NHPs are widely used, few ADRs are reported to pharmacovigilance systems. (Barnes, 2003; Green, Mottram, Rowe et al., 2001; Health Canada, 2007) What is not clear is whether the small number of reports received by Health Canada indicates that NHPs are so safe there is very little to report or simply reflects that fact the NHP-related ADRs are under-reported. It is well established that under-reporting of suspected ADRs is an important limitation of spontaneous reporting systems. (Fletcher, 1991b; Mann & Andrews, 2002; Rogers, Israel, Smith, Levine, McBean, Valente et al., 1988)
Previous research indicates that health care providers tend not to report ADRs associated with conventional drugs. (Charrois, Hill, Vu, Foster, Boon, Cramer et al., 2005; Inman, 1985) Health professionals appear to be more likely to report ADRs if they: a) see the reaction as serious; are confident that the product caused the reaction; b) are not busy; c) received continuing education about ADR reporting; and d) have been motivated to report ADRs in the past and if there is a specialist in ADR reporting on staff. (Green, Mottram, Rowe et al., 2001; Lee, Chan, Raymond, & Critchley, 1994; Sweis & Wong, 2000) Workplace challenges, such as lack of time, are cited as major obstacles for ADR reporting. (Granas, Buajordet, Stenberg-Nilsen, Harg, & Horn, 2007; Inman, 1996; Irujo, Beitia, Bes-Rastrollo, Figueiras, Hernandez-Diaz, & Lasheras, 2007)

Under-reporting is likely to be greater for herbal medicines and other NHPs than for pharmaceutical drugs. Safety monitoring is more difficult for herbal products than for conventional medications for many reasons. (Barnes, 2003) In particular, NHPs are often perceived as completely safe, and self-prescribed without advice of a qualified practitioner. It appears that patients are less likely to report ADRs due to herbal products than similar events due to pharmaceuticals, possibly because they consider ADRs associated with herbal medicines to be less worrying or because they do not think that herbal ADRs should be reported to conventional healthcare professionals. (Barnes, Mills, Abbot et al., 1998) Healthcare professionals are therefore often unaware of patients’ NHP use (Barnes, 2003; Barnes, Mills, Abbot et al., 1998; NHPD, 2005b; Wheaton, Blanck, Gizlice, & Reyes, 2005; Winslow & Shapiro, 2002), how to identify ADRs associated with NHPs and what to report (Charrois, Hill, Vu, Foster, Boon, Cramer et al., 2007; Herdiero, Polonia, Gestal-Otero et al., 2004). In Canada, NHPs have only been categorized as medicinal products and regulated by Health Canada since January 2004.
(NHPD, 2003) It is unclear whether the lack of NHP ADR reports suggests that they are truly rare, or reflects a history of inadequate effort (in Canada and internationally) to encourage, collect and assess reports of NHP ADRs.

2.2 Unique field of NHPs

NHPs make up a distinct class of products that are extremely diverse in composition and are available over-the-counter (OTC), without a prescription. This means that they, like other OTC products, are widely available and can be used at the consumer’s discretion. Several aspects unique to natural health products are not adequately addressed in literature on pharmaceutical medications. Most models of safety monitoring depend on physician contact and follow-up with patients. They also depend on pharmacist records of dispensing those medications. NHPs on the other hand, are similar to OTC products in that they are available without physician and/or pharmacist interaction. In light of this fact, studies evaluating NHP adverse events need to be modified to account for differences in exposure information collection, direct advertising to consumers, event incidence recording methods, risk factor identification and definitions of adverse events for NHPs specifically. For instance, when a consumer purchases the NHP, there need not be input from health care providers because the NHP is available over-the-counter – the patient is free to self-prescribe. This means that there is a lack of recorded exposure and event incidence information in the health care community. It also means that patients may be taking products while unaware of potential risks or contraindications. The availability of NHPs without a prescription also means that manufacturing companies are free to market their products directly to the consumer. Research that specifically evaluates the use of OTC medications relies on sales information for the product to provide baseline exposure information. These models identify the store location, which product was sold, the number of
units sold and the date. While these OTC monitoring models are able to identify demand and annual cyclical trends, there is no mechanism to identify patient characteristics and thus they cannot identify adverse events associated with those products.

Herbal NHPs are unique in that they may have natural variation based on environmental conditions during growth, harvest and storage, which can affect the concentration of active constituents and the profile of constituents present. (Barnes, 2003) These variations create differences in the products used and may impact the incidence of adverse events. In some cases adverse events have been associated with NHPs contaminated with pesticides, heavy metals, toxins. (Chan, 2003; Ionnides, 2002) Health Canada implemented regulations to increase quality assurance on the manufacturing processes of NHPs. (Fitzpatrick, 2004; NHPD, 2003) These regulations will help to ensure the quality of NHPs themselves, but they will not be completely implemented for several years. Even when quality can be assured, NHPs are often manufactured as standardized extracts or concentrated forms of particular herbal constituents. The chemical composition of these products, their biochemical properties as well as their potential for interaction with other NHPs and drugs may impact adverse event incidence. Furthermore, regulatory differences and patient perceptions of the overall safety of NHPs differentiate them from other OTC drugs. Current research therefore, on OTC drugs and pharmaceutical medications is not necessarily applicable to NHPs.

2.3 Safety of NHPs

NHPs are complex products that have important pharmacological properties. (Spinella, 2002; Williamson, 2001) ADRs may occur when the product is used alone, or when used in combination with other products or drugs. The incidence of adverse events due to NHPs and NHP-drug interactions is difficult to determine because they are available over-the-counter and
are thus often used without direction from a health care practitioner. Risk associated with the use of NHPs generally increases in patients who have confounding health, genetic and environmental factors, including those engaging in polypharmacy. (Foster, Arnason, & Briggs, 2005) A toxicological study conducted at the Guys’ Hospital in London identified 785 possible or confirmed adverse events (out of 1297 symptomatic inquiries) associated with the use of traditional and herbal remedies and dietary supplements in a 5-year period (1991-1995) reported to the National Poisons Information Service (London) (NPIS(L)). (Shaw, Leon, Kolev, & Murray, 1997)

The need to evaluate NHP safety and efficacy is becoming more urgent especially since there is an increasing amount of evidence regarding adverse events associated with certain NHPs. (Williamson, 2001) For example, there have been safety concerns with herbs such as black cohosh, ephedra and kava. (Dasgupta & Bernard, 2006; Health Canada, 2005; Wooltorton & Sibbald, 2002) Anecdotal and literature reports of adverse events and clinical studies with NHPs are increasing; however, they are often conflicting because of confounding factors influencing the production and use of NHPs. In the past, adverse effects, sometimes life threatening, have been associated with NHPs contaminated with pesticides, heavy metals, and toxins. (Chan, 2003; Ionnides, 2002; Koh & Woo, 2000) With improved regulation, it is hoped that safety concerns due to poor quality products will be less common.

2.4 Consumer reporting

The decision to report an adverse event appears to be based on the user’s perceptions of the severity of the adverse event as well as having access to resources to help report that event. Resources are available for the public should they experience an adverse event. Reports can be filed through a health care practitioner or directly to Health Canada. Knowledge of these
existing resources and access to them may influence whether or not an adverse event is reported. For example, if a consumer consults their health practitioner for advice on the products and potential interactions or contraindications, it may impact how the product is used, which then influences the likelihood of experiencing an adverse event.

Patient beliefs about the general safety of NHPs may impact whether or not they report an adverse event. It has been shown that patients are less likely to report adverse events associated with NHPs than with conventional OTC medicines. (Barnes, Mills, Abbot et al., 1998) Furthermore, patients may not discuss NHP use with medical doctors because they expect a negative response from their doctor. (Hsiao, Hays, Ryan, Coulter, Anderson, Hardy et al., 2005) If they believe in the general safety of NHPs and do not disclose use to their medical doctors, this may decrease the likelihood of reporting any adverse events.

2.5 Retailers and NHPs

2.5.1 Health food store personnel

Herbal medicines and other NHPs are available over-the-counter in Canada at community pharmacies, grocery outlets and health food stores (HFS), as well as from the internet. The Canadian regulatory status of NHPs (i.e. non-prescription, non-‘pharmacy only’) has provided an opportunity for HFS to respond to public demand, entering the market with a wide product selection. There are approximately 2700 HFS (typically, retail outlets where at least 50% of stock comprises NHPs and/or health foods) across Canada, mostly in the provinces of Ontario, Quebec and British Columbia. (Canadian Health Food Association, 2005) HFS may be independently operated or belong to a retail chain with multiple outlets city or nationwide. There are no legal requirements regarding educational background or training for staff, and each store has different requirements ranging from online courses or in-store training/mentoring to no
training/experience requirements. (Glisson, Rogers, Abourashed, Ogletree, Hufford, & Khan, 2003; Mills, Singh, Kawasaki, Bast, Hart, Majlesi et al., 2003) Research evaluating the quality of advice given by health food store personnel has illustrated the lack of standardization in training, which may result in poor quality recommendations, potentially leading to ADRs. (Brazier & Levine, 2002; Glisson, Rogers, Abourashed et al., 2003; Mills et al 2003; Koren et al 2006)

Although HFS are an important source of NHPs, their staff do not have a defined role in monitoring the safety of the medicinal products they sell. (Healey, Burgess, Siebers, Beasley, Weatherall, & Holt, 2002) Rather, their business is providing health-related products, meeting customer demands, and providing adequate customer service to remain viable in a competitive marketplace. In contrast, conventional healthcare professionals (e.g., doctors, pharmacists) are bound by professional and ethical standards to report serious or unexpected instances of suspected ADRs.

2.5.2 Pharmacists

Pharmacists can also be considered retailers of NHPs which are routinely sold at community pharmacies. As health care professionals, it can be argued that they should be responsible for monitoring ADRs that are associated with these products. (Kwan, Boon, Hirshkorn, Jurgens, Welsh, Cohen et al., 2007) Unique statutes in each province regulate the practice of Canadian pharmacists. Generally, pharmacists are responsible for attending to patients’ drug-related needs. Given that herbal products are now regulated as a subcategory of drugs in Canada, it could be argued that reporting of herbal ADRs falls within the pharmacist’s professional responsibilities, in the same way that reporting adverse reactions for pharmaceuticals does. (Farrell, Ries, & Boon, 2008) Presently ADR reporting is considered by
pharmacist associations as an ethical and moral duty, but is legally still a voluntary task (as is the reporting of ADRs suspected with drugs). (Farrell & Staughton, 1996)

Undergraduate curricula pertaining to NHPs vary widely across North America (Chang, Kennedy, Holdford, & Small, 2000; Johnson, 2007; Mackowiak, 2003; Shields, McQueen, & Bryant, 2003) and as a result, many pharmacists appear to have little knowledge of NHPs. (Byrne, 2008; Johnson, 2007) While pharmacists are increasingly being identified as important sources of information on NHPs (Farrell & Staughton, 1996; Kwan, 2006), this role is not supported by their actual training in NHPs. (Kwan, 2006)

Research indicates that the majority of consumers and pharmacists agrees that pharmacists need to be knowledgeable about NHPs. Consumers identify the informative role of the pharmacists as especially important since NHPs can be pharmacologically active and dosing instructions, as well as safety information for NHPs, are often confusing or missing from labels. Trends also indicate that many pharmacists receive questions about NHPs from patients and other health care providers regarding product differentiation, specific indications, and the safety of drug interactions or for patients with comorbidities. (Kalaria, 2003)

There is an expectation from regulatory associations for pharmacists to have knowledge regarding NHPs (Kwan, 2006; Miller, Hume, Harris, Jackson, Kanmaz, Cauffield et al., 2000), and yet only 12% of Canadian pharmacists said they are very satisfied with the quality of information available on herbal products. (Kwan, 2006) Overall, trends indicate that pharmacists’ knowledge about NHPs in general is low. (Kwan, 2006) Pharmacists themselves do not feel their knowledge of NHPs is adequate to make recommendations regarding use (Kwan, 2006). In addition, the rate of documenting, monitoring and inquiring about patients’ use of NHPs by pharmacists is low, but pharmacists who received training in alternative medications
or worked in in-patient settings were significantly more likely to make such inquiries in one study (Kwan, 2006).

Pharmacists’ attitudes towards the safety and efficacy of NHPs also vary widely. (Kwan, 2006) Studies have found that approximately half of the pharmacist respondents felt that NHPs are not safe (Dolder, Lacro, Dolder, & Gregory, 2003; Welna, Hadsall, & Schommer, 2003), while another study showed that many pharmacists described NHPs as having a high degree of placebo effect. (Bouldin, Smith, Garner, Szeinbach, Frate, & Croom, 1999) On the other hand, 19-48% of pharmacists reported thinking that NHPs are effective. (Dolder, Lacro, Dolder et al., 2003; Welna, Hadsall, & Schommer, 2003) These results varied based on the geographical location where the pharmacist practiced as well as the type of herb discussed. Interestingly, more than half of US pharmacists agreed that their colleagues did not accept herbal medicines. These differing attitudes of pharmacists towards NHPs may be important to explore when attempting to explain practice behaviours related to safety monitoring and ADR reporting.

2.6 Overall Theoretical Framework

2.6.1 Critical Realism

This study examined the topic of herbal product adverse event reporting using critical realism, situated within the critical social paradigm. Critical realism asserts that there is a reality independent of our perception of it (Russell, 1945). Reality consists of three levels: empirical, actual and real. The empirical level constitutes the perceptions, impressions and sensations of an experience. The actual level is made up of events and the worldly state of affairs. The empirical and actual are not possible without the real level of underlying structures, mechanisms and powers. (Bhaskar, 1975) In essence, reality is composed not only of events and our experiences or impressions of them, but also of structures and mechanisms, powers and tendencies that may not be directly observable, but nevertheless underlie actual events that we experience. (Lawson,
One of the key defining features of critical realism is that epistemological and ontological matters cannot and should not be collapsed or conflated. (Bhaskar, 1975, 1989; Williams, 2003) That is, what we know and how we know it (epistemology) should not be confused with what there is to know (ontology). Critical realism is therefore based on the ontological claim that the world exists independently of our thoughts or knowledge about it, and hence the meanings we place upon it. (Schmidt, 2001; Williams, 2003; Wilson & McCormack, 2006) In the context of this study, it follows that the concept of adverse events is more than a social construct. Labels such as “side effects”, “negative reactions” or “healing reactions”, describe how people view the phenomenon, but they do not themselves constitute the phenomenon. This study therefore presupposed the existence of adverse events, but attempted to discover how retailers and consumers understand and respond to this independent event.

In particular through the study, a focus was placed on comprehending generative mechanisms behind adverse event reporting. Generative mechanisms, in critical realism, refer to the structures and relations that explain how things work beneath a surface, or observable, appearance. (Bunge, 1997; Fleetwood, 2001; Harre, 1970; McEvoy & Richards, 2003; Pawson & Tilley, 1997; Sayer, 2000) However, in the real world it cannot be said that the pharmacist will always and in every case ‘cause’ a report to be filed – what if the patient does not communicate his/her symptoms to the pharmacist? What if the pharmacist is too busy to file the report? The understanding of underlying generative mechanisms, the powers or tendencies of the pharmacist to file a report, is both complex and deep. The principle research objectives for this study will thus be focused on attempting to uncover the generative mechanisms underlying consumer and retailer responses to ADRs.
Within this overall theoretical paradigm, this thesis draws on a number of different theoretical traditions, discussed below.

2.6.2 Theoretical Traditions

2.6.2.1 Consumerism

Decision-making in health care has been classified into three categories: paternalistic, shared and consumerist. (Murray et al, 2007) In paternalistic models, doctors make health care decisions based on what they believe to be in the best interests of the patient. In shared models, the physician and patient deliberate together to determine the best course of action. In the consumerist model, the patient makes his/her own decisions about health care. Technology and the trend towards health promotion may have resulted in more individuals preferring the consumerist model of decision-making. Consumerist theories are based on the principle that health care can be considered to be a commodity like any other consumer good. Many individuals are empowered to function as consumers when making choices about health maintenance and disease prevention activities. Since they view health care as a commodity, where it has been argued that the ‘new consumer’ is less willing to settle for instructions on how to behave. (Lupton, 1997) Instead the new consumer challenges his/her physician with questions about how and why s/he is taking a treatment, rejecting traditional expectations that “patients” will be passive. (Lupton, 1997; McDonald, Mead, Cheraghi-Sohi, Bower, Whalley, & Roland, 2007)

When individuals are behaving as consumers, expert knowledge in areas such as medicine and science is no longer simply accepted at face value but rather is open to skepticism and to challenge on the part of lay people due to an increasing public awareness of the uncertainties in science (Beck, 1994; Lupton, 1997a). In the area of complementary and alternative medicine, it has been shown that patients are unlikely to discuss their use of herbal
products with their doctor (Barnes, Mills, Abbot et al., 1998). This is often because of perceived negative attitudes of the health care provider or a strained doctor-patient relationship (Barnes, 2002; Winslow & Shapiro, 2002). The ‘new consumer’ is defined as being: information strong, information seeking, and increasingly demanding (Herzlinger, 1997; Traulsen, 2004). The public is more literate, better educated, and has access to more information resources than in the past (Traulsen, 2004). Canadians are also known to spend a lot of time doing research on medical information via the internet (Zamaria, Caron, & Fletcher, 2005).

Consumerism has been found to represent a significant challenge to medicinal surveillance. (Hibbert, Bissell, & Ward, 2002) Consumers seek out their own information regarding NHPs and many turn to “less informed sources” such as family, friends or the internet for advice, instead of consulting with a health care practitioner (Rowell & Kroll, 1998). It is argued that consumers turn to informal networks for NHP information largely because they believe that NHPs are “safe” because they are made from natural ingredients (Bailey, Cohen, Steblecki, Boon, Kurata, & Jantzi, 2008; Boon, January 16, 2008; Brown, Barner, & Shah, 2005; Miller, Hume, Harris et al., 2000; NHPD, 2005a), and can be trusted based on historical acceptance/traditional use (Boon, January 16, 2008; Kondro, 2004; Miller, Hume, Harris et al., 2000). This trend towards finding informal sources of information rather than discussing choices with health care providers makes safety monitoring more difficult.

2.6.2.2 Market forces

Marketing theories provide yet another perspective that informs the study described in this thesis because many NHPs are purchased in health food stores that are primarily guided by market forces. Market force theories are focused on explaining factors such as market transparency, warranty and the consumer experience of goods in consumer purchase decisions.
For example, marketing studies find that money-back guarantees are valuable to consumers because they reduce the purchase risk of finding a good product match or a product of good quality. These guarantees can signal a seller’s confidence in the quality of their products. (McWilliams & Gerstner, 2006) The economic rationale for return policies is that of warranty. Return policies insure customers against products that they are uncertain about, making risk-averse customers willing to pay for the product. (Che, 1996) The “no-questions-asked” full refund policy is customary with many retailers. In these cases, the rationale has to do with their “experience good” nature. That is, customers don not fully know their preferences for the products until after they gain some experience with them. (Che, 1996) Return policies allow customers to defer their purchasing decisions until after gaining some experience with the products. A customer who is dissatisfied can nullify his or her purchase decision by returning it.

In the case of herbal medicines, the uncertainty of the product’s benefit and the wide range of product options may create uncertainty in the buyer’s mind. From a retailer’s perspective, the strategy of offering a risk-free method to purchase self-prescribed NHPs, is an important way to maintain a good customer relationship. This customer relationship then facilitates friendship forming with the retailer, building trust and enabling a free flow of information. (Price & Arnould, 1999) Relevant to this thesis is the flow of safety information and the creation of a “safe” environment in which to discuss safety concerns.

2.6.2.3 Professions theory

A third perspective relevant to this thesis is that of professions theory. Pharmacists’ scope of practice (and the place of adverse event reporting therein) can be better understood by drawing on Abbott’s system of professions theory and conceptualization of jurisdiction. Jurisdiction refers to the link between a profession and its work. Abbott argues that members of
professions define their jurisdiction by claiming exclusive rights over particular tasks. (Abbott, 1988) In the case of ADR reporting, it is a task that was not claimed by pharmacists per se, but instead was conferred upon them by Health Canada. Pharmacists are not claiming exclusive rights over this task, it is a shared tenancy between pharmacists, medical doctors and other health care professionals. It is not an obligatory requirement in Canada (although is in some countries), but rather a voluntary act to be performed in the interest of advancing product knowledge and safety of health care overall. Since Abbott describes a system of professions where the allocation of tasks is negotiated and then exclusively claimed by one, his theory informs the research, but is not enough to fully contextualize the findings.

Understanding professions theory is important in order to characterize pharmacists’ role as health care providers in the area of NHP safety monitoring. However, Abbott and other professions literature theorists explain professional conduct in terms of the entire profession, perhaps in relation to other professions, as a whole and somewhat consistent unit. In ADR reporting, it is important to recognize that pharmacists may act differently based on individual characteristics or perceptions, despite what is expected of them as a pharmacist in that profession. Thus, it is necessary to review one final theoretical perspective as guidance for this study.

2.6.2.4 Bourdieu’s Theory of Practice

Although not a theoretical perspective that was originally used to design the study, Bourdieu’s theory of practice (Bourdieu, 1977) was identified near the end of data collection and analysis to be a useful way of helping to understand the pharmacists’ descriptions of their beliefs and behaviour. Bourdieu’s logic of practice emphasizes the importance of practices within the social world. According to Bourdieu, people (who are social agents) operate according to an
implicit practical logic – a practical sense – and dispositions. That is, they act according to their “feel for the game”, or their habitus within a particular field. For Bourdieu, the modern social world is divided into “fields”, social arenas in which people maneuver and struggle in pursuit of desirable resources, or capital. (Bourdieu, 1986) Habitus can be defined as a system of dispositions (lasting, acquired schemes of perception, thought and action). Each individual develops these dispositions in response to objective conditions her or she encounters. Bourdieu developed a theory of the action, around the concept of habitus, which seeks to show that social agents develop internal strategies that are adapted to the needs of the social worlds that they inhabit. After examining the data from the pharmacist group, it was apparent that there seemed to be a continuum of pharmacist practice behaviours. We had difficulty explaining pharmacists’ positions along this until we began using Bourdieu’s theory of practice. The concepts of habitus and field helped to situate our findings within this theory and enabled us to explain pharmacist behaviour in the context of ADR reporting. The usefulness of this theoretical perspective is further developed in chapter 6.

2.7 Conclusions

Despite the existence of literature discussing ADRs and ADR reporting, with regards to NHPs, there exists a considerable lack of definitive data on the safety profiles of these products. Missed information due to lack of data collection ability for OTC products generally and in particular for NHPs, makes regulation and monitoring extremely difficult. Compounding these issues is the fact that consumers often believe that NHPs are safe and thus do not discuss them with health providers prior to use. This results in the possibility of inappropriate dosage regimens or possible drug interactions, resulting in particular from self-prescribing. This study is needed to explore ADR reporting from consumer and retailer perspectives to understand key
themes and issues surrounding the barriers to improving our ability to collect information about ADRs associated with herbal products. In-depth information is required, through qualitative research, to allow a better understanding of the complexities involved in this topic.
2.8 References


CHAPTER 3. METHODS AND METHODOLOGY

3.1 Qualitative Methodology

Qualitative methods were best suited for this study because it was necessary to explore retailer and consumer perspectives in sufficient depth to allow an understanding of the issues at hand. Retailers and consumers had valuable experiences and exposure that shed light on this complex issue, in particular because the population of herbal product users is so diverse (Park, 2005) and difficult to study. Additionally, herbal products themselves constitute a highly contextualized category of medicines, in that they have their own unique classification and perceptions associated with them. Consumers, health professionals and retailers alike have different perspectives about natural products than they do about drugs. (Barnes, Mills, Abbot et al., 1998; Health Canada, 2005; Hsiao, Hays, Ryan et al., 2005) Other pharmaceutical research is therefore not directly applicable to the herbal medicine context. What is known from previous literature is that people use herbal medicines, and that they experience adverse events. (Drew & Myers, 1997b; Eisenberg, Davis, & Ettner, 1998; Health Canada, 2005) The gap in literature consists of how those adverse events are experienced empirically and how they affect reporting behaviour. (Bond & Hannaford, 2003; Ernst & Barnes, 1998) This study focused on retailer and consumer insights as well as their reporting behaviours after exposure to an adverse event. Qualitative methods are thus best suited for these unexplored, complex and contextualized generative mechanisms.

3.2 Methods

This study employed semi-structured interviews (Creswell, 1998a), which were conducted with retailers: pharmacists and health food store personnel; as well as consumers, in order to discover how they understand the topic of adverse events and reporting systems. As per
our methodological paradigm, critical realism, the study was not designed as an investigation of “what adverse events really are”, but instead focused on what retailers and consumers “claim to know” about adverse events and their processes, as well as both groups respond to them. This differentiation is essential to critical realism whereby there is a distinction made between what reality is and how reality is interpreted.

3.2.1 Sample

The sample was purposefully selected in order to obtain a diverse range of opinions. (Creswell, 1998a) Whilst seeking truth, critical realism recognizes that different representations of truth can exist through different perspectives. (Dzurec & Abraham, 1993) Thus each perspective, although potentially different, was seen as a valid account of the phenomena. (Proctor, 1998) Interviews were conducted with pharmacists (n=12), health food store personnel (n=12) and consumers (n=12). To be included in this study, participants had to satisfy the following criteria:

**Pharmacists**

- Practicing in a community pharmacy that sells herbal products, within the Greater Toronto Area.
- Able to conduct an interview in English.

Participants were selected to obtain a sample that included participants with a range of number of years in practice, number of hours working per week, gender, training and geographical location of work. Interviews took place between June 2006 and May 2007. Of the pharmacists recruited: 9 of 12 were female, 8 had been in practice for over 5 years; 9 were working full time; and 9 worked in a chain pharmacy.

**Health food store personnel**
• Working in a community health food store\(^1\) that sells herbal products, within the Greater Toronto Area.

• Able to participate in an interview conducted in English.

Participants were selected to obtain a sample that included participants with a range of number of years in the field, number of hours working per week, gender, position in the store (managers, owners, sales clerks), and training and geographical location of work. Interviews took place between July 2006 and June 2007.

Of the 12 health food store personnel recruited: 8 were female; 4 were owners or managers while the rest were sales staff; 4 had worked for over 5 years in the business; 3 had formal training in complementary and alternative medicine; 3 worked in a large chain, 4 worked in a small chain and 5 worked in an independent health food store.

**Consumers**

• Have self-identified as having had an adverse event to a natural health product\(^2\)

• Able to participate in an interview conducted in English.

We originally tried posters, listservs and other methods to obtain a sample of consumers that had experienced a suspected adverse event and varied with respect to sociodemographic characteristics. However, due to the difficulty in finding anyone who had experienced a suspected adverse event that was willing to be interviewed, a purposive sample could not be recruited. Instead, the project began with a convenience sample of contacts from friends and colleagues, which was then expanded using the snowball technique to recruit enough participants to reach theoretical saturation in the key emerging themes. The convenience sample of

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\(^1\) Health food store was defined as any store that sold at least 50% natural health products, with or without foods, including chain stores and independent stores, not including pharmacies, specialty stores (such as those that sold only traditional Chinese medicines).

\(^2\) The definition of natural health product was taken to include anything that the patient identified as a natural health product, not necessarily coinciding with Health Canada’s official definitions.
participants from the university and the researchers’ social contacts were not key informants per se, as they were not individuals who could provide unique insight into the experience of an suspected NHP-related adverse event. However, the contacts were able to discuss the project with family and friends, which led to recruiting of their contacts. The snowball technique is a sampling strategy that consists of seeking referrals from participants, where one participant gives the researcher the name of more possible participants. (Creswell, 1998a) This technique is used in populations where it is difficult to identify potential participants. Interviews were conducted in person where possible and over the phone for long-distance participants. Interviews took place between September 2007 and December 2007.

Of the 12 consumers recruited: 11 were female; 4 described their reaction as mild while 5 described it as moderate and 3 described it as severe. Their ages ranged from 22-43 years.

3.3 Data Collection

A letter introducing the study was given to all participants (see Appendix A and B). After several failed attempts at sending the letter by mail and by fax, potential participants were approached in person at the respective retail outlets to deliver the letter. Consumers were contacted by phone, email and in-person after a referral during the snowball technique. After answering questions about the study, written informed consent (see C and D) was received by each participant in-person, by mail or by fax and a mutually agreeable time was arranged to conduct the interview. Telephone interviews were only conducted with the few consumers who resided outside of the Greater Toronto Area. Otherwise, all other consumer interviews and all retailer interviews were conducted in person.

Before the interview, the researcher: explained the purpose of the study; described the amount of time it would take to complete the interview; informed the participant that they could
withdraw from the interview at any time or refuse to answer any questions; discussed how the data would be used; explained that the interview would be transcribed; and addressed any questions the participant may have had.

All interviews for this study ranged from 30 minutes to 90 minutes and data collection continued until saturation was reached in key emerging themes. Saturation is the point at which no new themes emerge from the data. (Guest, Bunce, & Johnson, 2006; Patton, 1990) Interviews were audio-taped and transcribed verbatim.

Interview questions were developed based on key sensitizing concepts from the literature on NHPs and ADR reporting. (See Appendix E and F) In addition, input from professionals in the field (the thesis committee) was included and the semi-structured interview guide was enhanced. After the first few interviews, interview questions were adjusted to include key emerging topics for subsequent interviews based on the experiences from previous interviews. While the questions covered the core areas of our interests, respondents were encouraged to add their own comments and opinions. On completion of the interview, respondents were asked if there was anything that they wanted to add or was there anything that was not discussed about which they would like to comment.

3.4 Analysis

Interview transcripts were transcribed verbatim into written text and entered into a qualitative computer software program NVivo 7 (Richards & Richards, 2002a) for analysis. Participant responses to the semi-structured interview questions were analyzed using interpretive content analysis (Huberman & Miles, 1994). Interpretive content analysis is an iterative process that facilitates analysis of text describing processes, activities, perceptions and beliefs. It is these processes, activities or beliefs that represent a collection of symbols expressing layers of
meaning. The analysis involved uncovering those layers of meaning and relationships among phenomenon described by participants in order to understand the generative mechanisms behind their actions.

The interview transcripts were analyzed for repetitive themes and relationships among these themes. While the interview guide determined the general content of the interviews, the broad range of themes and relationships among them could not be identified ahead of time but emerged from the data analysis. Each transcript was coded independently by a minimum of two investigators using content analysis (Huberman & Miles, 1994). The thesis committee also reviewed the themes that emerged from interviews and provided input on the coding tree. (See Appendix G, H, I and J) Data analysis was performed throughout the data collection period in order to enable adjustments of the interview questions to address new issues or topics that emerged from earlier interviews (Creswell, 1998b).

3.5 Privacy

All of the information collected for this study was kept strictly confidential. The participants’ names were not used during the research process. A professional transcriber was hired to transcribe interviews. The participants were identified by a unique study identifier code to ensure privacy, and the names of persons and organizations identified in the interviews were removed from the transcriptions. All of the data are kept on a password-protected computer known only to the researchers. No information was released or printed that would disclose any personal identity. Tape recordings and transcriptions will be kept in a secure locked cabinet for eight years at the University of Toronto and will then be destroyed. To ensure confidentiality, no names or identifying information will be presented with the quotations in any reports of study results.
3.6 Methodological Issues

3.6.1 Positionality

A key facet of qualitative methodologies has been the importance of recognizing the role that positionality plays in research. (Maton, 2003; Skelton, 2001) Positionality refers to those aspects of identity, for example race and gender, which indicate the frames of reference from which researchers collect, organize, disseminate and preserve information. (Waxman, 1993) As the main instrument of the study, my position as the researcher has implications for how I might regard and represent the world. This is so because my adopted position based on my position in the field affects every phase of the research process, from the way I originally construct the research question, design and conduct the study, to the ways in which reports and publications arising from the study are presented. (Borbasi, Jackson, & Wilkes, 2005) I also have a commitment to a particular social agenda, in this study, policy improvement. As the researcher, my views and experiences will weigh heavily on my approach to interviewing, analysis and interpretation. It is therefore necessary for me as a researcher to reflect upon my own identity and positionality.

I am a female researcher, with South Asian heritage. I have graduate level education and have been trained as a Naturopathic practitioner. My background, my training as a health care professional and my specialty in complementary and alternative medicine will play a role both in the data collection process as well as in my analysis. In the informed consent forms, my designation as a Naturopathic Doctor and a PhD student were clear. When introducing myself to participants, it was more productive with respect to recruitment to highlight my status as an ND to health food store personnel and as a pharmacy graduate student to pharmacists. With respect to consumers, I explained my position as a researcher. With regards to data collection, my
positionality may have consequences for the kind of knowledge that I may obtain, for instance in relation to the underlying structures at work within my area of research.

For example, from the perspective of natural medicine, while I could be considered an “insider” to health food store personnel for example, I might be considered an “outsider” to pharmacists. This has implications for my recruitment process as well as the opinions that my participants are willing to share. One pharmacist for example, agreed to participate without knowing all the details of my background – he knew only of my position as a PhD student. During the interview, he expressed a strong negative stance against herbal medicines. It is possible that this perspective might not have been articulated if he had known more about my position as a Naturopathic Doctor. In another instance, I contacted a health food store manager to request an interview. During our conversation, I explained that I was a student in Pharmaceutical Sciences and he seemed apprehensive about the interview. As we discussed the research project, I mentioned my interest in herbs and my position as a Naturopath. He immediately changed his tone and agreed to participate.

The above examples demonstrate how my position influenced the research process by impacting generative mechanisms, which may be revealed or hidden during interactions with my participants. These underlying structures or powers are not directly observable, but they influence the actual and empirical levels of reality.

There has been some literature published on the topic of how position influences data collection. Interviewees have been observed to respond differently to interviewers according to their gender, age and social class. (Silverman, 1993; Warren, 1988) It is also important to note that information given to the researcher might be different if the researcher is a health professional. (Barnes, Mills, Abbot et al., 1998; Murphy, Dingwall, Greatbatch, Parker, &
These issues have already potentially impacted my study and as a result, I will need to handle these positionality influences reflexively (discussed in the next section).

Another consideration is my viewpoint when evaluating the data. The characteristics of my identity described above contribute to my specific and situated viewpoint. I have only a partial view of the situation based on my position, and I act accordingly. Positionality can thus also be viewed in terms of ‘spatial’ position. In critical realism, the more perspectives from which something can be viewed, the better. This is because it would help to get a broader, more complete picture of the situation by including different representations of reality. In the analysis process, critical realism demands that I attempt to identify and characterize the actual and real levels of reality by analyzing the empirical level. These experiences and perceptions of the empirical level are relayed via semi-structured interviews from the participants. They constitute both what the participants claim to know as well as my interpretation of their knowledge claims. By using several data sources (from different populations), I enable a different ‘spatial’ position whereby I can evaluate the social context of their interview responses. This gives me a different perspective through which I can consider the data, thus enabling a more comprehensive analysis. The different sources of data collection are thus used not for validation of the findings but instead as different insights into reality. These sources of data will assist in identifying social conflict, and other structural determinants of behaviour. In addition, the fact that more than one person independently coded the data also validated the results.

**3.6.2 Reflexivity**

Reflexive research is characterized by ongoing self-critique and awareness that the research product can be shaped by the politics of location and positioning. (Chatterjee, Noldner, Koch, & Erdelmeier, 1998) It is a strategy to conceptualize whom the researcher is, what is going on
within her, and how a sense of self-consciousness can be put to analytical use. (Aamodt, 1991) Hertz describes reflexivity as scrutiny of a researcher’s interpretations and how those interpretations came about. (Hertz, 1997) The purpose of reflexivity is thus to enhance the credibility of the findings by accounting for research values, beliefs, knowledge and biases. In this study reflexivity will be used as a strategy for maintaining rigor and highlighting my positionality. (Cutliffe, 2003; Hanly & Fitzpatrick-Hanly, 2001; Koch, 1994; Maggs-Rapport, 2001)

Critical realists believe that true scientific objectivity is unattainable. As society is produced by social behaviour, they acknowledge that this behaviour is open to a number of influences. (Proctor, 1998) Critical realists argue for more awareness of these influences rather than for artificially controlling them. Awareness enables the researcher to reflect consciously on his or her role and impact on the research environment and respondents, to develop greater insight, and a greater ability to understand the phenomena. (Strauss & Corbin, 1990) According to Hammersley, an account is valid if it represents accurately those features of the phenomena that it is intended to describe, explain or theorize. (Hammersley, 1992) Given that from a critical realist perspective we have no independent, immediate and utterly reliable access to reality, we must judge the validity of claims on the basis of the adequacy of the evidence offered in support of them. All judgments about the truth of knowledge claims rest on assumptions, many of which we are not consciously aware of, and most of which have not been subjected to rigorous testing. (Hammersley, 1991) This includes the knowledge claims that I, as a researcher, might make about my study.

Rather than treating research findings as reproducing reality, we must recognize that they are a representation of reality. (Hammersley, 1990) My representation will inevitably reflect the
assumptions that I bring to my analysis. As a result, I must make explicit the personal and theoretical assumptions underpinning my work. (Murphy, Dingwall, Greatbatch et al., 1998) In a critical realist study the goal is not to commit the “epistemic fallacy”; that is, not to confuse the knowledge of what exists and that which does exist. Epistemic fallacy allows for the fallibility of knowledge claims and opens knowledge claims to criticism, testing and the need for further improvement. (Carolan, 2005) In order to minimize this fallibility of knowledge claims in my study, reflexivity will be used as a strategy for maintaining rigor. From this perspective, I am particularly concerned that I draw a distinction between my sense of reality and actual reality. My perspective emerges from my interaction with the external world, and thus there is a clear importance of an ‘internal conversation’ about myself, society and the relationship between us. (Rosenthal, Hall, DiMatteo, Rogers, & Archer, 1979) I have realized that my assumptions are not fixed. Over time they have changed with my progress in this project. It was important for me to make my perspectives and assumptions explicit during data analysis in order to assess my findings in light of these views.

In the present study, the focus is on generative mechanisms behind retailer and consumer behaviours in response to adverse events. The retailer perceptions are a key part of the analysis where I, as the researcher, examine not only the episode of interaction, but also the antecedent conditions. (Rosenthal, Hall, DiMatteo et al., 1979) Retailers and consumers respond to certain existing circumstances that have an objective existence, regardless of their perceptions. With this in mind, my analysis was therefore discriminating to the nature of those participating in all aspects of the social interaction. As the researcher, the main instrument of the study, my participation in the social interaction was a key part of the context within which I sought to collect information. Given my broad knowledge about natural medicine, as well as my health
care background, I had a responsibility to assess critically not only the participants’ perceptions, but also my own. I have my own preconceived notions about the generative mechanisms behind retailer behaviours and thus, it was necessary to evaluate my role and my beliefs analytically. I have reservations for example, about the quality of education that health food store personnel have in this field. One of my assumptions was that health food store personnel at the retail level are not trained well enough to recommend herbal products. One of my interviews however, was with a woman who opened a health food store after becoming certified as an herbalist and a nutritionist. Unless I recognized and challenged my own ‘taken-for-granted’ assumptions, there was a danger that I would fail to recognize that my participants might be drawing on a different, but equally logical set of assumptions. (Murphy, Dingwall, Greatbatch et al., 1998) Without a reflexive account I might have been blinded to important data.

Sayer argues that when a critical realist tries to elicit someone’s subjective beliefs about a topic, she could say she is trying to objectively (truthfully) represent his or her opinion. (Sayer, 2000) Sayer also uses subjectivity to refer to the subjective quality of all knowledge. In other words, what the researcher believes to be an objective account of the participant’s opinion is in fact the researcher’s interpretation of the information received. Reflexivity therefore, is a necessary process through which a researcher comes to understand how structural forces shape us as individuals and as members of larger society. (Habermas, 1987)

3.6.3 Rigour

There are several ways to ensure rigour in qualitative research. First, the research questions and methods used should match. (Eakin, 2003) In this study, interviews were deemed most appropriate to explore participant responses to ADRs because interviews allow an open dialogue between participant and researcher without ‘group effects’ such as those found in focus
group studies. Due to the sensitive nature of safety in a retail setting, ADR reporting, and practice behaviours, it seemed more appropriate to have one-on-one conversations with retailers, and pharmacists in particular, than group based discussions. Second, the sampling strategy has been described fully in order to assure the reader that it matches the purpose of the research and to allow others to assess whether the findings may be applicable to their settings. (Giacomini, 2000) In this study, a maximum variation sample was sought, in order to adequately capture all possible perspectives. Third, the role of the researcher needs to be transparent. (Greenhalgh, 1997) In this study, time has been taken to examine the role of the researcher and explicitly reflect on the position of the researcher and her role in the research process as well as the results. This reflection allows for the researcher to be objective about her biases and interpret the data more reliably when looking at it with her own opinions clarified. Fourth, during data analysis two independent researchers coded each transcript and the entire research committee reviewed the themes that emerged before the analysis or conclusions were drawn. (Giacomini, 2000) This strategy of inter-rater evaluation is used in qualitative methods not only as a verification tool but as a way to increase certainty in the emergent themes. Fifth, an audit trail was kept. (Koch, 1994) Records of any changes in the interview guide or coding tree as well as researcher comments during and after the interviews were all noted and those notes maintained. This strategy establishes trustworthiness in the data and the analysis.

3.7 Ethics

In applying for ethics approval, we considered four major ethical concerns: risk, benefit, consent and confidentiality. The study did not involve direct risk to participants since no active intervention was used. Participants were aware that participation was voluntary and that they
could withdraw from the study at any time. Participants were also free to skip any questions with which they felt uncomfortable.

Benefit was explained as an opportunity to inform literature and policy on current ADR issues and concerns. In addition, after participation, interviewees were given the opportunity to ask about current reporting procedures and in order to gain knowledge on the subject. There was no financial benefit to participants in the study.

Each participant gave written, informed consent to participate in the study (See Appendices C and D). The consent form was explained prior to beginning the study and questions were answered. Participants were informed that steps to ensure confidentiality would be taken. Participants were identified in any written reports by numbers only, not by names. Any identifying information was removed from the transcripts and all electronic files were kept password protected, while hardcopy files were kept in a locked cabinet. Each participant was aware that complete confidentiality could not be ensured if the interview took place in a public environment, such as their office at work, where their co-workers might be aware of their participation. However, each interview was conducted in a one-on-one manner in an attempt to ensure that their answers were kept confidential.

This protocol received ethics approval from the Ethics Review Office at the University of Toronto (See Appendix K).

3.8 Presentation of Results

Since this is a paper-based thesis, the results are presented as three distinct papers. Paper 1 (Chapter 4) focuses on the consumer data, paper 2 (Chapter 5) focuses on the health food store personnel data and paper 3 (Chapter 6) focuses on the pharmacist data. The findings from the three groups are compared and contrasted in the discussion (Chapter 7).
3.9 References


Byrne, A. (2008). Natural health products (NHPs) and Canadian pharmacy students: core competencies, Pharmaceutical Sciences, Leslie Dan Faculty of Pharmacy. Toronto: University of Toronto.


CHAPTER 4. RESULTS – CONSUMER INTERVIEWS

Preamble

This chapter was submitted for publication to Patient Education and Counseling on June 27, 2008; it is currently undergoing peer-review.

I, Rishma Walji, performed the entire work as published, under the guidance of Dr. Heather Boon, Dr. Joanne Barnes, Dr. Zubin Austin, Dr. Sandy Welsh and Dr. G. Ross Baker.

Consumers and herbal-related adverse reactions

4.1 Abstract

Objective: Natural health products (NHPs), such as herbal medicines and vitamins, are widely available over-the-counter and are often purchased by consumers without medical advice. This study examined how consumers respond when they experience NHP-related adverse drug reactions (ADRs).

Methods: Qualitative semi-structured interviews were conducted with 12 consumers who had experienced a self-identified NHP ADR. Key emergent themes were identified and coded using content analysis techniques.

Results: Consumers were generally reluctant to discuss their NHP-related ADRs with healthcare providers. When consumers did discuss them, or seek advice, they generally did not turn to healthcare providers but rather personnel from health food stores, friends or family with whom they had developed trusted relationships.

Conclusion: Consumers generally did not report their ADR information to healthcare providers. Passive reporting systems for collecting information on NHP ADRs cannot be effective if consumers who experience NHP ADRs do not report their experiences.
Practice implications: It is important for healthcare providers to develop good communication practices with their patients regarding their choices to take NHPs. This positive interaction can facilitate future discussions if ADRs do occur.
4.2 Introduction

Despite the popular belief that herbal medicines and other natural health products (NHPs) are safe, these products are pharmacologically active and therefore have inherent risk. The need to understand adverse drug reactions (ADRs) associated with NHPs is increasing now that over 60% of all North Americans report using some form of complementary and alternative medicine (CAM) (including herbal medicines) in the management of their health. (Center for Disease Control, 2004; NHPD, 2005) In the United Kingdom, CAM use is estimated at approximately 20%, while in Germany, CAM prevalence rates approach 60%. (Ernst, 2000)

An ADR is a noxious and unintended response to a particular medicinal product, meaning that there is a reasonable possibility that there is a causal relationship between the product and the reaction. (World Health Organization, 1995) In Canada, Health Canada collects ADR reports from healthcare professionals (and less often from consumers) about NHPs through the Canada Vigilance Program. (Health Canada, 2007) Similar systems exist in most other Western countries; however, experiences of (and the incidence of) herbal medicine-related ADRs are difficult to determine because under-reporting of suspected ADRs, a known problem with all passive reporting systems (Waller & Tilson, 2004), may be more substantial for NHPs than for conventional drugs. (Barnes, 2003)

One of the reasons for under-reporting of NHP-related ADRs may be that many consumers believe NHPs are safe because they originate from natural ingredients. (NHPD, 2005) Consumers frequently self-prescribe NHPs, without the advice of a qualified health provider. (Murray, Pollack, White, & Lo, 2007) Increasing consumerism, an environment in which individuals are taking their health matters into their own hands, partly explains this. (Alaszewski & Brown, 2007) Instead of passively following the advice of health providers,
individuals shop around for opinions and advice and increasingly challenge healthcare practitioners with questions about treatments. (Lupton, 1997) If consumers do not find the answers that they want from their health providers, they will turn to other sources of information that they feel are trustworthy or informative, such as the internet.

Since NHPs are non-prescription medicines, experiences of herbal-related ADRs must be reported by consumers to healthcare professionals, or directly by consumers to Health Canada, to be captured by the national reporting system. Since many consumers self-prescribe NHPs, it is perhaps not surprising that consumers appear less likely to report ADRs associated with herbal medicines to their healthcare providers than those associated with conventional over-the-counter drugs. (Barnes, Mills, Abbot, Willoughby, & Ernst, 1998) In this study, experiences of consumers who have what they believe to be an NHP-related ADR and their reasons for choosing to report (or not report) their reactions are investigated.

4.3 Methods

Ethics approval was granted by the Research Ethics Board at the University of Toronto. Twelve in-depth semi-structured interviews were conducted from September 2007 to December 2007 with NHP consumers who had experienced a self-identified ADR associated with an NHP. The participants were recruited from the Greater Toronto area, Ottawa and Vancouver through posters and advertisements as well as through a snowball sampling technique (in which participants were asked to identify other potential participants within their social circles). (Creswell, 1998) Interviews were recorded and field notes were hand-written during and immediately following the interviews. Interviews were transcribed so that the transcriptions and field notes could be coded by two independent coders using content analysis techniques; disagreement was resolved through in-depth discussion. A software program, NVIVO 7, was
used to organize the data. (Richards & Richards, 2002) Data analysis and coding took place throughout the process of data collection. The interview guide was updated and modified after the coding sessions to allow for increasingly detailed data collection in key emerging themes. Theoretical saturation of the key themes was achieved after 12 interviews. (Creswell, 1998)

**4.4 Results**

Participants varied in age and demographic background and had experienced a range of different suspected NHP-related ADRs (see Table 1). The final sample was predominantly female, and highly educated.

Participants described their ADRs by degree of severity – mild, moderate or severe. In medical terminology, ADRs are classified by degree of severity and also as serious or non-serious. Serious reactions are those that are fatal, life threatening (such as liver failure, abnormal heart rhythms, certain types of allergic reactions), result in persistent or significant disability or incapacity, require or prolong hospitalization, are congenital anomalies or birth defects, or are otherwise medically important. (World Health Organization, 1995) All the ADRs experienced by the participants in this study were non-serious, but differed in degree of severity. For details, see Table 1.

The main categories used to classify the themes from this research were: 1) how participants first identified their ADRs and associated them with their NHP treatments; 2) what influenced their likelihood of reporting the suspected ADR to someone; 3) with whom they discussed the suspected ADR. The last two themes were further sub-divided into: taking responsibility for self-prescribing, trust, and access.

**4.4.1 Identifying the ADR**

Most participants chose the NHPs that they associated with ADRs without advice or monitoring from a healthcare provider. Thus, when they experienced the ADR, they took it upon
themselves to interpret the reaction and then to decide how they would act. The main themes in this section related to participants methodically evaluating their reactions in order to determine the cause. They identified that the symptoms they were experiencing were likely related to the NHP after considering the possibility of alternative explanations for the symptoms, for example, changes in lifestyle or behaviour. They also proactively explored causality, for example, by trying a different product and, in some cases, stopping (de-challenge) and then re-starting (re-challenge) the product:

Question: How did you decide that it was the product that caused these things?
Answer: I guess because I’d never taken it before. In terms of actually, like, change in my routine as what I was eating or whatever, that was the only thing I could attribute it to. (Consumer #12)

From using one brand and then switching to another, the fact that they were different brands but they were the same ingredients I was using. They contained the same things. I was just trying another brand and I was still getting the same symptoms and then I also linked it because just at this time when I was taking it, I wasn’t taking any other products at that time. (Consumer #4)

4.4.2 Likelihood of reporting

Participants’ perceived severity of their ADR influenced the likelihood that they would seek help or support. If they perceived the reaction to be mild, they would generally attempt to mitigate the symptoms independently. If the reactions were perceived as being severe, they were more likely to seek information about what action to take from a third party:

Question: What would make you more likely to talk to someone about your reaction?
Answer: I suppose a cardiac event, like, for sure you would want to tell somebody about that. I think that would be significant. If you broke out into a rash, you should probably tell somebody about that. If a product, you know, made you nauseous or dizzy or something like that, you might want to mention that to somebody as well. (Consumer #7)

If the adverse event is mild then it just won’t come up, but if it is severe [meaning serious] and it’s an emergency situation or if it has ongoing repercussions in health then it’s vital that they be disclosed. (Consumer #5)
Interestingly, some participants who experienced what they defined as serious ADRs still did not report the reaction to anyone or seek advice about what to do. Reasons for this are explored below.

4.4.3 Responsibility for self-prescribing

Most participants reported self-prescribing NHPs. Consumers’ decisions regarding how to respond to NHP-related ADRs depended largely on whether or not the participants believed themselves to be responsible for the decision to initiate treatment with the NHP without medical advice. Many felt that since they had independently made the decision to take NHPs, they also had a responsibility to “deal with” the negative consequences of that decision on their own:

We often combine products in a way that it can be detrimental to our health and I believe that this adverse reaction had to do with that more than the product itself… so that just has to do with irresponsible consumption... So yeah, the adverse reaction is my problem. (Consumer #5)

I mean I told my doctor about the [pharmaceutical medication] because he was the person who prescribed it to me. I didn’t tell anybody about the [NHP] because nobody prescribed it to me so I thought, well, I guess I didn’t think that I should tell anyone. I think I just didn’t think I should tell anybody! (Consumer #7)

4.4.4 Trust

Two sub-themes under the category of trust were that consumers experiencing NHP-related ADRs did not report because they did not know who to talk to and/or have anyone they felt they could trust. The decision not to discuss their NHP-related ADR experiences with others was typically related to an effort to hide their actions from people (often physicians) who they perceived would disapprove of their use of NHPs:

I didn’t tell anyone because there wasn’t anyone really to tell about it because I was more sort of trying things on my own. After I figured out what was going on I knew it was me doing it to me, by choosing to take it, I knew that that I was the cause of it but my doctor wouldn’t do anything about it and she would just kind of blow it off so, there would be no point in taking it to her because I just didn’t have a therapeutic relationship with her. (Consumer #10)
Well our family doctor is, sort of, you know, she likes to take things lightly, so in a sense sometimes I feel like I shouldn’t even go so I should wait things out before I talk to her about them because I feel like she’s just going to say the same thing to me, like, oh well, whatever, just go home and have some rest and it will be okay. It’s a matter of, there hasn’t been the time, the time has not been permitted to go into much detail about it. (Consumer #7)

These quotes illustrate the poor relationships many participants had with their conventional medical practitioners, especially when discussing issues associated with NHPs. Most were of the opinion that their healthcare providers (most often physicians and pharmacists) would not support their decisions to try NHPs and this resulted in a lack of communication about suspected NHP-related ADRs:

It lasted all day and you know, I had to give my job interview and stuff so I just was in complete discomfort all day. So I tried to go to the pharmacy and get something… it was a natural product so I knew that it was, like, kind of sketchy already in [the pharmacists’] opinion and so, then her initial reaction when I said [what had happened], I was like, there’s no need for me to discuss this any further. (Consumer #1)

If participants thought their friends and family would understand their decision to use NHPs, they might share their NHP-related ADR experiences with people in their social network. Other participants, who wanted reassurance or guidance about their experiences, would find other advisors whom they felt that they could trust.

I’ve had a doctor tell me that I [the doctor] don’t really believe in all that [NHP] stuff. So I personally wouldn’t bother telling them about my adverse effects. I’d probably just tell the naturopath, or the health food store. (Consumer #4)

Consumers discussed the possibility of approaching other resources such as retailers at the location where they purchase NHPs, usually pharmacists and health food store personnel. Overall, they seemed not to have strong relationships with their pharmacists, which negatively affected their likelihood of reporting ADRs to pharmacists.

Let’s say that I buy something from [drug store name], if I’m not happy with it generally if I can’t return it, or if I’ve used it, I probably wouldn’t take it back or take any type of concern to that particular store because I feel like the people that work there would not
necessarily not care but that they just don’t want to deal with that kind of thing. They have so many other things that they’re selling in that store. It’s just not, it’s not an open and friendly environment to bring stuff to. With regards to smaller stores, smaller health food stores, it’s an environment where the owner always tries to have a good customer relationship. (Consumer #10)

Participants tended to trust their health food store personnel and often had developed good relationships with the staff working in these retail settings. Consumers reported reliance on the health food store staff for information and feeling comfortable talking to them about side effects or problems with their products.

I would trust [staff] more from a health food store because they do - usually the owners of the store have good information and have some knowledge whereby the pharmacies would have nothing, and a pharmacist would probably bash it down anyway! (Consumer #3)

4.4.5 Access

The final theme related to reporting NHP-related ADRs identified by participants was a concern about access. Several participants were concerned about reporting NHP-related ADRs due to fear that the products would be removed from the market if there were reports that they caused negative effects.

It is the only product that I’ve found effective for my health condition. It is something that I feel when used responsibly it doesn’t cause an adverse reaction. There’s a synthetic version of it that has really caused a lot of the hype, and there have been some publicized adverse events related to the herb that do have to do with a combination of things. You know that it shouldn’t be mixed with certain other things. Some adverse reactions have to do with that more than the product itself. And due to this, I think that it jeopardizes the status of products that may be required for certain health conditions and so that just has to do with irresponsible consumption, or production depending on who’s at fault for that. (Consumer #7)

Although Health Canada does accept direct reporting of suspected ADRs by consumers, the consumers interviewed did not seem to know that was an option. The only ones who were aware of their ability to independently report their suspected ADRs were told by their health
providers, or personally had some kind of health care training and were exposed to the reporting scheme through their professions.

4.5 Discussion

Participants in this study all experienced what they perceived to be an ADR associated with an NHP. The products were usually self-prescribed and most participants decided either to handle the situation on their own or, less commonly, to discuss it with someone whom they trusted. The trusted person was typically someone working in a health food store rather than a conventional healthcare provider. Participants’ behavioural responses to experiencing an NHP-related ADR were based partly on their perceptions of the severity of the reaction, reflecting the importance of individual perceptions in reporting ADRs.

While the demographic profile of the participants in this study is clearly not representative of the Canadian population, it resembles the average demographic characteristics of those who use NHPs. (Park, 2005) The diversity of the products used and types of suspected ADRs enabled an analysis of a range of experiences and saturation in the key themes.

The results of this study indicate that participants were able to identify suspected ADRs linked to particular NHPs. In fact, the thought processes they used to identify ADRs was sophisticated in many cases and mirrors the adjudication process used by ADR/pharmacovigilance experts to determine the likelihood that symptoms are caused by a specific product including: reviewing temporality of symptom appearance, the effects of discontinuing the product (de-challenge), re-challenging with the product, and other changes in medication regimen. Although consumers perceived the severity of the symptoms based on their level of distress, and not by seriousness (e.g., the need for hospitalization) as healthcare
professionals would, their identification of the ADR itself seemed to be based, at least in part, on a process of elimination to identify a causal link between the product and the reaction.

Most national ADR reporting schemes do not allow reports direct from consumers because of concerns about low quality reports (e.g., missing important clinical information) and about the potential for obscuring important signals due to large numbers of reports. (Hammond, Rich, & Gibbs, 2007; Woo, 2007) Although Health Canada accepts direct reporting of suspected ADRs by consumers, this is not widely advertised and consumer reports are adjudicated separately from reports submitted by healthcare providers. Consumers in this study generally were not aware that they could report to Health Canada and although most agreed that it was important to collect such information, they seemed more willing to report to persons whom they trusted rather than to Health Canada directly. In Canada, consumer reports are usually used to clarify or provide additional support for suspected reactions (or signals) raised from healthcare provider reports. Our data suggest that one way to enhance reporting rates may be to facilitate more consumer reporting. Future research in this area appears warranted.

In many cases, participants didn’t report the ADR because they didn’t know where to turn. Although NHP users are often highly educated and information seeking consumers, after experiencing an ADR, some participants sought someone trustworthy to whom they could turn for help. In this study, the trustworthy person was often not a medical doctor or pharmacist but instead usually a CAM provider or health food store clerk. Participants turned to health food store personnel because they were seen as being more knowledgeable about NHPs and because they were willing to listen to the consumers’ concerns without judgment. Although several consumers described their ADR as moderate or severe, they still did not report their ADR because they did not know where to turn. This finding supports other research that patients do
not act on a severe reaction, particularly if it is related to an NHP. (Barnes, Mills, Abbot et al., 1998)

A key finding was that the relationship between consumers and their service providers can act as a barrier or facilitator to reporting suspected ADRs. Other research suggests that participants perceive high quality healthcare to include recognition of their status as informed patients and acknowledgement of their personal worth. (Price & Arnould, 1999; Williams, Coyle, & Healy, 1998) In the present study, participants felt that their physicians or pharmacists would ‘blow them off [ignore their concerns]’ or ‘bash down [insult]’ their values and beliefs in NHPs. This type of response negatively impacts the patients’ abilities to maintain open and honest relationships with their healthcare providers. Participants who did not trust their conventional practitioners to respect their NHP-related choices sought out other advisors. In this study, that often included health food store staff. This can be problematic as Canadian health food stores are not regulated in any way. Thus, there are no common standards for employee training and research suggests that health food store staff generally have no knowledge of the ADR reporting systems (Glisson, Rogers, Abourashed, Ogletree, Hufford, & Khan, 2003; Healey, Burgess, Siebers, Beasley, Weatherall, & Holt, 2002; Walji, Boon, Barnes, Austin, Baker, & Welsh, 2008)

Despite the increasing awareness of the importance of patient-centered care, which includes nurturing mutual trust, both trust by the physician in the inherent truth of the patients’ experience and trust by the patient that the physician will help the patient towards the path to wellness, (Stewart, Brown, Donner, McWhinney, Oates, Weston et al., 2000) participants did not report positive experiences with physicians. Patient-centered communication has been found to improve health status and increase the efficiency of care by reducing diagnostic tests and
referrals. (Stewart, 2005) With better communication, it also seems likely that patients would be more willing to discuss ADRs with their physicians and pharmacists.

4.6 Conclusion

Consumers who have experienced an NHP-related ADR are unlikely to discuss their experiences after having self-prescribed the product. Perceived severity can be an impetus to ask for help. When consumers do seek advice about suspected ADRs associated with NHPs, they are most likely to discuss it with friends, family or health food store personnel. Consumers generally perceive that conventional healthcare providers will not understand their decisions to use NHPs and thus fear that they will not be supported to address the suspected NHP-related ADR. This study highlights the need for health professionals to be open-minded about their patients’ choices regarding NHPs and the importance of developing good communication around NHPs so that patients will be comfortable sharing suspected ADR experiences.

4.7 Implications

This study has implications for NHP safety monitoring, mainly with regards to patient-practitioner communication. Healthcare providers must attempt to develop a rapport with their patients, recognizing that many (likely at least half) may be using NHPs. Previous research suggests that initiation of NHP dialogue should occur at the first stages of patient contact, perhaps during regular medicine history taking. To do this, physicians and pharmacists need effective communication skills to fulfill a variety of roles including collecting medical histories, answering patients’ questions about NHPs, developing interpersonal relations and suggesting treatment. (Tasaki, Maskarinec, Shumay, Tatsumura, & Kakai, 2002) It is also important to recognize that while disclosure of NHP use is essential, successful communication does not mean that physicians have to approve of patients’ choices. (Verhoef, Boon, & Page, 2008) In the
case of NHP-related ADRs, communication of this type seems essential to enabling a trusting relationship. Our findings suggest that only when physicians are seen as sources of information and support will consumers disclose their concerns when experiencing an NHP-related ADR. This study also found that consumers are generally unaware that they are able to report directly to Health Canada and therefore, there is a need for initiatives to raise awareness among NHP users of this avenue for reporting suspected NHP ADRs. Spontaneous reporting systems are at present the mainstay of detecting signals of safety concerns associated with NHPs. (Barnes, Mills, Abbot et al., 1998) If suspected ADRs associated with NHPs do not reach the system, either through direct patient reporting or reported through healthcare professionals, then the detection of safety concerns may be missed or delayed. This has important implications for protection of the public health.
4.8 References


Richards, L., & Richards, T. (2002). *NVivo 2.0 [Software for Qualitative Research]* Melbourne: QSR Solutions


Table 1: Consumer Demographic Information

<table>
<thead>
<tr>
<th>Consumer #</th>
<th>Age</th>
<th>Sex</th>
<th>Product</th>
<th>Reason for taking NHP</th>
<th>ADR</th>
<th>Severity</th>
<th>Outcome</th>
<th>Reporting behaviour</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>25</td>
<td>F</td>
<td>Mental Calm</td>
<td>For alertness/stress</td>
<td>Rash</td>
<td>Moderate</td>
<td>Recovered with OTC treatment</td>
<td>Reported to PHM</td>
</tr>
<tr>
<td>2</td>
<td>28</td>
<td>F</td>
<td>Fish oil</td>
<td>For health maintenance</td>
<td>Rash</td>
<td>Mild</td>
<td>Recovered after d/c</td>
<td>Reported to CAM</td>
</tr>
<tr>
<td>3</td>
<td>43</td>
<td>M</td>
<td>Weight loss product</td>
<td>For weight loss</td>
<td>Stimulation, irritability, road rage</td>
<td>Severe</td>
<td>Recovered after d/c</td>
<td>Report to f/f</td>
</tr>
<tr>
<td>4</td>
<td>24</td>
<td>F</td>
<td>Digestive enzymes</td>
<td>For digestive concerns</td>
<td>Stomach pain, bloating, heartburn</td>
<td>Moderate</td>
<td>Rechallenged, Recovered after d/c</td>
<td>Did not report</td>
</tr>
<tr>
<td>7</td>
<td>42</td>
<td>F</td>
<td>Valerian</td>
<td>For sleep</td>
<td>Agitated, unsettled</td>
<td>Moderate</td>
<td>Recovered after d/c</td>
<td>Did not report</td>
</tr>
<tr>
<td>8</td>
<td>36</td>
<td>F</td>
<td>Fish oil</td>
<td>For health maintenance</td>
<td>Rash</td>
<td>Mild</td>
<td>Recovered after d/c</td>
<td>Report to CAM, f/f</td>
</tr>
<tr>
<td>9</td>
<td>38</td>
<td>F</td>
<td>Thyroid glandular</td>
<td>For weight loss</td>
<td>Headache, nausea</td>
<td>Severe</td>
<td>Changed dose</td>
<td>Report to MD</td>
</tr>
<tr>
<td>10</td>
<td>28</td>
<td>F</td>
<td>Multi-vitamin</td>
<td>For health maintenance</td>
<td>Nausea, vomiting</td>
<td>Severe</td>
<td>Rechallenged, recovered after d/c</td>
<td>Report to f/f</td>
</tr>
<tr>
<td>11</td>
<td>22</td>
<td>F</td>
<td>Weight loss product</td>
<td>For weight loss</td>
<td>Heartburn</td>
<td>Mild to moderate</td>
<td>Rechallenged, recovered after d/c</td>
<td>Report to f/f</td>
</tr>
<tr>
<td>12</td>
<td>34</td>
<td>F</td>
<td>Melatonin</td>
<td>For sleep</td>
<td>Groggy, uncoordinated</td>
<td>Mild to moderate</td>
<td>Recovered after d/c</td>
<td>Did not report</td>
</tr>
</tbody>
</table>

α some participants experienced reactions to more than one product, they are listed in numbers to organize different experiences.

β severity is classified according to patient definition of severity

d/c = discontinuation

CAM = complementary and alternative medicine practitioner

MD = medical doctor

PHM = pharmacist

F/f = friends and family
CHAPTER 5. RESULTS – Health Food Store Interviews

Preamble

This chapter was submitted to Healthcare Policy for consideration for publication on February 29, 2008. The editors asked for a revised version and the paper was resubmitted on June 27, 2008.

I, Rishma Walji, performed the entire work, that is, the conceptualisation of the study, the protocol design, the overall study management, the collection, analysis, and interpretation of the data, and the writing of the manuscript, under the guidance of Dr. H. Boon, Dr. J. Barnes, Dr. Z. Austin, Dr. G.R. Baker and Dr. S. Welsh.

Adverse event reporting for herbal medicines: A result of market forces

Keywords: natural health products, dietary supplements, health food stores, safety, adverse events, adverse drug reaction reporting, herbal medicines

5.1 Abstract

Herbal products are readily available over-the-counter in health food stores and are often perceived to be without risk. The current Canadian adverse event reporting system suffers from severe under-reporting, resulting in a scarcity of safety data on herbal products. Twelve health food store personnel in the Greater Toronto Area were interviewed about their responses to herbal product related adverse reactions. They generally fostered customer loyalty by offering generous return policies, which included collecting contact information to be sent with the returned product to the manufacturers. Despite a lack of knowledge about the formal reporting system, adverse reaction information was directed to the manufacturers whenever it resulted in a product return. The relationship between health food stores, industry and Health Canada, provides a new opportunity to facilitate adverse event reporting. Additional information could be
collected during the return process, and educational initiatives could be implemented to augment
current post-market surveillance procedures for herbal products.
5.2 Background

The extensive use of natural health products (NHPs), such as vitamins and herbal medicines, is partially explained by a widespread belief that such products are “natural” and thus safe. Increasingly, it has become clear that NHPs, especially herbal medicines, can have adverse effects, including drug interactions. (McNeill, 1999; Pittler & Ernst, 2003) Relatively little is known about the adverse effects associated with herbal medicines.

Adverse drug reactions (ADRs) are defined as unintended consequences suspected to be related to the use of medicinal products, including herbal medicines. (World Health Organization, 1995) Spontaneous reporting systems, such as the Canada Vigilance Program (previously named the Canadian ADR Monitoring Program), are used by many countries as a way of monitoring suspected ADRs. Voluntary reports of suspected ADRs; reports of serious or unexpected ADRs, and those associated with recently marketed products are particularly encouraged. (Fletcher, 1991) In Canada, physicians, pharmacists, other healthcare providers and consumers can submit reports which may be assessed to identify product safety concerns that require action, such as changes/additions to product labelling, dosing, or removal of products from the market.

Although NHPs are widely used, few ADRs are reported to pharmacovigilance systems. (Barnes, 2003; Green, Mottram, Rowe, & Pirmohamed, 2001; Health Canada, 2007) It is well established that under-reporting of suspected ADRs is an important limitation of spontaneous reporting systems. (Fletcher, 1991; Mann & Andrews, 2002; Rogers, Israel, Smith, Levine, McBean, Valente et al., 1988) Low ADR reporting rates associated with prescription medicines are recognized as an international problem. It is generally accepted that less than 10% of adverse drug reactions are reported. (Alvarez-Requejo, Carvajal, Begaud, Moride, Vega, & Arias, 1998;
Moride, Haramburu, Requejo, & Begaud, 1997; Rogers, Israel, Smith et al., 1988) Under-reporting is likely to be greater for herbal medicines and other NHPs than for pharmaceutical drugs for several reasons. For example, healthcare professionals are often unaware of patients’ NHP use (Barnes, 2003; Barnes, Mills, Abbot, Willoughby, & Ernst, 1998; NHPD, 2005; Wheaton, Blanck, Gizlice, & Reyes, 2005; Winslow & Shapiro, 2002), how to identify ADRs associated with NHPs and what to report (Charrois, Hill, Vu, Foster, Boon, Cramer et al., 2007; Herdiero, Polonia, Gestal-Otero, & Figueiras, 2004). In Canada, NHPs have only been categorized as medicinal products and regulated by Health Canada since January 2004. (NHPD, 2003) It is unclear whether the lack of NHP ADR reports suggests that they are truly rare, or reflects a history of inadequate effort (in Canada and internationally) to encourage, collect and assess reports of NHP ADRs.

Herbal medicines and other NHPs are available over-the-counter in Canada at community pharmacies, grocery outlets and health food stores (HFS), as well as from the internet. The Canadian regulatory status of NHPs (i.e. non-prescription, non-‘pharmacy only’) has provided an opportunity for HFS to respond to public demand, entering the market with a wide product selection. There are approximately 2700 HFS (typically, retail outlets where at least 50% of stock comprises NHPs and/or health foods) across Canada, mostly in the provinces of Ontario, Quebec and British Columbia. (Canadian Health Food Association, 2005) HFS may be independently operated or belong to a retail chain with multiple outlets city or nationwide. There are no legal requirements regarding educational background or training for staff, and each store has different requirements ranging from online courses or in-store training/mentoring to no training/experience requirements. (Glisson, Rogers, Abourashed, Ogletree, Hufford, & Khan, 2003; Mills, Singh, Kawasaki, Bast, Hart, Majlesi et al., 2003)
Although HFS are an important source of NHPs, their staff do not have a defined role in monitoring the safety of the medicinal products they sell. (Healey, Burgess, Siebers, Beasley, Weatherall, & Holt, 2002) Rather, their business is providing health-related products, meeting customer demands, and providing adequate customer service to remain viable in a competitive marketplace. In contrast, conventional healthcare professionals (e.g., doctors, pharmacists) are bound by professional and ethical standards to report serious or unexpected instances of suspected ADRs. In reality however, many health professionals do not report, despite expectations to do so. (Alvarez-Requejo, Carvajal, Begaud et al., 1998; Hazell & Shakir, 2006; Inman, 1985)

One way health food stores remain competitive is by offering generous return policies for dissatisfied consumers to reduce the purchase risk of finding a good product match or a product of acceptable quality. Money-back guarantees can signal a seller’s confidence in the quality of their products. (McWilliams & Gerstner, 2006) The economic rationale for return policies is that of warranty. Return policies insure customers against products about which they are uncertain, making risk-averse customers willing to pay for the product. (Che, 1996) With NHPs, uncertainty around product benefits and the wide range of product options may raise doubts for the consumer. This, along with the strong competition from other stores selling similar goods, provides a reasonable rationale for these return policies.

Against this background, this study examined HFS staffs’ views on herbal product safety issues. The work forms part of a larger study also involving pharmacists and consumers who had experienced NHP ADRs. This paper explores how business incentives influence collection and reporting of adverse effect information in HFS and how return policies may be related to HFS personnel’s ability to respond to Health Canada’s attempts to collect ADR information.
associated with herbal products. Herbal products were specifically selected based on the increased risks associated with these products, compared with other NHPs.

5.3 Methods

Ethics approval was obtained at the University of Toronto. In-depth semi-structured interviews were conducted with 12 HFS personnel by a single interviewer with extensive training in qualitative research methods (RW). A purposive sample was chosen to include participants from independent and chain HFS, from city and suburban areas as well as from different age and gender groups and with varying HFS experience. Participants from HFS located in the Greater Toronto Area, identified from telephone directories, internet listings and by word-of-mouth, were approached in person. Interviews were conducted until theoretical saturation of the key emerging themes was obtained. (Creswell, 1998) Interviews were audio-recorded and field notes were hand-written during and immediately following the interviews. Interviews and field notes were transcribed and coded using content analysis techniques by two independent coders; disagreement was resolved through in-depth discussion. NVIVO 7 software was used to organize the data. (Richards & Richards, 2002) Data analysis and coding took place throughout data collection. The interview guide was updated and modified after the coding sessions to ensure more elaborate data collection in key emerging themes.

5.4 Results

The results for this study show that HFS personnel were unaware of the reporting system for ADRs. They also perceived and identified ADRs differently than the medical community. When the ADR resulted in consumer dissatisfaction however, the product was returned to the
manufacturer, eliciting a ‘report’ of some type. Table 2 summarizes participants’ demographic characteristics.

Generally, HFS personnel did not know that suspected herbal-related ADRs could be reported to Health Canada, who to contact to report ADRs, or which types of reactions should be reported.

Q: Are you familiar with the reporting system in Canada for side effects?
A: No. [interviewer explains] A: I didn't know about it at all. (#10)

Most participants described examples of ‘side effects’ (a ‘lay’ term for ADRs as defined by Health Canada) associated with NHPs reported by consumers. HFS personnel considered predictable untoward responses, such as a niacin flush, or diarrhea from a ‘detoxification’ product, as examples of possible ADRs about which they might inform consumers prior to purchase of the product. They reported that these “true” ADRs were rare. More common was a situation they described as NHPs that “did not agree” with or “did not suit” specific customers. This could manifest as a stomach upset or “uneasy feeling” after taking the product. Although these effects would be classified as ADRs by Health Canada, HFS personnel did not consider these to be cause for concern about the product *per se*. Rather, this was conceptualized as a need to help the consumer find a better product “fit”:

I think I would take it back from them thinking that maybe it really didn’t suit them and then I will ask them why, what happened to you? Why don’t you feel that it suited you or maybe I will tell them why not try another one to see if it suits you. In that way I could guide them. (#8)

HFS personnel described more serious symptoms, such as rashes, as the result of individual allergies, which they did not classify as ADRs. Often, HFS personnel would attribute ‘side effects’ to inappropriate product use by consumers, rather than ADRs (allergies, and effects associated with inappropriate use are considered ADRs by Health Canada). HFS personnel
therefore perceived and identified ADRs differently than the medical community. Participants stated that they commonly referred customers to their healthcare providers, or the product manufacturer, for more information if they suspected a patient had a reaction.

Oh I take it very seriously. I want to make sure that... if it was really serious I would say go and see your doctor and if it was a side effect and I don’t really know why [it happened] I would give them the phone number and the website to contact the company so that they can directly call them and double check with them because they have to know that as well and if they don’t feel comfortable I will call them myself with them there. (#10)

This example also relates to another key theme that emerged from the data: HFS personnel’s strong drive to provide customer service. HFS personnel described the importance of developing and maintaining relationships with their customers, and this extended to provision of advice and information about NHPs. HFS personnel appear to encourage consumers to see them as an information source for NHPs to help maintain customer loyalty.

You know at the store level we have to be prudent to gain enough information about the dangers and risks of products to be able to guide the consumer and they are after all looking at us for advice. (#2)

[Customers] want technical information and they are looking to us as if we’re naturopaths in a health food store, not sales associates in a health food store. (#12)

Another component of providing good customer service was swift response to product dissatisfaction (possibly resulting from ADRs) by accepting returns. The return procedure included collection of customer contact information, subsequently submitted to the manufacturer in conjunction with the “reason” for the return in order to recuperate retailer losses on the product. HFS personnel had difficulty conceptualizing ADRs, and thus also had difficulty describing how they might respond if one occurred. They talked about how they would return products to the manufacturer and refund the cost if the customer was dissatisfied with the product for any reason:
Even if it is not a bad reaction… you believe them and you refund it regardless, but just by their answers. You have to trust them whether you believe it or not you have to return the product if they have a reaction and then we just take their information and we contact the company and sometimes the company calls them back. [It happens about] once a week. (#9)

Thus, participants essentially reported ADRs to product manufacturers as a consequence of processing product returns. They described their continuing relationships with the manufacturers, in particular how helpful manufacturing companies staff were at answering questions about their products and handling returns.

I know this company, because ...we buy many of the products, ... They give us very good information. Especially if they have enough time with you they don’t hurry you and they explain things and they also tell you things, you know we are not doctors - they just advise [us] so they are very good. (#8)

Participants described how the return policy was used as a mechanism to generate customer loyalty and satisfaction by reducing the customer’s perceived risk. It was also used to evaluate product quality to help decide whether they should continue to be sold in the store.

We have a very good return policy and we actually encourage people to give us the feedback: if they’re not satisfied we want to hear about it, because we might not carry the line in the future if there are problems with it. It helps us and it helps us not to lose the customer as well, where some people if they bought something they have no recourse to get any money back or refund, they might just stop shopping at this location, or other locations for that matter. Whereas if they come back here, well we could encourage them to exchange the product or try something else that may be more to their liking and that way we could have a satisfied customer that continues to come back. (#4)

The costs of the returned product can only be recuperated by the store that accepts the return from the customer if the product is returned to the manufacturer with customer contact information and a reason for the return:

We write up a credit request from the company and we fax the company the credit request. We phone them and we e-mail them and we put the paper work together, and leave the product to be picked up by the company at some point. It is just pretty much a form that just asks for return address, name, phone number, that sort of thing. (#11)

HFS personnel considered manufacturers responsible for providing good quality products.
Sometimes batch numbers are also messed up. We have had [product] recalls before. I would go with the company first. For sure it would be the company’s responsibility. (#6)

5.5 Discussion

Although HFS staff are unaware of the Canada Vigilance Program for reporting suspected ADRs, they learn of consumer experiences of suspected ADRs associated with NHPs, and return products to product manufacturers in cases where consumers may have experienced ADRs. The arrangement between HFS and manufacturers regarding product returns raises the question whether this could be harnessed to improve ADR reporting for NHPs.

Providing financial incentives has been used to encourage health professionals to complete ADR reports, but it is not clear whether this approach improves the number and quality of ADR reports. (Inman, 1985) For HFS personnel, providing information to the manufacturer along with the return is the result of a financial incentive – recuperating losses on returned products. In order to receive financial remuneration for their product costs, they provide consumer contact information and reason for the return. It is possible that this information could be utilized to facilitate submission of more information to the manufacturer by retailers that could then be used for ADR reporting to Health Canada by the manufacturer. Additional information (such as other medications/products taken at that time, the length of the exposure to the product, a description of the reaction) would need to be incorporated into the return reports to allow them to be used as ADR reports. The manufacturer would then send the information to Health Canada, as is currently required under the Canadian NHP regulations, as expedited reports for serious ADRs or included in the annual summary for non-serious ADRs. Given the close relationships between HFS and industry, reporting of ADR information by HFS staff to manufacturers would seem relatively straightforward to implement.
However, reliance on product manufacturers to submit reports of suspected ADRs to Health Canada has limitations. A key issue for pharmacovigilance for herbal medicines and other NHPs concerns the accuracy and comprehensiveness of manufacturers’ ADR reports to Health Canada as part of their legal obligations. Regulatory changes have been implemented to ensure quality, safety and efficacy of NHPs. Safety information is particularly important for appropriate regulation of these products. (Citizen Petition, 2008; Harvey, Korczak, Marron, & Newgreen, 2008; NHPD, 2003) When manufacturers or licensees receive information on serious ADRs (those that require hospitalization, are life-threatening, or result in significant disability or death), the NHP regulations (which are still being phased in) require them to provide Health Canada with case reports within 15 calendar days after becoming aware of the reactions. (NHPD, 2003) Licensees are also required to prepare an annual summary report containing an analysis of all ADRs occurring for their products within the previous year. Due to the inherent conflict of interest, questions remain over whether all relevant reports are included and whether the information presented complies with Health Canada’s requirements.

Another important limitation to submission of information to manufacturers is confidentiality. Manufacturers require a customer name and contact information as a measure of authenticity of the return. Health Canada’s ADR reporting form however requires anonymity to ensure confidentiality of health information.

If submission of suspected ADR reports by health-food stores to Health Canada via product manufacturers is not an ideal mechanism, how else could the information obtained by HFS staff reach the pharmacovigilance system? There are three ways in which HFS staff could be more actively involved in reporting suspected ADRs associated with NHPs. On learning of ADRs or ‘problems’ with herbal medicines or other NHPs, health-food store staff could:
1. Advise the purchaser to contact their doctor or pharmacist. While this approach would direct purchasers to conventional healthcare professionals (who are generally trained in identifying ADRs and have a formal role in reporting them), there are still several barriers to a report reaching Health Canada. For example, consumers appear to be hesitant to disclose use of NHPs to physicians and other conventional healthcare providers, particularly if they experience adverse effects associated with NHPs. In addition, the healthcare provider must recognize the symptoms as a suspected ADR, as well as follow through to complete an ADR report which is submitted to the Canada Vigilance Program. However, under-reporting from health care professionals is a problem due to lack of time, knowledge or uncertainty about ADRs and the ADR reporting system. (Hazell & Shakir, 2006; Herdiero, Polonia, Gestal-Otero et al., 2004; Sweis & Wong, 2000)

2. Advise the purchaser to report the event directly to the Canada Vigilance Program, possibly with the assistance of their conventional healthcare provider or HFS personnel.

3. HFS personnel report the event to Canada Vigilance Program on the purchaser’s behalf.

Options 2 and 3 above however, have their own limitations. Both HFS personnel reports and direct consumer reports would be categorized as public or ‘lay’ reports by Health Canada. While these reports may serve to improve signal detection on certain products, they may not have the detail or quality of information required – such as laboratory test results and accurate records of concomitant medications (although these details can also be missing from health professional reports). Health care providers are encouraged to submit all reports of suspected ADRs – it is not necessary for them to attempt to confirm causality or to undertake intensive investigations of the events. However, the quality and completeness of ADR reports are important factors in Health Canada’s ability to undertake causality assessments. Although some
argue that patient ADR reports may be less likely to represent true reactions than are physician reports, large-scale reporting from lay persons (such as HFS personnel) might be valuable for detection of symptomatic reactions to new drugs. (Mitchell, Henry, Sanson-Fisher, & O'Connell, 1988) For example, signals might be identified earlier when patient reports are included in the data analysis. (Hammond, Rich, & Gibbs, 2007; Jarernsiripornkul, Kraska, Richards, & Capps, 2003) Patient reports may be particularly important when little is known about the product and its use with other products, as is the case with many NHPs. (Woo, 2007) In fact, some research shows that consumer reports may be of higher quality than physician reports, with more complete descriptions of the event. (Medawar & Herxheimer, 2003/2004; Medawar, Herxheimer, Bell, & Jofre, 2002) Another challenge is that HFS staff would need training in Health Canada’s ADR reporting procedures. HFS personnel training varies widely and HFS staff are often untrained in disease recognition or medical terminology, making it difficult to assess whether or not a given return was associated with an ADR. False positives could be generated if customers exaggerate symptoms to receive refunds on purchased products. Additionally, suspected ADRs will only be identified if consumers attempt to return the products. Even if a system was devised to train HFS personnel on ADR recognition and completion of ADR reports, there is currently no way to enforce standards in the unregulated retail industry. Furthermore, there is no incentive for HFS staff to report ADRs directly to Health Canada, other than contributing to protecting the public health so willingness to participate may vary.

This study has some limitations. First, it involved only a small number of interviews. Nevertheless, participants varied in their demographic characteristics, and saturation of key themes indicates that additional interviews were unlikely to raise completely new views.
Participants reported very similar return policies and gave similar answers regarding their knowledge about the Canada Vigilance Program. The highly focused research questions for the study (regarding perceptions of herbal ADRs and how they are handled) may also have contributed to saturation. (Guest, Bunce, & Johnson, 2006)

Although the intent of the research was to ask participants primarily about herbal medicines, they interpreted the term more broadly and discussed perceptions related to all NHPs, implying that they would behave similarly regardless of the type of NHP associated with an ADR.

5.6 Conclusions and Policy Implications

Consumers utilize HFS personnel for information about NHPs and to make complaints about the products they are using. HFS personnel, through business and economic incentives, are motivated to process returns for dissatisfied consumers and, in so doing, transmit ADR information to industry. Through the existing process, with certain caveats, there may be an opportunity to improve ADR monitoring by enhancing the detail of information collected. Educating HFS personnel about the ADR reporting system to facilitate their direct reporting to Health Canada, or at minimum informing customers of the option to report to Health Canada, should be investigated.

This study has important policy implications for ADR reporting and post-market surveillance of NHPs. The encouragement of HFS personnel reporting might be an important step in populating the Canada Vigilance Program database with valuable information. Increasing awareness of the ADR monitoring system within the NHP sector is an essential part of improving safety monitoring. Important next steps will be to ensure health care providers and consumers understand the true degree of risk through improved communication. Additionally, it
is important to investigate how the HFS industry reacts to an invitation to actively participate in NHP pharmacovigilance including the quantity, quality and completeness of submitted ADR reports. Health Canada will need to assess how best to use this new source of information for protection of the public health.
5.7 References


Richards, L., & Richards, T. (2002). *NVivo 2.0 [Software for Qualitative Research]* Melbourne: QSR Solutions


Table 2: Health Food Store Personnel Demographic Information

<table>
<thead>
<tr>
<th>Interview</th>
<th>Gender</th>
<th>Position</th>
<th>Contact hours*</th>
<th>Years of experience</th>
<th>Training in Natural Health Products</th>
<th>Type of store</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>Advisory staff</td>
<td>Part time</td>
<td>10 years</td>
<td>3 years formal training</td>
<td>Small chain</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>Manager</td>
<td>Full time</td>
<td>16 years</td>
<td>Self-study</td>
<td>Independent</td>
</tr>
<tr>
<td>3</td>
<td>F</td>
<td>Staff</td>
<td>Part time</td>
<td>3 years</td>
<td>3 week in-store training</td>
<td>Chain</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>Manager</td>
<td>Full time</td>
<td>5 years</td>
<td>6 month store training</td>
<td>Chain</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>Sales rep</td>
<td>Full time</td>
<td>11 months</td>
<td>Graduate student in health care</td>
<td>Chain</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>Advisory staff</td>
<td>Full time</td>
<td>9 years</td>
<td>2 years formal training</td>
<td>Independent</td>
</tr>
<tr>
<td>7</td>
<td>F</td>
<td>Owner</td>
<td>Full time</td>
<td>8 months</td>
<td>Self-study</td>
<td>Independent</td>
</tr>
<tr>
<td>8</td>
<td>F</td>
<td>Sales staff</td>
<td>Full time</td>
<td>7 months</td>
<td>6 week in-store training</td>
<td>Small chain</td>
</tr>
<tr>
<td>9</td>
<td>F</td>
<td>Sales staff</td>
<td>Part time</td>
<td>1 year</td>
<td>6 months formal training</td>
<td>Small chain</td>
</tr>
<tr>
<td>10</td>
<td>F</td>
<td>Owner</td>
<td>Full time</td>
<td>1.5 years</td>
<td>Self-study</td>
<td>Independent</td>
</tr>
<tr>
<td>11</td>
<td>F</td>
<td>Sales staff</td>
<td>Part time</td>
<td>3 years</td>
<td>Self-study</td>
<td>Small chain</td>
</tr>
<tr>
<td>12</td>
<td>F</td>
<td>Sales staff</td>
<td>Part time</td>
<td>2 years</td>
<td>3 years formal training</td>
<td>Independent</td>
</tr>
</tbody>
</table>

* Part time < 24 hours per week; Full time ≥ 25 hours per week
CHAPTER 6. RESULTS – Pharmacist Interviews

Preamble

This chapter has been prepared for submission to Social Science and Medicine. It will be submitted following the dissertation defence to allow an opportunity to incorporate any final comments from the dissertation examiners.

I, Rishma Walji, performed the entire work, that is, the conceptualisation of the study, the protocol design, the overall study management, the collection, analysis, and interpretation of the data, and the writing of the manuscript, under the guidance of Dr. H. Boon, Dr. J. Barnes, Dr. Z. Austin, Dr. G.R. Baker and Dr. S. Welsh. Helpful comments and thoughtful contributions to the topics discussed in this paper were provided by Dr. P. McDonnough.

Pharmacists and reporting of herbal product adverse drug reactions: Whose responsibility is it?

6.1 Abstract

We draw upon Bourdieu’s theoretical insights to investigate pharmacists’ roles in herbal product adverse reaction reporting. Herbal medicines are sold in pharmacies as over-the-counter products. The current Canadian adverse event reporting system suffers from severe under-reporting, resulting in insufficient safety data on herbal products. The objective of this study was to explore pharmacists’ experiences with, and responses to, suspected adverse reactions associated with herbal products. In-depth, semi-structured interviews were conducted with 12 community pharmacists in Toronto, Canada. The pharmacists generally did not report adverse events and cited barriers such as lack of time, complexity of reporting and other workplace challenges within the field of community pharmacy. Using Bourdieu’s theory of habitus and disposition to understand pharmacist roles in adverse event reporting, it appears that the few
pharmacists that did assume a responsibility for adverse event reporting appeared to have
different perceptions of pharmacists’ place within the field of pharmacy. The pharmacists who
did report saw themselves as ‘knowledge generators’, contributing to overall health care
knowledge. There was found to be a continuum of pharmacists from those who performed only
the basic level of care for their presenting patients, to those who try to contribute to the larger
health care system. Placement on this continuum was dependent on the pharmacists’
professional disposition, which seems to be a result of individual experiences and personal
perspectives. Understanding the reasons for pharmacists’ underreporting of suspected adverse
events is key to improving current herbal medicine safety monitoring methods.

6.2 Introduction

Herbal product safety monitoring is increasing in importance, in part, because of
substantial exposure of North Americans and Europeans to herbal medicines and other natural
health products (NHPs). (NHPD, 2005; Thomas, Nicholl, & Coleman, 2001) There have also
been several high-profile safety concerns associated with herbal medicines in the past. (Chitturi
& Farrell, 2008; Health Canada, 2002) As a result, there is increasing recognition of the potential
for serious adverse drug reactions (ADRs) associated with the use of certain herbal medicines.
Since herbal products are widely available in community pharmacies, it can be argued
pharmacists are well placed to facilitate herbal medicine ADR reporting. However, the current
safety monitoring system in Canada suffers from severe under-reporting from health care
professionals, including pharmacists. (Charrois, Hill, Vu, Foster, Boon, Cramer et al., 2005)
Pharmacists’ knowledge, beliefs, and motivation, as well as logistical barriers such as lack of
time, are thought to be important factors in explaining why they so seldom report ADRs. (Green,
Mottram, Rowe, & Pirmohamed, 2001; Irujo, Beitia, Bes-Rastrollo, Figueiras, Hernandez-Diaz,
& Lasheras, 2007) If we can understand why some pharmacists report ADRs despite these barriers, it may be possible to improve the current reporting system.

In this paper, we draw upon Bourdieu’s theoretical insights to explore the link between pharmacist attitudes, the structures within the community pharmacies in which they work and their ADR-related reporting actions. Bourdieu enables this link by focusing our attention on an individual’s place, or perceived place, in society. (Bourdieu, 1993) This subjective perception provides a subconscious lens through which he or she interprets the world. (Crossley, 2001) Bourdieu (1990) argues that it is through this system that people view and understand the social world, and they then act accordingly. Using this theoretical lens, we focus on how pharmacists’ attitudes and actions may depend on their perceived position in their pharmacy, within the pharmacy profession and within the healthcare system as a whole. We explored the influence of the way pharmacists see themselves within the profession or the healthcare system, and how they comprehend their role(s) in community pharmacy on behaviour patterns when performing tasks such as ADR reporting.

Action, according to Bourdieu, is carried out within a particular structural context, with both ‘fields’ and ‘capital’ as part of this context. A pharmacist’s field can be described as the relationship between pharmacists and patients, or between pharmacists and other health care providers, or even between pharmacists and other pharmacists. Within any given field, one engages in struggles ongoing in that field. For example, pharmacists may struggle to be accepted as trusted health care providers by patients or they may attempt to be seen as legitimate in the eyes of other practitioners within the healthcare system. Within each struggle, one may use or accumulate capital (that which provides status including economic, social, symbolic or cultural such as knowledge and education) in order to achieve a certain position or particular
advantages. (Bourdieu, 1986; Bourdieu & Wacquant, 1992) In the case of pharmacists, their knowledge about drugs can be classified as cultural capital that enables them to answer patients’ questions about medicines. The way they are viewed by these patients, as legitimate sources of information, for example, is a type of symbolic capital.

Bourdieu (1993) argues that one’s strategy of action is determined by one’s position within a field and the overall distribution of capital. He predicts that action and decision-making strategies will differ based on one’s perceived position. A system of internal dispositions, or habitus, develops as a result of socialization either in childhood or within a shared socialization experience, such as within a profession or during professional training. These dispositions become ingrained modes of perception and action. A pharmacist who sees himself/herself only as a gatekeeper of medications for example, might perceive his/her place to be lower in the hierarchy of the healthcare system, deferring to physicians at every opportunity. In contrast, a pharmacist who believes himself/herself to be an agent for meeting a patient’s drug related needs, might actively solicit information from the patient and follow-up on health issues, or actively contribute to knowledge generation in the field of medicines as a whole. Since pharmacists are at the point of contact at community pharmacies, and herbal products are sold over-the-counter, pharmacists are in a position to serve as resources for herbal products, similar to other over-the-counter products. Despite variations in perspectives, herbal products can be considered within the pharmacists’ scope of practice.

6.2.1 Herbal product regulations

In Canada, herbal products are regulated as natural health products (NHPs) along with vitamins and minerals, homeopathic medicines, probiotics, amino acids and essential fatty acids. (NHPD, 2003) The 2004 Canadian regulations outline industry requirements for the manufacture, packaging, labelling, storage, importation, distribution and sale of NHPs. (NHPD,
The regulations are meant to increase quality standards for NHPs, including herbal products, making them safe for over-the-counter use, similar to over-the-counter pharmaceutical preparations. They also include requirements for reporting suspected herbal-related ADRs, defined as noxious and unintended responses to particular medicinal products, meaning that there is a reasonable possibility that there is a causal relationship between a given product and the reaction. (World Health Organization, 1995)

Health Canada collects suspected ADR reports associated with use of medicines, including herbal products, through the Canada Vigilance Program, formerly known as the Canadian Drug Reaction Monitoring Program. (Health Canada, 2007) In Canada, as in many other countries, the ADR reporting system is a spontaneous, passive system that encourages reports on a voluntary basis from doctors, pharmacists and other healthcare professionals and, more recently, the public. The current reporting system suffers from severe under-reporting, resulting in a lack of ADR information generally and particularly for herbal medicines. (Alvarez-Requejo, Carvajal, Begaud, Moride, Vega, & Arias, 1998; Fletcher, 1991)

6.2.2 NHPs, ADR reporting, NHPs and Pharmacists

It can be argued that since pharmacists sell herbal products, they should be responsible for monitoring ADRs that are associated with these products. (Kwan, Boon, Hirshkorn, Welsh, & Jurgens, Accepted July 1 2008) Unique statutes in each province regulate the practice of Canadian pharmacists. Generally, pharmacists are responsible for attending to patients’ drug-related needs. Given that herbal products are now regulated as a subcategory of drugs in Canada, it could be argued that reporting of herbal ADRs falls within the pharmacist’s professional responsibilities, in the same way that reporting adverse reactions for pharmaceuticals does. (Farrell, Ries, & Boon, 2008) Presently ADR reporting is considered by pharmacist associations
as an ethical and moral duty, but is legally still a voluntary task (as is the reporting of ADRs suspected with drugs). (Farrell & Staughton, 1996)

Previous research indicates that pharmacists, like other health care providers, tend not to report ADRs associated with conventional drugs. (Charrois, Hill, Vu et al., 2005; Inman, 1985) Health professionals appear to be more likely to report ADRs if they: see the reaction as serious, are confident that the product caused the reaction, are not busy, received continuing education about ADR reporting, have been motivated to report ADRs in the past and if there is a specialist in ADR reporting on staff. (Green, Mottram, Rowe et al., 2001; Lee, Chan, Raymond, & Critchley, 1994; Sweis & Wong, 2000) Workplace challenges such as lack of time, are cited as major obstacles for pharmacists in ADR reporting. (Granas, Buajordet, Stenberg-Nilsen, Harg, & Horn, 2007; Inman, 1996; Irujo, Beitia, Bes-Rastrollo et al., 2007)

Safety monitoring is more difficult for herbal products than for conventional medications for many reasons. (Barnes, 2003) In particular, NHPs are often perceived as completely safe, and self-prescribed without advice of a qualified practitioner. It appears that patients are less likely to report ADRs due to herbal products than similar events due to pharmaceuticals, possibly because they consider ADRs associated with herbal medicines to be less worrying or because they do not think that herbal ADRs should be reported to conventional healthcare professionals. (Barnes, Mills, Abbot, Willoughby, & Ernst, 1998)

In this study, we use Bourdieu’s concepts of field, disposition and habitus to examine pharmacist behaviours in response to herbal product related ADRs. We use this theoretical lens to try to understand reporting behaviours as they relate to herbal medicines and differentiate whether these are similar or different than those found for conventional medicines. We will
conclude by describing how professional disposition appears to be important in overcoming structural challenges to the reporting process.

6.3 Methods

This study was conducted in the Greater Toronto Area of Ontario (Canada). Ethical approval for the study was granted by the University of Toronto’s Research Ethics Board.

Participants

The data presented here focus on 12 interviews with pharmacists, as part of a larger study on retailer and consumer experiences with ADRs (n=36). A purposive sample of pharmacists practicing in community pharmacies was recruited to maximize variation in experiences and perceptions. Participants were selected to provide a sample that included individuals with a range of number of years in practice, number of hours working per week, gender, training and geographical location of work. Key demographic data are presented in Table 3. Pharmacists participated in in-person, individual, in-depth, semi-structured audio-recorded interviews between June 2006 and May 2007. Interviews ranged from 30 to 90 minutes and data collection continued until saturation was reached in key emerging themes. (Creswell, 1998) Core open-ended questions asked are summarized in Table 4.

Although the number of participants was small, participants varied widely in their demographic characteristics. Participants in the study reported very similar perspectives about the main barriers to reporting and the challenges that they face. This is evidence that data saturation in key themes was reached and additional interviews would not have provided additional depth to the topics analyzed. (Creswell, 1998; Guest, Bunce, & Johnson, 2006) Since the research question for the study (experiences of, and responses to, ADRs) was narrow, saturation was achieved quickly. (Guest, Bunce, & Johnson, 2006)
6.4 Analysis

All interviews were transcribed verbatim and manually coded by two independent coders. A qualitative software program, NVivo Version 7, was used to organize the data. (Richards & Richards, 2002) The process of coding involved reviewing all transcripts and identifying key concepts and themes that emerged from the data. (Boyatzis, 1998) Ongoing meetings with the coders and all authors were held to explore the coded data and dissent was resolved by discussion.

6.5 Results

Four consistent key themes related to reporting ADRs for NHPs emerged from the data: self-perception of competency, responsibility, workplace challenges and professional disposition. In general, pharmacists tended to lack confidence in their knowledge and training about herbal products. While pharmacists felt that it was their responsibility to report adverse reactions, they also felt that it was the responsibility of other health care providers, and they tended to pass this task to them. Workplace challenges such as time and complexity of the reporting process were identified as major obstacles to reporting adverse reactions. Finally, each individual pharmacist had a certain perspective on his or her role within the profession, which impacted whether or not they reported ADRs, despite the other challenges.

6.5.1 Self perception of competency

Pharmacists were generally concerned with their own knowledge base and competency with regards to advising patients on herbal products. A lack of knowledge on expected outcomes or possible side effects made it difficult to assess ADRs related to these products. Pharmacists in this study emphasized the lack of education received on herbal products in their pharmacy training, regardless of how long ago they graduated.
I can say this is good for this or that but in order for me to make a judgment on this Echinacea purpurea is for this and this is Echinacea ..whatever the other one is, is better for something else, I feel confused. I feel like I need more training in herbal products. (#7)

Like say for example, um, grape seed extract. I really have no knowledge of grape seed extract. So if it interacts with whatever… I really don’t know. (#1)

Lack of knowledge was identified as a barrier to reporting herbal ADRs that is not found in the literature about ADR reporting for conventional medications. Confidence in their own knowledge about herbs and what reactions are expected, was an important factor in both the pharmacists’ perceived ability to counsel patients on herbal medicines as well as their perceived ability to recognize and interpret a herbal product related ADR:

In terms of drug interactions, in terms of side effect profiles, and dosing, I mean, I won’t say I’m 100% comfortable addressing those questions, but at least I know where to go for information, for further clarification, that sort of thing. (#4)

I would say [my herbal knowledge is] above average I guess because of the material that is available to us through the resources that we have… I personally would look at it like it is a common side effect and it is not something unusual and I would not report it. If it was something more unusual than normal and we have the references to say what to expect then that might be something that we would investigate further. (#6)

The main concern related to difficulty in making a sound clinical judgment. Pharmacists asserted that they did not know how to probe about herbal medicine reactions and did not know what was expected as far as safety and efficacy information was concerned. The discourse on evidence-based medicine practice within the field of health care required pharmacists to make clinical judgments based on evidence. The lack of training and poor awareness of herbal medicine evidence created a perception of uncertainty around herbal medicines and greatly impacted pharmacists’ ability to make such decisions.

For instance the education I received, it’s all about scientific fact and if you don’t know you can’t recommend or make any judgment. But the products are out there and we don’t know as much as we’d like to so you have to make professional judgment … we all get
monographs with new drugs, what to tell patients – but you don’t see that about herbal products, there needs to be more information. (#2)

I just wish I knew what I was dealing with so that I could give more confident advice… Because from our background, we’re so desperate for fact and evidence. (#1)

There is also an element of how the pharmacist is perceived in the patient’s eyes. The symbolic capital of legitimating their own knowledge is important when discussing herbs with patients.

I think there’s a lot of things like saw palmetto -- a lot of people think it’s really good for prostate, but until there’s a standard dose... some things will say between 200 and 800 and what do you say to the person? So you feel stupid because you don’t even know what to say to them. (#1)

Pharmacists who were originally trained in a different environment, such as overseas or in areas where herbal medicine education was emphasized and incorporated into the curriculum, seemed more comfortable with clinical reasoning about these products. They perceived themselves to be in a stronger position because they were confident about the knowledge, or cultural capital, that they possessed, making them better able to make sound, evidence-based assessments. They also seemed more likely to report due to this confidence in herbal products.

Like back home we are continually learning everything about herbs... Even in my counselling when someone tells me they have a rash, I ask if they are taking any medicine or non medicine ingredient because it could be because of vitamins … Let’s say someone came me and told me I have been using this herbal drug, I will again look through, does it cause [that reaction] or it does not, I might report it so it’s known that this drug with this condition can cause this or that. (#8)

Pharmacists trained in hospital pharmacies were not necessarily well versed in herbal medicines, but they were more aware of how to react to serious ADRs and understood the importance of gathering and sharing information related to efficacy and safety of products. The social field of a hospital pharmacy seems to differ from that of a community pharmacy.

I also work in hospital so if someone comes in with [a reaction], we have to report it… We’re also constantly having sessions on different diseases and things like that so I don’t
actively seek out courses or mini-courses; it’s usually part of being in the hospital. It’s more available; we go to talks and stuffs. If you’re in community [pharmacy practice] then you have to seek it out. If you want to learn more, it’s not like someone’s coming to teach you. I think people become lazy and at the end of the day, when you’ve done an 8–10 hour shift standing all day, who wants to home and study unless you have to? So I think people should be forced to learn about it. (#4)

A degree of uncertainty about the ADR was another common result of lack of knowledge. Pharmacists were hesitant to report ADRs if they did not have complete information such as results of laboratory tests (e.g., plasma concentration of suspected drug) supporting the suspected reaction. They were also hesitant to report if they were unsure about whether the herbal product caused the reaction, which supports other existing research as to why pharmacists do not report. (Green, Mottram, Rowe et al., 2001)

It’s hard because we have to know the whole picture. By talking to the patient you can’t assess [if it’s a] true adverse reaction. (#12)

In reality, a report only needs to identify a suspected product; it does not need to have a defined causal link; however pharmacists seemed very hesitant to report reactions if they were not quite sure they were related to the product in question. Again, pharmacists tended to defer to physicians who would be able to get the whole picture and properly assess the patient to decide if it is a true ADR.

It seems that the pharmacists’ perceived position within their social field, and possession of cultural and symbolic capital – training, confidence and familiarity with herbal products and ADR reporting – as well as exposure to an environment where training is reinforced, all contribute to the pharmacist’s decision to report ADRs.

6.5.2 Responsibility

Pharmacists generally agreed that they had a responsibility to report ADRs, including those associated with herbal medicines, and that it was within their scope of practice to do so:
I think in general it’s health care professionals’ responsibility [to educate the public about herbs]. But I think if I found out about an adverse reaction, then I think I should, it’s my duty to report it as I think for doctors and nurses. How often does [reporting] happen? Probably not often. (#5)

Although agreeing that ADR reporting was their responsibility, many pharmacists admitted to not reporting. In this study we focussed on asking about herbal product related ADRs but many participants also mentioned that they didn’t report ADRs related to either herbal medicines or drugs.

If it’s [a] very severe [reaction] then [I tell them to] stop the medication but I don’t think report. We don’t usually report it. I think we’re supposed to… It’s common practice though, we don’t report. (#1)

That many pharmacists don’t report suspected ADRs supports previous findings that they are under-reported. (Ashcroft, Morecroft, Parker, & Noyce, 2006; Herdiero, Figueiras, Polonia, & Gestal-Otero, 2006)

Pharmacists interviewed in this study pointed out that there is a shared responsibility between pharmacists and other health care providers to report ADRs. This overlapping jurisdiction meant that many pharmacists tended to refer to other health care providers rather than take on the task themselves.

Well, I know we provide [herbs], but it’s very hard to monitor it… I think there are some other health professionals out there who are better suited, maybe, for doing that? (#9)

I think that doctors should do it, if the patient reported to them, then I just think that they shouldn’t just take it lightly. (#7)

While pharmacists referred patients to their medical doctors, they did not perceive the physicians to be necessarily more knowledgeable about herbs or herbal ADRs. Instead they regarded the medical doctor as someone who was more familiar with the patient’s blood tests and overall health and therefore better equipped to report complete information about the ADR. The pharmacists who deferred to the physicians took a more passive stance at patient inquiry and
investigation. Instead they assumed a secondary role, less dominant role, within the hierarchy of the health care system by deferring to the physician.

Sometimes it’s just like, once you send them to the doctor it’s out of sight out of mind, you have other things to do. (#3)

Doctors in society have more power. Whatever they say, we listen to them. (#11)

In contrast, other pharmacists actively accepted the role of investigator and took it upon themselves to seek cultural capital in the field of herbal medicines by learning about existing products and research. They took a more involved role in assessing the patient and worked in collaboration with physicians rather than under them.

You just try to ask if they are on any other medications to try to pinpoint any potential interactions that are known and usually you just have to tell them, if you feel strange or anything bad then come back and talk to us (#10)

Obviously we have a role here ... especially if it is a regular customer it is just like with anything, we would want to follow-up on the conditions to see how things are... but then if it is to treat something more serious as opposed to the cold then the doctor should get involved as well. Sometimes [pharmacists] will just turn the patient away ... which is responsible too because if they can’t give them the answer then they shouldn’t really say anything, but at the same time patients will get turned off and go to a health food store. Hopefully pharmacies will realize that they should know something [about herbs] or be willing to open themselves to this area. (#6)

In addition to passing the responsibility to medical doctors or other ‘more qualified’ practitioners for herbal and conventional ADRs, in the case of herbal medicines specifically, some pharmacists would also defer responsibility for decisions about herbal products to patients.

I just tell patients I don’t know what the effect will be and I don’t know how safe they are… I always give that disclosure. So you sort of leave it in the hands of the patient. (#5)

When viewed from the perspective of the field between pharmacist and patient, this approach seems counterproductive. However, when seen within the context of the larger health care system, a pharmacist who does not know about herbal medicines, expected ADRs and research concerning herbs would conceivably disconnect from giving advice and probing about
ADRs because of a perceived lack of evidence. This would be considered responsible practice within the social field of evidence-based medicine practice.

Some pharmacists specifically prompted their patients to keep them informed about responses to herbal products. Generally these were pharmacists who actively solicited information and took a more involved approach to their practice. These pharmacists tended to take on the responsibility of learning at least the basics about herbal safety in order to direct patients to the appropriate source of information. They recognized that not all other health care providers would know enough about herbal products and assumed a role in herbal medicine monitoring within the system as a whole, while also recognizing their own limitations. They mentioned that they would actively follow-up with their patients after advising on an herbal product to find out about the patient’s experience. These were often pharmacists who saw a need to provide patients with advice and information and/or firmly believed that herbal medicines were fundamentally no different than conventional medicines and thus an important part of pharmacists’ practice.

The role of the pharmacist is to ensure patient care and to make sure that they are getting… when they are getting medications that they are getting the proper medication at the proper dose and trying to minimize any side effects that may occur and ways of dealing with them. Medications can also include herbal products too. (#10)

These pharmacists encouraged patient-pharmacist interaction in their field of practice which made it more likely that their patients would communicate with them about ADRs.

6.5.3 Workplace challenges

Workplace barriers to reporting ADRs included structural factors - specifically time, complexity and type of pharmacy. Pharmacists cited a lack of time as a major obstacle to reporting adverse events, and the task of reporting was pushed to the bottom of their priorities.
The type of pharmacy, chain or independent, also influenced pharmacists’ decisions about reporting adverse reactions.

Pharmacists that did not report explained that in community pharmacies the retail setting, or workplace structure, did not afford enough time to report ADR incidents. In the pharmacy workplace setting, pharmacists were required to respond to customers, complete paperwork, inventory and deal with human resource management issues, which took priority over the performance of tasks like ADR reporting which were seen not to be of immediate importance.

People will go on about anything, that’s their way of talking or getting your attention. I’d love to say everything is an adverse event and give it all attention but in reality it’s hard to put into practice… I’d likely have 5 minutes or less… You’d have to be at a different level of care than what you can get in a retail setting. You don’t really get in the chance to get into the nitty gritty. (#2)

You know what, it’s a time thing. We’re so busy, we have so many other things you figure it’s not a big deal or I’ll do it later and never get to it. We are bombarded from every which way to sign a prescription to talk to someone in the aisle to check a drug company issue, it’s tiring standing all day, you don’t get a break or lunch unless someone is covering for you. (#11)

Complexity was also mentioned as a challenge to reporting. Many pharmacists described ADR reporting as requiring a lot of time because it was so complex:

One thing is probably the paperwork involved and there really is just not enough time. (#3)

I think it’s that usually you have to call this person and then this person and I just don’t have the time to do all these things. There’s a lot of red tape and then you never see the benefits of it so a lot of times you feel like it’s not even worth it. (#1)

Setting constraints, such as time, and the perception that the process was complex clearly influenced pharmacists’ ability to report ADRs. The social field of the community pharmacy setting is constrained by struggles to meet deadlines and address immediate needs of presenting patients. Judgments are made not to report ADRs in part because the task itself does not afford any form of capital that is worth the extra time and effort; and in part because everyday practice
sits within a social field between pharmacists and patients, not between pharmacists and
government. It is a responsive tendency to address the existing challenges, leaving less time and
focus on systemic knowledge that might help future patients.

Some pharmacists interviewed were generally unfamiliar with the reporting system for
herbal products.

Interviewer: Are you familiar with the adverse drug reaction reporting system?
Respondent: Not for herbals. (#1)

I think I might have reported something when I was in my internship about 8 years ago
and this is purely because we had to…and I don’t remember who I called. (#2)

When reporting adverse events, there is one form to be filled out and generally phone
calls are not used as a method of reporting to Health Canada, which demonstrates a lack of
awareness about the ADR reporting system. Lack of familiarity, however, was not the only
barrier. Even when pharmacists were aware of the reporting system for pharmaceutical
medicines, and they did not often use it to report pharmaceutical or herbal ADRs.

Pharmacists working in chain pharmacies mentioned a more constrained structural
environment, having less control over which products were stocked in the pharmacy. They also
reported having less ability to practice in the way that they want. To function in such a
restricted field changes the practice habits and decision-making for these pharmacists. In such a
situation, it serves as a constant reinforcement of workplace structures that in turn shape
pharmacists’ views of what they think their role is.

But it’s hard, you know, every company is trying to push their product and even our
company they try to push the sales on a particular product and they expect so much sales
and people ask you if it’s working then, you know, it’s hard to educate them by, you
know, by what I read. It may or may not be effective. People won’t buy it, right? We
just keep it to ourselves. (#11)
If pharmacists felt pressured to sell certain products then there might be the result of not fully discussing the safety issues with patients, which could influence the likelihood of them discovering and reporting ADRs.

Pharmacists in specialty pharmacies or independent pharmacies tended to mention a different motivation within practice. Some tried to cater to consumer demand by learning more about herbal products. This increased knowledge might play a role in the pharmacists’ ability to interpret an herbal product related ADR.

For your own practice you have to read, you have to have the information. Now how important this branch of the practice or how relevant your practice, very much depends—it is kind of individual thing, right? If I get lots of questions about herbal products then I think as a pharmacist and as a businessman, I have to be able to answer all these questions. (#6)

Some pharmacists did report ADRs despite workplace pressures. They were familiar with the reporting system and had previous experience using it.

[It] does take time, to gather all the information, and sometimes you may be the only one doing the investigation! If you’re just by yourself [in the pharmacy], I think there’s a certain limit of information you have… but again, I think it’s still better than nothing, if you can report just those limited information … (#4)

Whether the pharmacists took the time to report ADRs depended at least partially on their attitudes toward pharmacy practice and their role as a professional, that is, it depended on their professional disposition.

### 6.5.4 Professional disposition

The pharmacist’s disposition was an important factor in explaining their workplace behaviour and whether or not they reported ADRs. While self-perceived competence, acceptance of responsibility and workplace challenges were all important aspects, the likelihood of reporting seemed to also be related to differences in pharmacists’ professional dispositions.

All the pharmacists interviewed provided a basic level of pharmacy care to presenting patients.
Some pharmacists found workplace challenges to reporting ADRs insurmountable and only addressed the immediate patient’s needs when presented with a possible ADR:

I think most of the time we just help the patient, though we don’t go one step further to report the drug reaction. (#11)

All pharmacists made sure that the presenting patient was “safe”. This may have meant recommending they discontinue taking the suspected product, or making suggestions for another product to ameliorate the symptoms or replace the product with an alternative. The majority of pharmacists however, did not provide a population or public health contribution by reporting ADRs in order to help future patients.

Pharmacists were generally concerned about a lack of research on some herbal products and potential interactions. They were concerned about people taking herbs if they were also taking pharmaceutical products, because of possible interactions. But instead of ‘taking that next step’ to contribute to overall knowledge and understanding of the risks of herbs, they did not see the task of ADR reporting as a priority. It was considered to be lower on the priority list than day-to-day tasks, or perhaps, the tenancy of the task was more explicitly seen as that of another health care provider.

Those who had a strong professional disposition seemed more likely to report and less likely to allow workplace challenges to prevent their taking that extra step. Pharmacists who saw themselves as knowledge generators, rather than just knowledge users, were considered to have strong professional dispositions. They made extra efforts to contribute to an overall understanding of product safety.

I think it’s an individual choice whether as a health professional you need to also contribute to the overall safety of medicines. (#10)

Herbal supplements are something that I don’t think will go away so it is very important that pharmacies out there should try to get some sort of knowledge on them as there are
people who want to know and if they don’t get it from us they will get it from someone else and that is where it could get a bit dicey. It all depends on how much information a person [pharmacist] is willing to take in to give back to the customer. (#6)

You know what, I pretty much report anything just because… you know, I guess the more information there is, then the better, and then it can sort of teased out to what’s really important and what’s not. (#4)

This additional characteristic within their disposition, of seeing themselves as knowledge generators, seemed to often be present in those that reported suspected ADRs. These pharmacists were more likely to know more about herbal medicines, to learn more about safety and made extra efforts to keep updated with regulatory processes.

6.6 Discussion

The findings from this study support previous research about under-reporting of ADRs. (Green, Mottram, Rowe et al., 2001) Pharmacists who do not report ADRs cite structural workplace challenges as significant barriers to reporting on both conventional and herbal medicines. (Hazell & Shakir, 2006; Herdiero, Polonia, Gestal-Otero, & Figueiras, 2004) In particular, a lack of time and a misconception about the complexity involved in completing the ADR report were key obstacles to reporting in the community pharmacy setting.

At the same time, some pharmacists did report ADRs. They took it upon themselves to accept responsibility, learn things about which they were unfamiliar and contribute to the pool of existing knowledge. There was a continuum of pharmacists with respect to their level of participation, or their attitude in practice. On one end there were those who performed the basic level of care for their presenting patients and on the other, those who tried to contribute to the larger health care system by reporting ADR information. Placement on this continuum was dependent on the pharmacists’ professional disposition, a result of individual experiences and personal perspective. Bourdieu contends that there is a relationship between social positions and
field (structure), individual dispositions (habitus) and position-taking (choices made). (Bourdieu, 1998) The decision to report ADRs seems to be largely related to the pharmacist’s placement on a spectrum of possible professional orientations. All pharmacists acted responsibly by addressing the presenting patients’ symptoms. They all seemed to perform a basic level of standard care. Those whose professional disposition included a characteristic of being highly interested in generating knowledge tended to be more up-to-date on regulatory changes. These pharmacists were also more likely to make the extra effort to report ADRs despite workplace challenges and overlapping jurisdictions. The pharmacists who were likely to report ADRs seemed to want to generate knowledge, which was part of their professional disposition. They perceived their role as one that included contributing to the overall safety of medicines. This individual disposition, of knowledge generation seemed in part, related to social position or social structure, and in part it appeared to be an individual characteristic.

It has been argued that perception, interpretation and understanding are formed within the lived experience and social fabric of clinical practice and shaped by the shared cultural norms, attitudes and beliefs into which members are socialized. (Paget, 2004) When looking at pharmacists’ perceptions and reactions to presenting herbal product related ADRs, their thoughts about herbal medicines, their interpretations of evidence, their understanding of the importance (or unimportance) of prioritizing reporting all factor into their decisions of how to act. These opinions and thoughts are shaped by their social environment during training in pharmacy school, by the discourse of evidence based medicine, by other health care professionals, by their patients and possibly also by their upbringing.

In addition to shared socialization, such as that during pharmacy school, our study adds the idea that individual experiences and beliefs contribute to one’s attitude towards practice.
Disposition and interpretation of professional responsibility needs to be further explored. The characteristic of a knowledge generative disposition also needs to be further explored and explicitly defined. It seems likely that it can be, in part, developed during professional socialization in pharmacy education and influenced by other factors still untapped. If trying to motivate pharmacists to see themselves as knowledge generators, one must think of the educational institution itself as a field.

A new issue highlighted by these findings is an overlap in responsibility between pharmacists and other health care professionals. The task is within the scope of practice for several health care providers, so although pharmacists believed that they should report (as should doctors and nurses), they thought it was acceptable not to do it because someone else would. This study builds on previous speculation that pharmacists consider ADR reporting as an ‘additional duty’ whereas medical doctors consider it as part of their ‘normal’ duties. (Sweis & Wong, 2000) Pharmacists that passed on the responsibility did not see themselves as solely responsible for the patients’ health nor did they acknowledge their contribution to the greater health care system. The overlap in professional responsibilities influenced the choices that pharmacists made when responding to patients and resulted in passing the responsibility for ADR reporting to other professionals. Therefore, there is a potential for the ADR to go unreported by anyone due to a continual passing of responsibility. According to Bourdieu theory, this deferral to the medical professional could reflect a perceived inferior position by these pharmacists. Further research is needed to explore this finding.

6.7 Implications

The findings presented in this paper demonstrate a necessity to educate pharmacists about the current reporting system and what is involved in reporting. Education can change
misconceptions about the time and complexity involved in ADR reporting. Furthermore, education about reporting ‘suspected’ ADRs can minimize another current barrier: the perception that one must have all the information to report a ‘conclusive’ ADR. The finding that pharmacists generally did not perceive themselves to be knowledgeable regarding NHPs highlights the need for further training in this area.

The findings of this study also point towards a need to foster a strong professional disposition within the pharmacy curriculum. Pharmacy faculties can incorporate knowledge generation as a central role for pharmacists along with other professional values and ethics. Other authors have found that pharmacists consider it their professional obligation to report, but that they still do not report ADRs. (Green, Mottram, Rowe et al., 2001) Fostering a professional disposition within the training program might enable more pharmacists to overcome the contextual barriers to reporting.

6.8 Conclusions

The position-taking of pharmacists (whether they report ADRs) is influenced by structure (workplace challenges) as well as habitus, or individual disposition. The idea of professional disposition can be conceptualized as a range of personal motivations and tendencies. This study points towards ADR reporting as possibly one outcome of having a strong professional disposition. Further research is needed to adequately describe and characterize professional disposition and its component elements. This study also highlights a potential neglect of tasks that are not clearly defined exclusively in the scope of practice of pharmacists. The tasks are passed on from pharmacists to other health professionals depending on their perceived position. There is a need for future research examining professional disposition with respect to ADR reporting as well as research on how professions negotiate overlapping tasks.
6.9 References


Richards, L., & Richards, T. (2002). *NVivo 2.0 [Software for Qualitative Research]* Melbourne: QSR Solutions


Table 3: Pharmacist demographic information

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<tr>
<td>Continuing education course</td>
<td>1</td>
</tr>
<tr>
<td>Additional formal training</td>
<td>1</td>
</tr>
<tr>
<td>Self study from books, internet, journals</td>
<td>3</td>
</tr>
</tbody>
</table>

Table 4. Core questions from semi-structured interviews that pertain to risk and safety

- How do you feel about the safety of herbal products?
- What do you think the role of the pharmacist is with respect to herbal products?
- How do you feel about giving advice on herbal products?
- What information helps you make a decision about how to advise your patients?
- Whose responsibility is it to report suspected adverse drug reactions associated with herbal medicines?
- Is there anything else that you would like to tell me?
CHAPTER 7. SUMMARY AND IMPLICATIONS

The research reported here contributes to the academic literature addressing NHP safety monitoring in a number of ways. First, in this research, I address the ways in which consumers responded to having had an adverse drug reaction to an NHP. Second, I assess health food store responses to NHPs, their customers and safety concerns. Finally, I document the perspectives of pharmacists towards NHPs and adverse drug reaction reporting. This chapter begins with a brief summary of the results followed by a discussion of how the data from these three populations is relevant for clinical care, policy makers and sociologists. The chapter ends with a section on limitations of the study and the conclusions that can be drawn from the study.

7.1 Consumer Interviews

It is difficult to monitor safety issues associated with NHPs due to the over-the-counter access of these products which means they can be selected by consumers without advice from a health care provider. Consumers often take it upon themselves to research NHPs, or follow the advice of friends and family, and self-prescribe NHPs. According to our research, some factors that impact consumers’ decisions to report, or not report, possible NHP-related adverse drug reactions (ADRs) include: individual beliefs about the severity of the illness and risk associated with taking NHPs for their conditions, their personal value systems related to health and illness as well as personal experiences. Our findings also demonstrate that consumers’ likelihood to report is also related to their relationships, or perceived relationships, with health care providers. If consumers expect that health care providers will disagree with, or disapprove of, their choices to take NHPs, they are unlikely to discuss their suspected adverse drug reactions. The fear of being judged was a strong theme within the consumer interviews. In general after experiencing an ADR, consumers turned to people they believed would be accepting of their choices and
people whom they considered to be trustworthy sources of information. Often the consumers interviewed for this study turned to health food store personnel rather than health care providers of any kind.

### 7.2 Health food store interviews

Being in the service industry, health food store personnel were concerned with providing reliable and satisfactory service to their customers. (Porter, 1974; Price & Arnould, 1999) This often meant that they took time for their customers -- to listen to their concerns and to advise them on products available in the store. These interactions enabled relationships to be built with their customers, to the point where consumers of NHPs felt comfortable complaining to the health food store personnel about ADRs from both NHPs and conventional medications. Where the concerns were related to NHPs, health food store personnel took it upon themselves to accept returns of the products as a gesture of good faith. This could be seen as respecting the wishes of the customer and validating their complaints. In this manner, the health food store personnel were able to maintain customer loyalty and the consumers felt that their concerns are addressed.

This service provider relationship with the customer provides an interesting opportunity for safety monitoring. Chapter 5 explores how this relationship may be used to help collect additional information about NHP-related ADRs. However, our data also show that some people do report suspected NHP-related ADRs to health care providers such as pharmacists.

### 7.3 Pharmacist Interviews

Community pharmacist, are also in the service providing industry. Their duties as health professionals seem, in most cases, to supersede their business motivations. However, our findings indicate that consumers rarely report suspected ADRs to their pharmacists, thinking that pharmacists either didn’t know enough about NHPs or that they weren’t willing to listen. Many
pharmacists do lack the knowledge, skills and time necessary to adequately help a patient to investigate and report as suspect ADR associated with an NHP to Health Canada. However, our data seems to indicate that some pharmacists with certain professional dispositions perceive themselves as knowledge generators and are more likely to be able to help patients to report ADRs. Our data indicate that there was a continuum of pharmacist disposition, ranging from knowledge users (who provided a base level of care to their patients), to knowledge generators who, in addition to base care, also contributed to overall knowledge of the profession in the area of NHPs and ADRs by choosing to report ADRs as well as actively participate in other voluntary professional activities.

7.4 Implications for Clinical Care

This research uncovered key clinical findings in the area of healthcare communication. Consumers often took their health into their own hands by self-prescribing NHPs and then dealing with the ADRs on their own primarily as a consequence of not believing there was anyone to whom they could turn. It was apparent from the data that consumers who felt that they weren’t being listened to with an open mind or that their concerns were not taken seriously, rarely discussed NHP related issues with their health care providers and often turned to other sources of information. This poor relationship with health care providers resulted in a lack of communication about NHPs and associated ADRs.

In this way, ADR reporting by patients to health care professionals was related to their perceived relationship. Some consumers who did have a good relationship with their health care provider did disclose their ADR information. Those that felt they had a good relationship but did not discuss ADR experiences cited a lack of time within the visit as the main barrier. There is an
opportunity to improve communication between patients and health care providers to encourage communication and likelihood of collecting more detailed NHP related safety information.

Future research is needed in this area of patient communication related to NHP ADRs and suspected ADRs in general. While some health care providers may not know or believe in NHPs, their ability to discuss these issues with their patients is essential in obtaining relevant safety information. Presently, the pharmacovigilance system assumes that pharmacists and other health care professionals know enough about herbs and other NHPs to be able to identify and adequately report ADRs associated with these products. This is not necessarily the case. The voluntary nature of the reporting system also assumes that patients will seek someone out who has the responsibility to report their ADR. Our data indicate that this is also not happening. It is important that health care professionals actively seek out this information from their patients. More research is also needed within the NHP industry and at the health food store level since consumers were likely to turn to health food stores for information about NHPs and safety issues. Health food stores are functioning as NHP pharmacies for these over-the-counter products, which might require a change in regulation, legislation or standardization requirements for training and reporting.

7.5 Policy Implications

This study highlights the role of a new population, health food store personnel, who might be able to play a part in safety monitoring in a novel and unique way. This study found that health food stores are in an important position to receive ADR information about NHPs. Consumers trust health food store personnel and turn to them for information. Health food store personnel also receive safety information upon filing a product return. However, health food store personnel are not health care practitioners. Their training in NHPs varies from store to
store and they may not have any healthcare knowledge. (Brazier & Levine, 2002; Glisson, Rogers, Abourashed et al., 2003; Healey, Burgess, Siebers et al., 2002) If they are being relied upon as resources for safety monitoring and for providing information to consumers, more research is needed about their role in NHP safety monitoring.

If health food store personnel were formally encouraged to fill a role in NHP safety monitoring, this would raise the question of whether they have similar barriers to reporting as do pharmacists (such as lack of time). They might also have new barriers to reporting related to reluctance to report because of fears that products might be removed from the market and the impact that would have on their business. In order to make the most of this unique resource, more research is needed in the area of policy and market research to determine how health food store personnel can contribute to current ADR monitoring systems.

Since health food stores are returning products to industry, there is also the possibility for research in the NHP industry to see how it plays a role in safety monitoring for NHPs. NHP regulations require industry to report ADR information to Health Canada. If they receive ADR information via product returns, it is important to determine how this information can be enhanced and whether industry can and will follow-up with these reports. It is also important to evaluate strengths and limitations related to communication between health food stores, industry and Health Canada.

7.6 Theoretical Contributions

From a theoretical perspective, this study contributes to two key areas of research. First, to the professions literature and second to the literature on Bourdieu’s theory of practice. In his theory on systems of professions, Abbott argues that members of professions define their jurisdictions (the link between a profession and its work) by claiming exclusive rights over
particular tasks. (Abbott, 1988) The literature on professions outlines the process of task negotiation between professions and the delineation of responsibilities based on knowledge or skill. However, in Canada ADR reporting is a task that was not claimed by Canadian pharmacists per se. Instead this task was conferred upon them by Health Canada. In addition, pharmacists aren’t exclusively responsible for undertaking ADR reporting; it is a shared tenancy between pharmacists, medical doctors, other health care professionals and now the public. It is not an obligatory requirement in Canada (although is in some countries) (Wiholm, Moore, & Waller, 2002), but rather a voluntary act to be performed in the interest of advancing product knowledge and safety of health care overall. Abbott’s theory of the systems of the professions does not adequately explore what happens to tasks like ADR reporting that are shared and were never specifically claimed by a professional group. The ideal situation for safety monitoring would be that all professions claim responsibility for the task and that they all contribute to ADR reporting. However, the blurring of boundaries between task allocation results in a potential for the task to be ignored by all professionals. ADR reporting was not perceived as a core part of pharmacists’ jurisdiction by the participants in this study which largely explains why it is not given priority in pharmacists’ busy work days. This lack of prioritization may be because pharmacists feel that it belongs in another professionals’ jurisdiction, or because they do not see its importance compared to other day-to-day demands or because they do not see it as part of the professional role of pharmacists. It is not clear how pharmacists would react if this task was removed from their jurisdiction and given exclusively to others such as physicians and/or health food store personnel.

This study builds on previous speculation that pharmacists consider ADR reporting as an ‘additional duty’ whereas medical doctors consider it as part of their ‘normal’ duties. (Sweis &
Wong, 2000) The pharmacists in this study often did not report adverse drug reactions unless they were in the category of knowledge generators (i.e., had strong professional disposition). This study highlights the potential problem associated with tasks that lie within multiple jurisdictions and suggests potentially important future research in the areas of professional task negotiation, professional disposition, doctor-patient communication, the role of government expectations and ADR collection mechanisms. It is important to determine how professions negotiate tasks that belong in several jurisdictions, how these tasks are allocated and prioritized and who finally takes responsibility for their completion.

Another theoretical contribution of this study is its application of Bourdieu’s theory of practice to the field of pharmacy; specifically, to the concept of habitus within pharmacy. (Bourdieu, 1977, 1990) The professional disposition of pharmacists appears to be instrumental in guiding their actions and responses to safety concerns in the community pharmacy workplace. The pharmacist’s perception of his or her role in practice and within the health care system is another key aspect influencing behaviour in clinical situations. This analysis can therefore contribute to future research in the area of pharmacy education and efforts to foster professional disposition among pharmacy students. It is important to characterize what makes up professional disposition, how it can be identified or fostered and how it might change within and between professionals. Professional disposition may be a key to determining professional attitudes and behaviours and can be further explored in pharmacy as well as in other health related disciplines.

7.7 Methodological Insights

In chapter 3, positionality was mentioned with respect to my status as not only a PhD student in pharmaceutical sciences but also as a Naturopathic Doctor. This dichotomy of practitioner and researcher influenced my ability to collect data by allowing me to position
myself to the participants in a way that made them relate to me. Traditional positivist approaches support distance between observer and observed (de Laine, 2001), while postmodernists assert that the participant observer’s account is necessarily a ‘joint product of the group and the observer’. (Ashworth, 1995) I have chosen to be reflective about my position and my experience and how it may influence me as a researcher and my own research findings.

In critical realism, positionality is taken in a spatial sense, so that for every phenomenon under investigation, there are various (spatial) perspectives or positions from which it can be viewed. (Bhaskar, 1975) The more perspectives from which it can be viewed, the fuller, richer picture of the situation. By understanding my own experiences and that my knowledge is situated, I recognize that my views are context-bound and partial. This recognition of my positionality necessitates conscious reflexivity about my interpretations of my data and about my interactions with my participants.

As is described in nursing literature, many of the skills considered essential to effective clinical work are associated with interviewing skills, such as ‘careful listening, astute observation and interpretation on several levels simultaneously’. (Borbasi, Jackson, & Wilkes, 2005; Lipson, 1989) Being an ND allowed me to feel comfortable in health food store settings and discussing natural health products, rather than entering a field of a completely unknown culture. However, this familiarity might have negatively influenced my ability to be objective about my participants and their responses. When interviewing one health food store owner for example, I was particularly troubled upon hearing the type of medical advice she was giving to her customers despite having no training and less than a few months of experience in the field. I had to constantly be aware of my questions to be sure that I wasn’t leading her in a particular way. Thankfully, due to my training in interviewing skills, I was able to keep my questions open-
ended which allowed a wealth of data through which to interpret her responses. My interpretation of this data in particular, differed from those of some of the other members of my committee and we had to discuss all themes in detail. We then reached consensus on the major themes by discussion.

In order to address the pitfalls of the insider phenomenon (Finlay, 2002), my supervisor and I arranged a thesis advisory committee composed of individuals with differing backgrounds, both clinically and from a research standpoint. They were able to guide me with respect to perspectives I had overlooked. For example, their analysis of the health food store personnel transcripts were particularly useful since I had worked at one many years ago and drew on my experiences during my own interpretation of the data. The committee was able to offer other views and interpretations of the data. We were able to discuss the themes and reach consensus as a group.

Another issue with my dual perspective was that when talking to consumers, they sometimes asked me for advice regarding their NHPs and reactions. None were urgent or severe enough issues to warrant concern and I was able to address their questions generally or refer them to a qualified health provider. However, if the questions had been related to their health directly, my obligations as a practitioner would conflict with my responsibilities as a researcher. In our ethics proposal, we clearly indicated that should the need arise for urgent care, we would assist the participant in finding appropriate health care. When talking to consumers, I did not routinely mention that I am trained as an ND. However, it is clearly stated on the consent form. This was a difficult situation as I was not approaching them on a clinical level but rather as a researcher. If they had clinical concerns, I would answer them generally at the end of the interview and then
offered to refer them to a practitioner who would be able to be more specific about their particular health history and course of action.

I learned that the dual perspectives could be helpful in situating me well with people from diverse backgrounds and opposing perspectives. However, my authority as a researcher and my analysis could be compromised without adequate reflexivity and collaboration. In future research, it is important to consider the practical, ethical and epistemological difficulties surrounding the complex nature of the researcher/practitioner role.

7.8 Limitations

Limitations in this research are centered on the sample. For the retailer populations studied (pharmacists and health food store personnel), the sample sizes were small because the focused nature of the research question meant that theoretical saturation was reached quickly. Efforts were made to broaden the sample size by using posters, advertisements, listservs and internet resources. Also, efforts were made to include retailers who were part-time employees, managers, store owners, from small independent stores, local retail chains, larger retail chains and other diverse backgrounds. The sample size is not necessarily a significant limitation because the sample recruited was diverse in their background, demographics and experiences, and as such offered a wide range of opinions. Due to this diversity, it is unlikely that more interviews would have contributed to additional themes being uncovered. (Guest, Bunce, & Johnson, 2006) In the consumer group, after much difficulty recruiting participants, the sample was collected via a combination of purposive sampling and the snowball technique, which may have limited the variety of respondents. (Creswell, 1998a) The sample was composed of primarily female participants who were highly educated, which although not representative of the general Canadian population, is relatively similar to the demographics of NHPs users overall.
Also, the range of ADRs experienced varied widely, which suggests that additional key themes were unlikely to emerge with additional interviews. Two key groups were missing in the samples, elderly and children. While this study focussed on the adult population, it would be helpful to study these additional groups in order to determine if any differences exist in their experience with ADRs.

**7.9 Next Steps**

The present doctoral research points to several important next steps in research. Two key areas are highlighted below.

The first is to explore natural health product (NHP) industry relationships with government and consumers. The 2004 NHP regulations place legal requirements on the NHP industry that include reporting of suspected adverse reactions associated with NHPs, similar to those currently in place for other regulated health products. If industry can be considered a funnel through which ADR information may be channelled, this is an area of research that warrants further exploration. (NHPD, 2003) Current research in the pharmaceutical industry describes the delicate balance between the interests of pharmaceutical companies and regulators. (Abraham, 1994) While this literature focuses on the pharmaceutical industry’s role, there is a paucity of information on the NHP industry. The NHP industry is unique because their products are already available over-the-counter and the regulations will be applied retroactively. Also, NHPs in general have more variation and are often not patented and thus, research on the pharmaceutical industry cannot be easily generalized to this sector. Using an institutional sociology theoretical lens, future research could analyze NHP risk by exploring the role of experts and expertise in regulation. (Abraham, 2004) Manufacturers and governmental decision-makers together control the access of NHPs, thus their risk assessments can be interpreted as
socio-political judgments. (Abraham & Reed, 2001) The research could investigate the relationship between public safety and the production, interpretation and communication of NHP adverse drug reaction (ADR) assessments between industry, government and consumers. These include current policies, standards of conduct, codes of ethics and compliance to legal requirements. The general objectives of this research should therefore first be to determine the key dimensions of industry influence on, and obstacles associated with industry compliance to, the new regulations. Second, to explore industry-government relationships with respect to ADR assessments. Third, to consider the policy implications of these relationships in the context of evolving social dynamics. The ultimate aim of the research would be to enhance our understanding of the role of NHP manufacturers in safety monitoring in the context of recent, strict regulatory demands. (NHPD, 2003)

The second area of needed research stemming from this doctoral work is in the area of professional disposition. The current doctoral work identifies a personal, individual perspective or attitude towards practice. The tendency to report is one aspect of this larger concept of professional disposition. Future research could explore what characteristics make up professional disposition. This research could be conducted with pharmacists but also with physicians and other health care professionals. It seems that there may be a range of professional dispositions that may encompass a number of different aspects of practice. It is important to understand how these elements come together and what influences this disposition. Is it innate, for example, or can it be taught? Is it created as part of a socialization process during professional education or is there something cultural about it? Perhaps it is a combination of the above possibilities. This topic could be explored through qualitative research via participant observation, interviews or focus groups. Participant observation is essential as professional
disposition doesn’t seem to be a conscious tendency and thus may not be adequately explained
through interviews alone. The characteristics, once identified, could be tested on a larger group
of practitioners through a survey to identify the range of dispositions that exist and the
constellation of elements that contribute to them.

7.10 Conclusions

This study examined the perspectives of three populations with respect to NHP ADR
reporting: consumers, health food store personnel and pharmacists. Consumers often decided to
take NHPs on their own without guidance from health care providers. If they experienced a
product-related ADR, they used their knowledge and experience to identify the product involved
and decided whether or not to discuss their experiences. Most often, consumers dealt with the
suspected ADR on their own. In some cases, usually where the reaction was more distressing or
if they perceived their experience as relevant to others, they discussed it with family or friends.
If they needed more information or advice on how to handle the ADR, they turned to trusted
resources for information. It most cases, the trusted resource was not one of their health care
providers but instead, the health food store personnel. Consumers cited poor relationships with
health care providers and the health care providers’ lack of time or interest as main reasons for
not telling them about NHP-related ADRs.

In contrast, health food store personnel were described as being attentive to consumer
needs. Although the health food store personnel in the study did not have the knowledge or skill
to identify and report ADRs to Health Canada, they did their best to address the consumers
concerns, usually by returning the product to the manufacturer for a refund. This provides a
unique but complicated opportunity to harness health food stores personnel as a way to collect
more ADR information.
Pharmacists, although also selling NHPs, are often not the ones that consumers turn to for information about suspected NHP-related ADRs. Most pharmacists do not report ADRs disclosed by patients to Health Canada, even though they acknowledge this is part of their scope of practice. Whether a given pharmacist reports suspected ADRs appears to relate to his/her professional disposition. Future research is needed in the area of patient communication, industry roles, health food store regulation and professional disposition in order to improve understanding of these facets of ADR reporting.
7.11 References


Project Title: Reporting of Adverse Events Associated with Herbal Products

Dear Sir or Madam:

I am writing to you requiring your assistance and participation in a research project for my PhD thesis at the University of Toronto. I would like to invite you to participate in my study.

What is the purpose of the study?

The purpose of this study is to explore the experiences of Canadians. This project will describe the key factors and concerns that these groups describe with respect to herbal products.

When and where will the study take place?

Data for the study will be collected from September to December 2007.

Who is being asked to take part and what will they do?

Consumers, like you, will be asked to participate in a short interview. During the interview, each participant will be asked to describe his or her experiences with herbal products, and the risks and safety of these products. The interview will last between 20 minutes and 1 hour, depending on how much information you would like to share. The interview will be conducted at a mutually convenient time as soon as possible after consent is given.

What are the risks and benefits of the study?

The study has minimal risk. Your participation is completely voluntary. If a participant is uncomfortable answering a particular question, they do not have to answer. Furthermore, participants may withdraw from the interview or study at any time.

This study will allow an understanding of reporting behaviors and barriers to the current system to be explored. The study will contribute to research in a largely unexplored field. The project will provide practical information about the views about risks and safety of herbal products. These results may help the Natural Health Product Directorate (NHPD), the division of Health Canada responsible for administering the regulations, understand consumer needs and perspectives. Since the NHPD has shown interest in this topic, the agency may use the data to devise additional measures designed to specifically to educate the public or to improve herbal product regulations. A summary of results will be distributed to participants who are interested.

Is the study confidential?

All the information collected during the research process will be kept strictly confidential. The names of participants will not be used for any stage of the research. An identification code will be used in place of names that will only be known to the research team (listed below). All documentation with personal information about the
participant will be kept in a locked cabinet. Data from the interview that is stored on a computer will require a password only known to the researchers. Personal information will not be released to any one else without a court order.

Quotations from the interviews may be used in the final research report. However, names and identifying information will not be included with these notes. The final report may be submitted for publication in a peer-reviewed journal.

**What if something new comes up during the study that affects participation in the research?**

Participants can withdraw from the study at any time, for any reason.

**Will I be compensated for participating in this study?**

No, you will not be compensated for participating in this study.

**What are my rights as a research participant?**

If you have questions about your rights as a research participant, please contact Jill Parsons, Research Ethics Officer, Health Sciences in the Ethics Review Office, University of Toronto, at telephone 416 946 5806 or by email: jc.parsons@utoronto.ca

Your participation is important for furthering this research study. Please consider participating. I can be contacted at the number and email address below for any questions or concerns that you may have.

Sincerely,

Rishma Walji
PhD Candidate, Department of Pharmaceutical Sciences, University of Toronto
rishma.walji@utoronto.ca
Tel: 416-978-6951

**Other Members of the Research Team:**

Dr. Heather Boon, Dr. Zubin Austin, Dr. Ross Baker, Dr. Joanne Barnes
Thesis Supervisor, Committee Member, Committee Member, Committee Member
heather.boon@utoronto.ca
Tel: 416-946-5859
Fax: 416-978-1833
Appendix B: Study Information Letter – Retailers

Study Information Sheet

Project Title: Reporting of Adverse Events Associated with Herbal Products

Dear Sir or Madam:

I am writing to you requiring your assistance and participation in a research project for my PhD thesis at the University of Toronto. I would like to invite you to participate in my study.

What is the purpose of the study?
The purpose of this study is to explore the experiences of Canadian pharmacists and health food store personnel who sell herbal products. This project will describe the key factors and concerns that these groups describe with respect to reporting side effects associated with herbal products.

When and where will the study take place?
Data for the study will be collected from June to June 2007.

Who is being asked to take part and what will they do?
Pharmacists and health food store personnel, like you, who sell herbal products at pharmacies and health food stores, will be asked to participate in a short interview. During the interview, each participant will be asked to describe his or experiences with herbal products, and the risks and safety of these products. The interview will last between 20 minutes and 1 hour, depending on how much information you would like to share. The interview will be conducted at a mutually convenient time as soon as possible after consent is given.

What are the risks and benefits of the study?
The study has minimal risk. The participation of your company is completely voluntary. If a participant is uncomfortable answering a particular question, they do not have to answer. Furthermore, participants may withdraw from the interview or study at any time.

This study will allow an understanding of reporting behaviors and barriers to the current system to be explored. The study will contribute to research in a largely unexplored field. The project will provide practical information about the views about risks and safety of herbal products and why people chose to report or not report side effects from herbal products. These results may help the Natural Health Product Directorate (NHPD), the division of Health Canada responsible for administering the regulations, understand consumer needs and perspectives. Since the NHPD has shown interest in this topic, the agency may use the data to devise additional measures designed to specifically to educate the public or to improve herbal product regulations.

A summary of results will be distributed to participants who are interested.
Is the study confidential?

All the information collected during the research process will be kept strictly confidential. The names of participants will not be used for any stage of the research. An identification code will be used in place of names that will only be known to the research team (listed below). All documentation with personal information about the participant will be kept in a locked cabinet. Data from the interview that is stored on a computer will require a password only known to the researchers. Personal information will not be released to any one else without a court order.

Quotations from the interviews may be used in the final research report. However, names and identifying information will not be included with these notes. The final report may be submitted for publication in a peer-reviewed journal.

What if something new comes up during the study that affects participation in the research?

Participants can withdraw from the study at any time, for any reason.

Will I be compensated for participating in this study?

No, you will not be compensated for participating in this study.

What are my rights as a research participant?

If you have questions about your rights as a research participant, please contact Jill Parsons, Research Ethics Officer, Health Sciences in the Ethics Review Office, University of Toronto, at telephone 416 946 5806 or by email: jc.parsons@utoronto.ca

Your participation is important for furthering this research study. Please consider participating. I can be contacted at the number and email address below for any questions or concerns that you may have.

Sincerely,

Rishma Walji, B.Sc., N.D.
PhD Candidate, Department of Pharmaceutical Sciences, University of Toronto
rishma.walji@utoronto.ca
Tel: 416-465-7779

Other Members of the Research Team:
Dr. Heather Boon, Dr. Zubin Austin, Dr. Ross Baker, Dr. Joanne Barnes
Thesis Supervisor Committee Member Committee Member Committee Member
heather.boon@utoronto.ca
Tel: 416-946-5859
Fax: 416-978-1833
Participant Consent Form

Reporting of Adverse Events Associated with Herbal Products.

I have read the accompanying letter of information titled Study Information Sheet. The study has been explained to me and I agree to participate in the study described. The researcher has addressed all my questions and concerns.

I understand that Ms Walji, a PhD student at the University of Toronto, will be the interviewer and that this study is her thesis requirement for her degree.

I understand that any information I provide for the study is strictly confidential and that I will only be identified by a unique code that will only be accessible to the researcher, the research coordinator and the thesis supervisor. Quotations for the final report will not be included if the context could lead to the identification of an individual. All written information from this study will be stored in a locked cabinet at the University of Toronto. Data gathered as a part of this study will be destroyed after 8 years.

I understand that complete anonymity about participating in this study cannot be guaranteed, especially if interviews take place in a public place, where others in the location may be aware of my participation in the study.

I understand that my participation in this study is voluntary and that I have the right to withdraw at any time.

If you have questions about your rights as a research participant, please contact Jill Parsons, Research Ethics Officer, Health Sciences in the Ethics Review Office, University of Toronto, at telephone 416 946 5806 or by email: jc.parsons@utoronto.ca.

DATE: ____/____/____ (to be dated by participant)

day  month  year

SIGNATURE OF Participant: _________________________________________

PRINTED NAME OF Participant: _______________________________________

DATE: ____/____/____ (to be dated by researcher)

day  month  year

SIGNATURE OF Researcher: _________________________________________

Rishma Walji, Researcher  Heather Boon PhD, Thesis Supervisor
rishma.walji@utoronto.ca  heather.boon@utoronto.ca
Tel: 416-978-6951  Tel: 416-946-5859
Fax: 416-978-1833  Fax: 416-978-1833
Appendix D: Participant Consent Form - Retailers

Participant Consent Form

Reporting of Adverse Events Associated with Herbal Products.

I have read the accompanying letter of information titled Study Information Sheet. The study has been explained to me and I agree to participate in the study described. The researcher has addressed all my questions and concerns.

I understand that Rishma Walji, a PhD student at the University of Toronto, will be the interviewer and that this study is her thesis requirement for her degree.

I understand that any information I provide for the study is strictly confidential and that I will only be identified by a unique code that will only be accessible to the researcher, the research coordinator and the thesis supervisor. Quotations for the final report will not be included if the context could lead to the identification of an individual. All written information from this study will be stored in a locked cabinet at the University of Toronto. Data gathered as a part of this study will be destroyed after 8 years.

I understand that complete anonymity about participating in this study cannot be guaranteed, especially if interviews take place in my pharmacy or health food store, where others in the location may be aware of my participation in the study.

I understand that my participation in this study is voluntary and that I have the right to withdraw at any time.

If you have questions about your rights as a research participant, please contact Jill Parsons, Research Ethics Officer, Health Sciences in the Ethics Review Office, University of Toronto, at telephone 416 946 5806 or by email: jc.parsons@utoronto.ca.

DATE: ____/____/____ (to be dated by participant)
day month year

SIGNATURE OF Participant: _________________________________________

PRINTED NAME OF Participant: _______________________________________

DATE: ____/____/____ (to be dated by researcher)
day month year

SIGNATURE OF Researcher: ________________________________

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Heather Boon PhD, Thesis Supervisor
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Fax: 416-978-1833
Appendix E: Interview Guide – Consumers

Background Information for Consumer Interview to be filled out by researcher

<table>
<thead>
<tr>
<th>Participant ID number:</th>
<th></th>
</tr>
</thead>
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<tr>
<td>Age:</td>
<td>--</td>
</tr>
<tr>
<td>Sex:</td>
<td>--</td>
</tr>
</tbody>
</table>

Health Concerns: For example:
- High Blood Pressure □
- Heart Disease □
- Diabetes □
- Asthma □
- Other ___________________

Other Medications/Supplements (Name): Manufacturer: (not needed for conventional drug, but for herbs) Dose/Frequency:
- [ ]
- [ ]
- [ ]
- [ ]

Phase 2: Questions for Consumer Guided Interview

1. What prompted you to take this herbal product?
2. Where did you purchase your product?
   a. Health food store? Pharmacy? Internet? Other?
3. Is this where you usually buy your herbal products? Why do you buy them from there?
4. Our research study is about side effects from herbal products, can you describe what happened to you?
   a. How soon after you took the product did it happen?
   b. How severe was it?
   c. Exactly what symptoms did you experience?
5. What did you do about it? Why?
   a. Did you tell anyone (and why or why not)?
   b. If your side effects were more mild/moderate/severe, would you have responded differently?
6. Do you think that people should report their side effects? Why or why not?
a. Where would be an appropriate place to report? Medical Doctor, Pharmacist, Naturopath, Retail store where they bought it, Manufacturer, Media, Other.

7. What kinds of side effects do you think should be reported?

8. What would prompt you to report (or not report) a side effect?

9. What do you think about the safety of herbal products in general?
   a. How safe did you think the product you took was before you used it?

10. Where do you get information about herbal products? Why that source?

11. Are you familiar with the reporting system for adverse drug reactions in Canada (describe what you have heard if anything)? What do you know about it? Have you ever used it? What for? To send in a report? Or to look at the reports that other people have made?

12. What do you think are the major obstacles in reporting side effects from an herbal product?

13. Are you satisfied with the current procedure of adverse event reporting system for herbal products? Why or why not?
   a. Has Health Canada and/or your health practitioner provided any information, assistance, or feedback to you to help you become aware of side effect reporting procedures?
   b. What do you think should be done to enable reporting of side effects from herbal products?

Added October 2007:
Would you have acted differently if the product had a label or if you knew you would get a … (rash, diarrhea .. etc.)?
How do you feel about pharmacies and health food stores, both of which sell NHPs?
Appendix F: Interview Guide – Retailers

Background Information for Retailer Interview to be filled out by researcher

<table>
<thead>
<tr>
<th>Participant ID number:</th>
<th></th>
</tr>
</thead>
</table>
| Position               | Pharmacist ☐  
|                        | Health food store: owner ☐ employee ☐ manager ☐ |
| Sex                    | Male ☐ Female ☐ |
| Amount of time working in this position | (indicate months or years) |
| Number of hours working per week | (any store) |

Questions for Retailer Guided Interview

1. What are the most common herbal products that you sell?
2. What do you think about the safety of these products?
3. What do you think about the safety of herbal products in general?
4. How often do people ask for your advice when taking these products?
   a. What kinds of questions do they ask?
   b. What kinds of risk/safety questions do they ask (if any)?
   c. Can you provide some specific examples?
5. How would you describe your knowledge about herbal products?
   a. How do you decide what products to recommend?
   b. How do you differentiate between different brands of the same herb?
   c. Where do you get your information about contra-indications or drug interactions associated with these products?
   d. What kind of training do you have about herbal medicines?
6. How often do you have consumers tell you about side effects that they have experienced?
   a. Can you provide an example of when this happened?
7. What do you do about this information?
   a. Do you tell the patient to stop taking the product?
   b. do you report it to someone (who?)?
8. Are you familiar with the AE reporting system in Canada? (What do you know about it?)
9. What kinds of AEs would you report, if a consumer reported them to you?
   a. How do you decide?
10. What do you think about the current reporting system?
11. What do you think are barriers to reporting?

12. Case Study: If a 56 year-old man who took an herbal weight loss product came to you and said that they experienced (a, b, or c), how would you respond?
   a. Digestive disturbances and malaise
   b. A persistent skin rash on his forearms
   c. Palpitations and abnormal heart rhythms, and dizziness

13. Is there anything else that you’d like to add?

Added Sept 2006:
Role of the pharmacist, role of the HFS, MD, ND, etc.
Case, if someone came in with a mild rash, then another person same rash, then another (pattern) how would you respond?
What is the definition of an adverse event?
Where do consumers go for information?

Added Nov 2006:
EBM questions – what is research? What does it mean to be responsible?
What is the difference between a pharmacy and HFS?

Added Feb 2007:
JB: As stated during phone call: do HFS recommend herbal medicines to consumers who have visited HFS because they have had an adverse effect to a CONVENTIONAL MEDICINE and want to take something more natural instead – I think this is v important.

Added April 2007:
HFS perception of their role and responsibilities wrt adverse events and natural health products.
**Appendix G: Coding Tree – Consumers**

**Consumer Coding Tree – Nov 21, 2007**

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchasing Decisions</td>
<td>How they decide where to buy an NHP and why</td>
</tr>
<tr>
<td>Info Sources</td>
<td>Where consumers get their information about NHPs</td>
</tr>
<tr>
<td>Brand/quality</td>
<td>Any reference to preference or opinion about certain brands or quality of one brand over another, includes media sources</td>
</tr>
<tr>
<td>Family history</td>
<td>Reference to family use of NHPs</td>
</tr>
<tr>
<td>Recommendations</td>
<td>Any recommendations from the participant</td>
</tr>
<tr>
<td>Perceptions of</td>
<td></td>
</tr>
<tr>
<td>Severity</td>
<td>How severe they thought their reaction was</td>
</tr>
<tr>
<td>Sense making</td>
<td>Their idea about what happened and how it was related to the product, worse before getting better</td>
</tr>
<tr>
<td>Safety of NHPs</td>
<td>Any reference to safety of NHPs</td>
</tr>
<tr>
<td>Resolution</td>
<td>Satisfaction with how the AE was handled</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>Any reference to perceptions of their pharmacist, includes relationship with pharmacist</td>
</tr>
<tr>
<td>MD</td>
<td>Any reference to perceptions of their MD, includes their relationship the the MD</td>
</tr>
<tr>
<td>Industry</td>
<td>Any reference to perceptions of industry, NHP manufacturing companies, reaction of industry to report, etc</td>
</tr>
<tr>
<td>Drugs</td>
<td>Any reference to perceptions of drugs/pharmaceutical medications</td>
</tr>
<tr>
<td>CAM health provider</td>
<td>Any reference to perceptions of their CAM health provider, including ND, herbalist, etc., includes their relationship with this provider</td>
</tr>
<tr>
<td>Adverse Event</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Description of the AE</td>
</tr>
<tr>
<td>Action</td>
<td></td>
</tr>
<tr>
<td>Tx</td>
<td>seeking another treatment</td>
</tr>
<tr>
<td>Change dose</td>
<td>reference to changing the dose, taking less product, etc</td>
</tr>
<tr>
<td>D/c</td>
<td>discontinuing product, dechallenging, rechallenging</td>
</tr>
<tr>
<td>Report</td>
<td></td>
</tr>
<tr>
<td>Trigger</td>
<td>what made them or would make them report</td>
</tr>
<tr>
<td>To nurse helpline</td>
<td>reported to nurse helpline</td>
</tr>
<tr>
<td>To MD</td>
<td>reported to MD</td>
</tr>
<tr>
<td>To industry</td>
<td>reported to industry</td>
</tr>
<tr>
<td>To friends/family</td>
<td>told friends/family about AE</td>
</tr>
<tr>
<td>To CAM health provider</td>
<td>reported to CAM provider</td>
</tr>
<tr>
<td>Details</td>
<td>what they were asked to report, what info was included, how they did it</td>
</tr>
<tr>
<td>Barriers</td>
<td>what is or would be a barrier for reporting, lack of knowledge, loss of access</td>
</tr>
<tr>
<td>HFS</td>
<td>reporting to health food store</td>
</tr>
</tbody>
</table>
Appendix H: Conceptual Map – Consumers

Consumer Coding Tree
November 21, 2007

Safety

Info sources
Perceptions
Purchasing decisions
Brand/Quality
Family history
Adverse Event
Recommendations

Safety of NHPs
Industry
MD
CAM health provider
Risk
Drugs
Pharmacist
Regulations

Description
Resolution
Sense making
Severity

Action
Discontinue
Other tx
Change dose

Barriers
Trigger
To industry
To MD
To CAM health provider
To Nurse Helpline
To family and friends
Outcome
Details
Health food store

Report
Appendix I: Coding Tree - Retailers

CODING TREE: RETAILER PERSPECTIVES ON HERB SAFETY (June 2007)

SAFETY:

KNOWLEDGE:
Confidence – retailer’s confidence about own knowledge related to herbs and about their knowledge, and about their ability to recommend products, etc. their own knowledge about herbs e.g. “my issue is that I just don’t know enough about them”.

Advice Given – NOT related to safety

Recommendations – about products taken, how to take the product, which product to take for what

Referral – to someone else more knowledgeable

Education

Pharmacist
Undergraduate – any herbal education in pharmacy school
Continuing Education – any herbal education/ training after graduation

Health Food Store – includes references to training “in store”, “classes”, past training, self-directed learning, etc.

Research – scientific literature, evidence based, also includes other information ‘out there’ on herbs or perceived information. References to what knowledge exists in general about herbs

Information Sources – any information sources that the retailer uses for looking up information re: herb information, contraindication, side effects, etc.

Health care practitioner – calling a health provider for information, does not include references to referring the patient to their doctor for safety or AE issues (see safety advice referral doctor)

Customer feedback – any information about the herb given by another consumer e.g. “my information is anecdotal from other patients”, “I would say that I’ve heard [from other patients] that this product ..”

Textbooks – any reference to textbooks or journal articles used to look up information

Industry – manufacturer and chain stores e.g. “the franchise has a booklet” or “I’ll call the company to find out answers to my questions” or “I don’t think the company could answer my questions”

Professional Organizations – motherrisk, drug info hotline, pharmacist’s association, drug information center

Internet – websites referred to

Media – influence of media, e.g. “a lot has to do with the way it’s marketed”

PERCEPTIONS OF:

Brand / Quality – in reference to a particular brand or quality of the product “I have problem with quality control .. a lot of companies don’t have DIN numbers”. Includes references to “reputable brands”

NHP regulations – in reference to regulations for NHPs eg. “you don’t know the dose on the label is actually in the pill, and that’s probably an issue with the ministry ..”

(brand/quality issue)

Appropriate Use – in reference to appropriate use of a herbal product, consumers using things in a way they shouldn’t, for prevention. Depends also on getting appropriate info from pharmacist/HFS so a knowledge section is linked below.
Perception of consumer – general, SE/DI, behaviour eg. “consumer usually know what they want because they saw it on the internet or they heard from a friend”. “I think that consumers think ..”

Advice Asked

- **Frequency** – how often asked advice on a product
- **Content** – what are they asked about eg. “people ask about sleep herbs like valerian”

Perception of pharmacist – what they think, what others think of them, eg. reference to the role pharmacists should play in herbal products eg. “I think that biomedical practitioners are narrow-minded when they don’t take into account what patients might see as helpful”.

Also linked to merchandising

Perception of Health Food Store – what they think, what others think of them eg. in reference to how consumers and personnel interact, their perceived knowledge

- **Merchandising** – how to decide what to sell e.g. “we’re mandated to sell herbs” or “we only carry brands we trust”

Perception of Medical Doctor – what they think, what others think of them

Efficacy – in reference to the efficacy of an herbal product or lack of efficacy also of herbal meds vs conventional meds

Perceived Safety – a perception of safety of the herbal product, natural = safe, or perceived unsafe e.g. “I don’t believe that it’s safe just because it’s natural”, or perceived unsafe.

SIDE EFFECT/ DRUG INTERACTION

- **Frequency** – how often a side effect or drug interaction is come across
- **Definition** – how a side effect or DI is defined by the participant, eg. reference to the time after taking the product, the severity, the symptoms, “doesn’t agree with me” is not really an AE
- **Knowledge** – knowledge of participant about side effects and DI
- **Examples** – examples of side effects or drug interactions
- **Investigation** – the process of investigating symptoms of an AE e.g. pharmacists ask about when it occurred, what happened, etc – process they perform from their training, what are they looking for, what conclusions it helps them come up with.

Reporting

- **Previous experience** – has done/tryed to report an AE or DI, or has never reported i.e. what is their experience with reporting previously – includes reporting drug AE and herbal AE
- **Recommendations for change** – what people recommend to make the reporting system better, e.g. more education
- **Responsibility** – whose responsibility is it to report? E.g. “I think health professionals should be responsible for assessing health conditions and side effects”

Action

- **Trigger** – trigger for HFS worker or pharmacist to report
- **Unexpected** – something new that they haven’t seen
- **Severity** – how severe the reaction is by their definition “
- **Patient concern** – how concerned the patient is about the reaction
- **Pattern** – if it’s a repeated pattern of events
- **Notoriety of product/herb** – ie they have heard something about it before

Report to

- **MD/Health Care provider** – report S/E to MD
- **Health Canada** - file report with Health Canada
Manufacturer – call manufacturer
Public health – for a public health issue, eg. outbreak
Advice – related only to AE and DI
Approach – prevention, cautious, conservative e.g. “I always tell them to start with a low dose” or “I tell them that I don’t know much about the product and it’s up to them”
Discontinue – stop using the product
Referral – referral to health care provider, including CAM practitioners
Recommend treatment – for side effect or reaction eg. for rash recommend antihistamine
Recommend substitute product – in place of the product that caused the problem
Barriers
Reporting knowledge – of reporting system, includes knowledge of or lack of knowledge of reporting system
Complexity – to confusing
Time – takes too much time
Incidence – doesn’t happen enough, don’t see enough AEs
Patient Feedback – customers don’t tell them that there is an AE or DI
Not worth it – don’t get any acknowledgement, “what’s the point?”
Skepticism – ie the person who thought that patients were just trying to get their money back
Lack of info - we need all the information to report it. Can’t assess if it’s a true ADR.
Returns – return product if side effect or customer unsatisfied
Other - documentation
FREE NODES
Errors - wrong statements that are made in reference to a product or anything else during the interview
Demographics – basic demographic info about the participant.
Role of pharmacist – any reference to the role of the pharmacist
Corporation – any reference to corporations
Appendix J: Conceptual Map – Retailers

Coding tree HFS and PHM – June 2007

SAFETY

Knowledge

Confidence

Advice Given

Recommendations

Refer

Research

Education

Info sources

PHM

HFS

Health care provider

Customer feedback

Textbooks

Industry

Prof organization

Internet

Media

Perceptions of

Brand/quality

NHP regs

Appropriate use

HFS

PHM

Consumer

Merchandising

Advice asked

Frequency

Content

MD

Efficacy

Percieved safety

Side effect/DI

Example

Frequency

Definition

Investigation

Reporting

Prev experience

Recomend change

Responsibility

Action

Trigger

Unexpected

Severity

Pt concern

Pattern

Notoriety

Advice

Approach

Discontinue

Refer

Recomend treatment

Substitute product

Report to

Health care provider

Health Canada

Manufacturer

Public health

Advice

Barriers

Reporting knowledge

Time

Complexity

Incidence

Pt feedback

Skepticism

Lack of info

Returns

Other
UNIVERSITY OF TORONTO
Office of the Vice-President, Research and Associate Provost
Ethics Review Office

PROTOCOL REFERENCE #17385 now #20261

June 27, 2007

Dr. H. Boon
Faculty of Pharmacy
144 College St.
Toronto, ON M5S 3M2

Ms. R. Wallji
Faculty of Pharmacy
144 College St.
Toronto, ON M5S 3M2

Re: Your research protocol entitled, “Reporting Adverse Events Associated with Herbal Products”

ETHICS APPROVAL

Original Approval Date: June 6, 2006
Next Expiry Date: June 5, 2008
Renewal: 1 of 4

We are writing to advise you that the Health Sciences Research Ethics Board has granted annual renewal of ethics approval to the above referenced research study through the REB’s expedited process. Ongoing projects must be renewed prior to the expiry date.

We understand that there have been no changes to the consent documents since the original approval date. Participants should receive a copy of their consent form.

During the course of the research, any significant deviations from the approved protocol (that is, any deviation which would lead to an increase in risk or a decrease in benefit to participants) and/or any unanticipated developments within the research should be brought to the attention of the Ethics Review Office.

Best wishes for the successful completion of your project.

Yours sincerely,

Jenny Peto
Ethics Review Coordinator
UNIVERSITY OF TORONTO
Office of the Vice-President, Research and Associate Provost
Ethics Review Office

PROTOCOL REFERENCE #17385

June 6, 2006

Dr. H. Boon
Leslie Dan Faculty of Pharmacy
19 Russell Street
University of Toronto
Toronto M5S 2S2.

Ms. R. Walji
PhD candidate, Pharmacy
Leslie Dan Faculty of Pharmacy
19 Russell Street
University of Toronto
Toronto M5S 2S2.

Dear Dr. Boon and Ms. Walji:

Re: Your research protocol entitled, “Reporting Adverse Events Associated with Herbal Products” (Revised version received June 2, 2006) by Dr. H. Boon (supervisor), Ms. R. Walji (PhD candidate)

We are writing to advise you that the Health Sciences I Research Ethics Board has granted approval to the above-named research study, for a period of one year. Ongoing projects must be renewed prior to the expiry date. Your ethics protocol approval is valid for a period of 1 year. It is the responsibility of the investigator to maintain a valid approval throughout the duration of the research activity, and to report to the Ethics Review Office of its completion. Annual Renewal of Ethics Approval forms and Study Completion Report forms can be found at http://www.research.utoronto.ca/ethics/eh_forms.html

Consequences of expired ethics protocol approvals may include the freezing of funds and/or refusal to review new ethics protocol submissions.

The following documents — all to be printed on U of T departmental letterhead — (revised versions received June 2, 2006) have been approved for use in this study: Questions for PoS Guided Interview (Appendix 1), Questions for Consumer Guided Interview (Appendix 2), Study Information Sheet/Consent Form — Phase 1 (Appendix 3), Study Information Sheet/Consent Form — Phase 2 — Consumers (Appendix 4), and Recruitment Flyer (Appendix 5). Participants should receive a copy of their consent form.

During the course of the research, any significant deviations from the approved protocol (that is, any deviation which would lead to an increase in risk or a decrease in benefit to participants) and/or any unanticipated developments within the research should be brought to the attention of the Ethics Review Unit.

Best wishes for the successful completion of your project.

Yours sincerely,

[Signature]

Marianna Richardson
Ethics Review Coordinator

Simcoe Hall 27 King’s College Circle Toronto Ontario M5S 1A1
Telephone 416/978-3165 Fax 416/946-5763 email: ethics.review@utoronto.ca
Appendix L: Adverse Drug Reaction Reporting Form

1. Name (from label & manufacturer, if known)
   # 1
   # 2

2. Drug, frequency & route used
   # 1
   # 2

3. Therapy duration (if unknown, give duration)
   # 1 from (dd mm/yyyy) to (dd mm/yyyy)

4. Indication for use of suspected health product
   # 1
   # 2

5. Reaction lasted after use stopped or dose reduced
   # 1
   # 2

6. Lot # (if known)
   # 1
   # 2

7. Exp. date (if known)
   # 1 (dd mm/yyyy)

8. Reaction recurred after reintroduction
   # 1
   # 2

9. Concomitant health products (name, dose, frequency & route used), and therapy dates (dd mm/yyyy) (exclude treatment of reaction)

10. Treatment of adverse reaction (medication &/or other therapy), include dates (dd mm/yyyy)

D. Reporter Information
   (See "Confidentiality" section below)

1. Name, address & phone number

2. Health professional?
   Yes
   No

3. Occupation

4. Also reported to manufacturer?
   Yes
   No