FAMILY PHYSICIANS' INTERACTIONS WITH PHARMACEUTICAL SALE REPRESENTATIVES:
A FOCUS GROUP STUDY IN THREE COUNTRIES

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Thank you to all other members of the research team of the Pharma Rep Study, including co-PI Dr. Joel Lexchin, and local assistants from the four research sites who contributed in the earlier stages of the focus group study (i.e., prior to the analysis which is the subject of this 598 Report). Those named in this report are: Lilianne Bordeleau (LB), Bridget McGowan (BM) and Amanda Slaunwhite (AS), the research assistants who helped with transcript cleaning and initial coding into categories; Alan Cassels (AC), Line Guénette (LG), Mary Osborn (MO) and Claude Rousseau (CR) who assisted with pilot testing the facilitator’s guide. AC and CR also co-facilitated at some of the focus groups, and MO was an observer at the English focus groups. ER refers to me, Ellen Reynolds; BJM refers to Barbara Mintzes. Thank you to the local investigators at each research site, and their assistants: Dr. Marie-Dominique Beaulieu at Université de Montréal, Dr. Michael Wilkes at University of California-Davis, and Dr. Geneviève Durrieu at Université Paul Sabatier in Toulouse. Dr. Line Guénette at Université Laval oversaw local coordination of the Montreal focus groups. Thanks also to Dr. Guénette for sharing the literature review that she conducted of the regulatory frameworks as part of the regulatory policy analysis (i.e., a separate component of the study) when she was a postdoctoral fellow on the project.
STATEMENT OF AUTHORSHIP

I, Ellen Reynolds, certify that the work presented in this 598 Report is entirely my own, unless otherwise indicated. As this project is a follow-up to a previous study (Mintzes et al., 2013), key findings and other elements of previous collaborative work from the Pharmaceutical Sales Representatives and Patient Safety Study are included in this report; however, any parts of the work presented here that were developed or carried out previously or collaboratively are identified as such.

As this project is part of a larger study with certain elements already completed, the following describes my role in the study and the research prior to the analysis that is the subject of this 598 Report:

I assisted with the development of the proposal for funding for the follow-up focus groups—as part of a Canadian Institutes for Health Research (CIHR) operating grant renewal (awarded in 2012). I coordinated the set-up of the focus groups in all four locations (Vancouver, Montreal, Sacramento, and Toulouse), with local assistance for physician recruitment; co-wrote the facilitator’s guide, protocol, and ethics documents (e.g., informed consent forms); and facilitated focus groups in English and was the observer at the French focus groups. As the only person who attended all 12 focus groups (as facilitator or observer), I was centrally involved in all aspects of the focus group study. I coordinated transcription of the focus groups and was responsible for reviewing, cleaning, and anonymizing the transcripts with assistance from three research assistants. The research assistants also assisted with the initial coding into meaning units/categories. The names of those who contributed to the focus group project are listed in the Acknowledgements and referred to by initials in the report.

The principal investigator, Dr. Barbara Mintzes, provided regular feedback on the research activities along with other members of the research team; however, I have been the main person responsible for the focus group study with assistance as described above. For the purposes of this 598 Report, I have been responsible for carrying out the data analysis, and have written this report on my own, including the literature review, analysis results, and recommendations.
EXECUTIVE SUMMARY

Introduction
Family physicians are seeking accessible, evidence-based information on medicines to inform their prescribing practice and to care for their patients; yet physicians may often rely on biased or inadequate drug information from pharmaceutical sales representatives (PSRs), commonly referred to as "drug detailers," to inform prescribing decisions. The information provided by PSRs is often low quality and may lead to irrational prescribing of medicines that are inappropriate for the patient, resulting in potentially negative health outcomes for patients.

A recent observational study by Mintzes et al. (2013) examined the quality of information provided to family physicians by PSRs and the influence on prescribing practice within three different regulatory environments: Canada (Vancouver and Montreal), the United States (Sacramento), and France (Toulouse). The researchers hypothesized that PSRs would provide more drug safety information to physicians in countries with stricter regulations (i.e., France and the United States have more rigorous regulations governing physician-PSR interactions compared with Canada). Mintzes et al. (2013) found that indeed physicians in Toulouse reported that PSRs were more likely to provide safety information compared with the other sites; however, the study also indicated a serious problem in all research sites with the quality and balance of information provided by PSRs, potentially compromising patient safety. To further explore these findings, the researchers carried out a qualitative follow-up focus group study. The analysis of the focus group data is the subject of this 598 Project report.

The focus group data analysis was carried out guided by the following research questions:

1. What are the physicians’ perceptions of PSRs and PSR interactions, and the reasons they report for seeing PSRs?

2. What are the physicians’ opinions about key findings of the Pharma Rep Study, in particular opinions on the quality of information provided by PSRs during sales visits?

3. What influence, if any, do the physicians think their interactions with pharmaceutical sales representatives have on their practices/prescribing decisions (i.e., likelihood to prescribe)?

4. What differences in physicians’ experiences, perceptions, and opinions, if any, may be related to different regulatory environments or other site-specific factors of the three included countries?

The aim is to better understand the context of physician-PSR interactions from the physicians’ perspective, and to explore the influence of PSR interactions on physician attitudes and prescribing behaviour in three different regulatory environments.
Methods

Prior to conducting the focus group data analysis, a review of literature was completed to compile evidence on physician experiences of and attitudes toward PSR interactions, and related influences on prescribing practice. The review also explored literature on theory related to physician-PSR interactions, placing the focus group findings within a larger research context for discussion. The review is organized in four main sections aiming to inform the analysis and answer the research questions: 1) physician perceptions of PSR interactions and reasons for seeing PSRs; 2) physician opinions on the quality of information provided by PSRs; 3) factors influencing physician attitudes and prescribing behaviour (i.e., likelihood to prescribe); and 4) related theory.

Following the literature review, the focus group data analysis was conducted using the framework analysis approach described by Ritchie and Spencer (1994), which involved five stages: 1) familiarization with the data, 2) identifying a thematic framework, 3) indexing, 4) charting, and 5) mapping and interpretation. The thematic framework was developed as part of a team, using an iterative process to code the data into categories. Data management was with the open-source computer software TAMS Analyzer for coding, then Microsoft Excel for charting, mapping, and interpretation. Thematic charts were created for each focus group, charting the comments of each focus group participant over 23 sub-themes. Each excerpt was then summarized in one thematic chart per research site, including anonymous quotes from participants. This provided an overview of the data per site for analysis, mapping the range of physician experiences to identify attitudes, behaviours, and reasons for seeing PSRs as well as associations between attitudes and behaviours. The original transcripts were referenced throughout the process and analyst notes were compiled to record the analysis process.

Results are organized according to a conceptual framework developed based on the themes identified in the data, and are presented using the participants’ comments in their own words preceded by a brief descriptive text.

Results & Discussion

A total of 57 physicians participated in 12 focus groups (three in each of the four sites).

Physicians’ perceptions of interactions and reasons for seeing PSRs were consistent with previously conducted qualitative studies. Physicians reported similar characteristics of PSRs and the same reasons for seeing them. Physicians valued the PSR interactions especially for information on new drugs, and reminders of the promoted products. The value placed on drug reminders indicates a lack of awareness that reminders serve to reinforce promotional priorities to prescribe newer, patented drugs, and pharmaceutical solutions generally, leading to a less evidence-based and rational approach to prescribing. Another important reason physicians gave for seeing PSRs was to receive drug samples, except in Toulouse where drug samples are prohibited. Along with samples, physicians valued the provision of food, invitations to CME, handouts, and tools from PSRs. As found in the literature, physicians accepted these “gifts” often on behalf of their patients and staff, making them more socially acceptable and less of a conflict of interest in the opinion of physicians. Physicians also stated that they used PSR interactions as a teaching tool with medical residents but that residents
were often reluctant to participate. Across all sites, physicians reported that they were taking more control of PSR interactions, presenting this perceived control as evidence that they were not influenced by PSRs.

In terms of the **perceptions of information quality**, physicians stated that they were fully aware that PSR visits were part of a sales pitch, and their expectations about the provision of safety information in particular were low across all sites. Most comments revealed a level of cognitive dissonance related to the physicians’ stated awareness that the information provided by PSRs was biased, yet trusting them to answer questions about harmful effects with full and balanced information. Also, despite having low expectations about receiving drug safety information, most physicians expressed disappointment and concern that serious harms were rarely mentioned, and they did not expect it to improve without stricter legislation. Most physicians also provided possible justifications for why PSRs rarely provided safety information.

In rating the quality of scientific information provided by PSRs, many physicians explained that they had likely reinterpreted the question, rating the overall presentation by the PSR or the quality of the drug, and not the actual **scientific** quality of the information. Some explained that they did not feel qualified or did not have time to assess the scientific quality. Physicians seemed to offer these explanations to justify the study findings in which 57% of promotions were rated as **good or excellent**. When asked what would prompt physicians to rate an interaction as **good or excellent**, many referred to the quality and format of the PSRs’ presentation, and the provision of information and reference materials (e.g., journal articles).

As for the **perceived influence on prescribing** and responses to the Pharma Rep Study findings, mainly the physicians attempted to justify or sideline the findings, or they gave reasons why the findings did not apply to them. These justifications and contradictory attitudes and behaviours were apparent throughout the data across all sites and are consistent with the findings on cognitive dissonance by Chimonas et al. (2007). Physicians in all sites consistently declared their awareness of the conflict of interest related to PSRs, and most reported a high level of perceived control over their prescribing behaviour. As the literature indicates, **actual** behavioural control related to prescribing is not in evidence.

Most physicians reported that participation in the study increased their awareness about the interactions. Some stated that they had made changes in their practice, or planned to; however, they consistently added that they did not know how sustainable these changes would be. Physicians’ reflections on the influence of the study indicated the need for ongoing interventions to maintain a shift in practice or behaviour, and hinted at possible intervention methods to increase physician awareness of pharmaceutical industry influence.

To counter the bias in the information from PSRs, physicians described strategies such as asking questions of PSRs or conducting their own research using independent information sources. They also described external decision-making support, seeking to corroborate information by consulting specialists, although many physicians recognized the possible conflict of interest of specialists (e.g., being paid by drug companies to speak at CME events).
Sources of independent drug information mentioned included independent drug bulletins (e.g., Therapeutics Letter from Therapeutics Initiative at the University of British Columbia, Prescrire in France) and the Cochrane Collaboration. Physicians also praised the practice of “academic detailing” (i.e., independent and publicly funded drug detailers).

Several other themes associated with perceived influence on attitudes and prescribing emerged during the discussions, including the role of pharmacists, preferences for quick and accessible drug information, and the role of two high profile drug scandals, i.e., rofecoxib (Vioxx) in North America and benfluorex (Mediator) in France. The focus group discussions provided insight into the physicians’ likelihood to prescribe given the many factors influencing the decision-making process. The discussions also revealed physician preferences about sources and types of information as well as methods of delivery they would prefer at the point of care to assist them with prescribing decisions.

As for regulatory and other site-specific differences, the mention of regulation governing PSR activities varied from site to site. Toulouse physicians were most likely to mention regulation, and in Sacramento, physicians often referred to FDA regulation. In Canada, physicians rarely mentioned regulation except to say that there was a need for more and better legislation governing PSR activities, indicating a lack of awareness that legislation exists. Generally, the comments about the impacts of regulations were positive; however, several physicians in Toulouse in particular and several in Sacramento indicated that some regulations put too many restrictions on what PSRs were able to say, resulting in formulaic and less informative interactions.

When physicians were asked to reflect on the influence of PSRs on their prescribing practices and the possible influence of the study, there was a notable difference with physicians in Toulouse, seeming to reflect a generally higher level of awareness of the influence of PSR interactions in Toulouse physicians. Higher levels of awareness about regulations in Toulouse and Sacramento compared to the Canadian sites correlate with stricter regulations in France (i.e., the strictest) and the United States; whereas in Canada with its form of industry self-regulation (i.e., the least strict), physician awareness of legislation was the lowest. For physicians to avoid relying on biased promotional drug information, the focus group data were consistent with other researchers’ conclusions that the solution may be to limit or prohibit interactions with PSRs.

The focus group data provide contextual information and information on physician preferences that may be useful in identifying and targeting interventions. Also, the theory that stricter regulatory oversight in Toulouse and Sacramento resulted in physicians being more aware of PSR influences may indicate the first stages of change. According to models of human behavioural change, awareness that there is a problem is a key initiating factor in behaviour change, but without continued reinforcement (e.g., interventions, reminders), physicians themselves acknowledge that they will most likely return to “old habits.”

A possible limitation of the study is that physicians who participated in the focus groups may not have been representative of the larger Pharma Rep Study sample. However, most
characteristics of the focus groups were similar to those of the Pharma Rep Study, and the consistency of most findings across all focus groups indicates that the subsample was mainly representative of the larger sample. Another possible limitation is that the framework analysis approach has the potential to be reductive as a result of summarizing the participants’ discussions and distilling the themes. This risk was minimized through a systematic and well-documented approach to the analysis.

Conclusion
Physicians’ attitudes toward the information provided by PSRs are often contradictory. They report a high level of awareness that PSR interactions are biased sales promotions and their expectations of receiving balanced information about drug benefits and harms from PSRs are low. Yet many physicians continue to see sales representatives and to value the information on new drugs and drug reminders; drug samples; food; and invitations they provide. The majority of physicians did not acknowledge the influence of gifts of food or other items from PSRs. Physician strategies to counteract influence—asking questions of the PSRs, conducting their own research, and seeking corroborating information from specialists or CME events—often did not address information bias.

Physician perceptions and preferences related to PSR interactions identified in this study may inform the development of interventions to address the immediate lack of safety information provided. Interventions geared to meet physicians’ need for evidence-based prescribing information should aim to provide convenient access to summarized information on drugs, and supportive programs for physicians.

Physician perceptions and responses to the key findings of Mintzes et al. (2013) are generally similar across all sites. One significant exception is related to awareness of regulation. Physicians in Toulouse especially, and in Sacramento, demonstrated a higher level of awareness of regulations related to PSR visits compared with Canada. In Montreal and Vancouver, physicians were often not aware of federal regulations requiring PSRs to provide balanced drug information. Educational strategies may be helpful in raising awareness, but they are unlikely to be effective on their own. Most physicians themselves are generally unlikely to reduce or eliminate their contact with PSRs unless regulation requires them to do so. This regulatory approach could occur at various levels.

Recommendations
Recommendation 1 – Federal Government – Health Canada: Phase in legislation that prohibits drug promotion by pharmaceutical sales representatives to family physicians in Canada with the goal of improving patient safety.

Recommendation 2 – Provincial/Territorial Governments: Require pharmaceutical companies to provide a percentage of drug sales earmarked for provincial/territorial governments to fund the provision of independent drug information, including programs of academic detailing in all provinces and territories.
Recommendation 3 – Professional Regulatory Bodies (e.g., College of Family Physicians Canada, Royal College of Physicians and Surgeons of Canada, provincial colleges of physicians): Ensure that accredited medical educational programs, including CME and other medical training, are provided free from commercial bias and conflict of interest.

Recommendation 4 – Medical Students: Organize an ongoing national campaign by medical students to raise awareness among physicians about the influences of pharmaceutical sales representatives on the cost, appropriateness, and safety of prescribing.

Recommendation 5 – Colleges of Pharmacists and Pharmacist Associations: Establish local pharmacotherapy discussion groups on a regular and ongoing basis to promote collaboration between pharmacists, physicians, and patients related to the provision of drug information and appropriate prescribing.

Recommendation 6 – Patient/consumer organizations: Organize public education based on the study to inform patients/consumers about the results; discuss strategies for patients to inform themselves about prescription safety, and to improve patient-physician-pharmacist collaboration.

Recommendation 7 – Researchers: Conduct a study to pilot a mobile app to deliver evidence-based and independent drug information to physicians.
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1.0 INTRODUCTION

1.1 The Problem

Family physicians are seeking accessible, evidence-based information on medicines to inform their prescribing practice and to care for their patients. To be able to make evidence-based prescribing decisions, physicians need access to the best available information on medicines—unbiased and balanced information that includes information on benefits and harms of medicines (Jacobs, Jones, Gabella, Spring & Brownson, 2012, p. 2; Mintzes et al., 2014, p. 1374). Yet physicians may often rely on biased or inadequate drug information to inform their prescribing decisions often due to a lack of time or shortage of sources of quick and reliable information, among other factors (Anderson, Silverman, Loewenstein, Zinberg & Schulkin, 2009, p. 994; Manchanda & Honka, 2005, p. 809).

One source of prescribing information for family physicians is pharmaceutical sales representatives (PSRs) who visit physicians’ offices to promote brand name drug products. Indeed, in a survey of U.S. physicians in 2006-07, most physicians (76%) agreed that PSRs are a valuable source of information, especially for information on new drugs (Anderson et al., 2009, p. 996). At the same time, physicians generally acknowledge that the information from PSRs is part of a sales promotion and is therefore biased toward sales, not primarily patient care (Norris, Herxheimer, Lexchin & Mansfield, 2005, p. 22). The information provided by PSRs is often low quality and may lead to irrational prescribing of medicines that are inappropriate for the patient, resulting in potential negative health outcomes for patients (Mintzes et al., 2013, p. 1374; Wazana, 2000, p. 378).

PSR visits and the provision of drug samples are key promotional activities for pharmaceutical companies to increase drug sales. PSR visits to physicians make up a significant proportion of drug promotion spending with pharmaceutical companies spending up to twice as much on drug promotion as on research and development according to a recent independent estimate (Gagnon & Lexchin, 2008, p. 29). PSRs and the drug samples they provide are the two largest promotional spending categories of the U.S. pharmaceutical industry, constituting 63% of the entire drug promotion budget in that country (i.e., total budget was estimated at $57.5 billion in 2004): 35.5% on PSRs and 27.7% on drug samples (Gagnon & Lexchin, 2008, p. 30). In France, a 2004 estimate on drug promotion spending put PSR visits at 75% of the pharmaceutical industry’s promotional budget (Bra et al., 2007, as cited in Spurling et al., 2010, p. 2).

With increased prescribing volume and the potential for less rational prescribing, the risk of adverse drug reactions (ADRs) also increases (Spurling et al., 2010, p. 17). ADRs have been shown to cause serious harms, including hospitalization and death, with fatal ADRs ranking as the third leading cause of death in the United States (Gøtzsche, 2014, p. 629; Lazarou, Pomeranz & Corey, 1998, p. 1204). High profile examples such as the arthritis drug rofecoxib (Vioxx) in North America and the diabetes drug benfluorex (Mediator), which was marketed as an appetite suppressant in France, have highlighted the seriousness of this problem following the deaths of thousands of patients in the United States and up to a thousand in
France before the drugs were withdrawn from the market—rofecoxib (Vioxx) in 2004 and benfluorex (Mediator) in 2009—after the manufacturers disclosed known evidence of serious adverse events and deaths (Abraham, 2005, para 4; Prescrire, 2011, para 1). In these and many other cases, harms caused by ADRs may have been lessened or avoided altogether through safer and more rational prescribing that considered the full evidence, including the benefits and harms of medicines, prior to prescribing. For example, in the case of rofecoxib (Vioxx), the Therapeutics Initiative in British Columbia conducted an independent assessment of the evidence and recommended it not be included in the provincial formulary. Fewer patients in British Columbia compared with other provinces were exposed or potentially harmed by the drug (Morgan, Bassett & Mintzes, 2004, p. 273).

In efforts to improve prescribing, the interactions between physicians and PSRs have been the subject of many research investigations over the years, as documented in the summary of available evidence by Norris et al. (2005) and a more recent systematic review by Spurling et al. (2010). The latter found that physician-PSR interactions represented a significant influence on physician attitudes and prescribing practice, increasing prescriptions of the promoted drugs, and increasing drug costs, but decreasing the quality of prescribing, or at least providing no net benefit in terms of prescribing practices (Spurling et al., 2010, p. 19).

A recent observational study by Mintzes et al. (2013) examined the quality of information provided to family physicians by PSRs and the influence on prescribing practice within three different regulatory environments: Canada (Vancouver and Montreal), the United States (Sacramento), and France (Toulouse) (p. 1373). Researchers hypothesized that PSRs would provide more drug safety information to physicians in countries with stricter regulations (i.e., France and the United States have more rigorous regulations governing physician-PSR interactions compared with Canada) (Mintzes et al., 2013, p. 1368). Mintzes et al. (2013) found that indeed physicians in Toulouse reported that PSRs were more likely to provide safety information compared with the other sites; however, the study also indicated a serious problem in all research sites with the quality and balance of information provided by PSRs during promotional visits by PSRs, potentially compromising patient safety (Mintzes et al., 2013, pp. 1373-4). To further explore and interpret these findings the researchers carried out a qualitative follow-up study in 2012 with the study participants, conducting 12 focus groups with family physicians in the four research sites (Vancouver, Montreal, Sacramento, and Toulouse). The analysis of the focus group data is the subject of this 598 Project report.

1.2 Project Purpose & Objectives

The project client is Dr. Barbara Mintzes, Associate Professor at the School of Population and Public Health at the University of British Columbia and the Principal Investigator of the Pharmaceutical Sales Representatives and Patient Safety study (Pharma Rep Study). Dr. Mintzes is also a member of the Therapeutics Initiative, a publicly funded research group based at UBC that provides evidence-based drug therapy assessments to policy makers, health professionals, and the public.
The purpose of this 598 Project is to conduct the analysis of the previously collected focus group data for the qualitative follow-up of the Pharmaceutical Sales Representatives and Patient Safety study (Pharma Rep Study)—to further explore and interpret the findings of the study, and to gather feedback from the participants on the Pharma Rep Study findings. The analysis of the focus group data was carried out guided by the following research questions:

1. What are the physicians’ perceptions of PSRs and PSR interactions, and the reasons they report for seeing PSRs?

2. What are the physicians’ opinions about key findings of the Pharma Rep Study, in particular opinions on the quality of information provided by PSRs during sales visits?

3. What influence, if any, do the physicians think their interactions with pharmaceutical sales representatives have on their practices/prescribing decisions (i.e., likelihood to prescribe)?

4. What differences in physicians’ experiences, perceptions, and opinions, if any, may be related to different regulatory environments or other site-specific factors of the three included countries?

In answering the research questions, the aim is to better understand the context of physician-PSR interactions from the physicians’ perspective—specifically as it relates to the quality of information provided—and to understand physician perceptions on how the interactions with PSRs may have influenced their attitudes and their prescribing behaviour. The analysis also compares the contexts, attitudes, and behaviours to determine if there are notable differences related to differences in regulatory oversight. A better understanding of the context of physician-PSR interactions and physicians’ attitudes and perceptions provides the basis for developing recommendations aimed at addressing the problem of inadequate drug information leading to irrational prescribing. The recommendations are provided for the project client’s consideration and were developed based on the data analysis and research from the literature review.

1.3 Organization of Report

The report is divided into nine chapters including Chapter 1, the Introduction, which describes the research problem, the purpose and objectives of the study, and the research questions to be addressed. Chapter 2 provides the Background for the focus group data analysis, including relevant background on the Pharmaceutical Sales Representatives and Patient Safety study and regulatory environments of the three countries. The focus group data collection is also included, which was not part of the 598 Project. Chapter 3 is the Literature Review carried out as part of this 598 Project to inform the analysis. The review provides an overview of selected research evidence to support the analysis, discussion, and recommendations. Chapter 4, the Methodology and Methods sections, describe the methods for carrying out the analysis of the focus group data. Chapter 5 presents the Conceptual Framework developed following the literature review and preliminary analysis. The framework organizes the key study concepts in an explanatory model, providing a structure
for the analysis, results, and discussion. **Chapter 6** presents the study *Results*, including a summary of the study participation, followed by the results of the focus group discussions, organized using the structure of the conceptual framework. Illustrative quotes from the focus group participants are included. **Chapter 7** is the *Discussion* of the results after the mapping and interpretation stage of the framework analysis. **Chapter 8** is the study *Conclusion*, which presents the key messages from the results and discussion. **Chapter 9** lists the *Recommendations* for the client’s consideration based on the data analysis conclusions.
2.0 BACKGROUND

Chapter 2 provides contextual and other background information relevant to the analysis of the focus group data carried out for this project. This includes the history of the Pharma Rep Study by Mintzes et al. (2013) and the key findings presented for discussion during the focus groups. Information on the regulatory environments of the three included countries (i.e., Canada, United States, and France), in particular the regulation of physician-PSR activities, is provided along with any site-specific information relevant to the focus group analysis, results, and discussion. Finally, a description of the focus group data collection—completed previously—is included here as background to distinguish it as separate from the work of the 598 Project.

**Pharmaceutical Sales Representatives and Patient Safety Study**

The Pharma Rep Study was the first study to compare the quality of information provided to physicians by pharmaceutical sales representatives (PSRs) in different regulatory environments, and the first to focus specifically on safety information provided by PSRs (Mintzes et al., 2013, pp. 1372-1373). Led by Principal Investigator, Dr. Barbara Mintzes, the study is based at the University of British Columbia. The research for the Pharma Rep Study and the follow-up focus groups was conducted in English in Vancouver and Sacramento, and in French in Montreal and Toulouse. A link to the study, published in the *Journal of General Internal Medicine* in November 2013, is included in Appendix A.

Two hundred and fifty-five family physicians participated in the study and reported on 1692 drug-specific promotions by PSRs (i.e., “drug detailers”) in the four study sites (Mintzes et al., 2013, p. 1368). Physicians were included in the study if they saw PSRs as part of their regular practice, if they worked in clinical practice ≥ 20 hours per week and if > 50% of their practice was primary care (Mintzes et al., 2013, p. 1369). Participating physicians were asked to complete one survey per promoted drug following eight consecutive PSR visits. They answered questions about the interaction and the information provided, and rated the quality of that information as well as their likelihood to prescribe the promoted medicine following the interaction. During the study, physicians were asked to conduct the interactions with PSRs as they would normally, asking questions of PSRs if that was something they usually did.

In all research sites, according to the study, PSRs rarely (1.7% of promotions) provided information identified as “minimally adequate for safe prescribing” which was based on a subset of elements identified by a random sample of Canadian physicians and pharmacists as the desired elements of a drug detail (Mintzes et al., 2013, p. 1373; Strang, 2001, p. 76). The list of elements to be included were: mention of ≥ 1 approved indication, ≥ 1 serious adverse event, ≥ 1 common, non-serious adverse event, ≥ 1 contraindication, and no unapproved drug indications/uses, and no unqualified health claims such as “this drug is safe” (Mintzes et al., 2013, pp. 1369, 1373). To demonstrate the feasibility of including minimally adequate safety information even in brief interactions with PSRs, Mintzes et al. (2013) point out that these are a subset of elements required by the U.S. Food and Drug Administration (FDA) in 60-second television ads (p. 1373).
Figure 1 illustrates the number of promotions where PSRs made any mention of health benefits versus any mention of harms (Mintzes et al., 2013, p. 1373). In Vancouver, Montreal, and Sacramento physicians reported that in two-thirds of the promotions PSRs failed to mention a single harmful effect of the promoted medicine; in Toulouse, no harmful effects were mentioned in 39% of promotions (Mintzes et al., 2013, p. 1373). Yet, of the promotions examined in the study, 57% had either a U.S. “black box” warning or a Canadian safety advisory or boxed warning indicating serious or life-threatening effects (Mintzes et al., 2013, p. 1371).

Despite the lack of safety information provided by PSRs, physicians generally judged the quality of the information positively. In rating the scientific quality of the information, 57% of promotions were rated as good or excellent; 33% fair; and 10% poor or very poor; if harms were mentioned in the promotion, the participants were more likely to rate the information as good or excellent (68%). The physicians also indicated their likelihood to start or increase prescribing of the promoted medicine. Physicians reported that following the promotion they

Note: Of 1692 drug specific promotions, PSRs mentioned at least one health benefit in 80% of promotions, and at least one harmful effect in 41% of promotions. From “Pharmaceutical sales representatives and patient safety: a comparative prospective study of information quality in Canada, France and the United States” by Mintzes et al., 2013, Journal of General Internal Medicine, 28(10), p. 1373. Copyright 2013 Society of General Internal Medicine.

1 In the United States, the FDA requires certain drugs to display a “black box” warning on the label, indicating serious or life-threatening adverse events. In Canada, Health Canada issues health advisories to physicians and the public, and requires boxed warnings for some serious adverse events. These are the strongest warnings issued by the regulators.
were somewhat or very likely to prescribe the promoted medication two-thirds of the time (ranging from 62% in Toulouse to 66% in Sacramento) (Mintzes et al., 2013, p. 1372). The physicians’ stated likelihood to prescribe did not seem to be affected by whether or not they received drug samples (i.e., in France, physicians no longer receive drug samples).

Mintzes et al. (2013) concluded that the information provided by PSRs to family physicians was inadequate, especially in terms of safety information, and that this information deficit could threaten patient safety through irrational prescribing (p. 1374). According to the study authors, the fact that there were so few differences in the key findings from site to site may reflect a lack of government and agency monitoring of PSR activities. Mintzes et al. (2013) further concluded that unless regulatory oversight was strengthened to ensure the physicians received balanced information about benefits and harms, the most effective way to ensure evidence-based prescribing decisions may be to limit physician-PSR interactions (p. 1374).

To further explore the study findings, the Pharma Rep Study research team decided to conduct a qualitative follow-up using focus groups with a subsample of study participants. The purpose of the focus groups was to explore the physicians’ responses to two of the questions from the Pharma Rep Study survey, and to gather the participants’ reactions to key study findings. The charts illustrating the key findings that were presented during the focus groups are provided in Appendix C.

Background details about the development of the focus groups and the data collection in 2012 are provided later in this chapter. The following section provides information on the regulatory frameworks in each of the included countries as background for the analysis.

**Three Regulatory Environments**

The study took place in four cities and in three different regulatory environments—Canada (Vancouver and Montreal), United States (Sacramento), and France (Toulouse)—each with different levels and systems of regulatory oversight (Mintzes et al., 2013, p. 1396). Mintzes et al. (2013) hypothesized that the provision of safety information would differ depending on the level of regulatory oversight (i.e., that PSRs would provide more safety information to physicians in France because the regulations were more strict in France) (p. 1373). Similarly, one aspect of the focus group data analysis was to examine how the findings may differ in the three different regulatory environments described below.

In Canada, Health Canada is the ultimate regulatory authority for drug promotion under the *Food and Drugs Act* (Health Canada, 2011a, para 2). Health Canada regulations state that drug promotion (or “advertising”) must not be “false, misleading or deceptive” and PSRs are required to adhere to Health Canada regulations and related advertising codes (Health Canada, 2011b, para 4). The regulator is also responsible for the drug approval process, including the approval of the “product monograph” from the drug manufacturer, an official document that describes each drug in detail, including the approved uses (i.e., “indications”) of the drug, and all known benefits and side effects (Health Canada, 2014, para 2). Information from the product monograph is included in drug inserts, the drug information provided to patients when a pharmacist dispenses a prescription drug. The Pharmaceutical Advertising
Advisory Board (PAAB), an independent agency recognized by Health Canada, is delegated to approve promotional materials for the regulator (Health Canada, 2013).

As for PSR activities and ensuring that they comply with regulation, Health Canada delegates a large part of this responsibility to the pharmaceutical industry association, Canada’s Research-based Pharmaceutical Companies (Rx&D) as the “market authorization holders” (Health Canada, 2011a, para 2). The Rx&D Code of Ethical Practices sets out the requirements of PSR activities, stating that PSRs “must provide full and factual information on products, without misrepresentation or exaggeration” in their promotion of drugs and drug products (Rx&D, 2012, Sec. 5.1). The Rx&D Code states what is permitted as part of a physician-PSR interaction (e.g., offering meals/refreshments to physicians and their staff) and what is not permitted (e.g., no promotion of “off-label” or unapproved drug indications) (Rx&D, 2012, Sec. 5.1). In the case of complaints about non-compliance, they are referred to PAAB. Health Canada has the authority to intervene if drug promotions pose a safety risk, in cases of advertising directly to consumers, if the promotion involves an unapproved drug, or if PAAB does not resolve a complaint (Health Canada, 2013, Who reviews advertisements?). As Mintzes et al. (2013) points out, Health Canada rarely exercises this legislative authority to intervene in PSR activities through active monitoring or other mechanisms to ensure compliance, resulting in a form of self-regulation of PSR activities by the pharmaceutical industry (p. 1369).

In the United States, the Food and Drug Administration (FDA) oversees drug promotion and labeling under the Federal Food, Drug and Cosmetic Act (FFD&C Act) and the Code of Federal Regulations (CFR) through the Office of Prescription Drug Promotion (OPDP) (FDA, 2014a). The national regulator directly enforces the CFR’s “fair balance” provisions requiring that the entire message conveyed by PSRs be accurate, not misleading, and provide information on both the harms and benefits of the promoted product (FDA, 2014b, Sec. 5ii). The same fair balance provisions apply for 60-second television ads for drugs in the United States, demonstrating that even a brief interaction must include balanced information (Mintzes et al., 2013, p. 1373). Mintzes et al. (2013) hypothesized that with the U.S. fair balance provisions, PSRs would mention of harms more often in the United States than in Canada, but the findings show no significant difference between the two countries (Mintzes et al., 2013, p. 1373). The U.S. industry association, PhRMA has a code guiding the interactions between health-care professionals and the pharmaceutical industry, and health-care associations such as the College of Physicians also have guidelines on the interactions, both of which follow the lead of the FDA regulations (PhRMA, 2008, p. 4). As in Canada, the promotion of unapproved drugs uses (i.e., off-label uses or unapproved indications) is not permitted in the United States, although PSRs are permitted to provide physicians with scientific literature (i.e., journal articles) that describe off-label uses (Mintzes et al., 2013, p. 1369).

In France, as in the United States, there is direct government regulation of drug promotion, and PSR activities specifically. A number of agencies and organizations are involved. The French agency responsible for the safety of health products, Agence nationale de sécurité du médicament et des produits de santé (ANSM, formerly AFSSAPS) evaluates the promotional
materials used in PSR interactions with input from the department on advertising and appropriate use of health products (Département Publicité et bon usage des produits de santé) and the associated commission (Commission contrôle de la publicité et diffusion de recommandations sur le bon usage des médicaments) (CEPS & Leem, n.d., p. 2; Leem, n.d., para 3). The French public health code states that advertising must not be misleading and must not prejudice the protection of public health; it must only promote government approved indications of drugs and must comply with regulatory authorities. ANSM also enforces the French code and has the authority to suspend advertising, require a correction or have advertising banned for breaching regulation (CEPS & Leem, n.d., p. 3).

In 2004, the French government introduced the Charter of the Sales Visit Charter (Charte de la visite médicale), which prohibits PSRs from providing drug samples, food or gifts to health professionals, or inviting them to participate in research studies (Mintzes et al., 2013, p. 1369). The Charter also requires PSRs to be trained and certified through an official certification process and continuing education supervised by pharmacists (Leem, n.d., para 5). The Charter describes the information that PSRs should be providing during sales visits, and how that content must comply with regulation. Among other things, the Charter states that the sales visits must include information about the approved indication, adverse effects, interactions, contraindications and cost information. PSRs are required to provide a document evaluating the therapeutic advantage of the promoted product (i.e., ASMR or Amélioration du Service Médicale Rendu). Regulations and guidelines on drug promotion, including PSR activities, are developed and implemented by Haute Autorité de Santé (HAS) with other agencies responsible for the quality of medical information (i.e., Service de la qualité de l’information médicale and the Commission de la qualité et diffusion de l’information médicale) (Leem, n.d.).

On a regulatory continuum, the three countries rank from a form of pharmaceutical industry self-regulation in Canada, to stricter direct government regulation in the United States, to the most rigorous regulatory system of the three in France with direct government oversight and a detailed charter to specifically guide PSR visits and help ensure regulatory compliance. In Toulouse, with the strictest regulatory oversight, the PSRs were more likely to mention at least one harm compared with the other sites (61% compared with 34% in Canada and 39% in the United States); however, the primary outcome measure (i.e., minimally adequate safety information), including any mention of serious adverse events, did not differ significantly from site to site (i.e., 1.2% in Vancouver, 1.7% in Montreal, 0.9% in Sacramento, and 3.0% in Toulouse) (Mintzes et al., 2013, pp. 1369-1370). Also, despite stricter regulation in Toulouse where PSRs are prohibited from providing gifts (e.g., food) or drug samples to physicians, Mintzes et al. (2013) found that physicians reported they were equally as likely to prescribe the promoted medicine as physicians in the other research sites (p. 1373).

National regulations on the interactions between PSRs and physicians in all three countries require that promotions include information on risk or harm as well as benefits (FDA, 2014a; Health Canada, 2011b; Leem, n.d.). The fact that PSRs provided “minimally adequate safety information” in only 1.7% of promotions on average, and mentioned serious adverse effects in
only 5-6% of promotions in all sites, demonstrates that most of the physician-PSR interactions contravened regulations in all three included countries (Mintzes et al., 2013, p. 1373). These findings provide some of the context for the focus groups and for examining the physicians’ experiences, attitudes, and opinions about their interactions with PSRs.

Site-Specific Differences

In addition to regulatory differences, within each of the four research sites, there are several other site-specific differences relevant to the analysis context and several references in the results that need to be introduced.

Regarding site-specific differences, in Canada, even though national regulation is the same in Montreal and Vancouver, there are other differences between the two cities. The pharmaceutical industry has a much stronger presence in Quebec compared with British Columbia, which is demonstrated by the number of pharmaceutical companies in Montreal than in Vancouver, as well as much higher drug spending in Quebec compared with British Columbia. Quebec is home to the headquarters of 21 of the 54 current member companies of Rx&D; British Columbia is home to only two of the smaller member companies, neither of which are drug manufacturers (Rx&D, 2014, Member Profiles). Also, per capital drug spending in British Columbia is 27% lower than the national average, whereas per capita drug spending in Quebec is 30% higher than the average; this is due in part to lower prescription rates in British Columbia, but also due to less availability in Quebec of lower-priced generic drugs (Morgan et al., 2013, pp. 18-19). These differences suggests that the strong industry presence in Quebec has the potential to influence the culture in Montreal more than it does in Vancouver—a consideration in the interpretation of the focus group data. The drug spending differences between countries on the other hand are minimal; all three countries rank within the top four OECD countries in terms of per capital spending on drugs: the United States is the highest ($995); Canada is the second highest ($752); and France is fourth ($641) of all OECD countries (CIHI, 2013, p. 78). Using drug spending as a rough gauge for pharmaceutical industry influence, the influence is not significantly different from country to country.

Aside from the considerations mentioned above, there are several site-specific references in the Results and Discussion that should be introduced. As the focus of the analysis is on information quality, participants commonly referred to several sources of drug information.

In British Columbia, a source of independent information (i.e., unbiased and independent of the pharmaceutical industry) is the Therapeutics Initiative2 at the University of British Columbia, a group of researchers (including Dr. Barbara Mintzes) that conducts systematic reviews to evaluate drugs for research purposes and for the provincial government, which are then published in the Therapeutics Letter. In the United States and Canada, a common source of summarized online drug information is UpToDate.com,3 a privately run mobile source. Although not necessarily unbiased, it is a source that many physicians use because it is so

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2 Therapeutics Initiative website: http://www.ti.ubc.ca/
3 UpToDate.com: http://www.uptodate.com/home
accessible. In France, *Prescrire*\(^4\) is a subscription-based independent drug bulletin distributed to over 35,000 physicians in France (i.e., a substantial minority of physicians practising in that country) as well internationally in English and French. Like the Therapeutics Initiative, *Prescrire* conducts systematic reviews and publishes other independent scientific drug information to inform prescribing. Because it is so widely distributed, most if not all physicians in France are familiar with *Prescrire* whether they read the bulletin or not.

Internationally, the Cochrane library of systematic reviews is a respected source of independent information, and the Canadian Cochrane Centre based in Ottawa. Also, academic detailers (i.e., independent and publicly funded drug detailers) operate in several provinces in Canada, including British Columbia but not Quebec.

This information on site-specific differences and sources of drug information is provided because it is relevant to the analysis and referenced in the *Results* and *Discussion* of this report. The following section describes the data collection for the focus group study.

**Focus Group Data Collection**

Data collection for the focus groups\(^5\) took place in October and November 2012. A subsample of the family physicians who had participated in the Pharma Rep Study in 2009 and 2010 were recruited to participate in a total of 12 focus groups (three groups per research site). Personalized invitation letters were sent to all physicians (n=255) who participated in the earlier study (Mintzes et al., 2013, p. 1368). This was followed up with phone calls one week later and several subsequent phone calls, faxes, and emails to reach the physicians directly. Those who agreed to participate were offered one of three possible focus groups taking place on different dates and times to accommodate schedules. Physicians were contacted again one week prior to the focus groups to confirm their attendance and location details. Focus groups were held in central locations, and where possible in settings familiar to the participants (e.g., Vancouver General Hospital, University of Toulouse). Researchers aimed to have from five to eight participants per group and both male and female participants ranging in age and experience. Refreshments were provided and physicians who participated in the focus groups were given an honorarium of $150 (CAN), or the equivalent in local currency, to thank them for their participation.

Prior to the focus groups, a facilitator’s guide was developed, pilot tested, and revised. Three members of the research team shared the facilitation of focus groups, including a francophone facilitator hired to moderate the groups conducted in French (in Montreal and Toulouse). As the researcher carrying out the analysis, I attended all 12 focus groups, facilitated four of the six English groups, served as observer for all of the French groups, and participated in debriefing at all groups. Each group was between 60 and 90 minutes and included one facilitator and at least one observer taking field notes. Each group included a brief introduction to the study and time for participants to review and sign informed consent forms. The facilitator then presented four key findings from the observational study and


\(^5\) For more details about my involvement and responsibilities during the focus group study, please see the Statement of Authorship on page iii.
posed questions to gather the participants' opinions of the findings and to better understand their responses to questions from the Pharma Rep Study questionnaire. Table 1 lists the questions from the focus group facilitator's guide (See Appendix B for the full Facilitator’s Guide and Appendix C for charts of the findings).

Table 1: Questions from the Facilitator’s Guide

<table>
<thead>
<tr>
<th>Introductory questions</th>
<th>Reflecting on a recent interaction</th>
<th>In one or two words only, how would you describe the interaction?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>For you, what are the main benefits of seeing sales reps? Any negatives?</td>
</tr>
<tr>
<td>Contextual information</td>
<td>Circulated a list of the top 10 drugs promoted during the period of the study</td>
<td></td>
</tr>
<tr>
<td>Reactions to key results</td>
<td>Chart 1: Mention of harms</td>
<td>What are your thoughts about this result?</td>
</tr>
<tr>
<td></td>
<td>Chart 2: Serious adverse effects, interactions, contraindications</td>
<td>What are your thoughts on this result? Does anything stand out for you?</td>
</tr>
<tr>
<td></td>
<td>Chart 3: Scientific quality</td>
<td>&quot;How would you rate the quality of scientific information presented by the PSR?&quot; How do you feel about these results? What do you think would have prompted you to rate the information from a sales rep as &quot;excellent&quot; or &quot;good&quot;? And what would have prompted you to rate the information as &quot;fair&quot; or &quot;poor&quot;?</td>
</tr>
<tr>
<td></td>
<td>Chart 4: Likelihood to prescribe</td>
<td>What do you think about these results? What do you think would prompt you to start of increase prescribing a particular drug after a sales visit? And what would make you &quot;unlikely&quot; or &quot;very unlikely&quot; to start or increase prescribing?</td>
</tr>
<tr>
<td>Concluding questions</td>
<td>If you can remember, think back to when you were participating in our study, filling in the questionnaires following each sales visit. Do you think that participating in the study had an affect on you in any way? If so, how?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Based on the discussions today and your experiences with the study, do you have any suggestions for changes you would like to see?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Question in Toulouse only</td>
<td>If you were practising before 2005 when the regulations changed in France, what do you think of the changes and the repercussions on your practice? Do you think that the situation with the drug Médiator has had repercussions on your practice?</td>
</tr>
<tr>
<td></td>
<td>Is there anything you didn't get a chance to say? Any points you'd like to add?</td>
<td></td>
</tr>
</tbody>
</table>

Focus group discussions and debriefing sessions of co-facilitators were transcribed verbatim by two professional transcribers (i.e., one for English and one for French transcriptions). The transcriptions remained in the original language for the analysis carried out for this project.

This concludes the background section of the report, including information on the key findings of the Pharma Rep Study; the regulatory frameworks governing physician-PSR interactions in Canada, the United States, and France; site-specific references; and a description of the data collection methods. Along with the literature review that follows, this background provides contextual information for the Results and Discussion.
3.0 LITERATURE REVIEW

This chapter of the report presents academic literature related to physician-PSR interactions to inform the focus group data analysis by providing an overview of existing evidence with which to compare the results for the Discussion. The aim of the focus group analysis was to explore physician opinions and attitudes toward PSRs and the quality of information they provide, and to better understand the influence of PSR interactions on physician attitudes and prescribing behaviour. The literature review presents some of the existing research on physician experiences of and attitudes toward PSR interactions, and related influences on prescribing practice. The review also explores literature on theory related to physician-PSR interactions, which helps explain some of the dynamics common to physician-PSR interactions. In this way, the literature review aims to place the focus group findings within a larger research context for discussion, and to strengthen the validity of the conclusions.

The review began with an initial broad search of literature on drug promotion and prescribing through EBSCO, Google Scholar, and UVic’s Summon search engine. This was followed by searching the academic databases OvidSP, MEDLINE and Cochrane Database of Systematic Reviews (UVic Library’s recommended resources for evidence-based medicine). Search terms included: prescribing, primary care physicians, drug detailers, medical representatives, sales representatives, industry, patient safety, pharmaceutical, drug promotion, advertising, information quality, attitude, behaviour, qualitative study, focus groups. Sources included peer-reviewed journals as well as government and NGO reports; sources were international in scope due to the international scope of the study.

While Mintzes et al. (2013) was the first study of its kind to examine the quality of information provided by PSRs in three regulatory environments, and to specifically focus on patient safety, the literature available on how drug promotion may influence physician prescribing is vast (p. 1374). To narrow the scope of the search for the purpose of informing the focus group analysis, the search focused on articles with direct relevance to PSR interactions and prescribing by family (primary care) physicians. Mainly qualitative studies and reviews of qualitative studies provide evidence on physician opinions and attitudes about PSRs and information quality as well as physicians’ reported reasons for seeing PSRs. The literature search on the influence of PSRs on physician attitudes and prescribing behaviour included systematic reviews and recent comprehensive narrative, integrated, and thematic reviews, identifying key primary studies to examine further. The search also included literature on theory related to physician-PSR interactions and their influence on prescribing.

The literature review is organized in four main sections aiming to inform the analysis and answer the research questions: 1) physician perceptions of PSR interactions and reasons for seeing PSRs; 2) physician opinions on the quality of information provided by PSRs; 3) factors influencing physician attitudes and prescribing behaviour (i.e., likelihood to prescribe); and 4) related theory. The first three sections mirror the research questions guiding the focus group analysis, and the fourth section provides some theory-based support for the Discussion and Conclusions.
3.1 Physician Perceptions & Reasons for Seeing PSRs

This section of the literature review presents an overview of previous research documenting the physician perceptions of PSR interactions, frequency of PSR visits, and the reasons—as reported by physicians—for seeing PSRs. The literature presented includes surveys and recent reviews of qualitative studies in various countries as well as several key studies identified during the search. One key document described in Section 3.3 below is a review conducted by the World Health Organization (WHO) and Health Action International (HAI) summarizing the available evidence on drug promotion and its impact on physician attitudes and behaviour (Norris et al., 2005, p. 1).

The literature has shown that the majority of family physicians in various countries have regular interactions with PSRs. A national survey of U.S. physicians by Campbell et al. (2007) found that 94% of physicians had some relationship with the pharmaceutical industry, mainly receiving food and drug samples from PSRs or at industry-sponsored meetings and continuing medical education (CME) (p. 1742). The survey found that family physicians met with PSRs most frequently (4 per week) compared with physicians in other practice settings (2 to 10 per month) (Campbell et al., 2007, p. 1747). A review of PSR visits in different countries (Canada, United States, Britain, Australia, and New Zealand) found similar results with between 80% to 90% of physicians receiving regular visits from PSRs, although the frequency of PSR visits reported in Canada was lower (i.e., once every second week) (Lexchin, 1993, p. 1493).

Physicians have reported that their reasons for seeing PSRs regularly are also similar in different countries. Several qualitative studies have examined physician-PSR interactions using interviews and focus groups (Al-Areefi, Hassali & Ibrahim, 2013; Chimonas, Brennan & Rothman, 2007; Fischer et al., 2009; Prosser & Walley, 2003). In these studies, physicians reported similar reasons for continuing to see PSRs, including receiving drug samples, food, and other “gifts”; speedy and convenient access to information, especially on new drugs, or reminders about older drugs; information on drug costs; and invitations to industry-sponsored events/dinners. The research has shown that physicians value the convenience and time-saving aspects of PSR interactions (e.g., PSRs do the legwork to provide information and evidence about the promoted products) (Manchanda & Honka, 2005, p. 809; Ziegler, Lew & Singer, 1995, p. 1298).

Receiving drug samples has been one of the main reasons reported by physicians for continuing to see PSRs. In a random sample of 550 Canadian physicians, most (85%) felt that receiving drug samples from PSRs is an acceptable and valuable practice (Strang et al., 1996, as cited in Norris et al., 2005, p. 13). Physicians used drug samples to try or test a drug to see if it was tolerated and effective for their patient, for convenience, or to save patients the cost of paying for a drug (Norris et al., 2005, p. 41). As for receiving other gifts from the pharmaceutical industry, including food, physicians’ attitudes varied, but “gifts” that were relatively small or were perceived to have benefit for patients (i.e., altruistic motive) were seen as more acceptable (Norris et al., 2005, p. 14). Physicians did not believe that receiving gifts from PSRs influenced their attitudes or practices, but they suggested that gifts may have influenced their colleagues (Norris et al., 2005, p. 22). Oldani (2004), a former sales
representative turned anthropologist, summarized literature on the influence of food and other "gifts" for physicians and their staff, highlighting the effectiveness of gifts for building loyalty and an obligation of reciprocity (p. 334).

Another common reasons for seeing PSRs cited by physicians was for the social break provided by the PSR visit (i.e., a break from work and patients). Physicians have described PSRs as friendly, pleasant, and helpful; they have enjoyed spending time with them; and empathized with PSRs for having a job to do. The literature has indicated that social relationships have made it a barrier for physicians to refuse PSRs and some physicians have expressed guilt or embarrassment related to the social contract with PSRs (Al-Areefi et al., 2013, p. 338). Prosser and Walley (2003) concluded that the social aspect of the PSR interactions plays a significant role in legitimizing the information provided to physicians through the use of sales and marketing techniques (p. 308).

In the literature, physician experiences of PSR interactions in terms of frequency of PSR visits and reasons for seeing PSRs were similar in various countries. These reasons such as drug samples, gift giving (and reciprocity), and the social aspects of the interactions are key to understanding the relationship between physicians and PSRs. Also, as stated, one of the main reasons physicians report for seeing PSRs has been for information on drugs for themselves and their patients. Since information quality related to PSR interactions is the focus of this report, this element (i.e., information provision) is examined separately in the following section.

### 3.2 Quality of Information from PSRs

This section on the quality of information provided by PSRs draws on studies summarized in the review by WHO and HAI by Norris et al. (2005) and a qualitative study by Prosser and Walley (2003) in the United Kingdom, which examined generally why physicians see PSRs, and specifically physicians’ attitudes and opinions about the quality of information provided by PSRs.

The literature collected by Norris et al. (2005) since 1970, has indicated that most physicians who see PSRs have relied on them as an important source of information on drugs (p. 1). Physicians acknowledged that information from PSRs was biased, but they also found it useful, especially information about new drugs or new indications (Norris et al., pp. 22, 28). Prosser and Walley (2003) found that the frequency of PSR visits correlated positively with a high rating for the quality of information (p. 307). Physicians valued the speedy responses to questions from PSRs and provision of information (e.g., journal articles) sooner than it was available from independent sources (e.g., Prescrire) (Prosser & Walley, 2003, pp. 306-307). However, physicians with fewer years of experience and those working in university-based settings were less likely to value the information from PSRs (Norris et al., 2005, p. 27).

The role of the PSR in presenting themselves as trustworthy and legitimate sources of information was significant in this complex interaction (Prosser & Walley, 2003, p. 310). While physicians stated their awareness of bias on the one hand, on the other they stated that they valued the information provided, and felt confident in their ability to critically evaluate
the information and, contrary to the evidence, to only retain what was factual (Prosser & Walley, 2003, p. 310). The physicians’ opinion about the legitimacy of the information provided by PSRs was strengthened based on the credibility of individual PSRs, and PSRs that provided some information on medicine harms were judged as more credible and trustworthy (Prosser & Walley, 2003, p. 307). PSRs were considered less trustworthy if they engaged in aggressive sales techniques or attempted to appeal to physicians’ empathy in prescribing their products (p. 308).

Physicians themselves have expressed concerns about the quality of information provided by PSRs as a random sample of 550 Canadian physicians indicated in a national survey by Strang et al. (1996). Most respondents (80%) believed PSRs overstated a product’s effectiveness, stating that they understood the goal of the interaction was drug promotion, not providing information (Strang et al., 1996, as cited in Norris et al., 2005, p. 10). Despite this reported awareness of bias and inaccuracy of the information, the research evidence indicated that physicians’ attitudes were much more influenced by promotional information than they believed they were (Norris et al, 2005, p. 31). Norris et al. (2005) highlighted the research design of one study in 1982 that examined the influence of scientific information compared with commercial information about two specific drugs. Avorn, Chen, and Hartley (1982) found that although physicians reported that they were relying on the scientific literature to inform their prescribing, a survey showed that they were actually relying on the commercial information (Avorn, Chen & Hartley, 1982, as cited in Norris et al., 2005, p. 30).

The literature has indicated that physician perceptions of the quality of information provided by PSRs have been contradictory, and that physicians have underestimated the influence of PSR interactions on their prescribing practices. This evidence on information quality generally provides research context for the focus group analysis, which examines safety information in particular. Literature on the influence of PSRs on physician attitudes and prescribing behaviours is described in the following section.

### 3.3 Influence on Attitudes & Prescribing

Drawing on systematic reviews of the literature and several other reviews (i.e., narrative, integrative, thematic), this section presents evidence of the influence of PSR interactions on physician attitudes and prescribing behaviour, including the influence on medical residents as physicians in training. Again, the literature provides research context for the analysis of the focus group data to compare key findings from the Pharma Rep Study (i.e., likelihood to prescribe) as reported by physicians in the surveys with the data from the focus group discussions.

Many studies, including before-and-after studies, interrupted time series (ITS), and randomized controlled trials (RTCs) have examined pharmaceutical industry interactions with physicians and most have indicated that the interactions influenced physician attitudes and prescribing behaviour. A review by Lexchin (1993) examined research from 1978 to 1993 to determine the effect of various industry interactions with physicians on the quality of clinical trials, the content of continuing medical education (CME), and physician prescribing
behaviours (p. 1401). Lexchin (1993) concluded that physicians were influenced by their interactions with industry but that further research was needed to examine the impact on appropriate prescribing and that the Canadian Medical Association guidelines needed to be evaluated to see if they were effectively controlling physician interactions with the pharmaceutical industry (p. 1405). More recent studies have examined the influence and effectiveness of guidelines and regulation, including Mintzes et al. (2013), and found them lacking and not controlling the negative impacts of PSR interactions on prescribing decisions and patient outcomes (p. 1374).

Research has indicated that physician interactions with PSRs and industry-sponsored CME correlate positively with increased prescribing, lower quality prescribing, and increased drug costs. A systematic review conducted by Wazana (2000), which included a systematic review of literature and key informant interviews, found that attending industry-sponsored events and regularly seeing PSRs correlated positively with increased irrational prescribing and requests to add drugs to hospital formularies (Wazana, 2000, p. 378). Wazana (2000) noted that pharmaceutical industry-sponsored CME events specifically promoted a company's product(s) compared with non-industry sponsored CME, which did not include brand promotion (p. 377).

Norris et al. (2005) published a summary of research literature in 2005 by the World Health Organization and Health Action International (based in the Netherlands) in the report Drug promotion: What we know, what we have yet to learn (Norris et al., 2005). Based on the analysis of research literature from a database of 2700 journal articles, books and other documents on pharmaceutical promotion compiled for the project, the report examined attitudes toward pharmaceutical promotion, the impact of promotion on behaviour, and interventions that have been subject to evaluation (Norris et al., 2005, pp. 5-6). The authors found that there was a "strong consensus" from studies that physicians who see PSRs regularly prescribed more often, were less rational prescribers, and were quicker to prescribe new drugs (Norris et al., 2005, p. 34). Norris et al. (2005) also found that too many of the studies relied on survey methods, convenience or accessible samples (e.g., trainees and not practising physicians), and focused on describing attitudes instead of examining the relationships between attitudes and prescribing behaviour (Norris et al., 2005, p. 23). To measure how the influences on attitude may translate into effects on prescribing behaviour, Norris et al. (2005) cautioned against relying too much on self-reported data, which do not show causation (Norris et al., 2005, p. 33). They suggested further qualitative research was needed in this area to examine why and how physicians felt they were influenced (or not), and to explore the responses to survey questions in more depth (Norris et al., 2005, p. 23).

An integrated review by Manchanda and Honka (2005) concluded that increased exposure of physicians to the pharmaceutical industry had a significant influence on physicians to increase prescribing (p. 809). Manchanda and Honka (2005) had a business marketing perspective and concluded that the pharmaceutical industry would no doubt continue to fund PSR interactions so should focus on making the interactions more efficient and “maximize the welfare of their patients” (p. 811).
The most recent systematic review by Spurling et al. (2010) was less conclusive about the effects of exposure to the pharmaceutical industry (p. 19). Mainly due to differences in study design and setting, the authors judged that results of included studies could not be combined quantitatively in meta-analysis; studies were summarized mainly based on the direction of effect of promotions on outcomes (p. 19). In the final conclusion, however, the authors found there was evidence of increased drug costs and decreased quality of prescribing, and “no evidence of net improvements in prescribing” associated with more frequent exposure to the pharmaceutical industry (Spurling et al., 2010, p. 19). Given the cost of promotional interactions and how it drives up drug costs, as well as the lack of any evidence of benefit, Spurling et al. (2010) concluded that physicians should “avoid exposure to information from pharmaceutical companies” based on the available evidence (p. 19).

Zipkin and Steinman (2005) conducted a thematic review to examine the effects of PSR visits on physicians in training (i.e., medical residents), concluding that residents frequently saw PSRs and experienced an influence on prescribing, although residents thought the interactions were appropriate and did not think they were influenced (p. 784). The authors concluded that educational interventions, including changes in curricula, to teach critical evaluation of PSR interactions benefited residents by raising their awareness about the possible influence (p. 784). They also cited a role for stricter regulation and policies related to the exposure of medical residents to PSRs. Several studies cited by Zipkin and Steinman (2005) evaluated the effectiveness of educational interventions with medical residents and found that even a single workshop geared to teaching critical evaluation of PSR visits can have a significant influence on the attitudes of residents toward PSR interactions (e.g., questioning the accuracy of information from PSRs) (Zipkin & Steinman, 2005, p. 784). A more recent study by Grande, Frosch, Perkins and Kahn (2009) used an experimental design (i.e., randomized controlled experiment) to measure differences in self-reported attitudes of medical residents toward drug promotion. The study found that “subtle branding exposure” to pharmaceutical promotion shifted their preferences toward a specific brand-name drug and that policies restricting exposure resulted in an opposite shift (i.e., more negative attitude toward drug promotion) (p. 892). The influence of drug promotion, and specifically gifts, on medical residents is a significant factor in prescribing practices, and as King, Essick, Bearman, and Ross (2013) found, policies restricting medical student interactions with PSRs were associated with significant reductions in the prescriptions of newly marketed (i.e., highly promoted) drugs (p. 4). Holloway (2014) also examined the attitudes of medical students and found that despite having negative attitudes initially toward the influence of PSRs, the presence of PSRs in their workplace became normalized over time (p. 119).

Previous research consistently indicated that PSRs influenced physician attitudes toward prescribing specific promoted products, resulting in irrational prescribing. While some researchers were less conclusive about a causal link between physician attitudes and prescribing behaviour due in part to the lack of rigour of self-reported data, the body of evidence indicated that physician (and medical student) attitudes predict behaviour. These conclusions are also consistent with the findings of Mintzes et al. (2013) and inform the focus group analysis.
3.4 Related Theory

Several theories were identified during the literature review to help explain and interpret the focus group data. This includes persuasion theory, which is useful to explore how PSRs influence physician attitudes; and social cognitive and human behavioural theories, which are useful in examining the influence on prescribing behavior. With the aid of theory, it is possible to place the individual experiences and attitudes of physicians within the larger social and research contexts, pointing to the consistencies (or differences) within our data compared with existing theory. A theory-based examination also helps ensure that any recommendations stemming from the analysis are more solidly based on evidence (Roughead, 2006, p. 671).

Persuasion theory helps explain the dynamics of a physician-PSR interaction and how PSRs may influence physician attitudes by becoming friends with physicians and using effective sales techniques (Fugh-Berman & Ahari, 2007, p. 622; Roughhead, 2006, pp. 662-667). In the expert review by Roughhead (2006), the author describes how certain persuasion, communication, and behavioural theories may be used to “enhance the early uptake” of evidence on drugs by primary care providers (p. 661). Techniques such as message repetition, emotional appeals and altruistic motives (e.g., accepting drug samples for patients) are all part of persuasive communications used by PSRs (p. 662). Another technique is to provide “both sides of the story,” in this case for PSRs to provide some information on harms, to encourage physicians’ trust and engagement (Roughead, 2006, p. 663).

Research from the advertising industry describes similar techniques for persuasion as shown in the literature review by Rod and Saunders (2008). For example, the most significant influences of persuasion are summarized by Cialdini (1993, 1999) in the *International Journal of Advertising* using six psychological principles: 1) reciprocity or feeling loyalty or obligation; 2) commitment to a behaviour or practice if one has committed to it; 3) authority or being more willing to follow advice from specialists or others in authority; 4) social validation or being persuaded by what others do; 5) scarcity or believing one might miss out if they do not try; and 6) friendship or being more likely to say yes to someone who is likeable and friendly (as cited in Rod & Saunders, 2009, pp. 325-326).

In terms of how physician attitudes translate into changes in prescribing behaviour, Roughhead (2006) summarizes the literature on social cognitive theory and the central concept of self-efficacy or belief in one’s capabilities (p. 666). Physicians tend to have relatively high levels of self-efficacy and “perceived behavioural control” (i.e., beliefs about the level of control over one’s behaviour), a concept from the Theory of Planned Behaviour (National Cancer Institute, 2005, p. 17). Along with persuasion theory, physician self-efficacy and perceived behavioural control help explain perceptions related to prescription decision making and the impact of PSRs on prescribing behaviour.

Finally, the theory of “cognitive dissonance” presented by Chimonas et al. (2007) helps explain physician’s contradictory attitudes toward PSRs and the information they provide (Chimonas et al., 2007, p. 186; National Cancer Institute, 2005, p. 17). Chimonas et al. (2007)
described some of the ways that physicians managed cognitive dissonance and justified the contradictory attitudes they had about PSR visits. Physicians ignored their own conflict of interest, put the responsibility on the PSR, and emphasized the advantages/benefits of seeing PSRs, especially for information exchange (p. 187). Physicians have also used various strategies to offset PSR influences such as not taking the information at face value and seeking confirmation of information from other more reliable sources or from the PSRs of competing companies who would tell them the negative aspects of the competitor’s products (p. 188). Chimonas et al. (2007) also found that physicians, when presented with study findings showing the negative influence on attitudes and prescribing, disputed the findings and offered justifications to minimize findings, defending their decisions to continue seeing PSRs (p. 188).

In conclusion, the key points drawn from the literature to be used to inform the focus group analysis are:

1) The psychological and social research on gift giving and reciprocity are key to understanding the relationship between physicians and PSRs.

2) Physician perceptions of the quality of information provided by PSRs have been contradictory, and physicians have underestimated the influence of PSR interactions on their prescribing practices.

3) The body of evidence indicates an influence of PSRs on physician attitudes and on prescribing behaviour consistent with sales/marketing aims, and inconsistent (or neutral) with public health aims; there is no evidence of benefit to prescribing appropriateness or cost.

4) Persuasion theory and social cognitive theory help explain the dynamics between physicians and PSRs. In particular, physicians’ perception that they are not influenced by drug promotion and their contradictory attitudes about the information provided by PSRs are associated with perceived behavioural control and cognitive dissonance.

For this study this indicates the need to view the focus group responses within a broader context of physicians’ needs to manage decision making, time constraints, need for rapid information access, and the importance of social interactions to the physician. Cognitive dissonance is an expected component of the interactions given these contradictory pressures.

The literature is largely silent on the influence of regulation on physician perceptions and outcomes.
4.0 METHODOLOGY & METHODS

4.1 Methodology

The analysis of the focus group data carried out for this project followed the systematic method of framework analysis as described by Ritchie and Spencer (1994). This approach, as illustrated in Figure 2, involves a five-stage process: 1) familiarization with the data, 2) identifying a thematic framework, 3) indexing, 4) charting, and 5) mapping and interpretation (p. 178). According to Ritchie and Spencer (1994), the approach is geared for applied policy research such as this study where the ultimate goal was to inform policy and practice through a rigorous and transparent research process (p. 173).

Figure 2: The Five Stages of a Framework Analysis

The framework analysis approach provided a practical road map for analysis of qualitative data (Ward, Furney, Tierney & Swallow, 2013, p. 2428). The purpose of the study is essentially phenomenological, describing the experiences of physicians in their interactions with PSRs, identifying meaning, and using qualitative description to present the results (Patton, 2002, p. 482; Sandelowski, 2000, p. 335). The approach was primarily inductive, working from the data to develop a thematic index; however, it also included a deductive process once the key themes were identified and were used for mapping and interpretation (Patton, 2002, p. 453). The systematic approach of this method helped ensure a clear audit trail for the process of analysis, making it accessible and replicable, and contributing to the rigour, transparency, and validity of results (Ward, Furber, Tierney & Swallow, 2013, p. 2425).
While the results of focus groups were not generalizable, the rich data further illuminated the answers to specific survey questions from the Pharma Rep Study and helped understand the physicians’ experiences in their interactions with PSRs. Qualitative description was used to present the results, drawing from the tenets of naturalistic inquiry with a “low-inference” process that remained close to the data (Sandelowski, 2000, p. 335). This approach as described by Sandelowski (2000) acknowledged researcher interpretation throughout; however, it was “minimally theorized” and described the participants’ responses, opinions and attitudes as objectively as possible (p. 337). “Descriptive validity” of the analysis was achieved by describing an account of events that could be verified by other researchers looking at the same data (Sandelowski, 2000, p. 336).

Ethics approval was provided by the University of British Columbia Research Behavioural Research Ethics Board and the University of Victoria Human Research Ethics Board.

4.2 Methods

The main source of data for the analysis was the transcripts from the 12 focus group interviews. Additional data sources included: audio recordings of the focus groups; moderator’s guide; charts summarizing findings of Mintzes et al. (2013); observer notes; and transcriptions of debriefing sessions (following focus groups).

Focus group transcripts were first cleaned, anonymized, and reviewed to ensure consistency with the audio recordings, and to familiarize the researchers with the major themes and topics of the study (i.e., identify meaning units in Stage 1 of framework analysis). With assistance from three research assistants, I led the development of an initial thematic framework (Stage 2) based on the original aims of the research and key issues, concepts, and themes identified in the transcripts. This initial index (common to all groups) was used in an iterative process to code the data into a set of 10 categories and 46 sub-categories or meaning units. The research assistants and I completed initial independent and duplicate coding into categories using the open-source computer software TAMS Analyzer to manage the data (Weinstein, 2012). The team approach to developing the initial index and coding into categories was used to avoid bias and to increase the validity of the analysis process and subsequent results (Ward et al., 2013, p. 2425). Consensus was achieved by discussing the appropriateness of the categories to a piece of text, and where consensus could not be reached, a third researcher was consulted.

Following the development of the initial index and coding, I carried out the analysis independently. The initial categories were distilled into five key themes and 23 subthemes as illustrated in Table 2. This process (i.e., Stage 3: indexing) involved extensive review of the transcripts to ensure that the data were coded consistently and that the final index did not include any overlapping codes or irrelevant data. At this stage, the coded data were exported to Microsoft Excel for charting (Stage 4), using a data management system described by Swallow, Newton and Van Lottum (2003, p. 610).
Table 2: Key Themes and Sub-themes for Indexing and Charting

<table>
<thead>
<tr>
<th>Key themes</th>
<th>Sub-themes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0 Perceptions of PSRs/Visits</td>
<td>1.1 PSR characteristics</td>
</tr>
<tr>
<td></td>
<td>1.2 Visit characteristics</td>
</tr>
<tr>
<td></td>
<td>1.3 Sales orientation</td>
</tr>
<tr>
<td>2.0 Reasons/benefits for seeing PSRs</td>
<td>2.1 Drug samples</td>
</tr>
<tr>
<td></td>
<td>2.2 Food</td>
</tr>
<tr>
<td></td>
<td>2.3 Information on products/new products</td>
</tr>
<tr>
<td></td>
<td>2.4 Handouts/tools</td>
</tr>
<tr>
<td></td>
<td>2.5 CME invitations</td>
</tr>
<tr>
<td></td>
<td>2.6 Social/break</td>
</tr>
<tr>
<td>3.0 Quality of information</td>
<td>3.1 Mention of harms/benefits</td>
</tr>
<tr>
<td></td>
<td>3.2 Scientific quality</td>
</tr>
<tr>
<td></td>
<td>3.3 Bias</td>
</tr>
<tr>
<td></td>
<td>3.4 Format/presentation</td>
</tr>
<tr>
<td>4.0 Influence factors</td>
<td>4.1 Specialists/health professionals/consultants/CME</td>
</tr>
<tr>
<td></td>
<td>4.2 Independent information sources</td>
</tr>
<tr>
<td></td>
<td>4.3 Approved information/drug inserts</td>
</tr>
<tr>
<td></td>
<td>4.4 Cost</td>
</tr>
<tr>
<td></td>
<td>4.5 Direct-to-consumer advertising</td>
</tr>
<tr>
<td></td>
<td>4.6 Well-known drug events</td>
</tr>
<tr>
<td></td>
<td>4.7 Physician strategies/self reflection</td>
</tr>
<tr>
<td></td>
<td>4.8 Study participation</td>
</tr>
<tr>
<td>5.0 Regulation/legislation</td>
<td>5.1 PSRs</td>
</tr>
<tr>
<td></td>
<td>5.2 Drug safety</td>
</tr>
</tbody>
</table>

Notes: I distilled these themes from the original thematic index in an iterative process of revision and pilot charting (Stages 2 and 3 of the framework analysis). This final index was used to create thematic charts for the Charting, and Mapping (Stages 4 and 5). During Mapping and Interpretation (Stage 5), three key themes and six subthemes were used to create the conceptual framework for presenting the Results and Discussion.

Thematic charts were created for each focus group, which organized the transcript excerpts by theme in Excel charts (i.e., charting the comments of each focus group participant over the 23 sub-themes). Each excerpt was then summarized in one thematic chart per research site. The charts included anonymous quotes from participants and provided an overview of the data per site for mapping and interpretation (Stage 5). This stage of the analysis included mapping the range of physician experiences to identify attitudes, behaviours, and reasons for seeing PSRs as well as associations between attitudes and behaviours (Ritchie & Spencer, 1994, p. 175). Throughout this iterative process of refining the thematic index, applying it to the transcripts and summarizing the data, Krueger’s (2009) process of weighting the participants’ comments was used to help identify the main themes (i.e., frequency, specificity, emotion, and extensiveness) (p. 121-122). The original transcripts were referenced as needed throughout the process and analyst notes were compiled to record the analysis process.
The results are organized according to the conceptual framework described in the next section, and are presented using a qualitative description approach, presenting the participants’ comments in their own words (with little interpretation) preceded by a brief descriptive text. This presentation of the Results describes the physician perceptions and preferences related to interactions with PSRs, their perceptions of information quality, and the factors influencing their prescribing decisions. An interpretation of the Results is included in the Discussion section.

Note: For direct quotes, participants are identified using codes representing the city, focus group, participant number, and gender (e.g., VG1.1/F represents Vancouver, group 1, participant 1/female). I translated the quotes from Montreal and Toulouse from French to English during the analysis process as indicated using square brackets.
5.0 CONCEPTUAL FRAMEWORK

The conceptual framework is drawn from the thematic index in Table 2, distilling the themes into three main concepts: 1) physician perceptions of PSRs and visits, 2) physician perceptions of information quality, and 3) factors influencing physician attitudes and prescribing, and strategies for decision making. Figure 3 illustrates the framework, which structures the themes and subthemes to answer the research questions.

*Figure 3: Conceptual Framework of Physician-PSR Interactions*

Theme 1 presents the context (i.e., physician perceptions and reasons for seeing PSRs). Theme 2 focuses on the physicians’ opinions on the quality of information provided by PSRs and feedback on the study findings (i.e., responses to findings about safety information and the quality of scientific information). Theme 3 focuses on the factors influencing physician attitudes and prescribing and decision-making strategies (i.e., reflection on influence and strategies for prescribing). The three themes are placed within the regulatory/site environment to indicate the examination of how the experiences, perceptions, and influences may reflect different forms of regulatory oversight. The conceptual framework provides a structure to explain the context and dynamics of the physician-PSR interaction and the physicians’ perspectives on their likelihood to prescribe. The aim of the framework—with theory-based support—is to improve the understanding of the context of PSR interactions to allow for identification of points where interventions may be needed and how they may be effectively implemented. The framework is also used to provide a structure for the study Results and Discussion.
6.0 RESULTS

A total of 57 physicians participated in the focus groups in all four sites (Vancouver, 18, Montreal, 11; Sacramento, 16; and Toulouse, 12). The overall response rate was 31% based on a subsample of the 255 physicians who participated in the Pharma Rep Study (i.e., we were able to contact 184 of the 255 study participants to invite them to the focus groups). Lack of time was cited as the most common reason for declining participation. Each group ranged from 2 to 7 participants. Table 3 provides the characteristics of the focus groups. Thirty-three per cent of the focus group participants were women compared with 35% for the Pharma Rep Study. However, percentages of women who attended focus groups in Montreal (36%) and Toulouse (42%) were lower and higher respectively compared with the Pharma Rep Study (54% in Montreal, 22% in Toulouse). The range of years of practice for participants in the Pharma Rep Study was 4 to 49 years with a median (µ) of 24 years.

Table 3: Characteristics of Focus Groups

<table>
<thead>
<tr>
<th>Focus groups</th>
<th>Participants (# women)</th>
<th>% Women per site</th>
<th>Yrs in practice per site - range, (µ)</th>
<th>Group moderators</th>
<th>Group observers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vancouver Group 1</td>
<td>5 (2)</td>
<td>33%</td>
<td>6 – 49 (29)</td>
<td>AC</td>
<td>ER + MO</td>
</tr>
<tr>
<td>Vancouver Group 2</td>
<td>6 (1)</td>
<td>63%</td>
<td>6 – 49 (29)</td>
<td>AC</td>
<td>ER + MO</td>
</tr>
<tr>
<td>Vancouver Group 3</td>
<td>7 (3)</td>
<td>43%</td>
<td>6 – 49 (29)</td>
<td>ER</td>
<td>MO</td>
</tr>
<tr>
<td>Montreal Group 1</td>
<td>5 (1)</td>
<td>25%</td>
<td>6 – 49 (29)</td>
<td>CR</td>
<td>ER + LG</td>
</tr>
<tr>
<td>Montreal Group 2</td>
<td>4 (2)</td>
<td>36%</td>
<td>6 – 49 (29)</td>
<td>CR</td>
<td>ER + LG</td>
</tr>
<tr>
<td>Montreal Group 3</td>
<td>2 (1)</td>
<td>38%</td>
<td>6 – 49 (29)</td>
<td>CR</td>
<td>ER</td>
</tr>
<tr>
<td>Sacramento Group 1</td>
<td>6 (2)</td>
<td>25%</td>
<td>6 – 49 (29)</td>
<td>ER</td>
<td>MO</td>
</tr>
<tr>
<td>Sacramento Group 2</td>
<td>5 (1)</td>
<td>25%</td>
<td>6 – 49 (29)</td>
<td>CR</td>
<td>LG</td>
</tr>
<tr>
<td>Sacramento Group 3</td>
<td>5 (1)</td>
<td>25%</td>
<td>6 – 49 (29)</td>
<td>ER</td>
<td>MO</td>
</tr>
<tr>
<td>Toulouse Group 1</td>
<td>3 (1)</td>
<td>42%</td>
<td>6 – 49 (29)</td>
<td>CR</td>
<td>ER + GD</td>
</tr>
<tr>
<td>Toulouse Group 2</td>
<td>3 (2)</td>
<td>42%</td>
<td>6 – 49 (29)</td>
<td>CR</td>
<td>ER + GD</td>
</tr>
<tr>
<td>Toulouse Group 3</td>
<td>6 (2)</td>
<td>42%</td>
<td>6 – 49 (29)</td>
<td>CR</td>
<td>ER + GD</td>
</tr>
<tr>
<td>TOTAL</td>
<td>57 (19)</td>
<td>33%</td>
<td>6 – 49 (29)</td>
<td>3 moderators</td>
<td>4 observers</td>
</tr>
</tbody>
</table>

Notes: The range of “years in practice” is estimated based on graduation years (collected data). The median (µ) per site is used given the asymmetrical distribution of years in practice. The full names of moderators and observers are included in the acknowledgements.

Table 4 presents the focus group data for the frequency of PSR interactions in all four research sites. For physicians who saw PSRs two or more times per week, the number of visits ranged from two per week to two or more per day. The frequency of seeing PSRs reported in the focus groups was similar to the frequency reported by physicians in the Pharma Rep Study overall. Frequency of visits was highest in Toulouse, with 92% reporting that they saw PSRs two or more times per week (88% in the Pharma Rep Study overall) and in Sacramento (88% reported in both the focus groups and the overall study). Frequency of PSR visits was significantly less in Vancouver (56% reported in focus groups and 59% in the overall study),
and in Montreal (46% reported in the focus groups and 38% in the overall study). Gender differences were noted across all sites with women physicians reporting that they saw PSRs less frequently than their male counterparts. The three physicians who reported seeing PSRs only once per month were women, as was the one physician in Toulouse who saw PSRs once every two weeks.

Table 4: Frequency of PSR Interactions

<table>
<thead>
<tr>
<th></th>
<th>Vancouver</th>
<th>Montreal</th>
<th>Sacramento</th>
<th>Toulouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two or more times per week</td>
<td>10 (56%)</td>
<td>5 (46%)</td>
<td>14 (88%)</td>
<td>11 (92%)</td>
</tr>
<tr>
<td>Once per week</td>
<td>6 (33%)</td>
<td>3 (27%)</td>
<td>1 (6%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Once every two weeks</td>
<td>1 (5.5%)</td>
<td>2 (18%)</td>
<td>0 (0%)</td>
<td>1 (8%)</td>
</tr>
<tr>
<td>Once per month</td>
<td>1 (5.5%)</td>
<td>1 (9%)</td>
<td>1 (6%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

6.1 Physician Perceptions of PSRs & Visits

This theme describes the context for physician-PSR interactions from the physicians’ perspectives, addressing the research question: What are the physicians’ perceptions of PSRs and PSR interactions, and the reasons they report for seeing PSRs?

Perceptions of PSRs & Visits

Across all research sites, physicians agreed on many PSR characteristics in general, such as being physically attractive, well dressed, and for the most part having pleasing personalities. Younger PSRs were seen as less knowledgeable than the seasoned PSRs, generally, although physician perceptions of the level of knowledge and training of individual PSRs varied widely.

[Translation] “But they are much better than they used to be, the PSRs. They are better trained. I can definitely say that.” MG2.3/F

“So I mean, not to downplay their scientific, you know, background or anything, but I think if you hire a 16-year-old high school student, give them a one-hour tutorial, they can do it.” VG2.1/M

PSR visits were mainly by appointment and usually between 5 and 15 minutes, sometimes up to 30 minutes either one-to-one or in group meetings with other physicians. Often the meetings were arranged over lunch, which was provided for physicians and staff by the PSR. Some physicians reported that more recently, PSR meetings were arranged by a clinic liaison, set up in a separate room over lunch, and physicians were invited to drop in for a few minutes at a time. Many physicians would also see PSRs on a drop-in basis.

[Translation] “So to come and meet with us, we have criteria. They must bring something new. We no longer meet the reps in the corridor because they are no longer permitted to drop in. So we chose one of our colleagues as a liaison, so he is the one who sets up the appointments.” MG3.2/F
Physicians stated that they were aware of and expected the sales orientation of PSR visits, including repetition of the same key messages; however, they strongly disliked certain sales techniques, especially fear tactics.

“They're salespeople. The bottom line. ‘Oh, we're here for people's health.' No, you're not. You're here for the shareholders' bottom line. That's the bottom line.” VG1.1/M

“It's always, we want to get these five words into your head... I think they kind of know in their head or they've been taught how many times does a doctor need to hear it in order for it to stick in their head and so they'll repeatedly be saying things and saying things.” SG3.4/M

[Translation] “I appreciate it when they do not run down the competitor's products.” TG3.2/M

[Translation] “So he [the PSR] begins by saying to me, ‘To sell this indication, you need to scare the patient'...I say, ‘No way, you can leave now. I don't even want to listen to that at all. Good-bye’.” MG1.2/M

**Reasons for Seeing PSRs**

One of the main reasons cited across all sites for seeing PSRs was to receive information, especially on new drugs, new indications, and reminders about drugs. Physicians in Montreal, Vancouver, and Sacramento also mentioned the value of receiving cost information.

“Information about new drugs because sometimes you won't have the chance to look up the literature and they come up with.” VG2.6/M

[Translation] “If it's a drug that we have used, that has been around a while and there are several in the same class, I think the main purpose of the PSR is to provide a reminder about the product.” MG2.2/F

“When I worked at the university and we couldn't like use any new drugs because it was just, there were none, I felt like there was a void...Kaiser [Permanente] doctors have no clue, it seems like, about any brand name medicine. And I think that is a deficit.” SG1.3/M

[Translation] ”Also, the costs, yes! Often we have difficulty getting cost information from anyone other than the PSR.” MG3.1/M

“And, in fact when the drug has gotten Pharmacare approval there's a big push to let everybody know. And I mean, I appreciate that because I'd like to know when the drugs are covered, but that's a big factor.” VG2.4/M

Receiving drug samples from PSRs was another important reason for seeing PSRs, except in Toulouse where samples have been prohibited.

“I think samples are the only reason I do it [see PSRs].” SG3.4/M
[Translation] “I regret a bit that we no longer receive samples, especially for emergencies. Sometimes we are caught out without supplies at the clinic and have to buy them at the pharmacy.” TG2.1/F

As mentioned above, PSRs often provided lunch (food and drinks) and physicians accepted these gifts of food on behalf of themselves and the clinic staff.

“Starbucks...Well, that's the only thing that gets them past the nurses anyway” VG1.5/M

“And my point with the lunches, for the employees... With the lunch coming in, they [employees] get a 30-minute lunch instead of disappearing for an hour to have enough time to go somewhere and come back. That way I don't have two hours of nobody answering my phone.” SG1.1/M

Invitations to continuing medical education (CME) events/dinners were cited by most physicians as a reason to see PSRs.

“Certainly they can get us to, or invite us to attend CME events with some local experts and therefore there can be a discussion that is usually not biased towards their particular medication because so therefore we can hear from a lot of our local experts, and sometimes non local experts as well.” VG2.3/M

Generally, physicians spoke favourably about the PSR providing handouts, posters, tools and industry-sponsored health professional support programs for patients (e.g., PSR arranging for a dietitian or nurse to meet with diabetic patients).

“I'd say that is the one thing that I find positive is sometimes we get things that are useful tools for us in trying to motivate our patients to see some medical, you know, some aspect of their medical care as something they should be concerned about. And as long as it isn't biased towards a product, that is sometimes useful.” VG1.3/F

The PSR visit as a diversion and a social break from patients and work was common to all sites, with most physicians explaining that this was not a primary reason to see PSRs, but an added benefit.

[Translation] “The PSRs are either a pretty woman, someone very pleasant and engaging, a young man or young women, cute and friendly, who is not sick like the patients... It is a breath of fresh air.” TG2.2/M

“Sometimes they are a bother, but I mean, most of the reps, they're amazing, pleasant, up people. I don't know how they can stand to go around all day talking to a bunch of arrogant doctors...” SG1.2/M

[Translation] “You've just seen two patients that got on your nerves, then with the representative you have a pleasant exchange, you know. It’s a positive change to the day. And there are several reps I have known for a long time.” MG2.2/F
Physicians’ perceptions of and reasons for seeing PSRs were relatively consistent in all research sites. The focus group discussions indicated that physicians valued the interactions mainly for information on new drugs, drug reminders, cost information, drug samples for patients, gifts of food for staff, supportive services such as the provision of a nurse or dietician, and for the social break provided. Physicians in all sites mentioned efforts to better manage PSR interactions. Details about what physicians valued about PSR interactions and their preferences provide useful contextual information with which to inform interventions.

6.2 Physician Perceptions of Information Quality

This theme includes physicians’ general comments about the quality of information provided by PSRs and their reactions and responses to the findings in Mintzes et al. (2013), addressing the research question: What are the physicians’ opinions about key findings of the Pharma Rep Study, in particular opinions on the quality of information provided by PSRs during sales visits? Physicians’ comments fall into two subsections: 1) safety information related to mention (or lack of mention) of harms, interactions, and contraindications; and 2) scientific information related to how they defined and rated the scientific quality of the information provided.

Perceived Quality of Safety Information

When they were shown the study findings about the inadequate safety information, physicians in all sites stated that they were not surprised and did not expect PSRs to provide information on harmful effects without them asking for it. They offered reasons and justifications for the lack of safety information provided.

[Translation] “If we don’t ask questions, there’s a good chance they won’t mention harms. They will tell us about the benefits but not much about side effects, but if we ask, it’s another story. Then we will get answers. Usually, they won’t lie to us… they will tell us.” MG2.1/M

“Well, you know, the reps are exactly that, they’re sales reps, right? So they’re not going to give you harmful effects necessarily unless you prod them.” VG1.5/M

Although physicians at all sites did not express surprise at the lack of mention of serious harmful effects by PSRs, they did express concern about these findings, especially in Sacramento when the participants were told that 45% of the promoted products in the study had FDA black box warnings (e.g., collective “wow”); and in Toulouse, some physicians stated that this finding was unacceptable; one said it was “an absolute horror.”

[Translation] “We see the first harmful effects in 61% of cases; benefits in 80%; that is an absolute horror, no? Only 6% of promotions mentioned serious adverse events.” TG2.2/M

“It’s too bad that the percentages are so low, but again not surprising given the purpose of their visit and the time restraints that they have, and constraints that they have in being able to speak with us… especially contraindications and serious adverse events
needs to be, us docs need to be made aware of that in order for us to safely prescribe these medicines.” SG2.1/M

Physicians generally reported that PSRs rarely, if ever, mentioned drug interactions, except if they were making comparisons to a competitor’s product or in one case a physician who specialized in caring for patients with HIV/AIDS.

“The only time, the time they mentioned the drug interaction, to say that their drug is better than their competitors’ drugs. They say our drugs do not have drug interactions, compared to the other drugs.” SG1.4/F

The responses varied regarding mention of contraindications, with some physicians stating that they expected to hear about them but most physicians not expecting PSRs to mention them.

[Translation] “I don't really expect that they will mention contraindications if it is something we should already know, like contraindicated for pregnancy. But if it’s something like for everyone with blue eyes (I’m exaggerating) then they should be mentioning it.” MG3.2/F

Most physicians also offered possible reasons or justifications why PSRs rarely mentioned harmful effects, citing lack of time or attention, or, in one case, that “serious adverse drug reactions tend to be quite rare too.”

“I notice if they have more time they do mention adverse events. Like if they sit down with you for lunch or something they do go through the, I would say mostly maybe 95% of the time they don’t talk about adverse events, but if they just meet you in the hallway now and they don’t have time for that and maybe that’s what the reason why.” SG1.4/F

In terms of the physicians’ opinions on the quality of information provided by PSRs, physicians across all sites had low expectations to receive safety information from PSRs; physicians felt it was their responsibility to ask questions and offered justifications why they did not expect PSRs to mention harms. However, the majority of physicians expressed concern that serious adverse effects were so rarely mentioned by PSRs. Physicians in Toulouse expressed the strongest concern, and physicians in Sacramento were especially concerned after learning how many of the promoted products carried black box warnings.

Perceived Quality of Scientific Information
When asked about the study findings on how physicians rated the scientific quality of the information provided, responses varied. Some physicians stated that the scientific quality was mainly good. Others stated that they re-interpreted the question and were likely rating some other aspect of the interaction (e.g., the overall presentation, the drug, the PSR), not the scientific quality, when they answered that question on the questionnaires. Or they mentioned that they did not feel qualified to make a “scientific” assessment so their answers reflected their assessment of the overall interaction or some other aspect of the interaction.
“My reaction, I’m not an academic and so it’s kind of visceral reaction and then a lot of it you know is really, I don’t really feel qualified to be able to tell how scientific it really is.”

VG1.5/M

[Translation] “What does it mean ‘quality of scientific info?’ The rep could provide info on the medicine, how it works, the pharmacology and if they omit the harmful effects or serious effects, is that part of the scientific info? We’re talking about a brief meeting between patients; to evaluate the scientific quality, perhaps we need more time; what’s disturbing is excellent; very poor; yes that can happen.” TG1.1/M

Most physicians in Montreal were surprised that the rating of scientific quality in the survey was not more positive; they reported the PSRs were knowledgeable, well trained, and the quality of scientific information was often good. In Vancouver most physicians were surprised by how positive the ratings were and stated that while the information provided was often good, it would rarely be excellent, more often expressing skepticism about the quality of scientific information.

[Translation] “I’m a bit surprised by the poor and very poor ratings, 10%? [others agreed]... Yes, we do show the door to some PSRs when they are not good. Yes, that happens, but 10%? That is a bit too high.” MG2.4/M

“A lot of people find it very good [in the findings] and I’d be surprised that there’s very much really excellent information in there because, you know, again, it’s biased.”

VG3.5/M

[Translation] “Re: rating the scientific quality/presentation, I would be generally rate it as good; what might prompt me to rate a presentation as poor or very poor could be that I already know the medication and I don’t want to listen to the rep because I know the effects.” TG2.1/F

Physicians in all sites commented on the format or presentation of the information by PSRs, referring to how it has become more high tech (using tablets) and how that has, for the most part, improved the quality of the information.

[Translation] “Normally, with the tablet and the visual materials, the presentations are more and more sophisticated; also the materials and the mode of presentation could be seen as the scientific quality too; the presentation could justify a rating of excellent; I think the mode of presentation does influence our perception of the scientific quality [others agreed].” TG2.1/F

“That may have changed also with the advent of the iPad and empirically it seems like Pfizer has little graphs to show you and they kind of tool through it and so they end up on the negative with the adverse reaction slide at the end.” SG1.2/M
Physicians in all sites mentioned that PSRs sometimes arrive with a manager who sits in on the interaction, and they reported that the result is a more formal, less interesting interaction, and not necessarily more scientific.

“Oh yeah. It’s very different [when a manager is there]. You can tell. Just all of a sudden like they're spending so much time with you, going through everything. I’m like, what's wrong with you? You know, you're not like that normally.” SG3.5/M

Physicians in all sites reported that they valued the journal articles left by PSRs as scientific information but that they also challenged PSRs on some of the industry-sponsored studies or studies with questionable evidence.

“And the guy would come in and he would go over one of the recent studies and I thought he was fantastic. I mean, and he’d bring the article in and it was really good... That would have been an excellent.” SG1.2/M

“Well they do often bring, say, a CMAJ article or a New England medical journal article with them that promotes their product, but it’s often a research project that’s been funded by their company too.” VG1.5/M

Opinions about the quality of scientific information were mixed with most physicians (except those in Montreal) offering justifications for key findings of the Pharma Rep Study. Physicians reported that the format of PSRs presentations, presence of a company manager at the interaction, and provision of journal articles also influenced their opinions of the quality of information provided.

6.3 Perceived Influences & Strategies for Prescribing

This theme includes the physicians’ perceptions on the factors influencing their likelihood to prescribe and the strategies they use to make prescribing decisions, addressing the research question: What influence, if any, do the physicians think their interactions with pharmaceutical sales representatives have on their practices/prescribing decisions (i.e., likelihood to prescribe)? Physicians also mentioned other (non-PSR) factors related to prescribing. The section is divided into two subsections: 1) perceived influence on prescribing; and 2) physician strategies for prescribing.

Perceived Influence on Prescribing

After being shown the findings indicating they had been influenced by PSRs, physicians were asked what they thought about the findings and if they felt they were influenced by PSRs interactions.

“So I do not get influenced just because I’ve seen the rep. I like seeing them, I like to have the information but I like to do what I feel is evidence based.” VG3.2/F

“I almost never change my prescribing practice based on a rep visit.” VG1.3/F
“But one thing I was going to say about what makes me more likely is a new class of drug... I was a little more eager to try that because it's a new class of drug.” VG2.4/M

[Translation] “I am susceptible to presentations that are well structured and scientific which will influence my prescribing more than pure promotion.” TG3.5/M

[Translation] “I don't let myself be influenced by the attractive young women; I'm able to separate that, at least I hope I am; the findings are scary; it shows the reps have a strong influence on prescribing/on increasing sales; because I'm a bit of a sub-specialist, I'm more critical than others.” MG1.5/M

“I can see [from the findings] we are influenced by the reps; we can't ignore this, seeing the data. How is it that we can see the reps don't tell us the effects and yet we still have a good impression of the presentation? It frightens me. I'm always sorry that it's not the Fac [university] that organizes the rep visits. Why isn't there a network like this?” TG2.1/F

Physicians often reported that the reminder aspect of the PSR visit was valuable; that they might start prescribing a new drug after a promotion but then revert to “old habits” until the PSR returned to remind them.

[Translation] “I think the only effect of the interaction is to remind us. Once you start using a particular drug, this or that, you get used to prescribing it. On the other hand, a new one arrives, as effective and tolerated, and you start prescribing it from time to time but then suddenly you revert back to old habits. Then the PSR arrives and reminds you again. I think this is mainly for new drugs, but I don’t necessarily jump in with both feet.” MG2.2/F

When asked about the potential influence of participating in the study, most physicians in the North American sites reported that they thought it did have an effect on their attitudes and possibly on behaviours (e.g., “I'm going to set some ground rules”), although they added that they would probably return to “old habits” eventually.

“I think I'm more and more cautious about drug reps, and doing the study makes me even more cautious and realize how potentially affected I am.” VG1.4/M

[Translation] “Yes, filling in the questionnaires forced me to pay more attention and to retain more because I took notes to be able to report what the rep actually said.” MG3.2/F

The majority of physicians in most sites did not think they were influenced by PSRs, but suspected that their colleagues may be. The exception was in Toulouse where physicians pointed to the findings of the Pharma Rep Study and stated that the data show that they must be influenced. Physicians across all sites offered various justifications to explain the study findings.
Physician Strategies for Prescribing

Physicians at all sites shared some of their personal strategies to avoid conflict of interest and to ensure what they perceived as evidence-based prescribing. Asking questions of the PSR, challenging them, and requesting scientific articles from them were common personal strategies identified by physicians inform their prescribing practices.

[Translation] “But it’s our responsibility to know and understand what we read... but physicians don’t ask enough questions.” MG1.5/M

“Yeah, so if we don’t hear that, we assume that there’s no negatives. We don’t actively ask. We assume there they’re saying that. So we were from five years ago for that Vioxx lesson, probably all physicians learned. I know for me I would ask the negative. I don’t ask them. I ask the competition company. I said, ‘hey, what’s your comment on that drug? What’s your comment on that?’ And they give me this information.” SG1.6/M

“Well, I would hope that doctors would do their research. I mean, if it’s a new drug and you’ve never experienced, I don’t think you can really just on what a drug rep comes and tells you in two minutes. I mean, you’re going look at the insert, you’re going do your own research.” SG2.2/M

“I certainly don’t let them into my sample cupboard. I was working in a clinic the other day and walked in and there’s somebody rooting around in the sample cupboard. I said ‘Who are you?’ ‘Oh, I’m the rep.’ They just sent him in. So I went to the desk and said ‘Look, in my office I don’t let them near my sample cupboard.’” VG1.1/M

One of the main strategies cited by physicians in all sites, in addition to relying on their own personal strategies, was that they would not take the PSR information as “cash” or at face value but would seek corroborating information from external sources. Physicians in all sites reported that, before they prescribed a new drug, they looked to specialists and other health professionals for guidance.

“I would just want the drug rep to present me with the basics and then I will never prescribe it first, I will wait and I will see what my, the specialists are doing. And if I want to get more information I would probably ask my specialist colleagues rather that the drug reps.” VG2.2/F

Attending continuing medical education (CME) events was another common strategy reported by physicians in all sites.

[Translation] “I also like to plan CME with reps; often the speaker will be talking about a new product; I like to go to hear what the specialists have to say about the product and if it has side effects that I may not have heard about from the rep. The speaker at CME don’t mention a specific product; the company probably wants them to, but they don’t necessarily. MG2.2/F
“After this [CME] lunch or dinner talking or conference, we may feel more comfortable [to prescribe]... Of course if we know some have black box [warnings], that's gonna go the other direction.” SG1.6/M

Pharmacists were mentioned in all sites; in some cases as a helpful support to inform patients and in other cases as a problem for physicians.

“I think it deters some patients from taking medication. Because it's pretty overwhelming when you say 'I want you to take such and such,' and then they go to the pharmacist and get pages of reasons why they shouldn't take it.” VG1.3/F

[Translation] “Before prescribing I look to internists, specialists, other doctors, journal articles, but especially specialists; the pharmacists also has a role; e.g. someone who has been to three specialists and prescribed three medications with major contraindications because they are unaware, the pharmacists will phone to alert me; the pharmacists used to be more formal, now they do this more often and are more familiar; it's good they are paid, I'd rather they call me for nothing than not call me and miss a contraindication/ harmful effect; this is an important role for the pharmacists.” MG1.2/M

Many physicians in all sites reported consulting independent sources of drug information (i.e., independent of the pharmaceutical industry) as an evidence-based approach to prescribing.

“What I think, you know, is the professional academic detailing that they're starting to do, the stuff we get from the TI, the evidence-based medicine people, who are showing us the other side of the coin, is absolutely the way to go.” VG1.1/M

“I think some of the specialists too rubbish the Therapeutics Initiative because they're saying some things that don't go down so well... a cardiologist I do respect... I said, look, you guys are telling me one thing and TI is telling me something totally different. Where is it at? And he said, yeah, I really have a bit of a problem with a couple of things that they [TI] said in that article. So it's-- When two people you respect are at totally different ends, that's when it's difficult.” VG1.1/M

Many physicians stated a preference for information that was more convenient and brief. The online source, UpToDate, available through a Smart phone app was mentioned most frequently in Vancouver, and several times in Sacramento.

“Yes. I love UpToDate. It's great.” VG1.3/F

“A lot of times before giving a patient a new medication I print out the patient information sheet on the drug from UpToDate.” VG1.4/M

"I try to really get my information from UpToDate, which is not biased" SG2.2/M

“You need something, things which are useful at the point of care. You know, they need a paragraph on a drug saying, what is the likelihood that you're going to get this? Is this
5%, 10%, 90%, one in a million? That’s what would be useful to me as a family doc, not that you have a one in 200,000 of getting thrombocytopenia or whatever.” VG1.1/M

In Sacramento, physicians often spoke about the push to prescribe generic drugs as a cost-saving measure, and that part of their decision-making strategy was to assess the promoted product in comparison to a generic version. Several physicians spoke of the computer reminders that prompt them to consider prescribing a generic drug.

“On our computer system there’s a program that says, okay, have you considered using this? When you hit refill the name brand. And then we need to actually talk to that patient, a lot of times they are, ‘hey, this is the brand that works, I don’t want to change.’ ‘I’m like, well, you can save X amount of dollars. You can save $1,000 a year.’ ...Some people are willing, they are cost sensitive and if they’re paying for it they may change.” SG2.1/M

Physicians discussed the impacts of two high profile drug safety scandals of the drugs rofecoxib (Vioxx) and benfluorex (Mediator).

“So we were from five years ago for that Vioxx lesson, probably all physicians learned [to ask questions].” SG1.6/M

[Translation] “This environment [post-Mediator] has made us more vigilant, though we are probably guilty of being too close to the companies.” TG3.1/M

[Translation] “I would say it put on the brakes a bit; seems to me that since Mediator we have fewer requests for rep visits.” TG2.3/F

Several physicians in both Vancouver and Toulouse stated that they had used PSR visits as a training opportunity for medical residents, but physicians were critical of the residents’ negative attitudes toward PSR visits.

“I do a lot teaching the residents and the medical students are brainwashed that you should not be seeing the pharmaceutical [reps]... And I feel that it’s really wrong of the university to tell them not to see the [PSRs].” VG3.2/F

[Translation] “I bring my medical students to the interaction. When they see a rep, it’s like the devil has entered the office!” TG3.2/M

Physicians across all sites described the strategies they have used to avoid the conflict of interest associated with PSRs and to inform their prescribing decisions such as managing the contact they have with PSRs, asking questions, requesting journal articles from PSRs, and conducting their own research. Physicians also reported that they attempt to corroborate information from PSRs from other sources perceived as unbiased such as specialists and CME events. Other strategies and comments about perceived influences included accessing independent information (e.g., from academic detailers where they are available); the role of pharmacists and residents; and the impact of high profile drug scandals such as those related to rofecoxib (Vioxx) and benfluorex (Mediator).
6.4 Regulatory/Site-Specific Environments

This section includes physicians' comments specifically about regulations governing physician-PSR interactions in each of the included countries to address the research question: What differences in physicians’ experiences, perceptions, and opinions, if any, may be related to different regulatory environments or other site-specific factors of the three included countries?

In Sacramento and Toulouse, physicians discussed the effects of guidelines and regulations on PSR interactions, and the fact that, in Toulouse, drug samples are no longer permitted.

“One thing I’ve never had is somebody go out of the FDA guidelines. Boy, they've drilled it in. They say, I can't tell you. You ask one question, [the rep says] 'I really can't comment about this future study that's not out there.'… They don't even hint… After the Vioxx recall that changed, I think.” SG1.1/M

“This last year I went to a couple of dinner talks. The thing is they have, they say, the speaker said by regulation they have to refer to three slides that are the adverse events, adverse side effects. They have to say this first. They talk about the good things. I think that is a good regulation from the Pharma Code, FDA or whatever things, yeah.” SG1.6/M

[Translation] “Samples no longer exist; reps have become more sophisticated and we have become more demanding; it's not a societal change but due to stricter regulation; but I see a bias in all this in that being more demanding and brandishing the precautionary principle everywhere we won't ever prescribe a new medication and I don't think that will benefit patients." TG3.1/M

“By law they have to stick to the script; your next study could be the impact of iPad presentations on safety info; if you ask something outside script, they cannot answer, or don't know; they know a new study is coming out but cannot say anything about it.” SG1.2/M

[Translation] “I think it lowers the scientific quality to focus only on the regulatory requirements... it's one of the perverse effects [of stricter legislation] to present medicines only on the regulatory aspect and not to broaden the discussion.” TG3.5/M

In Canada, regulation and guidelines related to PSR interactions were rarely mentioned. Montreal physicians reported that PSRs sometimes made a special visit following a Health Canada warning letter to discuss the warning. Two physicians (one in Montreal and one in Vancouver) stated the need for better regulation and enforcement.

“So I'd like to see, take this a step further. I'm more radical perhaps but I'd like to see better legislation, better adherence to guidelines, rules, laws that say that if a rep, if they're going to be coming round with information they have to, they're obliged by law to give not only the benefits but the downsides too so that people can make more informed decisions. And if they don't provide a balanced presentation they shouldn't be coming round at all.” VG3.5/M
“I think they're always going to be selling and I don't think, I really think it's naive to think that...they're going to change because we legislate them to.” VG1.1/M

Of all focus groups, physicians in Toulouse were most likely to mention regulations governing PSR activities; physicians in Sacramento regularly referred to FDA regulations in discussions; and physicians in Canada only rarely mentioned regulation. In Toulouse, physicians’ comments were mainly positive, associating stricter regulation with better PSR training and better quality promotions. However, several physicians criticized the stricter regulations for being too restrictive resulting in lower quality promotions. Physicians in Sacramento had similar comments, applauding the FDA regulations that require mention of harmful effects, but suggesting that regulation restricted the interactions. In Canada, rare comments about regulation were mainly to suggest the need for better regulation to improve safety. Other site-specific differences are mentioned in the relevant sections above.

Interpretation of these results follows in the Discussion.
7.0 DISCUSSION

This chapter interprets the key results to answer the research questions. The discussion is organized according to the conceptual framework, including physician perceptions of PSRs; perceptions of information quality, influence, and strategies for decision making; and observations on differences related to the regulatory context. Existing research from the literature review supports the Discussion and places the results within the larger research context.

7.1 Physician Perceptions of PSRs & Visits

In terms of physician perceptions of and reasons for seeing PSRs, the results are consistent with previously conducted qualitative studies cited in the literature review (Al-Areefi et al., 2013; Chimonas et al., 2007; Prosser & Walley, 2003). Physicians reported the similar characteristics of PSRs, such as being attractive, pleasant, and “a breath of fresh air” and the same reasons for seeing PSRs (e.g., information, drug samples, social aspect). However, physicians’ opinions about the level of knowledge and training of individual PSRs varied considerably. Many physicians in all sites stated that they thought the level of PSR training had improved in recent years; Toulouse physicians credited regulatory changes in France, and Sacramento physicians mentioned the introduction of PSRs with specialized medical/pharmacological training.

A notable topic of discussion was that physicians and their staff were taking more control of PSR interactions, establishing systems for communicating with PSRs that sometimes involved a designated clinic liaison and group meetings. According to persuasion theory, one-to-one interactions are usually more effective for increasing sales; however, the physicians in the focus groups often reported that group meetings over lunch with PSRs were becoming more common, allowing the interaction to include peers (i.e., hearing the opinions of peers and the questions from peers enhanced the learning) (Roughead, 2006, p. 673). According to participants, this change was driven by the physicians and clinics to develop management systems for PSR interactions that limit the drop-in visits and put the interactions more in the control of physicians. Physicians presented this perceived control over the management of PSRs as evidence that they were not influenced by PSRs; however, the biased promotions accompanied by food still took place.

As evidenced in the focus group data, PSRs regularly used persuasive communication techniques such as repetition of key messages, and emotional appeals such as fear tactics, and reciprocal appeals such as asking physicians for support by prescribing their product (Roughead, 2006, pp., 662-663). Physicians valued certain persuasive techniques such as friendliness and providing information to gain trust, but strongly rejected others such as when PSRs demonstrated an aggressive “car salesman” approach, fear tactics or criticizing the competition. Physicians downplayed the sales intent of interactions, dismissing it as an annoyance or declaring their awareness of the sales orientation of the visit, and stating that because they were aware, they were less influenced by the sales techniques. In describing the sales techniques that they disliked most, physicians explained how they challenged PSRs on
these approaches and "showed them the door" asserting their self-efficacy and perceived behavioral control.

Physicians reported that they valued the PSR interactions for a number of reasons, especially for information on new drugs, including cost information that they did not receive from any other source, and reminders of the promoted products. The fact that physicians value these "reminders" and information on new drugs indicates a lack of awareness that "reminders" serve to reinforce promotional priorities to prescribe newer, patented drugs, and pharmaceutical solutions generally, leading to a less evidence-based approach to prescribing.

Physicians also reported that drug samples were an important reason and were seen as a way to save money for patients, for convenience, and in one case to trial a new drug. In Sacramento, physicians emphasized the importance of samples to their decision to continue seeing PSRs. Drugs samples were very important to physicians in Canada too. In Toulouse, where drug samples are prohibited, the social aspect of the PSR visit was more important to physicians. Drug samples were prohibited in France in 2005, yet physicians in Toulouse continued to see PSRs and report positively about the interactions. This is inconsistent with physician reports in other regions. The reports by North American physicians that samples are a key reason they see PSRs may be related to a social desirability bias in North American sites (i.e., samples are perceived as helping patients, therefore it is generally more acceptable to see PSRs to receive drug samples that it is to see them for social reasons).

Similarly, physicians valued the provision of food, invitations to CME, handouts, and tools from PSRs. Many physicians in Vancouver and Montreal highlighted the service of providing company-sponsored dieticians, nurses or other health professionals to put on clinics and meet with patients directly to provide health care information. Physicians reported that these services were useful for PSRs to gain access to them and their staff, and generally they valued these services because they made the physicians' jobs easier and more pleasant. As found in the literature, physicians accepted these services and "gifts" often on behalf of their patients and staff (i.e., altruistic motives), making them more socially acceptable and less of a conflict of interest in the opinion of physicians (Oldani, 2004, p. 334). Again, this reveals the physicians' lack of awareness of the promotional influence of gifts and the expectation of reciprocity.

Another valued aspect of the interaction reported by physicians was the social break provided by PSR visits. The social part of the interaction is complex, especially as physicians reported having known some PSRs for 20 to 25 years and that they had "grown old together." From the physician perspective, the social aspect of the interaction appeared not to highlight the sales intent of the promotion. This is consistent with the evidence about how PSRs befriend physicians and establish a social contract as part of the interactions, encouraging a feeling of social obligation (Fugh-Berman & Ahari, 2007, p. 621).

While physicians themselves mainly valued the PSR interactions, physicians at all sites spoke about the anti-PSR attitude of most medical residents or colleagues working in university-based centres. Physicians stated that they wanted to use PSR interactions as a teaching tool
with medical residents but that the residents were often reluctant to participate. The literature indicates, and the focus group data support, that policies limiting PSR interactions in university settings and curricula that teach critical evaluation of PSR interactions are having an impact on residents’ attitudes (Wilkes & Hoffman, 2001, p. 1276; Wofford & Ohl, 2005, p. 11). In response to this discussion, several physicians in the focus groups, in particular in Sacramento, stated that physicians who do not see PSRs end up with in an information deficit about new drugs.

The focus group discussions about the characteristics of PSR interactions were similar across all sites, with physicians citing similar perceptions and reasons for seeing PSRs in all sites. This contextual information, which adds to the body of evidence from previous research, provides insight into the physicians’ perspectives and preferences as they relate to PSR interactions (Al-Areefi et al., 2013; Chimonas et al., 2007; Prosser & Walley, 2003). A better understanding of the context of interactions and the needs and preferences of physicians helps translate the findings into “the language of implementation” and provide clues to inform the development of interventions (Sandelowski & Leeman, 2012, p. 1409).

7.2 Physician Perceptions of Information Quality

In terms of the provision of information by PSRs, physicians stated that they were fully aware that PSR visits were part of a sales pitch, and the information could not be taken at face value or as “cash.” Physician expectations about the provision of safety information in particular were low across all sites. The overwhelming response to the findings about the lack of safety information provided was that they did not expect PSRs to provide information on harmful effects unless the physicians asked specific questions. Most comments revealed a level of cognitive dissonance related to their stated awareness that the information provided by PSRs was biased yet trusting them to answer questions about harmful effects with full and balanced information (e.g., “they won’t lie to us”).

Despite having low expectations about receiving drug safety information, most physicians expressed disappointment and concern that serious harms were rarely mentioned. Physicians in Sacramento were especially concerned when they learned that 45% of the promoted drugs carry black box warnings for serious and life-threatening effects. Physicians in Toulouse also strongly supported the need for more safety information, with one physicians referring to the lack of information on serious adverse effects as an “absolute horror.” Most physicians also provided possible justifications for why PSRs rarely provided safety information (e.g., that they were not giving PSRs enough time to provide the information). Across all sites, physicians agreed that more safety information should be provided by PSRs but they did not expect it to improve without stricter legislation.

In rating the quality of scientific information provided by PSRs, many physicians explained that they had likely reinterpreted the question to rate the overall presentation by the PSR or the quality of the drug, and not the actual scientific quality of the information. Some explained that they did not feel qualified or did not have time to assess the scientific quality. Physicians seemed to offer these explanations to justify the study findings in which 57% of promotions
were rated as good or excellent. Many physicians expressed surprise that the majority of promotions were rated so positively, except in Montreal where physicians thought that too many of the promotions were rated as poor or very poor. This difference may be related to the strong pharmaceutical industry presence in Montreal and a higher percentage (34%) of physicians in that city receiving pharmaceutical funding (e.g., for study participation, advisory boards, speaker’s bureaus) compared with Vancouver (30%) and Sacramento (24%). Pharmaceutical company funding was highest in Toulouse (42%); however, this potential for influence may have been countered by France’s stricter regulation (see below).

When asked what would prompt physicians to rate an interaction as good or excellent, many referred to the quality and format of the PSRs’ presentation. Attractive presentations on tablets/iPads were mentioned across all sites as being impressive and engaging. But physicians also emphasized the need for a knowledgeable and personable PSR who provides useful information and reference materials (e.g., journal articles) for an interaction to be considered good or excellent. As for interactions that would prompt a poor or very poor rating, physicians cited PSRs who did not know enough about the drug and were unable to answer questions or those using overly aggressive sales approaches. At several sites, physicians also mentioned that the practice of regional company managers sitting in on the interactions to assess the PSRs’ performance resulted in interactions that were “by the book” but that lacked the friendly social aspect and were not necessarily more scientific.

7.3 Perceived Influences & Strategies for Prescribing

In terms of perceived influence on prescribing and in response to the Pharma Rep Study findings, mainly the physicians attempted to justify or sideline the findings, or they gave reasons why the findings did not apply to them (e.g., "I’m more critical than others"). They also offered justifications for why PSRs did not mention harms (e.g., “they don’t have time for that”). These justifications and contradictory attitudes and behaviours were apparent throughout the data across all sites and are consistent with the findings on cognitive dissonance by Chimonas et al. (2007). The theory of cognitive dissonance presented by Chimonas et al. (2007) is especially useful in the examination of the contradictory attitudes reported by physicians (e.g., being aware that information is biased for promotion, yet valuing that information and using it to inform prescribing decisions). The dissonance indicates a general lack of awareness of how PSR interactions may impact physician attitudes. This in turn puts into question the ability of individual physicians to determine in what ways they may be vulnerable (or not) to influence from the pharmaceutical industry (Norris et al, 2005, p. 23). If we examine the preferences of physicians as related to the PSR interactions, including what they value most about the interactions, it provides clues about their vulnerability to influence (e.g., the value they place on the social contact with PSRs which implies an obligation to reciprocate).

During the focus groups we asked physicians if they thought their participation in the study had any impact on their practice (i.e., the act of filling out the survey following interactions, and participating in the focus groups). Most physicians in North America reported that participation in the study increased their awareness about the interactions. Several
commented that the act of actually filling in the questionnaires forced them to pay closer attention. They also reported that participating in a focus group discussion about the interactions with other physicians was a new experience and many of them commented that it had been interesting and thought provoking. Some indicated that they had made changes in their practice, or planned to (e.g., setting ground rules for interactions, making sure to ask PSRs at least one question about serious adverse events). However, they consistently added that they did not know how long it would be before they returned to “old habits.”

Physicians’ reflections on the influence of the study indicate the need for ongoing interventions to maintain a shift in practice or behaviour, and hint at potentially effective intervention methods to increase physician awareness of industry influence. Physician perceptions of the study influence also point to one of the successful persuasion strategies used by PSRs, which could also be used in interventions: repetition. Physicians in all sites confirmed that this was a successful strategy and one of the main benefits of seeing PSRs (i.e., drug reminders).

The theory of human behaviour, in particular the concept of perceived behavioural control from the theory of planned behaviour is useful to help explain the physicians perceived control over what influences their prescribing decisions (i.e., beliefs about their level of control over their behaviour) (National Cancer Institute, 2005, p. 17). While physicians in all sites consistently declared their awareness of the conflict of interest related to PSR interactions, most reported a high level of perceived control over their prescribing behaviour, often not acknowledging that they were influenced by PSRs. As the literature indicates, actual behavioural control related to prescribing is not in evidence. All research sites indicated an association between PSR interactions and reported likelihood to prescribe the promoted drug.

Most physicians in the focus group discussions reported that their prescribing decisions were evidence-based despite previous study findings indicating otherwise (Anderson et al, 2009, p. 994). All physicians identified the strategies they used to ensure evidence-based decision making. This included personal strategies such as asking PSRs questions during interactions and even questioning PSRs from the competing drug company for information that the manufacturer may not provide (e.g., harmful effects, contraindications). Several physicians stated that it was their responsibility to find out about the drugs they were prescribing and that they conducted their own research about the promoted products. However, many reported that they often did not have time to research the drugs themselves and they valued the service provided by the PSRs. As mentioned above, asking questions of the PSRs indicated that physicians had a certain level of trust of the information provided, contradicting the physicians’ statements that the information is biased and not completely trustworthy.

To counter the potential bias in the information from PSRs, physicians also described strategies for external decision-making support, seeking to corroborate information from PSRs with other sources. Specialists were mentioned most frequently as sources that could confirm or deny the efficacy or safety of a particular product, although many physicians recognized the possible conflict of interest for specialists (e.g., being paid by drug companies to speak at CME events). Several physicians stated that they tended to try prescribing new
practices cooperation between pharmacists and physicians has the potential to improve prescribing problems (e.g., drug interactions) with prescriptions as a support to physicians, more pharmacists’ expertise on drugs and the computerized systems for identifying potential problems (e.g., drug interactions) with prescriptions as a support to physicians, more cooperation between pharmacists and physicians has the potential to improve prescribing practices (Muijrers, 2005, p. 630).

Attitudes about information bias at CME events were variable. In the Vancouver site only there were strong negative comments about the CME accreditation process and having to attend “rubbish two hours at a drug dinner,” whereas in other sites, most physicians stated they were aware the meetings were industry-sponsored, but thought they were “fairly objective” and that speakers do not usually push a specific product. So, while physicians acknowledged the potential bias of information from company-sponsored CME, they also valued these sources in their decision-making processes.

Physicians also mentioned sources that were independent of the pharmaceutical industry. Independent drug bulletins, including the Therapeutics Letter from Therapeutics Initiative (TI) at the University of British Columbia, and Prescrire (available in French and English) in France were mentioned most frequently along with the drug review summaries from the Cochrane Collaboration. Most comments about Prescrire and the TI were positive (e.g., “evidence based”), but some were critical (e.g., [Therapeutics Letter] “can be shrill sometimes” and some PSRs “often speak quite disparagingly of Therapeutics Initiative”). A couple of physicians in Toulouse complained that the time lag between when a new drug came on the market and the publication of Prescrire’s assessment of the drug made the information less useful. As for other sources of independent information on drugs, in Vancouver and Sacramento, physicians praised the practice of academic detailing, and in Montreal and Toulouse where they do not have academic detailing, physicians agreed that this was an excellent practice and should be more widely available.

The role of pharmacists was discussed at all sites, with physicians expressing both positive and negative opinions. Pharmacists would call physicians to inform them of a contraindication, for example, which physicians found helpful; in other cases pharmacists would change a prescription to a generic drug from the branded drug that was prescribed, a practice that physicians did not appreciate. Pharmacists were also criticized for giving patients drug inserts or product monographs that overwhelmed patients and “scared” them from taking their prescriptions due to the long list of possible side effects. The tensions between pharmacists and physicians were evident in the discussions but so too was the potential for collaboration (e.g., pharmacists providing academic detailing). Given pharmacists’ expertise on drugs and the computerized systems for identifying potential problems (e.g., drug interactions) with prescriptions as a support to physicians, more cooperation between pharmacists and physicians has the potential to improve prescribing practices (Muijrers, 2005, p. 630).
Access to convenient and speedy information, especially on new drugs, was highly valued by physicians; many in Vancouver especially and several in Sacramento spoke enthusiastically about UpToDate.com, which is available as a mobile app in a brief, accessible format. Having reliable information at their fingertips was what physicians were looking for, and they found the product monographs and government-approved information too detailed for what they needed for prescribing decisions. As one physician in Vancouver put it, they want “a paragraph on a drug” at the “point of care.” Having computer-generated reminders at the point of care was also mentioned by several physicians in Sacramento, referring to the computer reminders that prompt them to consider a generic drug when they prescribe. Physicians reported that these high tech systems were effective ways of delivering information and providing regular reminders about drugs.

As for the two high-profile drug withdrawals of rofecoxib (Vioxx) in North America and benfluorex (Mediator) in France, rofecoxib (Vioxx) was mentioned in Montreal and Sacramento as a cautionary tale that physicians have learned from; and benfluorex (Mediator) was mentioned in all Toulouse groups, although physicians’ comments were mixed. Many reported having adopted a more cautious approach to prescribing post-Mediator (e.g., “made us more vigilant”), although some blamed the media for creating an unnecessary scandal around the drug. Despite the mixed comments, all physicians were well aware of the scandals associated with the withdrawals, and there were mixed opinions about whether changes such as stricter legislation and fewer requests for PSRs visits were related or not.

The focus group discussions provided insight into the physicians’ likelihood to prescribe given the many factors influencing the decision-making process. The discussions also revealed physician preferences about sources and types of information as well as methods of delivery they would prefer at the point of care to assist them with prescribing decisions. Through the discussions we gain a better understanding of the physicians’ opinions on the influence of PSRs on their prescribing decisions, and their opinions on the study findings as they related to their likelihood to prescribe.

7.4 Regulatory Environments & Other Site-Specific Differences

The mention of regulation governing PSR activities varied from site to site. Toulouse physicians were most likely to mention regulation, and in Sacramento, physicians often referred to FDA regulation. In Canada, physicians rarely mentioned regulation except to say that there was a need for more and better legislation for PSR activities, indicating a lack of awareness that legislation related to the provision of safety information by PSRs in Canada does exist. Generally, the comments about the impacts of regulations were positive (e.g., presentations were more scientific, PSRs were better trained than they used to be). In Sacramento, a couple of physicians mentioned how the use of the iPad for presentations ensured that at least one slide about serious adverse effects was included due to FDA regulations. IPad presentations are also easier to monitor than the verbal messages from PSRs. However, several physicians in Toulouse in particular and several in Sacramento indicated that some regulations put too many restrictions on what PSRs were able to say (e.g., no mention of off-label uses), resulting in formulaic and less informative interactions.
While the regulatory differences were compared from country to country, there were notable differences in physician attitudes and perceived influence of the PSR interactions within Canada—between Montreal and Vancouver. Vancouver physicians were generally more sceptical of PSR interactions and the information they provided, challenging PSRs to find evidence-based scientific information on their products, and regularly questioning the information they provided. In terms of rating scientific quality, most Vancouver physicians were surprised that the scientific quality was rated as good and excellent in the majority of promotions (57%), stating that only rarely, if ever, would they rate an interaction as excellent. In contrast, several Montreal physicians were surprised that the scientific quality in 10% of promotions were rated as poor or very poor, stating that more should have been rated as good or excellent. Montreal physicians, while stating an awareness about the potential for pharmaceutical industry bias in information, had much more positive opinions of the information and services provided by PSRs. Montreal physicians often stated their awareness of industry sponsorship (e.g., of CME or patient programs), but they felt that these events and services were fairly objective and did not promote specific branded products. The strong industry presence in Quebec compared with British Columbia as well as the presence of the TI in British Columbia (i.e., raising awareness about the potential risks associated with company-sponsored drug information) may be contributing factors in these differences.

When physicians were asked to reflect on the influence of PSRs on their prescribing practices and the possible influence of the study, there was a notable difference with physicians in Toulouse, which may be linked to differences in regulatory oversight. Very few physicians in Vancouver, Montreal, and Sacramento acknowledged that they were apparently influenced by PSRs, yet the majority of physicians in Toulouse pointed to the study findings presented and acknowledged that they must have been influenced. In contrast, when asked if they thought participation in the study had any affect on their attitudes or practices, physicians in Vancouver, Montreal, and Sacramento consistently stated that participating in the study had made them more aware and vigilant during PSR interactions. Fewer physicians in Toulouse thought that their participation in the study increased their awareness.

These differences seem to reflect a generally higher level of awareness of the influence of PSR interactions in Toulouse physicians possibly due to the Charter and generally stricter legislation in France. Higher levels of awareness about regulations in Toulouse and Sacramento correlate with stricter regulations in France (i.e., the strictest) and the United States, whereas in Canada with its form of industry self-regulation (i.e., the least strict), physician awareness of legislation was the lowest. A higher level of self-awareness, as Tentler et al. (2008) point out, is an important factor in prescribing decisions (Tentler, Silberman, Paterniti, Kravitz & Epstein, 2008, p. 56). However, a higher level of awareness in Toulouse does not eliminate the potential influence of PSRs on prescribing practice. In all three countries, PSR activities continued to consistently contravene regulations and guidelines related to the provision of drug safety information. For physicians to avoid relying on biased promotional drug information, the focus group data were consistent with other researchers’ conclusion that the solution may be to limit or prohibit interactions with PSRs, a choice that is gaining popularity in some centres, including university-based clinical settings and medical
organizations (e.g., the medical group Kaiser Permanente in the U.S.) (Chimonas et al., 2007, pp. 184; Mintzes et al., 2013, p. 1374).

Finally, in terms of the focus group dynamics, the focus groups in France were more social and chatty (and slightly longer) compared with the environment in Sacramento where physicians were more focused on keeping to one hour and keeping to business. This difference between the English-speaking and French sites was not apparent in comparisons between Vancouver and Montreal where focus groups in both sites had similar dynamics (i.e., actively engaged but not as social or chatty as participants in France).

The impact of some of these differences on physician prescribing decisions is unclear as physicians in all four research sites reported similar “likelihood to prescribe” in the Pharma Rep Study. However, the focus group data provide contextual information and information on physician preferences that may be useful in identifying and targeting interventions. Also, the theory that stricter regulatory oversight in Toulouse and Sacramento resulted in physicians being more aware of PSR influences may indicate the first stages of change. According to models of human behavioural change, awareness that there is a problem is a key initiating factor in behaviour change, but without continued reinforcement or “maintenance” (e.g., interventions, reminders), physicians themselves acknowledged that they would most likely soon return to “old habits” (Roughead, 2006, p. 667).

7.5 Limitations

The subsample of physicians who participated in the focus groups (n=57) was as projected (n=60); however, one possible limitation is that it may not have been representative of the larger Pharma Rep Study sample (n=255). The percentages of women who attended the focus groups in Montreal (36%) and Toulouse (42%) were lower and higher respectively than the percentages in the larger Pharma Rep Study (54% in Montreal, 22% in Toulouse). The gender balances were representative for Vancouver and Sacramento. Despite this limitation, the consistency in findings across all focus groups indicates that the subsample was mainly representative of the larger sample, including the number of years in practice. Additionally, as with all focus group data, the generalizability of the data is less important than the richness of the data from individual participants.

Also, the framework analysis approach has the potential to be reductive (i.e., to miss relevant data) as a result of summarizing the participants’ discussions and distilling the themes (Trochim & Donnelly, 2008, p. 284). This risk was minimized by referring back to the full transcripts (i.e., discussion in context) following the development of the thematic index and also during the charting, mapping, and interpretation stages of analysis to check for data that may have been missed or lost in the process. Group dynamics and the potential for one or more participants to influence the responses of others within a group were noted during the focus groups. Facilitators ensured that participants were invited to address all questions. Facilitators also provided a brief summary of the discussions at the end and gave participants the opportunity to clarify or add further comments. Participants were actively engaged in all focus groups.
8.0 CONCLUSION

Physicians are in need of timely access to evidence-based drug information that provides a balance of benefits and harms to ensure rational prescribing and patient safety. Instead, physicians often rely on inadequate and biased drug information from PSRs whose primary role is promotional. The information provided by PSRs to family physicians focuses only on pharmaceutical solutions, often on newly patented brands, not generic drugs. Drug safety information is often lacking as demonstrated by Mintzes et al. (2013). This situation potentially threatens patient safety, especially if physicians are unfamiliar with the medicine or if it is less safe for a specific patient than other available treatments for the same condition.

Physicians’ attitudes toward the information provided by PSRs are often contradictory. They report a high level of awareness that PSR interactions are biased sales promotions and their expectations of receiving balanced information about drug benefits and harms from PSRs are low. Yet many physicians continue to see sales representatives and to value the information on new drugs and drug reminders; drug samples; food; and invitations they provide. Most physicians who participated in the focus groups reported that they valued the break from work provided by PSRs and the social interaction with energetic and attractive young sales representatives or with seasoned PSRs with whom they may have long-term relationships and, in some cases, close friendships. The majority of physicians did not acknowledge the influence of gifts of food or other items from PSRs.

Physician strategies to countervail influence—asking questions of the PSRs, conducting their own research, and seeking corroborating information from specialists or CME events—often did not address information bias.

Physician perceptions and preferences related to PSR interactions identified in this study may inform the development of interventions to address the immediate lack of safety information provided. Interventions geared to meet physicians’ need for evidence-based prescribing information should aim to provide convenient access to summarized information on drugs, and supportive programs that may include a social interaction and/or a break from treating patients for physicians.

Physician perceptions and responses to the key findings of Mintzes et al. (2013) were similar across all sites. One notable exception is the higher level of awareness in Toulouse especially, and in Sacramento, compared with Canada (Montreal and Vancouver) where physicians seemed less likely to be aware that federal regulations require PSRs to provide balanced drug information.

While educational strategies may be helpful in raising awareness, they are unlikely to be effective on their own. Given the widespread cognitive dissonance as described by Chimonas et al. (2007) and the perceived benefits of PSR interactions, most physicians themselves are generally unlikely to reduce or eliminate their contact with PSRs unless they are regulated to do so (p. 189). This could occur at a variety of levels. The findings of Mintzes et al. (2013) and the focus group data are consistent with this conclusion.
9.0 RECOMMENDATIONS

Key study findings and literature provide the basis for recommendations for multiple stakeholders in Canada.

**Recommendation 1 – Federal Government – Health Canada:** Phase in legislation that prohibits drug promotion by pharmaceutical sales representatives to family physicians in Canada with the goal improving patient safety.

This study and the literature indicate that drug promotion by PSRs routinely contravenes the Food and Drugs Act in terms of information provision and is shown to contribute to inappropriate prescribing that may threaten patient safety. The study findings support previous findings that stricter regulation may not fully address the problem. Given the physician perceptions of the PSR visits, the value they place on the information and services provided, and the lack of awareness of the influence on prescribing, a stepped approach to phase in a prohibition is advised. Firstly, Health Canada could follow the Toulouse example and implement more direct government regulation of drug promotion, including the activities of pharmaceutical sales representatives, and actively monitor and enforce federal regulations that drug promotion (or “advertising”) must not be “false, misleading or deceptive.” This would include effective sanctions for companies that violate the regulation and evaluation of the effectiveness of preventing repeat violations by the same company. Combined with educational interventions (e.g., the Bad Ad Program in the U.S.), these steps could raise awareness among physicians about the degree of influence and its potential impact on their prescribing, as well as involving them in the monitoring process, which would help facilitate the implementation of a prohibition.

**Recommendation 2 – Provincial/Territorial Governments:** Require pharmaceutical companies to provide a percentage of drug sales earmarked for provincial/territorial governments to fund the provision of independent drug information, including programs of academic detailing in all provinces and territories.

Physicians are seeking evidence-based drug information, yet they value the biased information from PSRs, and have low expectations related to the provision of drug safety information. To address the problem of biased and unbalanced information, physicians in all sites recommended an expansion of the practice of academic detailing, including to areas where the program does not yet exist. The additional funding for academic detailing could come from requiring the drug manufacturer to pay a percentage of drug sales to provincial/territorial governments to fund academic detailing. This blinded source of funding would ensure the sustainability of such programs, addressing the need for ongoing intervention. The fund could also support other programs that provide of high quality, independent drug information and drug assessments (e.g., Therapeutics Initiative at UBC). Additionally,

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6 An educational program sponsored by the FDA to involve health professionals in the monitoring of drug promotion. See the FDA website: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/DrugMarketingAdvertisingandCommunications/ucm211498.htm
provincial/territorial governments could link decisions about drug financing to companies' information provision similar to the model proposed in France (accompanied by monitoring).

**Recommendation 3 – Professional Regulatory Bodies (e.g., College of Family Physicians Canada, Royal College of Physicians and Surgeons of Canada, provincial colleges of physicians):** Ensure that accredited medical educational programs, including CME and other medical training, are provided free from commercial bias and conflict of interest, and that they address physicians' lack of awareness of pharmaceutical industry influence.

As indicated in this and previous studies, physicians are often unaware of the commercial bias of the information provided at industry-sponsored CME events, and they often rely on CME to support their prescribing decisions. To reduce the potential for bias and help ensure that physicians receive evidence-based drug information at CME events, the professional medical regulatory bodies could require the establishment of a blind fund for CME financed by the drug manufacturers (i.e., a percentage of drug sales earmarked for training and education). CME events could provide an opportunity to raise physician awareness about the influence of drug promotion on attitudes and prescribing, sharing the study results, and informing physicians about existing legislation on the provision of drug safety information. To address a knowledge gap reported by many of the physicians in the focus groups, CME events could also provide physicians with training to interpret scientific information and identify risk of bias in medical journal articles.

**Recommendation 4 – Medical Students:** Organize an ongoing national campaign by medical students to raise awareness among physicians about the influences of pharmaceutical sales representatives on the cost, appropriateness, and safety of prescribing.

As identified in this and other studies, medical students are being trained at university to understand how vulnerable they may be to the influence of PSR visits and the potentially harmful impacts on their prescribing practice. Students are learning to critically assess interactions with PSRs and the information they provide, or they are deciding to avoid the interactions altogether. While this sometimes causes tension between medical students/residents and the physicians they train with, as identified in the study, it also presents an opportunity for medical students to organize a campaign to effectively share the information and tools they have learned with practising physicians. Such a campaign could be supported by national and provincial medical associations and/or student groups at universities in Canada. Physicians in the study were particularly concerned that PSRs did not mention serious adverse effects, especially those with black box or other warnings. This could provide a “hook” for the student campaign to appeal to physicians. Student groups could present at CME events, for example. This initiative could help raise awareness among physicians about the influence of PSRs on their prescribing decisions, helping to address the cognitive dissonance identified in the study, and leading to more appropriate (and safer) prescribing.

**Recommendation 5 – Colleges of Pharmacists and Pharmacist Associations:** Establish local pharmacotherapy discussion groups on a regular and ongoing basis to promote
collaboration between pharmacists, physicians, and patients related to the provision of drug information and appropriate prescribing.

With the goal of promoting safer and more appropriate prescribing, colleges of pharmacists and pharmacist associations could host regular pharmacotherapy discussion groups similar to those established successfully in the Netherlands where physicians and pharmacists meet and discuss pharmacotherapy issues and jointly develop guidelines for appropriate prescribing (Kocken, 1998, p. 31). The findings of this study and the Pharma Rep Study, for example, could serve as the basis for a series of discussion groups. Involving medical students could also help facilitate more collaboration between physicians, pharmacists, and patients, providing a natural link between groups as the students carry out their practical training with family physicians. One opening for collaboration between pharmacists and physicians could be to jointly develop accessible and evidence-based drug information summaries for patients that provide the necessary drug information for safe prescribing, but that do not “scare” patients with too much information.

**Recommendation 6 – Patient/consumer organizations**: Organize public education based on the study to inform patients/consumers about the results; discuss strategies for patients to inform themselves about prescription safety, and to improve patient-physician-pharmacist collaboration.

To avoid conflict or interest and commercial bias associated with many patient or disease groups in Canada that are funded by the pharmaceutical industry, the public education would be carried out only by patient/consumer or other non-profit organizations that receive no pharmaceutical company funding. This could be organized through the Canadian Health Coalition, for example, and its provincial/territorial affiliates. Public education could be carried out through organization websites, newsletters, public presentations, and social media based on summarized study results.

**Recommendation 7 – Researchers**: Conduct a study to pilot a mobile app to deliver evidence-based and independent drug information to physicians.

Physicians are seeking accessible and timely independent drug information at the point of care. This could take the form of a mobile app that links physicians to brief evidence-based, independent drug summaries on a selected number of commonly prescribed drugs and recommendations for evidence-based alternative treatment options. Based on the physician preferences identified in this study, the app could include information on drug cost, formulary information, and prompts for brand name and generic alternatives (where available). The app could also clearly flag drugs that carry black box warnings in the U.S. or advisories or warnings in Canada, and list minimally adequate safety information as identified in the Pharma Rep Study.
REFERENCES


APPENDICES

Appendix A – Mintzes et al. (2013) in Journal of General Internal Medicine


Now available online at:

Appendix B – Focus Group Facilitator’s Guide

FACILITATOR’S GUIDE FOR PHYSICIAN FOCUS GROUP DISCUSSIONS

Introduction (10 minutes)

[Ellen] Hello and welcome. My name is Ellen Reynolds, Research Coordinator on the Pharmaceutical Sales Representatives and Patient Safety study, and I’ll be facilitating the discussion today. And this is XXXXX who be taking notes and observing. [Ellen] Thank you all for taking the time to participate today.

- Washroom location
- Please turn off your pagers and phones if you can.
- Help yourselves to some food and a drink and we’ll get started.
- Our aim is to get through this focus group in about one hour, but it may be a few minutes longer.
- Before leaving, don’t forget to see Ellen to receive your honorarium.

During the focus group:

- We’re interested in your opinions and perspectives;
- There are no right or wrong answers;
- It’s okay to disagree;
- My job is to encourage participation, guide the discussion, keep us on the rails and make sure we get out on time;
- And because we are recording your comments, please speak one at a time.

Before we begin, I’ll need you to sign the “informed consent” forms—a typical requirement of university research. The forms explain that the information collected today is confidential, no names will be attached to reporting, we’ll be recording the discussion, and you are free to withdraw at anytime.

Please sign one copy of the informed consent form and keep the second copy of the form for yourself. XXX will collect them.

The purpose of this focus group

Briefly, and to refresh your memories about the study, the aim of the Pharmaceutical Sales Representatives and Patient Safety study is to examine the information provided to family physicians by pharmaceutical sales reps, especially in terms of drug safety information. The study, which began in 2008, is taking place in four sites: Vancouver, Montreal, Sacramento and Toulouse in France. This is the first study to examine the
information provided by pharmaceutical sales reps in Canada, or to compare information quality in countries with differing regulatory standards.

Data collection for the study took place between May 2009 and June 2010, which is when you would have completed questionnaires following visits with pharmaceutical sales representatives. Don’t worry though, we aren’t asking you to remember your responses; it was a while ago. We will be presenting summarized results of the study.

[Make this clear] The purpose of the focus group today is:

1) to get your reactions and opinions on summarized results of the study AND

2) to explore some of the specific results in a bit more depth with you as participants in the study, particularly in relation to prescribing decisions and patient safety.

Round of introductions for participants.

Introductory statements (10 minutes)

To get things started, I’d like you to think about your most recent interaction with a pharmaceutical sales representative.

1. In one or two words only, how would you describe the interaction? I will give you a couple of minutes to write down your answer.
   [Wait about 2 minutes. Then go around the room inviting participants to discuss what came to mind.].

2. For you, what are the main benefits of seeing sales reps? Any negatives?

Response to summarized results: (40 minutes)

In the discussion today we will focus on your feedback on the results of the study. We are not providing detailed results because we have limited time and we’d like to focus on getting your opinions and feedback on several key results. Also, the results are pre publication. Once published in a medical journal, which should be very soon, we will send you a copy of the article with the full results.

Also, to give you a bit more context in terms of the drugs that were promoted by sales reps, there were over 250 different drugs promoted to doctors at all four research sites. Here is a list of the top 10 drugs promoted in the Vancouver area.

[Hand out drug list. Give them a minute to review.]
Before showing you the results, I’d like to go over a few things that will help make the graphs as clear as possible.

If you remember, during your participation, following each visit with a sales rep, you filled in one questionnaire for each drug that was promoted by a sales representative.

All of the data in the graphs refer to drug-specific promotions. That is our unit of measurement in the study, based on the questionnaires doctors filled out on each promoted drug. There were 1692 drug-specific promotions included in the analysis from all four study sites. The results we are discussing today are those from the Greater Vancouver site—a total of 418 promotions.

To be considered “a promotion” for the purpose of this study, a drug sales rep met with had to have made at least one claim about the drug being promoted. [Note to facilitator: any claim; it doesn’t have to be a drug indication]. Drop-offs of drug samples were excluded because if it was just a drop-off, the rep made no claims about the drugs.

Any questions so far? Okay, now we will look at the summarized data.

[Hand out Graph 1]

Graph 1:

Have a look at the results. This is what doctors reported that they heard from the sales representatives: In three-quarters of individual drug promotions, the representatives mentioned at least one health benefit, and in one third they mentioned at least one harmful effect.

3. What are your thoughts about this result? [Probe: any surprises?]
(Go around the group, exploring the results—the goal is to drill down into the subject matter and encourage them to discuss and give their opinions as to what they may think the results).

[Note to facilitator: if they ask, we can explain how we calculated these numbers, and also that the reason it's not a 100% with health benefits mentioned is that sometimes promotional claims were only made on cost or convenience advantages; the "claim" could be about anything.]

[Hand out Graph 2]

Graph 2:

Here we are looking at specific types of harm that sales representatives may have mentioned. This includes non-serious adverse events (common side effects), contraindications, serious adverse events and drug interactions. [EMPHASIZE THIS POINT] For the data on serious adverse events and contraindications, we looked at the drug product labelling and included only the drugs that had at least one serious adverse event or at least one contraindication listed in product labelling.
Doctors [in Vancouver] reported that sales reps mentioned at least one common side effect in around one-quarter of individual drug promotions, at least one contraindication in 15% of promotions of drugs with contraindications and at least one serious adverse event in 6% of promotions of drugs that had serious adverse events listed in the monograph.

4. What are your thoughts about these results? What stands out for you?

[Note to facilitator: if doctors ask, mention of at least one serious adverse event in 6% it means no mention of a single adverse event in 94% of promotions]

________________________________________________________________________

[Hand out Graph 3]

Graph 3:

This pie chart shows the answers to a specific question in the questionnaire: “Generally, how would you rate the quality of scientific information presented by the sales representative?”

Participants felt that information was either “excellent” or “good” in 57% of drug-specific promotions, “poor” or “very poor” in 10% or “fair” in the remaining third.

5. How do you feel about these results?
6. If you think of your own responses (if possible); what do you think would have prompted you to rate the information from a sales rep as “excellent” or “good”?
7. And what would have prompted you to rate the information as “fair”, “poor” or “very poor”?

________________________________________________________________________

[Hand out Graph 4]

Graph 4:

This graph also shows the answers to a specific question in the questionnaire.

In two-thirds of drug-specific promotions doctors reported that they were “somewhat” or “very” likely to start or increase prescribing of the promoted drug as compared with before the sales visit and that after just over one-third said they were “somewhat” or “very unlikely” to start or increase prescribing of the promoted drug.

8. What do you think about these results?
9. What do you think would prompt you to start or increase prescribing a particular drug after a sales visit?
10. And what would make you unlikely/very unlikely to start or increase prescribing?

[Probe: If the group is having difficulty responding, build on earlier comments on graphs 1 and 2]
Concluding questions (10 minutes)

11. If you can remember, think back to when you were participating in our study—filling in the questionnaires following each sales visit. Do you think that participating in the study had an affect on you in any way? If so how?

[Probe: Has anything changed for you in terms of your interactions with sales reps since then. How do you feel about future interactions with sales reps?]

12. Do you discuss these issues with your colleagues?

13. Based on the discussions today and your experiences with the study, do you have any suggestions for changes you would like to see?

[For Toulouse physicians only – ADD HERE]

14. Is there anything you didn’t get a chance to say? Any points you’d like to add?

Thank you all for your participation today. Please see me on your way out, to sign for and receive your honorarium. And if you would like to discuss anything further following this session, please get in touch with me, Ellen or Mary at UBC.
Appendix C – Charts of Key Pharma Rep Study Findings
Charts 1 and 2 include Vancouver data only; Charts 3 and 4 include data from all sites.

Graph 1 shows the percentage of promotions where the sales representative mentioned at least one benefit or at least one harm. In three-quarters of individual drug promotions, the representatives mentioned at least one health benefit, and in one-third they mentioned at least one harmful effect.

Graph 2 shows the specific types of harm that sales representatives mentioned during promotions. Doctors reported that non-serious adverse events were mentioned in 23% of the 418 promotions; drug interactions were mentioned in 2% of the 418 drug promotions.

NOTE: For the data on serious adverse events and contraindications, we included only the promotions of drugs that had at least one serious adverse event or at least one contraindication in product labeling. Contraindications were mentioned in 15% of the 412 promotions; serious adverse events were mentioned in 6% of the 412 promotions.
Graph 3 shows the answers to a specific question in the survey questionnaire: “Generally, how would you rate the quality of scientific information presented by the sales representative?”

Participants felt that information was either “excellent” or “good” in 57% of drug-specific promotions, “poor” or “very poor” in 10% or “fair” in the remaining third.

Graph 4 shows the answers to another question from the questionnaire: “How likely are you to start or to increase your prescribing of this drug compared with before the visit?”

In two-thirds of drug-specific promotions doctors reported that they were “somewhat” or “very” likely to start or increase prescribing of the promoted drug as compared with before the sales visit and that after over one-third said they were “somewhat” or “very” unlikely to start or increase prescribing of the promoted drug.
## Appendix D - Sample Charting - Framework Analysis of Focus Group Data

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<th>SUMMARY</th>
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