Pharmacist Immunizers: An Analysis of their Experiences and Perceptions of Pain

by

Sandra Gerges

A thesis submitted in conformity with the requirements for the degree of Master of Science
Graduate Department of Pharmaceutical Sciences
University of Toronto

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Abstract

OBJECTIVES: In 2012, Ontario pharmacists were granted immunization privileges for administering influenza vaccines to the public. This study explored the experiences and practices of pharmacist immunizers and the impact of immunization pain on their practice.

METHOD: Semi-structured interviews were conducted with 12 pharmacists in the Greater Toronto Area. Transcribed interview data were coded and analyzed via thematic analysis.

RESULTS: Pharmacists felt satisfied in their new role, despite the associated increased workload. Pharmacists felt that immunization pain was not a key consideration when administering vaccines and that pain management was not necessary. Fear was identified as more important than pain and vaccinating children was challenging and time intensive. Pharmacists’ main focus was on injection techniques when asked how they minimize pain.

CONCLUSION: These findings suggest that pharmacists are accepting of their role as immunizers. More research is needed to examine impact on workload and patient satisfaction.
Acknowledgments

First I would like to thank my supervisor, Dr. Anna Taddio for allowing me to volunteer in her lab 4 years ago and for continuing to foster my interest in research. Her support and advice throughout the years has been truly invaluable to me. I would also like to thank my other committee members, Elizabeth Peter, Susan Bowles and Heather Boon for their encouragement, unique perspectives and expertise.

I would like to thank the pharmacists that participated in this research study, without whom this project would not be possible.

I am also grateful for the financial support I received from the Leslie Dan Faculty of Pharmacy and for the Hospital for Sick Children Restracomp Award.

Finally I would like to thank my family and friends (Fadie, Medhat, Amel, Androu and Rose) for supporting me and encouraging me to pursue a Master’s degree.
This thesis is dedicated to my husband Fadie, who is always there for me, and my mother Amel, who is my biggest supporter.
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Chapter 1
Introduction

This chapter will give the reader an explanation of the purpose of the thesis and the statement of the problem, as well as highlight the outline of the thesis.

1.1 Statement of the Problem

During 2012 in Ontario, the scope of pharmacy practice was expanded to include administration of the publicly funded influenza vaccine. In the 2012 to 2013 influenza season pharmacists delivered more than 200,000 flu shots to Ontarians through the Ontario Universal Influenza Immunization Program (UIIP). This number has increased to over 650,000 patients in the 2013 to 2014 influenza season. Pharmacists are well-suited to this role due to their accessibility to the public, their ability to maintain accurate electronic records and their trustworthiness in the eyes of the public. Canadians also rely on pharmacists as an important source of health information, more so than in other countries, such as the US. In order to become certified to offer immunization services, pharmacists must complete a skills and knowledge course approved by the Ontario College of Pharmacists (OCP) and immunization injections are limited to patients 5 years of age and above.

The OCP has approved 6 courses for pharmacist injection training. These courses must include an online learning module and a live training session. Approval of these courses is dependent upon their addressing 14 immunization competencies for immunization by Health Care Professionals as outlined in the Canadian Immunization Competencies and a 15th competency for pharmacist injections outlined by the OCP Council. Of these 15 competencies none focuses on mitigating pain and anxiety during vaccine injections. One of the objectives in competency 8 addresses the ability to use techniques to reduce immunization pain during administration; however this objective is usually covered briefly during the online training module and does not discuss needle fear. Furthermore, there is no practice or evaluation of pharmacists’ competency for reducing pain and fear.

Pain is a primary concern of vaccinations as it affects the quality of care delivered. Approximately 2/3 of children and 1/3 of adults are afraid of needles, and fear of needles can lead to traumatic experiences with immunization and in about 10% of children, non-compliance
with immunizations altogether. Needle fears persist into adulthood and contribute to non-compliant behaviors including refusal of immunization and other health care interventions involving needles (e.g. blood tests, dental appointments), contributing to the risk of resurgence of vaccine-preventable diseases and other poor health outcomes.

1.2 Purpose of the Study

Because immunization is a relatively new role for pharmacists in Ontario, we aimed to understand how they perceive this new role. We conducted a qualitative descriptive study to examine pharmacists’ general perceptions and experiences regarding immunizations and more specifically, their perceptions and experiences regarding pain and pain management. No a priori hypotheses were made. Qualitative research can be used for “initial exploration in an area where there is little known, or to gain subjective views”\(^8\). It is hoped that the findings of this study can be used to understand the experiences of pharmacist immunizers and their perceptions of immunization related pain, and also to determine what needs, if any, are not being met.

1.3 Research Questions

The research questions that the study aimed to answer are:

1) What are the experiences of pharmacists offering immunization services?

2) What is the impact of immunization pain on pharmacists’ practice?

1.4 Outline of the Thesis

This thesis will describe a qualitative study conducted in order to understand the experiences of pharmacist immunizers in the Greater Toronto Area and their perceptions of and attitudes on immunization related pain. First, the literature review will highlight the gaps in the literature and the importance of this study. Secondly the study design and procedures will be discussed. Finally the results will be reviewed and discussed.
2 Literature

The purpose of this chapter is to summarize relevant literature on pharmacists as immunizers. Most of the literature in this area is quantitative survey data, thus a search was also done to highlight pharmacists experiences in another new scope of practice – prescribing. The lack of qualitative literature addressing pharmacist immunizers and their role in pain management will be highlighted. Due to this gap, the experiences of other health care providers with immunization pain and fear will be summarized. The literature on immunization pain differences in children and adults will be described and an overview of the recommended pain management strategies will be provided.

This literature review was conducting using MEDLINE and EMBASE and was restricted to English articles published from the inception of the database through June 2015 (see Appendix F for detailed search strategy). Relevant articles were also identified by reviewing bibliographies of published work and by consulting with content experts.

This chapter will review the relevant areas of literature: 1) pharmacists’ increased scope of practice including their perceptions of their role as immunizers and prescribers, 2) the importance of immunization related pain, 3) a summary of studies that discuss other health care professionals’ experiences with immunization pain and patients’ fears of needles, 4) immunization pain in adults and children, and 5) proper management of immunization pain in adults and children.

2.1 Pharmacists’ Increased Scope of Practice

In October of 2012, Ontario pharmacists’ scope of practice was expanded to include a variety of additional services. Ontario’s Minister of Health and Long-Term Care at the time said, “we are maximizing the services provided by pharmacists so that Ontarians can receive the care they need safely, quickly and closer to home. Pharmacists are highly trained and trusted health providers. It’s time that we benefit fully from all the services they can provide”. These expanded services include the ability to administer publically funded influenza vaccine, renew or adapt
existing prescriptions, prescribe medications to help people quit smoking, demonstrate how to use an asthma inhaler or inject insulin and perform procedures on tissue below the skin to support patient self-care and chronic disease monitoring\(^1\). Some research has been done on pharmacists as prescribers and pharmacists as immunizers.

### 2.1.1 Pharmacists as Immunizers

Although pharmacists are extensively trained in the selection and management of prescription medications, their role in the past has focused mostly on dispensing medications. Within the past few years in Canada legislative authority has allowed expansion of pharmacists’ scope of practice\(^9\). This includes the authority to administer the influenza vaccine. The uptake of this new scope of practice was high among pharmacists\(^1\). Not only did pharmacists vaccinate more than 750,000 patients in the 2013-2014 flu season, studies also suggest that a net gain of almost half a million vaccinations occurred due to pharmacist immunizers\(^10\).

Many studies have examined the experiences of pharmacists as immunizers via quantitative surveys. Although there is a relatively large amount of survey data, there is a lack of in-depth qualitative data describing pharmacists’ perceptions of their new role and the impact of immunization pain on their practice.

The research regarding patients’ and pharmacists’ perspectives on pharmacist immunizers will be presented in this section. The available survey data describing the experiences of pharmacists as immunizers is summarized in Table 2 and explained below. One study addressing patients’ perspective of pharmacist immunizers in Ontario is explained briefly.

#### 2.1.1.1 Pharmacists’ Perspective

Kummer and Foushee surveyed pharmacists in North Carolina to determine their perceptions of possible barriers and challenges to providing pharmacist-based immunization services\(^11\). All survey participants perceived time and area/space as barriers to providing immunization services. Other barriers that were cited by immunizers were availability of vaccine, North Carolina’s rule on pharmacist-administered immunizations (pharmacists are prohibited from administering vaccines to patients under 18 years of age and are required to consult with the patient’s primary care provider before administering pneumococcal vaccines), the inability to obtain
reimbursement from major third-party payers and Medicaid and availability of physician support\textsuperscript{11}.

In 2001 a group of researchers in the United States sent a national survey to a random sample of pharmacists in order to obtain information about pharmacists' current involvement in and willingness to provide immunization services, and to assess perceived barriers to providing immunization services\textsuperscript{12}. The researchers found that only a small percentage of pharmacists were involved in administering vaccinations (2.2% administering adult and 0.9% administering childhood vaccinations). Pharmacists who attended immunization-related educational programs were more likely to provide immunization services and less likely to perceive many barriers to doing so. Men, independent pharmacists and owners/ partners were also more willing to provide immunization services.\textsuperscript{12}

The same survey was repeated in 2003 in order to determine any changes in pharmacists willingness to provide immunization services and any changes to perceived barriers.\textsuperscript{13} The survey results indicated that the willingness to provide adult and childhood immunization services increased. In addition to flu shots and pneumococcal vaccines, pharmacists were now also administering vaccines for hepatitis A and B, Lyme disease, tetanus, and chicken pox, but flu shots accounted for the majority of immunizations being administered.\textsuperscript{13} The results of this survey indicates that over time, pharmacists became more confident in their new role as well as more willing to expand their services beyond administering the flu shot.

Valiquette and Bédard surveyed 115 pharmacists in Quebec, Canada in order to describe their knowledge, beliefs and attitudes towards immunization and determine their perceived barriers to pharmacist-led immunization\textsuperscript{14}. Half of the pharmacists who responded believed that pharmacists should be able to prescribe and administer vaccines. Lack of time and training were the leading barriers to pharmacist-led immunizations, and increased immunization training and adequate remuneration were the more common factors that would help its implementation.\textsuperscript{14}

Community pharmacists in Canada were surveyed in order to determine their attitudes with respect to expanding their scope of practice to include administration of vaccinations\textsuperscript{15}. The majority of pharmacists agreed that pharmacists as immunizers would increase public access, improve rates, and be acceptable to the public. The majority of pharmacists believed that a certification course should be mandated for pharmacists to administer vaccines. Pharmacists
believed that education, reimbursement, and negative interactions with other providers were barriers to pharmacists administering vaccines.\textsuperscript{15}

Pharmacists working in different practice settings in Texas were surveyed regarding their experiences as immunizers and their responses were compared to non-immunizers.\textsuperscript{16} The survey found that pharmacists became certified because of concern for public health and personal satisfaction as opposed to increased revenue or business purposes. The pharmacists also reported that initiation of immunization services required multilevel support including support from staff, management, adequate training and time as well as liability coverage. Interestingly, certified and non-certified pharmacists had a similar job satisfaction scores.\textsuperscript{16}

In Arkansas, community pharmacists immunizers and nonimmunizers were surveyed and it was found that 79\% of them believe that pharmacist immunizers had a positive effect on advancing the profession.\textsuperscript{17} The pharmacists who stated that being able to provide immunizations had increased their desire to implement other patient care services were almost 4 times more likely to be certified to immunize than those who responded that being able to provide immunizations had not increased their desire to implement other patient care services. The pharmacists also stated that time, reimbursement, legal liability and staff and physician support were barriers to them providing immunization services.

In summary, survey data describing pharmacists’ experiences and attitudes towards administering immunizations portray an overall positive attitude and willingness to participate. Common barriers to providing immunization services include lack of time and space, lack of support from other providers, reimbursement issues and lack of education and training. Although survey data is available, there is a lack of in-depth qualitative data examining pharmacists’ perceptions of their role as immunizers to help to understand these issues/barriers.
Table 1: Summary of articles examining experiences of pharmacists as immunizers

<table>
<thead>
<tr>
<th>References</th>
<th>Population &amp; Setting</th>
<th>Study Aim</th>
<th>Methods</th>
<th>Number of Participants</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kummer and Foushee. (2008)¹¹</td>
<td>All pharmacists with an active pharmacist license in North Carolina</td>
<td>To determine types of immunization services offered, level of participation in immunization services, and perceptions of possible barriers and challenges to providing pharmacist-based immunization services.</td>
<td>Electronic survey</td>
<td>1,274 pharmacists</td>
<td>All respondents perceived time and area/ space as barriers to providing immunization services. Other barriers included: availability of vaccine, North Carolina’s rule on pharmacist-administered immunizations (pharmacists are prohibited from administering vaccines to patients under 18 years of age and are required to consult with the patient's primary care provider before administering pneumococcal vaccines), the inability to obtain reimbursement from major third-party payers and Medicaid and availability of physician support.</td>
</tr>
<tr>
<td>Madhavan et al. (2001)¹²</td>
<td>Pharmacists in the United States</td>
<td>To obtain information about pharmacists' current involvement in and willingness to provide immunization services, and to assess perceived barriers to providing immunization services.</td>
<td>Mail survey</td>
<td>1,348 pharmacists</td>
<td>Only 53.1% of respondents knew correctly whether their state allowed pharmacists to administer immunizations. Although a significant number of pharmacists were involved in immunization activities, such as counselling and promotion, only 2.2% and 0.9% of respondents were involved in actual administration of adult and childhood immunizations, respectively. In general, men, independents, owners/partners, and pharmacists who had attended immunization-related educational programs were more willing to provide immunization services than were women, chain and staff pharmacists, and educational program non-attendees. Pharmacists who had attended immunization-related educational programs also perceived pharmacist- and patient-related factors as less problematic for pharmacy-based immunization services than did non-attendees.</td>
</tr>
<tr>
<td>Study</td>
<td>Title</td>
<td>Overview</td>
<td>Methodology</td>
<td>Sample Size</td>
<td>Findings</td>
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<tr>
<td>-------------------------------------------</td>
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<tr>
<td>Kamal et al. (2003)</td>
<td>Random sample of pharmacists in the United States</td>
<td>To collect data about pharmacists' current involvement in adult or childhood immunizations, perceived obstacles to such involvement, and characteristics of pharmacist-administered immunization services.</td>
<td>Mail survey</td>
<td>1,266</td>
<td>Willingness to provide adult and childhood immunization services increased during the 1998-2001 period. In addition to flu shots and pneumococcal vaccines, pharmacists were administering vaccines for hepatitis A and B, Lyme disease, tetanus, and chicken pox, but flu shots accounted for the majority of immunizations being administered.</td>
</tr>
<tr>
<td>Valiquette and Bédard (2015)</td>
<td>Community Pharmacists in Quebec</td>
<td>To describe the knowledge, beliefs and attitudes of pharmacists towards immunization and determine their perceived barriers to pharmacist-led immunization</td>
<td>Online questionnaire</td>
<td>115</td>
<td>Approximately 52% answered that pharmacists should be able to prescribe and administer vaccines, pending a legislative change. These pharmacists were more interested in administering travel (92%), flu (88%) and pandemic (85%) vaccines than regularly scheduled vaccines for adults (65%) or children (18%). Leading barriers to pharmacist-led immunization were lack of time (90%) and training (92%), and the most common factors that would help its implementation were increased immunization training (95%) and adequate remuneration (92%).</td>
</tr>
<tr>
<td>Edwards et al. (2015)</td>
<td>Community Pharmacists in Canada</td>
<td>To determine the attitudes of pharmacists with respect to expanding their scope of practice to include administration of immunizations</td>
<td>Internet based survey</td>
<td>495</td>
<td>The majority (88 %) agreed that pharmacists as immunizers would increase public access, improve rates (84 %), and be acceptable to the public (72 %). However, only 68 % agreed that pharmacists should be permitted to immunize. The majority of respondents (90 %) agreed that certification in vaccine administration should be required for pharmacists to administer vaccines. Pharmacists identified education, reimbursement, and negative interactions with other providers as barriers to pharmacists administering vaccines.</td>
</tr>
<tr>
<td>Nehauser et al. (2004)\textsuperscript{16}</td>
<td>Pharmacists in different practice sites in Texas</td>
<td>To document the demographics, professional activities and job satisfaction of immunization-certified pharmacists compared with pharmacists not certified for immunization.</td>
<td>Mail survey</td>
<td>259 pharmacists</td>
<td>More certified pharmacists were involved in immunization services. Factors that encouraged pharmacists to become certified were: desire to improve health care of the public and personal satisfaction. Pharmacists required adequate training, time, support from management and staff, and liability coverage in order to incorporate immunizations into their practices. No differences in job satisfaction was found between immunization certified and noncertified pharmacists.</td>
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</tr>
<tr>
<td>Pace et al. (2010)\textsuperscript{17}</td>
<td>Community pharmacists in Arkansas</td>
<td>To determine the perceived barriers to providing immunizations, pharmacists’ attitudes regarding immunizations, number of immunization-certified pharmacists, immunization administration rates within the last year and senior student pharmacists utilization.</td>
<td>Mail survey</td>
<td>129 pharmacists</td>
<td>79% of pharmacists believed that administering immunizations has advanced or significantly advanced the profession. Commonly reported barriers included time (76%), reimbursement, legal liability and staff and physician support.</td>
</tr>
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</table>
2.1.1.2 Patients’ Perspective

A few studies have reported patients’ perspective on pharmacist immunizers. Papastergiou et al conducted surveys of patients who were immunized at 4 community pharmacies in Ontario and found that 25% were not regular annual vaccine recipients and 47% were classified as being at high risk for influenza complications. Also, 28% of total patients reported that they would not have immunized this year if pharmacist immunization services were not available. The survey data also indicated that 92% of patients were very satisfied with the pharmacist’s injection technique and 99% of patients would recommend that friends and family be vaccinated by a pharmacist. The average age of patients completing this survey was 49 years old and 96% of patients were above the 18 years old.

2.1.2 Pharmacists as Prescribers

The data on pharmacist immunizers is restricted to quantitative survey data. Qualitative data can better describe the experiences of pharmacists in their new role and give a deeper understanding of their perceptions. Thus the qualitative studies addressing the experiences of pharmacists as prescribers, another increased scope of practice privilege pharmacists were granted, will be summarized in order to draw more information on how pharmacists respond to a new role.

Pharmacists are able to continue, modify and initiate prescriptions in many provinces in Canada. Pharmacist prescribers are thought to have the potential to improve access to medications and improve patient care. Many studies evaluating the experiences of pharmacists as prescribers have taken a qualitative approach because of the shortage of prior research and lack of prior understanding of this topic. Table 2 summarizes 3 qualitative studies investigating this topic.

McCann and colleagues conducted a qualitative study with the aim to provide an in-depth understanding of pharmacist prescribing from the perspective of pharmacists, physicians and other key stakeholders in Northern Ireland. Semi-structured qualitative interviews revealed three major themes: the effect on patient care, challenges facing pharmacist prescribers and the importance of the interprofessional team. Pharmacists believed that their prescribing might have the potential to reduce the medication burden for patients, as they tended to provide a more comprehensive medication review than doctors.
In Alberta, Makowsky and colleagues studied the factors that influenced pharmacists’ adoption of prescribing using the Diffusion of Innovations theory\textsuperscript{20}. In this qualitative study, pharmacists’ adoption of prescribing was dependent on the innovation itself, adopter, system readiness, and communication and influence. Pharmacists viewed prescribing as a legitimization of previous practice and advantageous to instrumental daily tasks. Pharmacists who were in practice settings that were patient focused were more likely to adopt advanced prescribing practices. Physician relationships impacted their prescribing behaviors and individual pharmacists’ decisions to apply for independent prescribing privileges.

Another study set in Alberta asked the question of what “prescribing” means to pharmacists practicing in Alberta\textsuperscript{21}. Like the other two studies, this study used semi-structured interviews to explore the experiences of pharmacist prescribers. This study found that prescribing had a variety of meanings to the pharmacists, which included writing a new prescription, extending an existing prescription as well as advising on over-the-counter medications. Pharmacists’ sense of responsibly was increased due to their prescribing privileges.

All three qualitative studies examining pharmacists’ experiences with the expanded scope of prescribing revealed that pharmacists felt that they were making a positive impact on patient care although they felt an increased sense of risk and responsibility. These pharmacists felt the importance of an interprofessional health care team but also worried about breeching physician territory. The experiences of pharmacist prescribers may be similar to those of pharmacist immunizers in that both have the opportunity to participate in a new scope of practice.
Table 2: Summary of articles examining experiences of pharmacists as prescribers

<table>
<thead>
<tr>
<th>Reference</th>
<th>Population &amp; Setting</th>
<th>Study Aim</th>
<th>Methods</th>
<th>Number of Participants</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>McCann et al. (2012)</td>
<td>Pharmacists in Northern Ireland</td>
<td>To provide an in-depth understanding of pharmacist prescribing from the perspective of pharmacists, physicians and other key stakeholders</td>
<td>Semi-structured interviews</td>
<td>11</td>
<td>Three major themes emerged in relation to pharmacist prescribing: 1) the effect on patient care; 2) challenges facing pharmacist prescribers and 3) the importance of the interprofessional team. Pharmacist prescribing may have the potential to reduce the medication burden for patients (as reported by pharmacists) as pharmacists tend to provide a more comprehensive medication review than doctors. Further research is required on how interprofessional team working can be maximized in the context of pharmacist prescribing, particularly in relation to the management of multi-morbidity.</td>
</tr>
<tr>
<td>Makowsky et al. (2013)</td>
<td>Pharmacists in Alberta</td>
<td>Factors influencing pharmacists’ adoption of prescribing</td>
<td>Semi-structured telephone interviews</td>
<td>38</td>
<td>Pharmacists’ adoption of prescribing was dependent on the innovation itself, adopter, system readiness, and communication and influence. Adopting pharmacists viewed prescribing as a legitimization of previous practice and advantageous to instrumental daily tasks. Individual adopters had higher levels of self-efficacy toward prescribing skills. Pharmacists who were in practice settings that were patient focused were more likely to adopt advanced prescribing practices. Physician relationships impacted their prescribing behaviors and individual pharmacists’ decisions to apply for independent prescribing privileges.</td>
</tr>
<tr>
<td>Hughes et al. (2013)</td>
<td>Pharmacists in Alberta</td>
<td>What does “prescribing” mean to pharmacists practicing in Alberta?</td>
<td>Semi-structured telephone interviews</td>
<td>38</td>
<td>Prescribing had a wide breadth of meaning to the pharmacists, which included writing a new prescription and extending an existing prescription, as well as advising on non-prescription medications. Pharmacists described prescribing in terms of the physical act of writing the prescription and as part of the patient care process as well as the legislated definition of pharmacist prescribing. Many pharmacists noted a sense of increased responsibility associated with prescribing.</td>
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</table>
2.2 Influenza Vaccinations in Ontario

Influenza is a serious illness caused by the influenza virus, types A and B\textsuperscript{22}. Seasonal flu activity begins in October and ends in May and approximately 30% of the Canadian population get the flu each year\textsuperscript{23}. In Ontario, influenza vaccine is publicly funded for the immunization of anyone aged 6 months or older if they live, work or attend school in the province. The Canadian National Advisory Committee on Immunizations recommends that everyone 6 months of age and older should get a flu vaccine every season\textsuperscript{24}. It is particularly important for people who are at high risk of serious complications from influenza to get vaccinated every year. This includes children younger than 5 years of age, adults 65 years and older, pregnant women and residents of nursing homes and other long-term care facilities\textsuperscript{24}.

Currently in Ontario, pharmacists can only immunize patients 5 years of age and above, and can only administer the influenza vaccine\textsuperscript{1}. Children 6 months to 5 years old must get the influenza vaccine from a physician, registered nurse or nurse practitioner, not a pharmacist. The Ministry of Health pays pharmacists $7.50 for the administrative costs associated with delivering the publicly funded influenza vaccine to eligible Ontarians\textsuperscript{1}.

2.3 Immunization Related Pain and Fear

Immunizations, like the influenza vaccine, involve a needle puncture, which can cause pain. The most frequent adverse effects following immunization are injection-induced pain and anxiety\textsuperscript{25}. Untreated needle pain and negative experiences with injections can lead to needle fears\textsuperscript{26}. In addition, unmanaged fear and anxiety can lead to increased stress and pain responses during needle administration\textsuperscript{25}. A cross-sectional survey conducted in Toronto, Canada found that 24% of adults and 63% of children have a fear of needles\textsuperscript{6}. Almost 10% of participants reported that needle fear was the primary reason for immunization non-compliance\textsuperscript{6}.

Negative experiences with injections can lead to the development of health care avoidance behaviors, including refusal of immunization and other health care interventions involving needles (e.g. blood tests and dental appointments)\textsuperscript{26}. Studies have also cited that outbreaks of vaccine-preventable diseases can begin in individuals that refuse immunization\textsuperscript{27}. Thus, it is clear that the success of immunization programs can be compromised by immunization related pain and fear-induced avoidance of immunizations.
Healthcare providers have expressed that they experience stress when immunizing patients who fear and resist needles and that they do not want to inflict pain on their patients\textsuperscript{28}. However, there is no literature examining pharmacists’ attitudes and perceptions of immunization related pain and fear. Thus the nursing and physician literature will be reviewed below.

2.3.1 Nurse Immunizers and Immunization Related Pain and Fear

There is no data available that addresses pharmacist immunizers’ experiences with immunization pain. As such we reviewed qualitative and quantitative data exploring the experiences of nurses and physicians with immunization pain and patients needle fears. Table 3 is a summary of qualitative nursing studies that discuss nurses’ experiences with immunization pain and patients with needle fears.

Kikuta and colleagues conducted a focus group with 10 nurses in order to determine nurses’ attitudes and practices surrounding acute pain during vaccine injections pain in children\textsuperscript{29}. Three main themes emerged from the data: 1) environmental and process factors, 2) perceptions regarding the effectiveness of different analgesic interventions and 3) perceptions regarding pain and fear. Nurses reported a lack of control over their environment, resulting in fear and discomfort for children. They recommended increased support from external partners such as teachers and administrators. Nurses also reported that pharmacological interventions, such as topical local anesthetics, were not used; however, psychological and physical interventions were commonly used. Nurses questioned the effectiveness of topical anesthetics, and indicated that more education was required regarding effective analgesic interventions. Needle pain was reported to be the most prominent concern for children undergoing vaccine injections, and children were described as being fearful\textsuperscript{29}.

Ives and Melrose conducted 3 focus groups with public health nurses in order to examine the experiences of nurses immunizing frightened and needle-resistant children\textsuperscript{28}. Four themes emerged from the data: Four themes: 1) nurses experience stress when immunizing children who fear and resist needle injection, 2) the strength of child resistance and some parent behavior creates an ethical dilemma for nurses, 3) some parent responses make immunizing difficult and unsafe and 4) Resources to help nurses cope with these situations are inconsistent\textsuperscript{28}. 
These studies gave rise to various themes focusing on nurses’ perceptions of pain and fear, the effect of the environment and process factors and lack of resources available to help nurses cope with children with needle fears. This rich qualitative data is unfortunately only available in nursing and physician literature but may prove to have similar themes when investigating pharmacists’ experiences with immunization pain.
Table 3: Summary of articles examining experiences of nurses with immunization related pain and fear

<table>
<thead>
<tr>
<th>Reference</th>
<th>Population &amp; Setting</th>
<th>Study Aim</th>
<th>Design</th>
<th>Number of Participants</th>
<th>Results</th>
</tr>
</thead>
</table>
| Kikuta et al. (2011)²⁹           | 10 nurses who immunize children in Toronto                | What are nurses’ attitudes and practices surrounding acute pain during vaccine injections? | One focus group | 10                     | 3 Themes:  
  1) Environmental and process factors: Nurses reported a lack of control over their environment, resulting in fear and discomfort for children. They recommended increased support from external partners such as teachers and administrators.  
  2) Perceptions regarding the effectiveness of different analgesic interventions: Participants reported that pharmacological interventions, such as topical local anesthetics, were not used; however, psychological and physical interventions were commonly used. Nurses questioned the effectiveness of topical anesthetics, and indicated that more education was required regarding effective analgesic interventions.  
  3) Perceptions regarding pain and fear: Needle pain was reported to be the most prominent concern for children undergoing vaccine injections, and children were described as being fearful. |
| Ives and Melrose (2010)²⁸        | Public health nurses from 5 different health units        | What are the experiences of nurses immunizing frightened and needle-resistant children? | 3 focus groups  | 35 nurses              | Four themes:  
  1) Nurses experience stress when immunizing children who fear and resist needle injection  
  2) The strength of child resistance and some parent behavior creates an ethical dilemma for nurses  
  3) Some parent responses make immunizing difficult and unsafe  
  4) Resources to help nurses cope with these situations are inconsistent. |
2.3.2 Physician Immunizers and Immunization Related Pain and Fear

Physician Immunizers and Immunization Related Pain and Fear

Similar to nurse immunizers, physician immunizers also expressed concerns regarding inflicting pain on their patients. Woodin and colleagues conducted a survey of physicians and parents to determine their opinions regarding the administration of multiple childhood immunizations by injection\textsuperscript{30}. They found that physicians were more concerned than parents about the administration of multiple injections at a single visit and that pain was a major concern\textsuperscript{30}.

In order to determine why physicians in the Paterson and Jersey City area were non-adherent to vaccine schedules, Askew and colleagues conducted telephone surveys in private and public clinics\textsuperscript{31}. They found that private providers were less likely than public clinic providers to vaccinate children and less likely to believed that all recommended vaccine doses should be administered simultaneously. Private providers were also more commonly stated that multiple injections should be avoided because of potential psychological and physical trauma to the child. Physicians cited pain as one reason for their non-adherence\textsuperscript{31}.

Overall, physician immunizers’ decisions and practices regarding vaccinations were impacted by immunization related pain.
Table 4: Summary of articles examining perceptions of physicians regarding immunization related pain and fear

<table>
<thead>
<tr>
<th>Reference</th>
<th>Population &amp; Setting</th>
<th>Study Aim</th>
<th>Design</th>
<th>Number of Participants</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Woodin et al. (1995)</td>
<td>Physicians and parents from Rochester, New York.</td>
<td>To determine parent and physician opinions regarding the administration of multiple childhood immunizations by injection.</td>
<td>Mailed surveys</td>
<td>215 practicing physicians and 74 residents</td>
<td>Physicians have more concerns than parents about the administration of multiple injections at a single visit. Pain for the child was the main concern of all respondents. While most physicians have strong concerns about administering three or more injections at one visit, most parents prefer this practice.</td>
</tr>
<tr>
<td>Askew et al. (1995)</td>
<td>All pediatric providers in both private and public clinics in the Paterson and Jersey City areas.</td>
<td>To determine vaccination beliefs and practices in areas of high noncompliance.</td>
<td>Telephone survey</td>
<td>37 physicians in private clinics and 25 physicians public clinics</td>
<td>Pain was cited as a reason for immunization non-adherence. Private providers were more likely to believe that multiple injections should be avoided because of potential psychological and physical trauma to the child.</td>
</tr>
</tbody>
</table>
2.4 Immunization Related Pain Differences in Adults and Children

Both children and adults experience pain during immunizations. Studies suggest that children feel more pain than adults during immunizations\textsuperscript{32}. The current immunization schedule recommends up to 20 vaccines to be administered to children, and sometimes multiple injections are administered at a single visit. Jacobson and colleagues found that approximately 20% of children aged 15-18 months and 22% of children aged 4-6 years experienced serious distress during immunization appointments\textsuperscript{33}. They also found that approximately 93% of children aged 15-18 months and 44% of children aged 4-6 years experienced serious distress or worse during the actual needle insertion. Thus, immunization can cause significant pain and distress in children and this can vary among different age groups, with the younger children experiencing more pain and distress.

Adults and children also differ in their responses to pain management strategies. A meta-analysis conducted by Hogan and colleagues found that the use of vapocoolants were ineffective in children but effective in adults when compared to no treatment\textsuperscript{34}. This may be due to a difference in response to treatment or due to higher levels of pain experienced by children, indicating that children need additional pain management interventions. Another study investigating the effect of age on the efficacy of topical anesthetics found that younger children are more likely to benefit from the use of prilocaine-lidocaine\textsuperscript{35}.

Overall, adults and children of different ages experience pain differently and respond different to pain management strategies.

2.5 Immunization Related Pain Management Strategies

2.5.1 Recommended Strategies for Children

Taddio and colleagues published evidence based clinical practice guidelines highlighting the recommended immunization pain management strategies for children\textsuperscript{36}. This section will briefly highlight the recommended strategies published at the time this study was conducted. Since then, newer guidelines have been published\textsuperscript{37}.
2.5.1.1 Physical Strategies

It is recommended that at the time of injection, children are not placed in a supine position. Children should be held by a parent in a position that is most comfortable for them, such as on the parent’s lap. It is also recommended to support children without using excessive force, as studies have suggested that restraining a child may increase their distress.

Another physical strategy that can reduce pain is the use of tactile stimulation. It is recommended for children four years of age and older to offer to rub or stroke the skin near the injection site with moderate intensity before and during vaccination.

2.5.1.2 Psychological Strategies

Distraction and coaching are two psychological strategies that are recommended for use in children undergoing immunization. Chambers and colleagues conducted a systematic review to determine the efficacy of various psychological strategies for reducing pain and distress in children during routine immunizations. It was found that breathing exercises, child-directed distraction, nurse-led distraction, and combined cognitive-behavioural interventions are effective in reducing the pain and distress associated with routine childhood immunizations.

2.5.1.3 Pharmacological Strategies

To reduce pain at the time of injection the use of topical anesthetics during vaccination of children is recommended. A systematic review and meta-analysis conducted by Shah and colleagues examined 32 studies found that topical anesthetics significantly reduced children’s pain scores during immunization. They found that the number needed to treat to prevent 1 child from having clinically significant pain using a pain scale was 3.7. Topical anesthetics are available without a prescription in Canada. The three main available products in Canada are lidocaine-prilocaine 5% cream or patch, amethocaine 4% gel and liposomal lidocaine 4% cream.

2.5.2 Recommended Strategies for Adults

Hogan and colleagues conducted a systematic review of measures for reducing injection pain during adult immunizations. The results are summarized below.
2.5.2.1 Pharmacological Strategies

The systematic review found one trial comparing lidocaine-prilocaine with a placebo cream\textsuperscript{43}. This study found that the topical anesthetic group experienced significantly less pain from the injection. Thus, topical anesthetics are recommended for use in adults to reduce the pain from immunizations. This is considered the gold standard in reducing pain from adult immunizations\textsuperscript{44}.

2.5.2.2 Physical Strategies

Physical strategies such as rubbing the area before and during the injection and sitting in a comfortable and relaxed position have been shown to be effective at reducing pain\textsuperscript{43}. In one randomized controlled trial, tactile stimulation was shown to be just as effective as using topical anesthetics\textsuperscript{44}.

2.5.2.3 Psychological Strategies

Distraction techniques was also shown to work in decreasing adult immunization related pain\textsuperscript{43}. However, in one randomized controlled trial, it was found that distraction did not work as well as topical anesthetics in reducing immunization related pain in adults\textsuperscript{44}.

Overall, the use of topical anesthetics, distractions, sitting in an upright and comfortable position and tactile stimulation have been found to be effective in decreasing immunization related pain in both adults and children, and are recommended for routine use during vaccinations.

2.6 Summary

In summary, the data on pharmacist immunizers are lacking an in-depth understanding of their experiences and perceptions of their new role. Although there are data indicating that pain and fear negatively impact nurse and physician immunizers, there is no data investigating pharmacists’ attitudes of immunization pain and fear. Therefore, a study is needed to investigate pharmacists’ experiences with immunizations and immunization pain and fear.
Chapter 3
Objectives and Methods

3 Objectives and Methods

This chapter will highlight the objectives and methods of the study. The researcher positionality, study design, sampling strategies, and study procedures will also be elaborated on in this chapter.

3.1 Objective

The objective of this study was to gather an in-depth understanding of pharmacists’ perceptions of their role as immunizers and the impact of pain on their practice.

3.2 Researcher Positionality

In qualitative research, the researcher is the instrument and “researcher reflexivity is now considered central to the process of qualitative research”\(^{45}\). Reflexivity is the process by which the researcher engages in critical self reflection regarding their personal biases, assumptions and relationship to their research in order to understand how it may affect the research\(^{45,46}\).

In order to reflect on my own personal encounter with this research project, I must first mention my identity and positionality. I am a licensed pharmacist in Ontario, graduating from the Doctor of Pharmacy program at the University of Toronto in May 2013. I occasionally work in a community pharmacy where I sometimes administer the influenza vaccine to patients, and part time at Sunnybrook Health Sciences Centre as a hospital pharmacist in the Neonatal Intensive Care Unit. I am also a pharmaceutical sciences Master’s student studying under the guidance of a world-renowned pain researcher.

My background in the pharmacy program was heavily focused on evidence-based medicine and critically appraising randomized controlled trials before applying their results to patient care. Thus I have a strong positivistic ideology and believe that there is one objective truth that can be found. Qualitative research is not something that was focused on in pharmacy school, so I took a graduate level course in order to familiarize my self with it. I found qualitative research very interesting because it allows for the voice of its participants to be heard but found it difficult to completely remove myself from my positivistic beliefs.
As a pharmacist that administers the influenza vaccine I could identify with the experiences of other pharmacists who have to do this for the first time. I also have an understanding for how the immunization certification courses work, since I had to take one, and how the pharmacy undergraduate curriculum works.

Finally, as a master’s student conducting research under the guidance of a pain researcher I had the unique opportunity to look at this research through the perspective of immunization related pain. I have participated in studies that have shown that a large percentage of children, and even some adults, are afraid of needles and that needles cause them pain and distress and have wondered if pharmacists in Ontario have experienced this while immunizing their patients.

3.3 Study Design

Coming from a positivistic perspective, this study used a qualitative descriptive design following the guidelines presented by Sandelowski\(^{47}\) and Neergaard et al\(^{48}\). Qualitative description is preferred when a description of a phenomenon is required and does not rely on a theoretical framework. Qualitative description is relevant in research projects where the aim is to gain firsthand knowledge of patients’ or professionals’ experiences with a particular phenomenon\(^{48}\). Qualitative description is founded in existing knowledge, thoughtful linkages to the work of others in the field and clinical experiences of the research-group\(^{48}\). Qualitative interviews are used in order to get insight into a subject.

Semi-structured interviews with pharmacists were conducted in a private area at the pharmacists’ work place. A semi-structured interview guide (Appendix A) was used to guide the interview process. This interview guide included a series of open-ended questions in order to allow participants to speak openly about their experiences. It also contained a few specific questions to aid the interviewer with further probing.

3.4 Population and Sampling Strategies

The inclusion criteria of this study were pharmacists practicing in a community pharmacy in the Greater Toronto Area (GTA) who were certified to administer influenza vaccinations and who were administering vaccinations for a minimum of one month in the current immunization season. This was done in order to capture pharmacists who had recent experience immunizing patients. There were no exclusion criteria.
This study used purposive sampling strategies. Convenience sampling was first used in order to contact pharmacists who met the eligibility criteria. Snowball sampling strategies were then used whereby recommendations made by early study participants for additional participants were pursued. Participants were sought with varied number of years in practice, gender, number of hours working per week, number of influenza vaccines administered, location of training and geographical location of work. Qualitative studies use purposive, non-random sampling strategies in order to select participants that would serve to answer the research question best and give the richest, most in depth data. In this study, purposefully selecting pharmacists with recent and relevant experience immunizing patients was thought to aid in answering the research questions.

### 3.5 Sample Size

Data saturation was used to guide the required sample size. Saturation is the point in the interviews in which no new data is being collected. It has been suggested that after 12 interviews, no new data is generated, although this depends on the type of study. We obtained ethics approval in order to interview a maximum of 30 pharmacists but planned to stop once saturation was reached.

The principles of sampling in qualitative research differ than those in quantitative research in that “the methods of drawing samples is not based on theories of the statistical probability of selection, but on other, purposive or theoretical sampling criteria” That means that qualitative researchers do not worry about collecting a large random sample, but focus on a small sample size that they believe is rich in information.

### 3.6 REB approval and Consent Process

This study was approved by the University of Toronto Health Sciences Research Ethics Board (Appendix G).

Pharmacists recommended by the research team were initially asked to participate via a phone call or email invitation. After they expressed interest in the study, they agreed on a time and place that would be most convenient for them to complete the interview. Pharmacists were given 10 – 20 minutes to review the consent form and ask any questions. Pharmacists then signed the consent form and agreed to be interviewed and audio-recorded. One copy of the signed consent form was given to the pharmacist and another was retained by researchers.
3.7 Study Procedures

Twelve interviews were conducted at various pharmacies in the Greater Toronto Area (GTA) from May 20, 2014 to January 22, 2015. All interviews were conducted at the pharmacists’ place of work and lasted approximately 15 – 25 minutes. Prior to starting the interview, pharmacists filled out a demographics questionnaire. After the interview, participants were asked to help identify other pharmacist immunizers that may be interested in participating with varied immunization experiences, years in practice, work environments and training.

A semi-structured interview guide (Appendix A) containing both semi-structured and structured questions was used to guide the interview process. Experts in immunizations and pain reviewed the interview guide. The interview guide was also reviewed during the data collection period and was slightly modified to focus on key themes emerging from the interviews. All interviews were conducted by a single interviewer (SG). The interviews were audio-recorded and transcribed verbatim.

The interview guide consisted of a series of questions and a subset of probes for each question. It focused on 2 areas of inquiry in order to match the research questions. The first area focused on overall experiences of pharmacists’ immunizers such as reasons to be certified to administer immunizations, the immunization process, immunizing children, and the effect on the relationships of pharmacists with patients and physicians. The second area of focus was on the impact of pain on the practice of pharmacist immunizers which included the perceptions of immunization pain in adults and children, pain management strategies used, practice changes as a result of new role, and pain management information sources used to inform practices.

The interviews were audio-recorded, transcribed verbatim and kept anonymous. After the first interview was done the research team met to assess the quality and clarity of the research questions. This interview was repeated two more times in order to gain more insight into the participants’ perspective and to practice interviewing techniques. The transcripts were reviewed with the study team and feedback regarding this interview transcript was used to guide wording of the interview questions as well as interviewing techniques used by the interviewer (SG).
3.8 Qualitative Content Analysis

The aim of Qualitative Description differs from that of other qualitative methods. It aims to produce a rich, straight description of an experience or an event. Thus during analysis process and presentation of data, researchers stay closer to the data, whereas other qualitative approaches often aim to develop concepts or analyze data in a reflective or interpretive way using existing theories. The final product of Qualitative Description is a description of informants' experiences in a language similar to the informants' own language.48

In this study, interview transcripts were used to generate codes using qualitative content analysis as per the approach described by Sandelowski. Qualitative content analysis has been described as “a systematic, replicable technique for compressing many words of text into fewer content categories based on explicit rules of coding”.52 This is done in order to produce themes and to attain meaning from a textual data such as that attained through interviews.

Data collection and analysis occurred simultaneously in order to be able to modify the interview guide as needed and to modify emerging themes as necessary. After the first interview, the research team met to discuss the interview process and preliminary themes that emerged. The interviewer then went back and interviewed the pharmacist a second time to clarify responses to certain questions. After this, the team met again and discussed changes to the interview guide. The interview was then conducted a third time. Regular meetings were held throughout the process to discuss themes and to assist with coding. Line by line coding was done using the software package QSR NVivo version 10. Emerging themes were modified based on the data from the interviews. When no more new themes relevant to the research question emerged from the interview data and when all existing themes were saturated, saturation was felt to have been achieved. This occurred after 10 interviews. Two more interviews were conducted in order to ensure that saturation was met and that no new themes emerged. Coding and thematic analysis were discussed and verified with the research team in order to ensure the validity of the interpretation of the data.

Braun and Clarke state that qualitative analysis can be applied across a range of theoretical and epistemological approaches, including realist or constructivist paradigms. This study used a realist thematic analysis and identified themes at a semantic/explicit level. This means that the analytic process started by describing the data, organizing it to show patterns in content and then
summarized and interpreted in order to find significance in the patterns and broader meanings and implications and finally it was compared to previous literature.
Chapter 4

Results

4 Results

This chapter will review the characteristics of participants and the results; specifically, the perceptions and experiences of pharmacists as immunizers and the impact of pain on their practice.

4.1 Participant Characteristics

Twelve pharmacists were approached for consent to participate in semi-structured qualitative interviews. All 12 pharmacists agreed to participate. The lack of study refusals may be due to the fact that most pharmacists were referred by study staff or by other participants. Demographic characteristics of participants are listed in Table 5 below.

A diverse group of pharmacists were included in the sample. Pharmacist ages ranged from 26 to 66 years old. Half the pharmacists interviewed were males. Half were owners or managers of their store and the other half were employees. However, only 2 out of the 12 pharmacists worked for independent pharmacies. Although this is a small number, this is representative of the number of independent pharmacies compared to chain pharmacies currently in the Greater Toronto Area (GTA). Pharmacists also worked in a variety of locations in the GTA, which are listed in Table 6 below.
Table 5: Pharmacist Demographics

<table>
<thead>
<tr>
<th>N=12 Pharmacists</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean(range)</td>
<td>39 (26-66)</td>
</tr>
<tr>
<td>Sex, Male (%)</td>
<td>6 (50)</td>
</tr>
<tr>
<td>Ethnicity, Caucasian (%)</td>
<td>8 (67)</td>
</tr>
<tr>
<td>Asian (%)</td>
<td>3 (25)</td>
</tr>
<tr>
<td>Carribean (%)</td>
<td>1 (8)</td>
</tr>
<tr>
<td>Position, Manager/Owner (%)</td>
<td>6 (50)</td>
</tr>
<tr>
<td>Pharmacy Type, Chain (%)</td>
<td>10 (83)</td>
</tr>
<tr>
<td>Country of Training, Canada (%)</td>
<td>8 (67)</td>
</tr>
<tr>
<td>Hours of Work per Week, mean (range)</td>
<td>32.5 (4-47)</td>
</tr>
<tr>
<td>Years of Practice in Ontario, 1-10 years (%)</td>
<td>8 (67)</td>
</tr>
<tr>
<td>Estimated Total Immunizations Since Certification, mean (range)</td>
<td>287 (20-1400)</td>
</tr>
<tr>
<td>Received the flu shot this year? Yes (%)</td>
<td>9 (75)</td>
</tr>
</tbody>
</table>

Table 6: Pharmacy Location

<table>
<thead>
<tr>
<th>Pharmacy Location</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>City of Toronto = 7 (58%)</td>
<td></td>
</tr>
<tr>
<td>York = 3 (25%)</td>
<td></td>
</tr>
<tr>
<td>Durham= 1 (8%)</td>
<td></td>
</tr>
<tr>
<td>Peel= 1 (8%)</td>
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</tbody>
</table>
4.2 Four Main Themes

The four themes that emerged from the data will be discussed below.

Theme 1: Expanded Scope of Practice as an Enhancement and Challenge to Relationships.

This theme represents how pharmacists believed their new role has affected their relationships with patients and physicians.

Theme 2: Professional Satisfaction and Workload Demands.

This theme focuses on the professional gains and the increased demands that pharmacists have achieved via their new role.

Theme 3: Knowledge and Attitudes about Pain Versus Fear.

Pharmacists’ perception of pain and fear is the focus of this theme, including their belief that pain is not an important factor to consider when immunizing patients.

Theme 4: Practices Regarding Pain and Fear Management.

The different pain and fear management strategies used are represented by this theme. The way that pharmacists managed children’s pain and fear will also be highlighted.

4.2.1 Expanded Scope of Practice as an Enhancement and Challenge to Relationships

The first theme that emerged from the data referred to pharmacist immunizers’ relationships with patients and physicians. Participants found that overall this new role helped to strengthen their relationship with patients as well as increased patient satisfaction. Many pharmacists noted the increased convenience that this service provided for their patients as portrayed by Participant 8: “A lot of folks were, uh, happy that we were doing it and they were impressed, I guess, by us. And, just pleased at the accessibility and convenience of it.” In addition to this, pharmacists felt that immunizing patients helped to increase their patients’ trust in them as well as allow for more time for clinical interactions.

P2: It gives me a good opportunity to chat with them sometimes and talk to…talk about different things, about - sometimes about their medicine. They have a question and uh
they don’t come and approach the pharmacist and they think it’s a good opportunity to do that while we’re in the consultation room. So it’s um it improves the relationship and we get to know each other. Like where I start to do the immunization I was a new pharmacy manager at that location and I- it was a good opportunity for me to introduce myself as well and get to know the people more.

Pharmacists also noted that administering the influenza vaccine allowed them to serve patients they may not have had the opportunity to otherwise.

P12: I think you’re probably getting access to a pocket of the population that you may not have access to otherwise because a lot of these patients are maybe seeing a pharmacist for the first time or a lot of them weren’t even clients of our pharmacy.

However, when it came to immunizing children pharmacists felt that this was a challenge. Almost all pharmacists when asked to state the negative experiences they had with administering immunizations stated that immunizing children was the most difficult.

P9: Um, I mean when you're immunizing kids, that's probably one of the biggest challenges.

A few pharmacists even reported having the parents hold down the child in order to be able to give the immunization.

P1: Um so for the squirmy children you usually need an adult um to hold the child in the lap and kind of calm them down.

P5: It was that one time with the child where the father basically had to end up holding the- the- the daughter pretty tight so that I could actually give the injection.

When it came to relationships with physicians, pharmacists either noticed no change or expressed concerns about breeching physician territory. Some pharmacists expressed that their relationship with physicians was not affected at all by the increased scope and that they did not have to increase their collaboration with physicians due to this new role. A few pharmacists worried that physicians would be unhappy with their expanded scope because it would take patients away from them.

P2: See the physician colleagues sometimes like uh if they’re very busy they like to see that but if they’re seeking more business they hate to see that. So it depends… who you are dealing with and what kind of relationship you have with them. Like before I had this position I used to work somewhere else that I was worried that the doctors would know that I am doing that they will get so mad if they know that I’m doing that as if I’m competing with them.

P11: I know that some people have negative impact uh especially if they have like a walk-in clinic inside the pharmacy or if they have a family physician that needs to get all the patient immunized inside the clinic.
In summary, pharmacists’ relationships with others were affected by their new role. Pharmacists perceived that it strengthened their relationships with patients due to increased convenience, trust and time for clinical interactions. Pharmacist felt that immunizing children was the most challenging experience. In addition, pharmacists expressed either no change in their relationship with physicians or perceived that immunizing patients would be a breech in physician territory.

Figure 1: Theme 1- Expanded Scope of Practice as an Enhancement and Challenge to Relationships

4.2.2 Professional Satisfaction and Workload Demands

The second theme focuses on the balance between professional satisfaction and additional workload demands caused by the new scope of practice. Pharmacists felt satisfied with their new scope of practice because it allowed them to offer an additional service to patients and provided them with increased knowledge and skills. Participant 8 stated, “I like it. Wish they would expand it to all the other vaccines.” Participant 4 said, “Umm I could say that I’m happy and proud that I know how to do it.” Participant 3 explained, “It’s a very… good experience, very fulfilling.”
Some pharmacists also saw it as a way to expand their pharmacy business and attract new patients.

P7: Well, the opportunity to serve, to supply, to, you know, it's a public service thing. It's it's also a method of, um, generating some income, as little as it is, it generates. But it gives you an opportunity to interact with people that perhaps you haven't interacted with before, which is also an opportunity to solicit their patronage in the future; get their prescriptions transferred here.

However, all pharmacists expressed concern regarding the additional workload that this service added.

P3: It makes it very hectic. Very tiring. Because we’re already busy a hundred percent of the time when the pharmacy is open so to add one more thing that takes a long time to do it’s been very very tiring and hectic and really like companies or pharmacies should keep that in consideration that this is another job and it needs time. There should be more help or overlapping pharmacists or something like that.

P9: It is more labour intensive, and I mean, it's an added job... added responsibility to the the pharmacists job, so... you're gonna have to manage that extra duty with respect to just, uh, all the other things you usually do: med checks, signing scripts, things like that, uh... So, I have that, just, um, added workload with respect to the same amount of labour.

Furthermore, some pharmacists stated that they were pressured to reach certain daily quotas by their employers in terms of the number of flu shots they should administer per day. Pharmacists felt that this was an infringement on their professional autonomy and was unfair and unprofessional.

P5: Putting quotas on things, it’s like asking a doctor to also give a number of you know… vaccines in-in their you know everyday, or asking a dentist to- to do this many number of root canals per week, it’s the same thing. Um and I’m pretty sure no dentist and no family doctor is going to accept those terms, but somehow pharmacists are just saying okay and we’re just doing it.

In addition, some pharmacists expressed concerns about keeping their jobs if they had not attained certification to administer the flu shot. When asked why they became certified, one pharmacist answered:

PH9: I guess, um, pharmacy, the pharmacy field is changing. And, uh, with the surplus of grads, there is, uh, there is no, no longer a shortage of pharmacists, there is a surplus. So, you need to improve and enhance your skills, um, so that you're still in demand. So, that's probably the main reason, is to get trained so I'm more valuable to a corporation. So, more for job security, I would say.

In summary, pharmacists felt a struggle between their professional satisfaction and increased workload. They valued the ability to learn and provide a new skill to patients but had an increase
in their workload with no additional support provided. Pharmacists disliked having quotas and felt that is was unprofessional.

**Figure 2: Theme 2- Professional Satisfaction and Workload Demands**

![Diagram of Professional Satisfaction and Workload Demands]

### 4.2.3 Knowledge and Attitudes about Pain Versus Fear

The third major theme focused on knowledge and attitudes about pain and fear. Pharmacists felt that immunization related pain was not a factor they needed to consider when immunizing patients and that pain management was not necessary. P6: “Actually, flu shots, it's not really painful.”

PH1: Considering that it’s a very small amount of pain ummm it’s a non-issue for me. I think the cost-benefit is…a no brainer and… the pain is really non-existent after the actual injection.

P5: Um…with the Agriflu, which is the only one I’ve had the experience of uh um using, it actually does not cause pain.

One pharmacist also felt that patients who experienced pain were exaggerating. P1: “I’ve had one elderly patient um exaggerate the pain. I mean it might have been real to her.” Pharmacists
felt that the minimal amount of pain associated with the flu shot comes with the territory of getting immunized and thus doesn’t need to be treated.

P1: Um it kinda comes with the territory. I mean you wanna get immunized you’re gonna have to withstand a needle prick and typically from my experience and other patients’ experience um its not a painful procedure ummm so…it hasn’t really impacted the way I immunize.

Pharmacists also felt that the pain associated with the flu shot is the same in both adults and children.

Interviewer: Can you tell me about the needle pain you think adult patients experience during immunizations?
P1: I would describe it as a pinch.
Interviewer: And how about children?
P1: I would describe it as a pinch.
Interviewer: Okay so what are the differences between them?
P1: I just described them both as a pinch.
Interviewer: So no differences at all?
P1: No.

When asked about the pain they thought their patients experienced, many of them referred to fear instead of pain, stating that they felt that pain was not a huge concern for their patients.

P9: I mean it's not so much needle pain. I see a lot of patients probably have, uh... it's the anticipation, or, or the fear of a needle.

P7: Needle pain is really minimal and it's a mindset, it's not, uh, uh, a true pain, of sorts. So, if you can alleviate the fears – or not instill the fears – then you, you basically won't have the pain.

Also, pharmacists felt that children and adults differ in the amount of fear that they experienced.

P8: (Children) seem to be much more, uh, worried about it. And they probably react more.

When asked what they thought patients were afraid of, pharmacists said it was an irrational fear and were unable to identify with it.

P2: No it’s – it’s mainly again the fear before. Even there are adults are more scared than kids but I don’t think it causes pain…that much pain for them to think about it this way after.

P1: So I think it’s a fear of the unknown

In conclusion, pharmacists reported pain was minor and not important to them as immunizers. Fear, however, is an important aspect of immunizing patients, particularly children, but pharmacist did not link patients’ fear to pain.
4.2.4 Practices Regarding Pain and Fear Management

Pharmacists had a variety of techniques to manage pain and fear in their patients during immunizations. The most common way of managing pain was by focusing on the injection technique as portrayed by Participant 7: “If you know how to give a needle, you don't have any pain” and Participant 9: “You have to be...You just do it quickly, and uh, that minimizes that.”

Sometimes pharmacists managed fearful patients by telling them to come back later. Fear sometimes interfered with their practice. There is no indication of whether or not these patients came back.

P5: Um if they’re very fearful to the point where they don’t want it, I would just say come back later. You know? I don’t think I would be too comfortable with having to hold on to them to give the injection and I don’t think that would be a good experience for the patient either.

When it came to dealing with children, pharmacists relied heavily on their parents to assist in managing pain and fear.

P9: The young boy, and he had a fear for needles, so we were in the counseling room for a few minutes before his parents calmed them down, calmed them down enough to actually allow me to immunize him.
Pharmacists often referred to offering bribes to children as a way to convince them to get immunized.

P4: I would tell them don’t look you know just look away. Look away, it’ll just be one second. Choose your Band-Aid. We have like fun Band-Aid for the kids.

Another pain and fear management strategies employed by pharmacists was to talk the patient through the needle. P9: “And you reassure them, so, it is a factor, but it's just how you approach it and how you relax a patient and calm them.”

Some pharmacists stated that they did not manage needle pain at all in their practice, but when subsequently probed about specific techniques, did report using distraction techniques.

P1: So distractions for adults I typically say if um you’re not comfortable with injections um I would say look away, umm I would count down um things like that. Umm for children, um we would have the… parents distract them.

P5: Well…in that case, the parent was with the child and asking the parent to somehow distract the child, have the child not look at it, talk to him about maybe a toy, or something to to take their mind off what I’m going to do.

When asked about pharmacological strategies, pharmacists did not use topical anesthetics and believed that they are not worth using due to the minimal pain caused by the flu shot.

P10: Like, um, you gonna wait like almost an hour to get it now, while the needle is only – what – three seconds pain? And that's it? And... why do you need that? And then you spend money, you know. So, I don't think so. It's not needed, but I can see that... it's more, it's just a matter of explaining.

However, pharmacists did say that they offered patients pain medications such as acetaminophen and ibuprofen for soreness after the injection.

P4: There’s like a few pieces of advice that you’d give them afterwards, you know ice, and Advil or Tylenol if they need.

All pharmacists stated that there are no resources they consulted to assist them in managing pain and fear. Pharmacists learned their pain management techniques from work experience.

P9: ... life and interacting with people, um... And seeing the response to, when you inject, um, and people have anxiety and fear, like... You learn, and uh you learn to be more empathetic, and other strategies to help deal with pain, like distracting the patient, uh... And you, you become more comfortable as you inject them, and then being more quicker, um, certainly helps too, so... From experience.

Overall, pharmacists employed a variety of pain and fear management strategies. They felt satisfied in their ability to manage pain, since they felt that pain from flu shot was very minimal.
and did not need to be heavily managed. Some pharmacists felt that they could improve their knowledge of fear management strategies.

Interviewer: Are you satisfied with your overall ability to manage pain in your patients?
P5: I think I can. If it happens, I can take care of it.
Interviewer: Sure. And how about fear?
P5: Umm I have to work on that (laughs).

Interviewer: Do you think you need more or less education about how to handle needle pain?
P6: I think we need more education.

Figure 4: Theme 4- Practices Regarding Pain and Fear Management
4.3 Summary

Although pharmacists felt an improvement in their relationship with patients, they experienced no change in their relationship with physicians, yet sometimes worried about breeching physician territory. Pharmacists felt satisfied in their new role, despite the associated increased workload. Fear was identified as more important than pain because it impeded their efficiency and vaccinating children was challenging and time intensive. Pharmacists employed a variety of pain and fear management techniques, but often believed that pain management was not necessary. They felt less confident in their ability to manage fear in their patients.
Chapter 5
Discussion and Conclusions

5 Discussion and Conclusions

This chapter will summarize the findings of the study and explain how they relate to previously published work, explain the strengths and limitations of the study and give recommendations for future studies.

5.1 Discussion

Some findings of this study warrant discussion including pharmacists’ overall satisfaction, increased workload demand, fear of breaching physician territory, attitudes regarding pain and fear, the pain management strategies they used and the challenges of dealing with children.

5.1.1 Pharmacists’ Overall Satisfaction

Pharmacists felt that their ability to provide immunization services was appreciated and valued by the public. They also felt an increased sense of professional satisfaction because they were able to add an increased convenience for their patients. This is similar to the research surrounding pharmacist prescribers that believed they were improving patient care by providing an expanded scope. However, it differs from previous survey data investigating pharmacist immunizers. After surveying both immunization certified and noncertified pharmacists in Texas, it was found that there was no significant difference between the two groups in terms of job satisfaction. This may be due to the significant barriers that pharmacist immunizers faced such as training, time, and gaining staff and management support. Since this was a survey, no in-depth information was gathered regarding why pharmacists’ satisfaction was not increased as it has been previously shown in other surveys and in this study.

Pharmacists felt that they were increasing patient convenience by providing influenza vaccination services and that patients were satisfied with this service. The impact of pharmacists participating in immunization services has already been documented by a group of researchers in Toronto that found an increase of almost 30% in the number of patients receiving the influenza vaccine. The survey data also indicated that almost all patients would recommend that friends and family be vaccinated by a pharmacist.
5.1.2 Increased Workload Demand

Pharmacists perceived that the new scope of practice and employer quota demands increased their workload. Pharmacists felt that their increased workload was not met with increased resources. This increased demand has not been previously documented, although in survey data pharmacists noted that common barriers to providing immunization services included lack of time and space, with lack of time being cited by up to 90% of participants\textsuperscript{11,14,15}. Pharmacists’ perception of employer-enforced quotas is a new finding and there has been no documentation to date on pharmacies setting quotas. Pharmacists felt that these quotas are unreasonable and that additional resources are needed to assist them in their new role. The implications of enforced quotas and increased workload demands have not been investigated and may impact patient safety by increasing error rates\textsuperscript{54}.

5.1.3 Fear of Breeching Physician Territory

Participants’ fear of breeching physician territory is very similar to that of pharmacist prescribers in multiple studies\textsuperscript{19-21} and other pharmacist immunizers in survey studies\textsuperscript{15,17}. This fear of over stepping their boundaries is typical of a health profession gaining an expanded scope of practice and other health care professionals are often resistant to an expanded scope of practice. The Ontario Medical Association best portrays this conflict when a representative publically announced that “letting pharmacists prescribe is like letting a flight attendant fly a plane”\textsuperscript{55}, when referring to the expanded scope of prescribing. However, in this study, when asked whether they have been met with real resistance from physicians they often said they have not. This may indicate that pharmacists perceived resistance from physician is not actually real. Currently Nurses in Ontario have the ability to administer vaccinations to patients and are responsible for the majority of vaccine administration in Ontario\textsuperscript{1}. However, pharmacists did not express any concern in breeching nursing territory, but only discussed their fears of upsetting physicians by administering the influenza vaccine. This may be due to the fact that community pharmacists interact with physicians on a daily basis and their interaction with nurses is not as frequent so they may not feel concerned with breeching nursing territory. However, this question was not asked specifically and thus may still be an issue. It is important to understand and address the relationship between physicians and pharmacists in light of the new scope of practice in order to ensure that each profession maintains its’ unique identity. The perceived tension between
pharmacists and physicians has the potential to threaten the teamwork between physicians and pharmacists and thus affect patient care.

5.1.4 Attitudes Regarding Pain and Fear

Pharmacists felt that their relationship with patients was improved and that they were improving patient care but they felt that immunization related pain was not an important factor and that for the most part, it did not impact the way they immunized. These attitudes towards pain are similar to previously documented research. For example, one survey found that the public felt that pain from vaccination is not worth treating because vaccines do less harm than good and that medications, even over the counter, should not be used. Pharmacists also felt that pain in this context does not warrant treatment. However, exposure to untreated procedural pain has been linked to many unwanted outcomes such as hyperalgesia, needle phobia, healthcare avoidance behaviors and poor health outcomes. Pharmacists in this study believed that adults and children feel the same amount of pain with respect to the flu shot, showing a lack of understanding of the subjective and individual nature of pain. This may be due to the lack of focus on immunization related pain and fear in the mandated immunization training courses.

Pharmacists often described fear of needles as more distressing to their patients than the pain of needles. Pharmacists’ focus on fear rather than pain may be due to the fact that fear and anxiety often hindered pharmacists’ ability to administer the vaccine and thus interfered with their workflow and efficiency, while patients’ pain was not as evident and did not affect their workflow. Although this issue was not explored specifically in this study, it is supported by the fact that time management was more of an issue for pharmacists than pain and fear management.

It is important to note that the themes involving pain and fear were derived from the questions that asked specifically about them. However, most participants discussed pain and fear when asked about what general negative experiences they have had while immunizing patients.

5.1.5 Pain Management Strategies Used by Pharmacists

Pharmacists’ main focus was on non-pharmacologic measures such as injection technique when trying to minimize pain. This may be because pharmacists felt that additional pain management strategies were not needed and that it would increase their workload. Over time as pharmacists develop more confidence in their skills as immunizers, pain management strategies may become
more important to them as it is for other experienced immunizers such as nurses\textsuperscript{38}. More time to develop their injection technique in a real practice setting under the guidance of a more experienced immunizer may assist pharmacists in perfecting their technique and understanding other ways to mitigate pain.

The pain and fear management strategies that were employed by pharmacists may have been used in order to successfully inject their patients rather than to reduce patients’ pain and fear. Thus pharmacists did not always attribute the strategies they used to pain management strategies. An example of this is distraction; when asked if they used any pain management strategies most pharmacists said no, but upon further probing they stated that they used distraction methods in order to calm patients down in order to be able to inject them.

Although pharmacists used distraction techniques frequently they did not use or advocate for use of topical anesthetics (e.g., EMLA). When asked why this was, participants stated that the pain did not warrant drug treatment. Some pharmacists felt that treatment with topical anesthetics was costly, time consuming and ineffective. Nurses and physicians have described these perceived barriers to pain management previously\textsuperscript{56,60}. A systematic review found that topical anesthetics were associated with reduced pain during immunizations and should be recommended for use in clinical practice\textsuperscript{42}. Studies and systematic reviews have found that the use of topical anesthetics is more effective than distraction techniques at reducing pain and thus should be considered when possible\textsuperscript{42-44}. The application time of topical anesthetics range from 30-60 minutes and the cost ranges from $5 – 10 CAD\textsuperscript{61}.Studies have shown that there is enough time to include pain management in an ambulatory setting\textsuperscript{62} and patients are used to waiting for their prescriptions in pharmacies.Studies have also shown that parents are willing to pay for analgesics\textsuperscript{63}.Education that addresses pharmacists’ perceptions of topical anesthetics may be useful in increasing their use of topical anesthetics and their compliance with current pain management guidelines.

5.1.6 The Challenges of Dealing with Children

Although pharmacists reported that their relationships with patients were positively affected they often cited that immunizing children was a challenging experience and felt uncomfortable and unprepared dealing with them. Children took more time and required more effort from the pharmacists. Pharmacists utilized restraint in children in partnership with parents in order to administer vaccinations. Restraining children contributes to children’s fear\textsuperscript{64}. Pharmacists’
challenges in dealing with children are consistent with that of other health care providers. This was previously reported in qualitative nursing literature that described that nurses experienced stress when immunizing fearful children\(^{28}\).

When Deshpande and colleagues surveyed parents about their satisfaction with pharmacists immunizing their children they found that parents were satisfied\(^{65}\). This may be due to the fact that the average age of children was 12 and that parents were only asked one simple question about satisfaction and were unable to elaborate on their experiences. Also, parents may expect immunizations to be challenging based on past experience\(^{6}\). It is possible that parents reported being satisfied primarily due to the increased convenience that pharmacist immunizers provided. This was found to be the case when Ndiaye and colleagues surveyed parents in West Virginia\(^{66}\). They found that the determining factors of mothers’ decision to take their children to pharmacies for immunizations were convenient locations of pharmacies and convenient times when they offered these services. They also found that pharmacists overestimated the trust that parents put into them while immunizing their children.

This is the first time that there is documentation of challenges with immunization of children by pharmacists. Pharmacists may need additional support to assist them with the challenges of administering vaccinations in children and to allow for better relationships between pharmacists, children and parents. The findings of this study suggest that additional training and support may be useful for pharmacists administering immunizations to children. Before expanding pharmacist immunizations to all routine vaccines and/or lowering the age that pharmacists can immunize, additional research should examine ways that pharmacists can be better supported to deal with the potential challenges involved in immunizing children.

### 5.2 Implications for Future Research

Some of the findings of this study warrant future research. Further exploration is needed regarding the relationship between pharmacists and their employers in terms of expectations and workload issues; the relationship between physicians and pharmacists regarding role identity and responsibility; as well as patient and parent satisfaction with pharmacist immunizers.
5.2.1 Relationship between pharmacists and their employers

There has been no research to date describing employers demanding that pharmacists meet immunization quotas. This is an area that needs to be further investigated as it has implications for the pharmacy governing body and policy makers.

5.2.2 Relationship between pharmacists and other health care professionals

The perceived tension between pharmacists and their physician colleagues regarding their increased scope of practice is an area that needs to be studied. Although this has been thoroughly documented in studies of pharmacist prescribers\(^{19-21}\), it has not been well documented in studies with pharmacist immunizers. One survey found that only half of physicians in North Carolina supported pharmacist immunizers, with physicians who were newer to family practice having more positive attitudes than physicians who were in practice for longer periods of time\(^{67}\). It is uncertain if pharmacists are actually being met with resistance from physicians or if pharmacists need educations regarding accepting their new role and the responsibilities associated with it. More research involving understanding the perceptions of both pharmacists and physicians is needed.

Since nurses administer the majority of vaccinations in Ontario, the relationship between pharmacists and nurses in relation to the new scope of practice should also be explored as it was not specifically asked in this study and may impact the relationship between nurses and pharmacists.

5.2.3 Patient and parent satisfaction with pharmacist immunizers

Although many quantitative surveys have suggested that patients are mostly satisfied with their experiences with pharmacist immunizers, no qualitative research in this area has yet been done\(^{10,65,68}\). There is a need to gather in depth knowledge in this area in order to understand patients’ subjective experiences and needs, especially in relation to pain and fear management.

The need to understand parents’ experiences with pharmacists immunizing their children is also important as pharmacists’ scope of practice may be expanded in the future to allow them to administer childhood vaccination and because of the challenges that pharmacists in this study stated they experienced with children. One survey in the United States found that approximately
97% of the responding parents felt confident about the pharmacist providing influenza vaccinations to their children\textsuperscript{65}. However, this survey did not ask parents about their satisfaction with pain and fear management and the average age of children was 12. Furthermore, pharmacists in this study had over 10 years of experiences immunizing patients. More research in this area is needed.

More research is also indicated in order to understand if patients felt that pharmacists were able to properly manage their immunization related pain and fear. This will help in identifying areas of improvement for pharmacist immunizers.

5.3 Implications for Education

The challenges pharmacists in this study faced while immunizing patients, especially children, and the impact it had on efficiency may indicate the need to incorporate more information into the education curricula of pharmacist immunizers, including continuing education. Continuing education programs should focus on the rationale for pain and fear mitigation, evidence-based interventions and implementation strategies. Education may serve to reduce time needed to administer the needle, increase pharmacist satisfaction and reduce patients’ pain and anxiety. Pharmacists stated they used pain and fear management techniques learned from experience and did not recall learning this in pharmacy school or in the immunization certification course. Including this knowledge in both pharmacy school and in immunization certification programs can help pharmacists ensure they provide the best quality of care possible when administering vaccine injections. Continuing education courses and pharmacist newsletters may also be useful in teaching pharmacists this information. Educating pharmacists before they administer vaccinationseither in the undergraduate curriculum or in the immunization certification courses is ideal because it has been found in prior research that provider habits are difficult to change once they have been thoroughly established\textsuperscript{69}. Education at their workplace may also be beneficial in order to ensure that pharmacists learn how to incorporate evidence-based strategies into their practice.

5.4 Implications Health Policies and Governing Body

Pharmacists felt that they are providing an additional convenient service to patients and that they were contributing to patient care. Survey data not only suggest that patients agree with this but
also indicates that immunization rates in Ontario have increased due pharmacists immunizers\textsuperscript{10}. Thus policy makers and governing bodies should consider expanding pharmacist immunization services to vaccines other than the flu shot, which in turn will increase access to health services. However, before allowing pharmacists to immunize children younger than 5, it is important to first investigate further the challenges that pharmacists in this study identified for immunizing children as these challenges may be more magnified when dealing with younger children.

Also, it is important to address perceptions regarding workload issues associated with immunization injections, especially in chain pharmacies. Most pharmacists in those practice settings reported increased workload and lack of support with immunization services. Pharmacy chain head offices and regulators need to be aware of these concerns, as they may impact on pharmacist satisfaction, and performance, including error rates.

5.5 Strengths and Limitations

5.5.1 Strengths

Strengths of this study included the use of a qualitative approach and the methods taken to improve the credibility of the study. A qualitative approach allowed for an in-depth understanding of pharmacists’ experiences with administering immunizations and immunization related pain. This is the first study in this research area to employ qualitative methods. This is a major strength because it allowed for a deeper understanding than the prior surveys. The methods used to improve credibility included multiple meetings with the research team with review of transcripts, interviewing patients multiple times to get a thorough understanding of their experiences and checking the content of the themes with experts in the field. These improve credibility by ensuring the contents of the themes are truly representative of the participants’ experiences and that the interpretation of the data is consistent among members of the research team\textsuperscript{70}.

5.5.2 Limitations

The interviewer effect is a potential limitation of this study. The interviewer effect is the effect of the interviewer on the responses of participants\textsuperscript{71}. Denscombe says “the sex, the age, and the ethnic origins of the interviewer have a bearing on the amount of information people are willing to divulge and their honesty about what they reveal”\textsuperscript{72}. Participants have a tendency of answering
questions the way they think the interviewer wants them to. The interviewer (SG) is a pharmacist that has experience immunizing patients in a pharmacy in the GTA. Thus the interviewer had her own attitudes and perceptions regarding immunizations, which may have affected the responses of pharmacists. An attempt to minimize this was made by explaining to all participants at the beginning of the interviewer that the purpose of the interviews was to gain an idea of their personal experiences. The interviewer also practiced multiple times asking open-ended questions without imposing her own personal beliefs. The interview guide was also meant to aid in decreasing interviewer effect by making sure that all questions are asked in the same way, without any interviewer bias.

The usability and generalizability of qualitative research such as this has often been questioned. Hall argues that qualitative research should only be conducted if it is thought to have clinical relevance. Qualitative research can facilitate the interpretation of subjective data, such as the experiences of pharmacists as immunizers, and thus can be clinically useful. Hall warns that, “qualitative research needs to be untangled from a web of criticism about vagueness and nebulousness that has prevented the full force of qualitative findings to enhance or change practices”. In terms of generalizability she says, “using analytic generalization, precise descriptions of similar contexts, locales and time frames, enhances and particularize generalizability”. Such is the case with this study in which a precise description of the context (pharmacists in the Greater Toronto Area) and locale and time frame (within the first two years of providing immunization services) can increase the ability to generalize these findings to pharmacists who find themselves in similar situations. Thus, these findings may not be applicable to pharmacists later on who have years of experience with immunizations. Also, since this study employed purposive sampling strategies in order to find pharmacists practicing in various settings in the GTA, with a broad range of experiences, and other demographic characteristics, analytic generalizability is enhanced. Thus despite the critique against the usability and generalizability of qualitative research, the results of this study can be applied to practice.

5.6 Conclusion

Pharmacists expressed an overall positive experience with immunizing patients and the affect it had on their relationship with patients. Pharmacists worried about breeching physician territory.
Pain had minimal impact on their practice but patients’ needle fear, on the other hand, was an impediment to efficiency, particularly when immunizing children. Pharmacists used injection techniques and non-pharmacological techniques during immunization intended to ensure successful and quick injections. They did not use topical anesthetics. These findings suggest that pain is not an important factor to pharmacist immunizers.
References


Appendix A: Semi-Structured Interview Guide

I am going to be reading from a script so I ask everyone the same questions in the same way. Is that ok? Thanks.

1. As you are aware, pharmacists’ scope of practice has been expanded to include the ability to administer influenza vaccines to the public. You have obtained certification to be able to do this. Can you tell me about the main reasons that have led you to become certified?

2. What have your experiences been with immunizing patients? Can you describe the last immunization you administered?
   a. What is your approach to immunizing a patient? Can you describe your process?
   b. What negative experiences have you had while immunizing patients?
   c. What positive experiences have you had while immunizing patients?
   d. How does administering vaccinations fit in with your overall workflow?

3. At present, pharmacists only immunize patients aged 5 years and older. Does your practice currently include immunizing children? If yes, what ages?
   a. Can you explain why or why not?
   b. What have been your experiences immunizing children?
   c. How have your experiences immunizing children been different from immunizing adults?
   d. Are you a parent? How do you think this may influence your feelings about immunizing children? How does this influence your approach to immunizing children?

4. How do you feel that your new immunizer role has influenced your relationships with your patients?
   a. Has your new role influenced how your patients interact with you?
   b. What has been positive?
   c. What has been negative?
   d. What is your overall satisfaction with your new role as an immunizer?

5. How do you feel that your new immunizer role has influenced your relationships with your physician colleagues?
   a. Has your new role influenced how they interact with you?
   b. What has been positive?
   c. What has been negative?

6. Immunizations involve giving injections, and this can cause pain.
   a. Is needle pain a factor when you immunize?
   b. Can you tell me about the needle pain you think adult patients experience during immunizations? How about children?
   c. What are your experiences with immunization-related pain in adults? In children?
   d. How does inflicting pain on your patients during immunization affect you?
   e. Do you feel you have enough knowledge to manage pain in your patients during injection?

7. How do you manage needle pain in your practice?
   a. What strategies do you use to manage needle pain in adults? Do you use different strategies for children?
   b. Do you inform patients that there will be pain associated with the immunization you will be administering?
c. What experiences have you had with topical anesthetics?
   What experiences have you had with distraction?
   What else have you tried that you can tell me about?
8. What did you know about managing needle/injection pain during vaccination prior to becoming an immunizer?
   a. What do you know about managing injection pain now that you are an immunizer?
   b. How did you learn about how to manage needle pain?
   c. How do you use your knowledge of pain management when immunizing patients?
   d. Are there barriers to pain management in your practice?
   e. Are you satisfied with your overall ability to manage injection pain in your patients?
   f. Have you made any changes about how you advise parents about needle/injection pain since you became an immunizer? Can you describe these changes?
   g. What advice do you give parents about managing needle pain in their children?
   h. What would you tell a new pharmacist immunizer is the most important thing to know about needle/injection pain?
9. What information or tools have been helpful to you in your practice to manage needle/injection pain? How do you use the tools?
   a. What do you like and dislike about these tools?
   b. Is there anything else that you would like to suggest to help pharmacists in their immunizer role?
   c. Do you need more/less education about how to handle needle pain?
   d. How do you think education about needle pain should be delivered?
10. Is there anything else that you would like to tell me?
Appendix B: Consent Form

CONSENT FORM

Title of Research Project:

Experiences of patients and pharmacists with pharmacist-administered flu shots

Investigator(s):

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Introduction:

You are being asked to take part in a research study. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study investigator or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary.

Background and Purpose of this Research:

Pharmacists in Ontario have recently gained immunization privileges for administering the influenza vaccine to the public. This increased scope of practice has allowed pharmacists to deliver over 200,000 flu shots to Ontarians in the 2012 to 2013 flu season. This number has increased to over 650,000 patients in the 2013 to 2014 influenza season. Since this privilege to immunize is new for pharmacists, we want to know what their experiences are and the experiences of patients who have received immunizations from pharmacists.
You are being asked to participate in a one-on-one interview to tell us about your experiences as a pharmacist immunizer and satisfaction with this new role. Separately, patients will also be asked to give us their opinions. You will also be asked for your feedback on a new pamphlet about immunizations.

**Description of the Research:**

If you choose to participate, a research assistant will ask you questions about your experiences and opinions about your role as a pharmacist immunizer. The interview will be held in a private and convenient location, such as the pharmacy, and audiotaped. The audiotape will be immediately transcribed verbatim and then erased. The transcribed interview will not contain your name – you will be identified by study number only. The transcribed interview will be reviewed to look for key ideas. You will also be asked to complete a brief demographic questionnaire with questions about your age, sex, years of practice, and practice setting. After completing the interview, you will be asked to answer a few questions on a new immunization pamphlet.

Your participation is voluntary and no information that discloses your identity will be shared. If changes are made to the study or new information that might affect your willingness to continue to participate in the research becomes available, you will be informed.

**Potential Harms/Inconveniences:**

There may be some inconvenience due to the time required to answer questions. Approximately 1 hour will be spent in the interview process. To minimize this inconvenience, the interview will be arranged in person at a time convenient to you.

**Potential Benefits:**

You will receive a copy of a new immunization pamphlet. You may benefit from participation by being able to share your views about your role as a pharmacist immunizer.

The results from this study will be used to inform future education and implementation services for pharmacist immunizers in order to meet the needs of pharmacists and patients.

**Alternatives to Participation:**

The alternative to participation is not being interviewed about your experiences or opinions.

**Confidentiality:**

Personal Health Information
If you agree to participate in the study, you will be asked to provide some basic information about you. Personal health information is any information that could be used to identify you and includes: age, sex, years of practice, practice setting.

This information will be used to describe the demographics of participants in the study. The study investigator will keep the information that is collected for the study in a locked and secure area for 7 years. Only the study team will be allowed to look at the records. The following people may come to the research lab to look at the study records to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines:
- Representatives of the University of Toronto Research Ethics Board.

All information collected during this study, including personal information, will be kept confidential and will not be shared with anyone outside the study unless required by law. You will not be named in any reports, publications, or presentations that may come from this study. Audiotapes will be transcribed and all identifying information (such as names) removed. Once transcribed, the audiotapes will be destroyed. If you decide to leave the study, you can request for the information that was collected about you to be removed up until the time when the data are analyzed. After that point, your data may not be removed from the analysis. No new information will be collected about you without your permission.

5.6.1.1.1 In Case You Are Harmed in the Study

We do not anticipate any harm to you by participating in the study. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

Expenses and Reimbursements Associated with Participating in the Study

There is no direct cost involved in participating and no reimbursement for participation.

5.6.1.1.2 Conflict of Interest

The researchers have no conflict of interest to declare. Their interests in completing the study should not influence your decision to participate. You should not feel pressure to join this study.

Voluntary Participation:

Your participation in research is voluntary. You may decide not to be in this study, or to be in the study now and change your mind later. If you choose not to participate, it will not impact you. If you choose to participate in this study you can withdraw from the study at anytime up to the point where the data has been analyzed, after which you may no longer withdraw. You can also choose to not answer any questions during the one-on-one interview if you do not feel comfortable doing so.
Questions about the Study:

If you have any questions, concerns or would like to speak to the study team for any reason, please call: Dr. Anna Taddio at # 416-978-8822 or anna.taddio@utoronto.ca. If you have any questions about your rights as a research participant or have concerns about this study, call the Research Ethics office number at 416-946-3389. Everything that you discuss will be kept confidential.

Consent:

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to take part in this study.

_________________________    ___________________    ________
Print Study Participant’s Name    Signature    Date

(You will be given a signed copy of this consent form)
My signature means that I have explained the study to the participant named above. I have answered all questions.

_________________________    ___________________    ________
Print Name of Person Obtaining Consent    Signature    Date
### Appendix C: Participant Demographics Form

**Participant Demographics - Pharmacists**

<table>
<thead>
<tr>
<th>Age</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>Male ☐  Female ☐</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Caucasian</td>
</tr>
<tr>
<td></td>
<td>Origins in Europe, Middle East, North Africa (Arabic origins), Western Russia including Afghanistan and South Russia) and Hispanics of European origin.</td>
</tr>
<tr>
<td></td>
<td>Afro-American or African</td>
</tr>
<tr>
<td></td>
<td>Origins in any of the original peoples of Africa.</td>
</tr>
<tr>
<td></td>
<td>Asian</td>
</tr>
<tr>
<td></td>
<td>Origins in the Indian sub-continent (eg. India, Pakistan, Bangladesh and Sri Lanka), OR in the Far East and Southeast Asia (eg. China, Japan, Korea, Philippines, Thailand, Eastern Russia and Samoa).</td>
</tr>
<tr>
<td></td>
<td>Other - specify</td>
</tr>
<tr>
<td></td>
<td>Includes origins not represented above, eg. Inuit, Maori, Australian Aborigine, North &amp; South American Native Peoples, Hispanics of Caribbean, Central &amp; South American origin, and Pacific Islanders.</td>
</tr>
<tr>
<td>Position</td>
<td>Owner ☐  Employee ☐  Manager ☐</td>
</tr>
<tr>
<td>Country of Training</td>
<td></td>
</tr>
<tr>
<td>Years of practice in Ontario?</td>
<td></td>
</tr>
<tr>
<td>Years of practice elsewhere? Indicate where.</td>
<td></td>
</tr>
<tr>
<td>Amount of time working in this position</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(indicate months or years)</td>
</tr>
<tr>
<td>Pharmacy Type</td>
<td>Chain ☐  Independent ☐</td>
</tr>
<tr>
<td>Number of hours working per week</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(in any store)</td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>Which immunization-training course did you take?</td>
<td>(name of training course)</td>
</tr>
<tr>
<td>When did you receive your immunization-training course?</td>
<td>(indicate year of training)</td>
</tr>
<tr>
<td>How long have you been administering immunizations?</td>
<td>(indicate in months or years)</td>
</tr>
<tr>
<td>Approximately how many immunizations do you personally administer weekly during the flu season?</td>
<td>&lt;5/week 5-10/ week &gt;10/week</td>
</tr>
<tr>
<td>Approximately how many immunizations have you administered since you became an immunizer?</td>
<td></td>
</tr>
<tr>
<td>Have you received the influenza vaccine this year?</td>
<td>Yes ☐ No ☐ Not yet, but will soon ☐</td>
</tr>
<tr>
<td>If no, why not?</td>
<td></td>
</tr>
</tbody>
</table>

For Study Personnel:
Please indicate the method of recruitment:
☐ Recruited by study staff
☐ Recruited by referral from another study participant
☐ Recruited by referral from non-study participant
☐ Other: ___________________________
Appendix D: Coding Tree

♦ Pharmacists’ Relationships
  o Relationship with physicians
    ▪ No affect on their relationship
    ▪ Worry about infringement on territory
  o Relationship with patients
    ▪ Positive Experiences
      • Increased trust
      • Appreciation for the service/ Convenience/ Customer service
      • Allows for more face-to-face/ clinical interactions
    ▪ Negative Experiences
      • Vaccinating children as a negative/ difficult experience
♦ Professional Satisfactions
  o Overall positive experience
    ▪ Do more as a pharmacist/ additional service to patients
      • Be part of the change
    ▪ Increased knowledge
♦ Workload Demands
  o More support/resources needed
    ▪ Workflow disruption
    ▪ Increased wait times for patients
  o Worry about job security
    ▪ Be competitive in the job market
  o Pharmacy imposed quotas
♦ Worrying about allergic reactions
♦ Vaccinations as a different service
  o More intimate/personal
  o Separate from other services
♦ Attitudes and knowledge about needle pain
  o Flu shot causes no pain/ minimal pain
  o No difference between adults and children in pain
  o Not worth treating/managing
  o Pain comes with the territory
♦ Attitudes and knowledge about needle fear
  o Children have more fear than adults
  o Needle fear is more important and prevalent than pain
♦ Pain Management Strategies Used
  o Strategies used for adults and children
    ▪ Importance of technique in minimizing pain ie. “Do it quick”
- Distraction
- Come back later
- Explanations/ reasoning
- Acetaminophen and ibuprofen for pain after
- Using prior work experience
  - Strategies used for children only
    - Colorful Band-Aids/Coloring material/Candy/ Rewards
    - Restraining/ holding down children
    - Parental involvement
  - Topical anesthetics not effective/not worth it
  - No resources available for pain management/ none used
    - Rely on work experience
- No change in advising parents about needle pain
Certificate of Completion

This document certifies that

Sandra Gerges

has completed the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans Course on Research Ethics (TCPS 2: CORE)

Date of Issue: 16 January, 2014
Appendix F: Search strategies using two search engines for pharmacist immunizers and pain management

Database: Ovid MEDLINE(R) 1946 to Present with Daily Update
Search Strategy:

1 Pharmacists/ (10753)
2 exp Immunization/ or Influenza Vaccines/ (150153)
3 1 and 2 (110)
4 Qualitative research/ (19969)
5 Nursing Methodology Research/ (15586)
6 ("mixed model*" or "mixed design*" or "multiple method*" or multimethod* or triangulat*).mp. (13616)
7 or/4-6 [***GENERAL Research Type***] (44919)
8 Questionnaires/ or Self report/ or Interviews as Topic/ or Focus Groups/ (359968)
9 Video Recording/ or Tape Recording/ (21291)
10 Narration/ or narrative*.mp. or diary/ or (diary or diaries).mp. (31668)
11 ("semi-structured" or semistructured or unstructured or informal or "in-depth" or indepth or "face-to-face" or structured or guide or guides) and (interview* or discussion* or questionnaire* or "focus group*" or qualitative or ethnograph* or fieldwork or "field work" or "key informant").ti,ab. (79695)
12 program evaluation/ or benchmarking/ (57562)
13 attitude/ or "attitude of health personnel"/ or attitude to computers/ or attitude to death/ or attitude to health/ or health knowledge, attitudes, practice/ or catastrophization/ (269870)
14 educational measurement/ (28103)
15 or/8-14 [***Evaluation Methods***] (697075)
16 consumer satisfaction/ or patient satisfaction/ or patient preference/ (79847)
17 Patient Dropouts/ or patient compliance/ or medication adherence/ or treatment refusal/ (71371)
18 professional competence/ or clinical competence/ or dentist's practice patterns/ or physician's practice patterns/ (126243)
19 or/16-18 [***Outcome Measures***] (270951)
20 7 or 15 or 19 [***ALL QUALITATIVE REASERACH TERMS - SENSITIVE***] (898877)
21 3 and 20 (27) Qualitative research
22 pain measurement/ or exp Pain Perception/ or exp pain/ (332481)
23 1 and 22 (134)
24 20 and 23 (48)

25 3 and 22 (0)
26 3 not 21 (83) general
Search Strategy:

1 pharmacist/ or pharmacist attitude/ (47037)
2 exp immunization/ or influenza vaccine/ (246448)
3 1 and 2 (690)
4 Qualitative research/ (23235)
5 Nursing Methodology Research/ (13732)
6 ("mixed model*" or "mixed design*" or "multiple method*" or multimethod* or triangulat*).mp. (17619)
7 or/4-6 [***GENERAL Research Type***] (50883)
8 Questionnaires/ or Self report/ or Interviews as Topic/ or Focus Groups/ (669029)
9 Video Recording/ or Tape Recording/ (81559)
10 Narration/ or narrative*.mp. or diary/ or (diary or diaries).mp. (46271)
11 ("semi-structured" or semistructured or unstructured or informal or "in-depth" or indepth or "face-to-face" or structured or guide or guides) and (interview* or discussion* or questionnaire* or "focus group*" or qualitative or ethnograph* or fieldwork or "field work" or "key informant")).ti,ab. (104498)
12 program evaluation/ or benchmarking/ (290914)
13 attitude/ or "attitude of health personnel"/ or attitude to computers/ or attitude to death/ or attitude to health/ or health knowledge, attitudes, practice/ or catastrophization/ (197428)
14 educational measurement/ (311317)
15 or/8-14 [***Evaluation Methods***] (1457763)
16 consumer satisfaction/ or patient satisfaction/ or patient preference/ (124460)
17 Patient Dropouts/ or patient compliance/ or medication adherence/ or treatment refusal/ (1269489)
18 professional competence/ or clinical competence/ or dentist's practice patterns/ or physician's practice patterns/ (225518)
19 or/16-18 [***Outcome Measures***] (1584927)
20 7 or 15 or 19 [***ALL QUALITATIVE RESEARCH TERMS - SENSITIVE***] (2830607)
21 3 and 20 (275) Qualitative research
22 pain/ or pain thresholds/ or nociceptors/ or pain assessment/ (275070)
23 21 and 22 (5)
24 3 not 21 (415) General
Appendix G: Ethics Approval Letter

PROTOCOL REFERENCE # 30102

May 2, 2014

Dr. Anna Taddio  
FACULTY OF PHARMACY

Ms. Sandra Gerges  
FACULTY OF PHARMACY

Dear Dr. Taddio and Ms. Sandra Gerges,

Re: Your research protocol entitled, "Experiences of patients and pharmacists with pharmacist-administered flu shots"

ETHICS APPROVAL  
Original Approval Date: May 2, 2014  
Expiry Date: May 1, 2015  
Continuing Review Level: 1

We are writing to advise you that the Health Sciences Research Ethics Board (REB) has granted approval to the above-named research protocol under the REB's delegated review process. Your protocol has been approved for a period of one year and ongoing research under this protocol must be renewed prior to the expiry date.

Any changes to the approved protocol or consent materials must be reviewed and approved through the amendment process prior to its implementation. Any adverse or unanticipated events in the research should be reported to the Office of Research Ethics as soon as possible.

Please ensure that you submit an Annual Renewal Form or a Study Completion Report 15 to 30 days prior to the expiry date of your current ethics approval. Note that annual renewals for studies cannot be accepted more than 30 days prior to the date of expiry.

If your research is funded by a third party, please contact the assigned Research Funding Officer in Research Services to ensure that your funds are released.

Best wishes for the successful completion of your research.

Yours sincerely,

Elizabeth Peter, Ph.D.  
REB Chair

Daniel Gyewu  
REB Manager