# HOW TO INTEGRATE A PHARMACIST INTO AN ALREADY ESTABLISHED PRIMARY HEALTH CARE TEAM

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## **ABSTRACT**

Over the past several years, both government and the profession of pharmacy have acknowledged that pharmacists are not being used to their full potential in our health care system. In order to advance the profession of pharmacy in this area, guidance on how pharmacists can be integrated need to be investigated.

The purpose of this study was to identify how to integrate a pharmacist into an already established primary health care team, at the Student Health Centre at the University of Saskatchewan. The project was divided into three phases: defining the role of the pharmacist, implementing the proposed role and then evaluating and prioritizing the role. Using action research, an expert panel consisting of established primary health/ambulatory care pharmacists from across Canada helped to identify possible clinical activities for a Student Health Centre pharmacist. The results were presented to the primary health care team, who then collaborated with the pharmacist and researchers to define the role of the pharmacist. Once an agreement was reached, a pharmacist provided eight weeks of full-time clinical services. Upon completion, focus groups with the primary health care team members were used to evaluate the pharmacist's clinical services.

The role of the pharmacist was tailored specifically for the student health care centre selected for the study. However, the process of integrating and evaluating the role of the pharmacist, will serve as a template for other pharmacists desiring to be involved in any primary health care team interested in expanding their multidisciplinary service.

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## **CHAPTER 1: INTRODUCTION**

## 1.1 Background

It has been approximately five years since Commissioner Fyke and Commissioner Romanow released their reports regarding the provincial and federal status, respectively, of our health care system. Both documents acknowledged that pharmacists were not used to their full potential in our health care system and recommended the role of pharmacists on primary health teams be enhanced. Since then, some literature has surfaced which explored possible activities and responsibilities of pharmacists in this field, such as Saskatchewan's Pharmacy Coalition on Primacy Care position statement, *Role of the Pharmacist in Primary Health care*. However, there were no published articles discussing the actual implementation process of a pharmacist into a primary health care site.

The profession of pharmacy places a high value on evidence-based medicine, and encourages both pharmacists and pharmacy students to incorporate this systematic approach into their practice. Due to the demand for evidence-based medicine, not only in pharmacy but our entire health care system, research into how pharmacists can be integrated into primary health care centres is essential. To advance the profession of pharmacy, guidance on how this integration can be achieved is needed. Several studies using quantitative research methods suggest pharmacists can have a positive effect on patient care; however qualitative inquiry has not been implemented to investigate the conditions that contributed to this positive effect.

## 1.2 Research Question

How can a pharmacist be integrated into an already established primary health care team? More specifically:

1) Can action research be used to assist with this integration process?

- 2) How do the primary health care team members feel about having a clinical pharmacist join their team?
- 3) What recommendations can be provided to support the integration of pharmacists onto primary health care teams?

## 1.3 Objectives

The study objective was divided into three phases:

# Phase I: Define the role of the pharmacist.

Lack of a defined role has been identified as an obstacle for pharmacists desiring to join primary health care teams.<sup>4</sup> Successful interdisciplinary teams are able to dialogue on their differences about roles, responsibilities and timing of integrated care. Role ambiguity, due to difficulties in defining roles, can lead to dissatisfaction within the team.<sup>5</sup> Therefore, it is essential that the role of the pharmacist be defined and agreed upon prior to providing any clinical services. Both the primary health care team and established primary health and ambulatory care pharmacists were consulted to help shape the pharmacist's role.

## Phase II: Implementing the purposed role.

Once the role of the pharmacist was defined, I provided two months of clinical pharmacy services for the Student Health Centre at the University of Saskatchewan. All clinical activities and interactions were documented. After one month, a team meeting was held to discuss how the role of the pharmacist had been received by the staff to date. The pharmacist's role would be modified if needed, based on the recommendations that surface from the meeting.

## Phase III: Evaluate and prioritize the role of a clinical pharmacist.

At the end of two months of clinical services, focus groups were organized with Student Health Centre staff. Participants were asked to reflect on their experience of having a clinical pharmacist on the primary health care team. The purpose of the focus groups was to identify what went well, what did not and areas for improvement from all stakeholders' perspectives.

# 1.4 Significance

The role of the pharmacist was defined, implemented, evaluated and prioritized to meet the specific needs of the primary health care centre chosen for this project. However, the intent was to develop a process that could be generically applied to any primary health care team. This study will provide guidance on how to integrate a pharmacist into a primary health care team and serve as a stepping stone toward other investigations.

# 1.5 Important Terms

**Action Research:** an inquiry that is conducted by or with the insiders of an organization or community, but never to or on them. It is a reflective process oriented to some action or cycle of actions that organizational or community members take to address a particular problematic situation. This approach is based on the theory that changes occur either within the setting and/or within the researchers themselves.<sup>6</sup>

**Clinical Pharmacist:** a pharmacist who contributes to health care teams by optimizing drug therapy. They improve patient outcomes by educating patients, optimizing medication use, and monitoring medication endpoints. Activities are tailored to the needs of the patient population and seldom include dispensing medications.<sup>4</sup>

**Primary Care:** a level of care, which is accessible to patients when they seek services offered at the first level of contact with the health care system. It is the element within primary health care that focuses on health care services, including health promotion, illness and injury prevention, and the diagnosis and treatment of illness and injury.<sup>7</sup>

**Primary Health care:** refers to an approach to health and a spectrum of services beyond the traditional health care system. It includes all services that play a part in health, such as income, housing, education, and environment.<sup>7</sup>

## **CHAPTER 2: LITERATURE REVIEW**

## 2.1 Primary Health care

# 2.1.1 Background

Primary care is a level of care, which is accessible to patients when they seek services offered at the first level of contact with the health care system. It is coordinated care provided to individuals to address a particular problem of basic everyday health need – focusing on both treatment and prevention. Primary care is an element within primary health care that centres on health promotion, illness and injury prevention, and the diagnosis and treatment of illness and injury. Primary health care encompasses primary care, as well as the other determinants of health – like social and economic influences. These primary health care services are delivered by a group of health care professionals, and the interdisciplinary team offers a holistic approach to patient care. 8, 9

To provide optimal care, primary health care teams assess and evaluate the health needs of their patient population, and subsequently customize their services based on these needs.<sup>4</sup> A diverse group of health care professionals offers a broader range and higher quality of services to address the health needs of a population. Ultimately, this multidisciplinary collaborative approach can result in a more sustainable system of primary health care services.<sup>1</sup>

## 2.1.2 Primary Health care in Saskatchewan

In 2001, Commissioner Kenneth Fyke released his *Commission on Medicare* report, which recommended an action plan to enhance the sustainability of Saskatchewan's health care system. His report focused on the development of an integrated approach for the delivery of primary health services. The document also recognized that pharmacists were not utilized to their full potential in the health care system. One of Fyke's recommendations was to enhance the role of the pharmacist on primary health teams and to allow the profession to apply their knowledge as full participants in prescribing decisions.<sup>1</sup>

Commissioner Fyke's document served as a valuable resource for Commissioner Roy Romanow, who used the information when preparing his report, *Building on Values: The Future of Health care in Canada*. His recommendations echoed those of Commissioner Fyke, regarding the under utilization of pharmacists. This widely reviewed federal initiative, acknowledged the potential for pharmacists to have a progressively important role on primary health care teams.<sup>2</sup>

Soon after the release of the reports of Commissioners Fyke and Romanow, the Saskatchewan's Pharmacy Coalition on Primary Care circulated their position statement, the *Role of the Pharmacist in Primary Health care*. The paper highlighted the fact that pharmacists throughout the province were eager to become members on primary health care teams. The potential role of the pharmacist was investigated, and the Coalition stated that the clinical pharmacy activities should be site specific. As such, the team should consider the patient population needs; the professional diversity and strengths of team members; cross-training requirements; and the pharmacist's experience, interest areas, and availability. At the end of the consultation process, the Coalition concluded the weaknesses of the profession were limited experience with team establishment and no clear understanding of its role on primary care teams.<sup>3</sup>

# 2.1.3 The Value of Primary Health care Pharmacists<sup>10</sup>

Current evidence supports the addition of clinical pharmacy services in primary health care. Randomized trials have demonstrated a positive effect from clinical pharmacy services on patient outcomes, particularly in the areas of chronic disease management. More specifically, involving pharmacists in the provision of health care can result in greater patient safety, enhanced disease and drug therapy management, as well as improved compliance and quality of life. In addition, clinical pharmacy services can improve health care spending, resulting in an overall savings to the health care system.

## 2.1.4 Bridging the Gap

In addition to the Pharmacy Coalition on Primary Care position statement; there are a number of examples cited in the literature discussing the role of a clinical pharmacist in primary health care. The provincial government is encouraging pharmacists to become involved in primary health care. Saskatchewan pharmacists have expressed interested in

this unique approach.<sup>3</sup> The value of adding a clinical pharmacist to health care teams has been demonstrated;<sup>10</sup> yet, pharmacists have not been incorporated into primary health care to the degree that the profession is able to make a substantial impact on patient care.

In the current health care system, health care professionals strive to incorporate evidence-based medicine into their daily practice, and the evolution of health care relies on this emergence of clinical evidence and expertise. As stated earlier, limited experience with team establishment and lack of a defined role have been identified as barriers for pharmacists desiring to be part of a primary health care team.<sup>3</sup> To date, there are no published articles discussing the actual implementation process of a pharmacist into a primary health care team. Until literature is available highlighting solutions to these concerns, as well as guidance on how to successfully integrate a pharmacist into a primary health care team, the profession of pharmacy may be unable to exploit this opportunity.

## 2.2 Defining the Role of a Pharmacist

To aid with successful integration into a health care team, the new team member's role, responsibilities, and timing of the care need to be clearly defined prior to joining the team. This process should be a collaborative effort put forth by all of the members of the team. Role conflict, role overload, and variable acceptance for the new team member can result when there is a lack of role clarity and inconsistent expectations. In addition, dissatisfaction within the team can occur when uncertainty with a job description (i.e. role ambiguity) exists. 18

As mentioned, the primary health care team should assess and evaluate the needs of the patient population. To tailor the clinical pharmacy activities based on these patient needs it would seem logical to initiate discussion with those who know the population best that is, the primary health care team. However, this can be very difficult and frustrating when the team has no clear understanding of the spectrum of activities that can be offered by a clinical pharmacist.

An example of when this problem can occur is found with the Seniors Medication Assessment Research Trial (SMART).<sup>19</sup> The study evaluated the collaboration between specially trained expanded role pharmacists and family physicians. A major drawback for the pharmacists involved was the physicians did not recognize their full potential. The

physicians expected the pharmacists to stick specifically with investigations involving overthe-counter medications. In addition, the pharmacists could not discuss possible alternatives with patients as the physicians felt this would be a criticism on their performance. This inhibited the pharmacists from having significant impact on patients' drug therapy. In addition, the pharmacists were not aware of occasions when physicians had unsuccessfully tried a particular therapy or plan because they were restricted from discussing therapeutic alternatives with patients.<sup>19</sup>

Another study, conducted in California, investigated physician expectations of pharmacists. A questionnaire was used to capture medical residents' and physicians' (office and hospital based) current and future expectations, as well as their current experiences with pharmacists. A total of 463 physicians (19.3% response rate) participated in the study. The authors concluded the physicians did not know what to expect of pharmacists. In addition, there was no correlation between the responses and practice setting.<sup>20</sup>

If health care professionals do not realize the range of clinical activities that can be implemented or do not know what to expect from pharmacists, integration is jeopardized. Interdisciplinary teams report an increased awareness of each member's role, however difficulties in defining the roles of professional groups may still exist.<sup>4</sup> Another approach for defining the role of a pharmacist involves discussion with those who hold a similar role within another organization. These colleagues can offer their expertise on how to establish activities based on the needs of the patient population. In addition, establishing relationships with these key players can lead to greater peer support in the future.<sup>21</sup>

# 2.2.1 Nursing Practitioners

Pharmacy is not the first profession to investigate role expansion in the area of primary health care. In the 1990s, nurse practitioners began to extend their role in health care.<sup>22</sup> However, their success was not without the same obstacles that pharmacists are currently facing.<sup>14</sup> Nurse practitioners credit clearly defined roles as an integration strategy for incorporating themselves in primary health care.<sup>14, 23-25</sup>

# 2.3 Implementing the Purposed Role

Several published articles are available which highlight the roles pharmacists' have developed in family medicine, ambulatory care and primary health care settings. Review of this literature sheds light on the diverse range of services that pharmacists have successfully implemented in these practice areas. Examples include: <sup>7, 9, 13, 26-44</sup>

#### Patient Care

- Advise on medication use in pregnancy.
- Respond to medication related telephone calls from patients.
- Provide patient education and counselling on medications and disease states.
- Identify actual or potential drug therapy problems.
- Identify barriers to patient compliance and provide strategies to improve adherence.
- Obtain medication histories: past and present prescription and over-the-counter medications, drug allergies, and vaccinations.
- Review of current medications for drug-drug interactions, drug-disease interactions, and adverse drug reactions.
- Ensure drug choice and dosage regimen is appropriate.
- Confirm that no duplicate therapy exists and medications are having the desired effect.
- Provide health promotion services (for example, smoking cessation).
- Advise on sexual health (for example, supply emergency contraception).
- Maintain medication profiles.
- Calculate appropriate dosages.
- Demonstrate proper use of a medical device.
- Counsel patients on financial reimbursement for drug costs.
- Provide information concerning cost and availability of drugs.
- Participate in multidisciplinary reviews of patients' progress.

## Monitoring Drug Therapy

• Ensure safe and efficacious drug use.

- Assess objective lab values (for example: blood glucose, blood pressure).
- Perform clinical pharmacokinetic interpretation: reviewing drug blood levels and providing recommendations.
- Follow-up on culture and sensitivity reports (for example, throat cultures).

## Drug Information & Guidelines

- Organize & maintain drug information services.
- Prepare and distribute medication newsletters.
- Create and present educational sessions to the staff.
- Develop disease treatment protocols.
- Develop formulary guidelines.
- Meet with representatives of pharmaceutical companies and dispense samples to the patients.
- Perform drug utilization reviews: chart or prescription review.
- Participate in clinical drug trials.
- Provide academic detailing to physicians.

## 2.4 Evaluation of the Integration Process

## 2.4.1 Qualitative Analysis

Qualitative inquiry seeks to find the quality or meaning of experience. These approaches are exploratory in nature and can identify outcomes, including unforeseen problems and benefits, from several perspectives.<sup>45</sup> Qualitative analysis has been employed in health care research to evaluate interdisciplinary teams,<sup>17</sup> collaborations between community pharmacists and family physicians,<sup>15</sup> the integration of nurse practitioners into primary health care,<sup>21</sup> and defining roles for health care professionals<sup>4</sup>.

## 2.4.2 Action Research

Action research is a qualitative methodology which is a cyclical, dynamic, and collaborative process where researchers strive to improve their practices. In action research, the object under study is human or social action versus behaviour. In other words, the

researcher does not simply observe the participants in his/her environment. Change is instituted, and it is how the participants respond to this modification which is evaluated. It is purposive, intentional, and goal directed versus a physical response to stimuli. There are two main aims within action research – improvement and involvement. The first aim, improvement, refers to the desire to change the situation in which the practice occurs, to enhance practitioners understanding of their practice, and/or to remake the practice itself. As for involvement, action research is a collaborative process and stakeholders are encouraged to participate in all phases of planning, acting, observing, and reflecting.<sup>42</sup>

Ernest Stringer developed an action research model, which cycles through three stages: Look-Think-Act. During the "Look" stage, researchers gather relevant information and data to define and describe the situation. The "Think" stage requires the participants to explore, analyze, interpret and explain. In other words, reflect on what is occurring. Then for the "Act" stage, researchers plan, report, implement or evaluate.<sup>42</sup>

Recently action research, as a qualitative method of inquiry, has gained popularity in the health care field with health care professionals desiring to improve their daily practices. Hore specifically, nurses have used action research for investigating and implementing changes within primary health care teams, Patients have been involved in this form of research to enhance an integrative approach to their cancer therapy, and action research has been used to develop the role of a pharmacist specializing in menopause.

## 2.4.2.1 Positionality in Action Research

Qualitative researchers are encouraged to identify their positionality – i.e. the position they take towards the setting and participants under study. For example, this may include their gender, race, and socioeconomic background. Action research adds another dimension to positionality, as researchers should define their relationship with the group or team involved in the initiative. The terms 'insider' and 'outsider' are used to describe these connections. An insider is an action researcher who is already part of the team, whereas an outsider is not part of the group under study but uses relevant skills and resources to assist with conducting the research.<sup>1</sup>

Although positionality should be acknowledged, it is also important to note that it does not always fall into clearly defined categories. For example, some outside researchers may have extensive knowledge of the setting they are investigating, while other may not. In addition, these relationships can shift throughout a study and at times, a researcher may simultaneously be an insider and outsider in various dimensions.<sup>1</sup>

# 2.4.3 Focus Groups

There are several different methods of collecting data for qualitative inquiry.<sup>51</sup> Focus groups are an option, which allow researchers to obtain a richer understanding of participants' experiences with an intervention and provide immediate and vivid feedback.<sup>52</sup> The interaction that occurs amongst individuals during a focus group provides a stimulus for discussion and the generation of ideas, resulting in a wider range of ideas than would result from individual interviews.<sup>53</sup> The topic under debate is discussed in great depth and allows researchers to assess if group consensus exists on major themes. Focus groups allow participants to be involved and provide them with a forum to meet and develop recommendations for the project under consideration.<sup>45</sup>

Focus groups have become increasingly prominent in health care research over the past several years.<sup>49</sup> Nursing groups have incorporated focus groups as a means of qualitative inquiry to evaluate the role and development of clinical nurse specialists, the relationship between nurse/patient and doctor/patient, and client satisfaction.<sup>19, 20, 54</sup> Focus groups have also been employed to evaluate the collaboration between pharmacists and medical practitioners.<sup>41</sup>

## 2.4.3.1 On-line Focus Groups

On-line focus groups have been used as a data collection tool in qualitative health services research. <sup>49, 55, 56</sup> As with in-person focus groups, on-line focus groups have the advantages of obtaining a broader range of responses and elicitation of details that are not captured during individual interviews. <sup>57</sup> Despite not having the participants physically in the same location, on-line focus groups are still able to create active engagement and group interaction. <sup>51</sup> In addition, studies show when face-to-face focus groups are compared to online focus groups, similar themes emerge from both methods. <sup>58, 59</sup> Due to the confidential

nature of on-line focus groups, these trials have also revealed participants feel more comfortable and offer more input via on-line focus groups, versus face-to-face focus groups, when the focal point of discussion is of a sensitive or health related issue.<sup>54, 55</sup> Compared to in-person focus groups, on-line focus groups offer several advantages, such as: <sup>51, 52, 60</sup>

- No stringent time limits;
- Quick to assemble and disassemble;
- Less expensive than in-person focus groups;
- More convenient for subjects as they can participate without leaving their home or office;
- Anonymity can be protected for subjects concerned about the nature and sensitivity of the discussion topic;
- Potential for better quality of data as comfort level is increased;
- Participants from geographically distant locations can be easily incorporated into the group;
- Data entry and analysis are faster and cost less; and
- Group size is not an issue therefore more participants can be included.

Disadvantages may include:51,52,56

- Limited participant access to computers;
- Can be more time consuming for the moderator;
- Lack of nonverbal and vocal cues:
- Individuals may feel too free to express themselves resulting in less discretion and tact;
- A few participants may engage in their own exclusive dialogue and alienate the rest of the group;
- Technological problems may arise; and
- Participants may not be comfortable with using an electronic medium.

There are two main types of on-line focus groups – synchronous and asynchronous. Synchronous focus groups use chat rooms or focus group software packages to allow real time interactions between the moderator and participants. Disadvantages of synchronous focus groups include inconvenience for participants in different time zones; most software

packages do not save transcripts and have a limited scrolling function, and therefore it may not be possible to view all that has been discussed. Asynchronous groups use discussion or message boards, listservs, or mailing lists, which allow participants to log in and reply to discussion questions on their own time. Benefits include producing more in-depth and richer responses versus synchronous environments; transcription is already completed which saves time and money, and increases the accuracy of the transcripts; global time differences are not an issue; more time is allotted for participants with variable typing skills; and participants have longer to focus and reflect on responses. <sup>56</sup>

# 2.5 Study Objective

The purpose of this study was to identify how to integrate a pharmacist into an already established primary health care team. Action research was the methodology employed to answer this question. The project was divided into three phases: defining the role of the pharmacist, implementing the purposed role, and evaluating and prioritizing the implemented role. The role of the pharmacist was tailored specifically for the primary health care centre selected for this study. However, the process will serve as a template for other pharmacists desiring to be integrated into primary health care teams.

## **CHAPTER 3: METHODOLOGY**

## 3.1 Researcher's Story

In qualitative research, researchers are encouraged to share their position, values and judgments on the study subject, due to the interpretive nature of the research.

I received my Bachelor of Science in Pharmacy degree, from the University of Saskatchewan, in 2003. While I was working towards this degree, I volunteered with a peer health education group – the Student Health Initiatives Program (SHIP), through the Student Health Centre. My involvement as a volunteer lead to a summer student position as assistant to the Health Education Coordinator. This opportunity was extended into the school year, and I was fortunate to hold the position for approximately one and one-half years. During my employment, I worked closely with several of the Student Health Centre employees while developing pamphlets, presentations, and displays. I was always impressed with their dedication to patient care and the team approach they used to deliver health services.

This exposure to a health care team influenced my decision to practice as a hospital pharmacist. I had witnessed the benefits of working in a collaborative fashion, and was eager to transfer this experience into a hospital setting. Once I had completed my pharmacy degree, I moved to Winnipeg, Manitoba to work in a community hospital. During my eighteen months in Winnipeg, I had the opportunity to specialize in pain and palliative care. A hospital setting was the perfect environment to foster my interest in a team-based approach to direct patient care. However, the clinical pharmacy services at the hospital were inconsistent due to the pharmacist storage. As such, it was difficult to establish relationships and roles with the other health care professionals on the wards.

After working for a year and a half in Winnipeg, I relocated to Regina, Saskatchewan and worked at the Regina General Hospital. I practiced in the therapeutic areas of cardiology and psychiatry, where clinical pharmacy services were well established. I really enjoyed working with the health care teams dedicated to these wards. However, with my increased direct patient care interactions and level of participation on the teams, I soon

became frustrated with the lack of preventive measures in the community which led to some of the hospital admissions. This sparked a new found appreciation for primary health care.

As I am sure is true for most pharmacists, I often reflect on where the profession of pharmacy stands within our health care system. As a hospital pharmacist, I feel very fortunate to have had the clinical pharmacy opportunities to which I have been exposed. Yet, I also realize that barriers exist which may inhibit some pharmacists from expanding their role to include clinical functions. These concerns led me to wonder whether providing guidance on how to deal with obstacles would assist the profession in further establishing clinical roles.

My background as a single, educated, Caucasian female focused on career advancement, brought opinions and values to this study, as I was the research instrument. Bias and subjectivity are natural and acceptable in action research, providing they are identified rather than ignored.<sup>6</sup> Reflexivity is built into the research process when the researcher acknowledges the perspectives they have acquired via their unique experiences.<sup>6</sup> Keeping a reflexive diary throughout the study is another measure, which can articulate evolving perspectives. In addition, my interpretation of the study findings have to meet the approval of my committee members – which increases the trustworthiness of the research.<sup>6</sup>

I really did enjoy the two months that I spent with the Student Health Centre staff as their clinical pharmacist. It was great to reconnect with the team members I had previously worked with and meet the new staff who had joined the team since I had left my position in Health Education. In addition, I was able to interact with patients and practice as a clinical pharmacist – which was something I really missed, as I no longer worked full-time due to graduate studies. However, there were times that I felt frustrated with my perceived lack of progress to establish a clinical role for a pharmacist at the Centre. I was eager to create clinical opportunities, similar to the services I was used to providing as a hospital pharmacist, yet I sometimes failed to pause and remind myself that a clinical pharmacy role was novel to the Student Health Centre staff. I did experience obstacles, but I was there for the team and not myself. Therefore, I was willing to be patient and compromise, as to not jeopardize my integration into the team. By the end of the two months, I was pleased with how much we were able to accomplish. I do wish that I would have been able to establish a

stronger/larger direct patient care role; however I accept only so much could be achieved in the study timeframe.

## 3.2 Qualitative Inquiry

There are numerous quantitative studies in the literature which portray the positive impact pharmacists have on patient care, <sup>22, 23, 27-29, 31, 40, 61</sup> the favourable impressions that physicians and nurses have towards clinical pharmacist's interventions, <sup>22, 27, 31, 32, 62</sup> and the satisfaction patients express regarding their interactions with clinical pharmacists. <sup>22, 63</sup> However, to date, there are no studies that tried to capture the social aspect of how this positive impact on patient care is created or how relationships are formed. Therefore, a qualitative approach was selected as the research methodology for this project; it not only informed us of what went well and what did not, but also provided us with rich detail that gave us a sense of *why* things were successful or not, from several stakeholders' perspectives.

Action research was the qualitative method employed for the project. The improvement or change sought was the integration of a pharmacist into a primary health care team. To ensure a truly collaborative process, primary health and ambulatory care pharmacists, the primary health care team members, and patients were encouraged to participate in various phases of the research project.

Stringer's action research model of Look-Think-Act was applied throughout the three phases of the project: defining, implementing, evaluating and prioritizing the role of a pharmacist (see Appendix I). This unique research methodology allows the researcher to become more knowledgeable with each Look-Think-Act cycle, ultimately leading to a solution for the research question.<sup>2</sup>

For our study, the results we obtained from Phase I helped form Phase II, and Phase II results shaped Phase III. Our research questions, however, were not answered until Phase III. Therefore, some of the results from the first two phases are presented and discussed under the methodology section to ensure continuity and flow for the reader. The results and discussion sections of the report focus on the data collected in Phase III and answering the research questions.

# 3.3 Primary Health care Centre Chosen for this Project

The Student Health Centre at the University of Saskatchewan was selected as the primary health care centre for this project. The centre received its primary care designation in March 2000 and is one of eight primary care sites within the Saskatoon Health Region. The centre provides comprehensive health care services to students registered at the university and their families. The team includes a variety of health care professions including physicians, a nurse practitioner, psychiatrists, dietitian, nurses, massage therapist, chiropractor, social worker, orthopedic surgeon, internal medicine specialist, obstetrician/gynecologist resident, and health education coordinator, along with a manager and front office staff. Prior to our study, a pharmacist had never been incorporated into this mix. There is no pharmacy or dispensary located in the Student Health Centre; therefore the role of the pharmacist was solely clinical.

# 3.4 Ethics Approval

Our project received ethics approval from the Behavioural Research Ethics Committee of the University of Saskatchewan on July 28<sup>th</sup>, 2006.

# 3.5 Phase I: Defining the Role of the Pharmacist

The first step using the action research model was to "Look" by gathering all relevant information and data through observation, interaction and discussion with stakeholders. The goal was to create a picture of the situation and identify who will be involved.<sup>42</sup> Information on the Student Health Centre and literature view helped form the research project.

# 3.5.1 Look: Gather information from the Student Health Centre

The Student Health Centre served as a valuable resource for identifying the needs and patient population for this project. More specifically, these resources included the staff, program evaluations and administrative documents. The following paragraphs take a closer look into each of these sources, which helped set the stage for developing clinical pharmacy activities.

#### 3.5.1.1 Student Health Centre Staff

As mentioned in the literature review, the primary health care team knows the patient population best and therefore should be consulted when developing the clinical pharmacy activities. The manager at the Student Health Centre informally presented the project to the team during a staff meeting. The team welcomed the idea, however because they had never worked with a clinical pharmacist, they were unsure of what the role of this new team member would be. As such, the staff could not identify any specific activities or role for a pharmacist.

## 3.5.1.2 Program Evaluations

In 1997, the Centre conducted their first needs assessment survey on student health behaviour and knowledge.<sup>65</sup> A second needs assessment was subsequently conducted in 2003 to update their original findings, obtain more in-depth demographic data, and evaluate the existing services offered by the centre.<sup>66</sup> The survey participants were selected amongst all university students, not just those who received services from the Student Health Centre. Both of these documents offered insight into the demographics and health needs of students enrolled at the University of Saskatchewan. <sup>61,66</sup>

## 3.5.1.3 Administrative Documents

Administrative documents that contain data on demographics and billing codes revealed the type of students and their medical reasons for accessing the services.

## 3.5.1.4 Shadowing Team Members

Observation is another method for collecting information. On Thursday, February 23<sup>rd</sup>, 2006, I spent an entire day shadowing staff members at the Student Health Centre to gain a deeper appreciation of the day-to-day medical concerns that students present with to the staff. The morning was spent shadowing a registered nurse while the afternoon was set aside to observe a physician. There was also an opportunity to witness an interaction between the nurse practitioner and a female student regarding contraception.

## 3.5.2 Look: Gather information by conducting a literature review

A literature review of how other health care professionals, such as nurse practitioners, expanded their role into primary health care provide guidance for the profession of pharmacy. Additional articles were retrieved and reviewed to aid with the project. For example, information on the importance of having a clearly defined role before joining a team; possible clinical pharmacy activities; and methodology that had been previously employed in health services research – such as action research and focus groups.

# 3.5.3 Think: Explore & analyze collected information

The information collected from the Student Health Centre helped to define the patient population and identify the health needs of this group, which were in turn used to explore possible roles for the pharmacist. Reflecting on how other health care professionals have integrated themselves into primary health care also assisted with defining the role.

# 3.5.4 Act: Develop a plan for enacting the investigation

# 3.5.4.1 On-line Focus Group with Pharmacists

Since the Student Health Centre staff was unsure of what would be the role a clinical pharmacist, pharmacists already established on primary health care teams were consulted to help tailor clinical pharmacy activities for the Centre. Ambulatory care pharmacists function in a similar capacity to primary health care pharmacists on health care teams, therefore we felt that ambulatory care pharmacists could also help shape the role of the pharmacist. Bringing experts together in this manner has previously been used by nurse practitioners for establishing their role in primary health care.<sup>19, 20</sup> To establish consensus amongst these specialists, focus groups can be used.<sup>49</sup>

Primary health and ambulatory care pharmacists are relatively new to the Canadian health care system. As such, there are a limited number of pharmacists specializing in these areas throughout the country; therefore, both provincial and national pharmacists were invited to participate in this stage of the study. An asynchronous on-line focus group was an economical method of extracting information and formulating ideas from the geographically dispersed panel of pharmacists. In addition, an asynchronous web-based data collection method allowed the pharmacists to tailor their participation around their

hectic schedules. Focus groups allowed the pharmacists to draw on their own experiences and discuss with colleagues a range of possible clinical activities that could be implemented at the Student Health Centre.

The focus group pharmacists were selected by using purposeful sampling, in other words selecting participants based on their characteristics.<sup>47</sup> The list of potential participants was developed by Dr. Shannan Neubauer, Dr. Alfred Rémillard, and myself; however the bulk of the names were provided from Dr. Neubauer, who specializes in both primary health and ambulatory care. The inclusion criteria were pharmacists who:

- 1) had established themselves on Canadian primary health or ambulatory care teams;
- 2) were the first pharmacist to join their primary health or ambulatory care team;
- 3) were willing to share their experiences with primary health or ambulatory care teams using an on-line focus group; and
- 4) were willing to complete a survey regarding the use of an on-line focus group

Dr. Neubauer contacted the potential participants via e-mail in June, 2006, to introduce the study and invite them to be a member of the panel (see Appendix II). A letter was also sent in the mail to follow-up with the potential participants. In the event there was not enough interest generated in the on-line focus group, we planned to use the snowball technique to recruit additional pharmacists. As such, the pharmacists who agreed to participate would be asked for the names of other potential people to recruit.<sup>67</sup>

Ten of the twelve pharmacists contacted agreed to participate in the study, and this was a sufficient number to proceed with the focus group without additional recruitment.<sup>67</sup> Over half of the pharmacists (n=7) practiced in primary health/ambulatory care settings within Saskatchewan – one from Fort Qu'Appelle, one from Leader, two from Regina, one from Saskatoon, and two from Wynyard. Two of the participants were from Ontario – one from Toronto and the other from Hamilton. The remaining participant was from Halifax, Nova Scotia. The majority of the pharmacists (n=8) specialized in general medicine. As for the other two, one pharmacist specialized in a lipid clinic and the other in a chronic renal insufficiency clinic.

WebCT® has previously been used by nurses for on-line focus groups in Australia.<sup>51</sup> We worked closely with the Information Technology Services department at the University of Saskatchewan to create an on-line focus group website through WebCT® for the study.

In addition, I completed a WebCT® orientation workshop offered by the Information Technology Services department to gain a better understanding of the software – particularly designing a website and moderating an on-line discussion. The WebCT® website for the study was designed to be an asynchronous, closed site, multithreaded discussion board. Participants required University of Saskatchewan network services identification (NSID) numbers and passwords to log into the website. Some of the participants, as alumni, already had NSID and passwords, however, those who did not were provided with a user account for the project.

The on-line focus group questions, instructions for using WebCT® and the WebCT® website were pre-tested for one week in July, 2006. Eight were asked to participate in the pre-testing, which included two of the researchers, two committee members with qualitative backgrounds, a College of Pharmacy & Nutrition faculty member who specializes in survey and questionnaire design, a primary health care pharmacist and two graduate students. A friendly e-mail reminder was sent mid-week to the eight pre-testers. Unfortunately, the two graduate students did not assist with the pre-testing (one had technical difficulties and the other had no time), but valuable feedback for the wording of the focus group questions was obtained from the rest of the participants.

Prior to executing the on-line focus group with the pharmacist experts, each participant received an information package. The contents of the package included the consent form; background information on the Student Health Centre – such as team structure, patient demographics, the types of services offered and their utilization, and the needs of the patient population; instructions for using the on-line focus group website; the focus group questions for discussion; and background information on the research project (see Appendix III). The purpose of providing participants with this information was to enable them to contribute to the focus group from an assumed baseline knowledge.<sup>68</sup>

The on-line focus group with the pharmacists ran for the first three weeks in September, 2006. I initially posted a few questions for discussion, and posted additional questions at the beginning of the second week to encourage further dialogue. For the final week, a summary of the focus group discussion was posted, and the participants were asked to verify the summary was accurate and complete. Refer to Appendix IV for a list of the focus group questions and posting schedule. All focus group questions for the study were

formulated using the question categories recommended by Richard Krueger. Participants were asked to log onto the website at least once a week. Discussions between the participants were automatically saved and were available to view throughout the entire focus group duration. Subjects were also informed that an activity log was kept to assess how many times each participant logged onto the website, which could also serve as a means of identifying passive members and to encourage them to participate to a greater extent. 51, 52, 54, 56

To facilitate the discussion, I served as the moderator and logged onto the website at least once a day. During this time, I strived to maintain the discussion and keep it focused. As such, I posted additional questions or comments to clarify participant responses or probe deeper into a subject. Participants were asked to refrain from composing their own separate messages; however, some of the pharmacists asked specific individuals questions pertaining to their primary health or ambulatory care practice. As moderator, I felt that the questions were relevant and allowed them, with the hopes that the participants would not only contribute to the process, but also learn from each other as well.

Friendly reminder e-mails were sent to the participants once a week to encourage them to continue reading responses and posting replies. Each participant contributed to the discussion at least once a week. Some logged on more than one weekly, to either finish posting their responses or to comment on/add to other participants' statements. Overall the pharmacists were motivated to assist with this stage of our study. In fact, two participants emailed me after the on-line focus group was completed to provide me with further guidance on our project.

Participants had all three of the researchers' e-mail addresses and office phone numbers, in case of they had any questions. In addition, each were provided with the University of Saskatchewan's computer help-line contact information, in case of technical problems with the on-line software. <sup>51, 52, 56</sup> Upon completion of the focus group, the participants received a \$50 honorarium to partially compensate them for their time.

Thematic coding occurs when researchers abstract general ideas or common threads from data.<sup>47</sup> This was the method of analysis that was implemented to evaluate the data collected from the on-line focus groups. Analysis began as soon as data were generated by the participants, and continued throughout the three week period.<sup>47</sup> Themes and ideas that

surfaced during the focus group were used to create a list of possible clinical pharmacy activities to be implemented at the Student Health Centre. Both Dr. Neubauer and I conducted the thematic coding - first independently and then together we discussed the findings, to ensure we were in agreement. Computer word documents were used to sort, categorize and rearrange statements.

## 3.5.5 Look: Use the on-line focus group data to define and describe the situation

Approximately halfway through September, 2006, a meeting with the Student Health Centre staff was organized to formally introduce the project. An overview of the study was provided via a PowerPoint presentation and each staff member was given a copy of the PowerPoint presentation slides, as well as the project plan (see Appendix V). The staff was made aware I would be one of the researchers involved in the study, while also serving as their clinical pharmacist. The inclusion criteria to participate in the study were discussed with the staff, and were as follows:

- 1) willing to participate in a discussion with other staff members and the researchers to define and tailor the role of a clinical pharmacist for the Student Health Centre;
- 2) willing to participate in a staff meeting at the end of November, 2006, to discuss how the role of the pharmacist had been implemented to date and provide recommendations for the remaining month;
- 3) willing to participate in a focus group after the clinical pharmacist had provided two months of service to discuss their experience; and
- 4) employed at the Student Health Centre between September, 2006 to January, 2007 Ideally, staff members would participate in all three sessions all meetings and the focus group discussion. Consent forms were distributed to those in attendance. Copies of the signed consent forms were returned to the staff members the same day. For staff members who could not attend the meeting, copies of the PowerPoint presentation, project plan and consent form, were left in their mailboxes at the Student Health Centre, along with a cover letter (see Appendix VI).

Once we had completed the data analysis of the on-line focus group discussion with the primary health and ambulatory care pharmacists, a second meeting was held with the Student Health Centre staff. During this time, a list of possible clinical pharmacy activities, generated by the expert panel was presented to the primary health care team (see Appendix VII).

## 3.5.6 Think: Explore, analyze and interpret on-line focus group findings

Together, we reflected with the staff on possible clinical pharmacy activities. The staff had the opportunity to comment on the pharmacist focus group findings and explore how the activities could complement the Centre's current services. Preliminary discussion regarding a process of referring patients to me, their pharmacist, also took place.

Prior to the second meeting with the staff, we decided to schedule an additional meeting with the team. It was our belief that since a clinical pharmacist had never been integrated into the team before, it would be beneficial for the team members to have a longer reflection period on the list of possible clinical pharmacy activities. During this reflection time, the staff was encouraged to mentally fuse the focus group findings with their patient interactions to identify areas where a pharmacist's expertise would be valuable.

This additional meeting took place at the end of October, which provided us and the staff with an opportunity to finalize my role as clinical pharmacist and further discuss the logistics of adding me to their team. It was agreed upon that I would initially focus on three therapeutic areas: mental health, asthma, and contraception; however I would also assist in the care of any patient at the request of individual team members. Answering drug information questions and providing patient medication histories were also identified as part of my role. Project ideas included expanding and updating the Contraception Counselling program information for the staff; investigating last minute travel concerns, medication use in athletes, appropriate antibiotic use, herbal therapy as well as concurrent medication and alcohol consumption. In terms of logistics, we decided that patients could be referred to me on a walk-in and appointment basis. It was also determined that an appointment book would be kept with the receptionists in the front office to block off one-hour time slots with the referred patients.

After the meeting, I sent a memo out to the entire staff, summarizing what we resolved during the discussion (see Appendix VIII). I created a *Pharmacist Referral* form (see Appendix IX), which was also delivered to the staff that afternoon as they were encouraged to start referring patients to me at their earliest convenience. The form was to be filled out

by a staff member and then given to the patient, who would subsequently take it to the receptionists to book the appointment. I also developed a *Patient Documentation* form to record pertinent patient information for my own files (see Appendix X).

## 3.6 Phase II: Implementing the Proposed Role of the Clinical Pharmacist

## 3.6.1 Act: Implementation

I provided two months of full-time clinical pharmacy services at the Student Health Centre for the months of November and December, 2006. During this "Act" stage of the action research cycle, the first month of clinical services was conducted. It is important to note that the amount of time I invested into the Student Health Centre, as their clinical pharmacist, was approximately forty hours per week. We wanted to ensure the hours devoted to the Centre reflected a full-time position to help assess whether full-time or part-time pharmacy services were required for and desired by the primary health care team. In addition, controlling the time I spent working with/for the team decreased the risk of me dedicating additional hours to the project since I was the researcher and pharmacist.

## 3.6.2 Look: Gather information to define and describe the situation

During the first month of providing clinical services, I documented all clinical activities and interactions with staff members and patients. The time required to complete each task was also tracked. In addition, I kept a reflexive diary to fully capture my experiences.

## 3.6.2.1 Projects

Knowing that it would take time for the staff to adapt to having a clinical pharmacist on site and start referring patients, I immediately began working on projects to make the best use of my time. I wanted to start establishing credibility with the staff, and felt that the projects would help with this transition. My goal was to use a team approach, and I therefore consulted with several team members with each initiative I undertook.

For each activity, I would start by gathering input from individual team members who had a vested interest in the project at hand. During this time, I also investigated what the current practice was for dealing with the issue, within the Centre. To use time efficiently,

both mine and the team members, I would approach only one staff member with my initial draft, to obtain feedback on the content, logistics and feasibility of what I developed. This team member was usually the senior physician or the person who initially requested the specific project. I selected the senior physician as my primary contact for most scenarios, as he was one of the two full-time physicians at the Centre, and was responsible for overseeing the clinical responsibilities of the staff. The team members who I originally gathered input from were subsequently approached for their thoughts on what I had created, and revisions were made until a final draft was agreed upon.

#### 3.6.2.1.1 Antibiotics

When we met with the staff during Phase I, to define my role, we had discussed the possibility of adding antibiotics to my list of clinical activities. Suggestions that surfaced included assessing the appropriateness of prescribed agents, following up with patients to see if their symptoms were resolving, and developing an antibiogram. Shortly after I started at the Student Health Centre, I started exploring these ideas to further investigate a potential role for a pharmacist.

### Antibiogram

An antibiogram is a tool for guiding empiric antibiotic therapy based on the local sensitivity patterns of bacteria to different antibiotics. My co-supervisors and I felt that an antibiogram would be a good starting place. The project would be relatively easy and was something we were sure the team would find valuable, thus aiding with establishing my credibility. I met with a faculty member from the College of Pharmacy & Nutrition, Dr. Yvonne Shevchuk, who specializes in infectious diseases. She agreed that an antibiogram was a good project for me to work on, but through further discussion, it became evident that the project would not be as easy as we originally thought.

The biggest barrier to creating an antibiogram was getting the local laboratory on board with the project. The bulk of the work, i.e. collating the data, would fall onto the shoulders of the laboratory department. Dr. Shevchuk had provided me with a name and phone number for a contact person, and helped generate a list of questions for me to ask. First off, there is more than one medical laboratory in the city of Saskatoon, and I was not

sure if all of the isolates from the Student Health Centre went to the main department, located in the Royal University Hospital. If isolates were sent to various laboratories, it would complicate the process, possibly making the project impractical. Secondly, we needed to know whether or not the laboratory was able to extract the Student Health Centre data from all of the Royal University Hospital results. One of the benefits of having an antibiogram is the assurance that the sensitivity rates are specific to the patient population. A few other questions included how many years of isolates was the laboratory able to provide us with, along with the number of isolates for each bacterial species. And lastly, I needed to know what timeframe we were working with, as I was only going to be at the Student Health Centre for two months. Unfortunately, none of my e-mails or phone calls to the contact person at the laboratory were returned. As such, I could not go ahead with the antibiogram project.

# Antibiotic Management Form

Despite not being able to create an antibiogram, I decided to continue exploring another potential role with antibiotics. I conducted a literature search to see if there were any published articles describing the role of a pharmacist in an ambulatory care setting with regards to antibiotic management. Unfortunately, at the time, there were no such articles available. I developed a draft form in which I would review culture and sensitivity reports when they arrived. The goal was to save time for the physicians/nurse practitioner, create a clinical role for myself and help establish credibility with the staff.

I met with the senior physician to brainstorm a possible protocol and discuss the draft form that I created. Initially, we thought that I would review all culture and sensitivity reports, as that would be easiest for the front office staff and decrease the workload for the physicians/nurse practitioner. We discussed several scenarios, which were dependent on the results of the reports, and are as follows:

- 1) The culture and sensitivity report comes back stating there was no significant growth (i.e. not a bacterial infection). The patient's chart is pulled to see if a prescription was given when the specimen was taken.
  - a. If a prescription was provided, whether or not action was needed depended on the duration of therapy. If it was a short course of therapy for example,

three days of sulfamethoxazole/trimethoprim for a urinary tract infection, no action was required as typically the patient would be finished the antibiotic before the laboratory results were available. For longer courses of therapy, a phone call to the patient was required to inform them to discontinue the antibiotic.

- b. If no prescription was provided, the culture and sensitivity report was signed indicating that it was reviewed, and placed in the patient's chart.
- 2) The culture and sensitivity report returns showing significant growth. Again, the patient's chart is pulled to see what occurred during the appointment.
  - a. If no prescription was provided, then a prescription would need to be written, the patient informed and the prescription faxed to the patient's pharmacy.
  - b. If a prescription was provided during the initial patient visit, and was appropriate based on the culture and sensitivity report, no further action was required other then signing the report and placing it in the patient's chart.
  - c. If a prescription was provided, but the culture and sensitivity shows that the bacteria were resistant to the empiric therapy, an alternative medication may need to be prescribed and the patient contacted.

The senior physician agreed that I could responsible for orchestrating all of the above, except for the last scenario. He acknowledged that a pharmacist was capable of recommending an alternative antibiotic when a bacterial species is resistant to empiric therapy. However after further discussion, we both were concerned that adding a pharmacist to the process may complicate things and result in additional phone calls to the patients. In order for me to be able to make a sound recommendation, I would need to call the patient to assess allergies, identify previous courses of antibiotics and investigate any change in symptoms. The senior physician felt that the physicians/nurse practitioner would still want to contact the patients as well, to assess whether or not antibiotic therapy was even required, since some bacterial infections spontaneously resolve. Therefore, we abandoned the idea of a protocol and the draft form.

#### 3.6.2.1.2 Mental Health

### Antidepressant Counselling

Back in 2004, the Student Health Centre developed a contraception counselling program based on the results of two needs assessments they conducted, as well as the high volume of patients they see who desire contraception. To ensure the patients receive comprehensive care and to assist with the documentation between nurses and physicians/nurse practitioner, a *Patient History Contraception* form was developed. The form outlines all the required information to gather from the patient, along with a list of items which should be discussed during the medical appointment.

Expanding on this concept, I decided to create a similar form that I could use when counselling patients suffering from depression. My primary intent was to offer a comprehensive outline of what a pharmacist-patient interaction could consist of. This in turn would hopefully alleviate some of the staff's concerns surrounding the unknown capabilities of a clinical pharmacist. Prior to starting the project, I had preliminary discussions with the senior physician and a few of the nurses, and they agreed it was a good idea. I then proceeded to conduct a literature review, particularly focusing on pharmacists' roles when counselling depressed patients and the management of antidepressant side effects. Literature was also sought to help tailor the information to the patient population – i.e. university students. For example, the effects of binge drinking while on antidepressants. Some of this information was difficult to track down, and I therefore sought the advice of one of my co-supervisors, Dr. Alfred Rémillard, who specializes in mental health. He was able to provide me with the required information – both in the form of articles and his experience as a clinical pharmacist practicing in the area.

My initial draft consisted of two appointments, at minimum, with the patients – an initial visit in close proximity to when an antidepressant was prescribed or changed, preceded by a follow-up visit to assess compliance, presence and severity of side effects, and to address any questions the patient may have (see Appendix XI). Once my first draft was ready, I consulted with Dr. Rémillard again to obtain his feedback on my proposed outline. With his approval, I felt prepared to present the Student Health Centre team with the idea.

The senior physician was the first team member I met with to discuss this first draft. He liked the format and content of the template, but had very valid questions regarding the logistics of me providing this care. As such, he suggested that we discuss it with the rest of the staff during the next staff meeting. In the meantime, he had given me permission to use the format while seeing his patients. To help the staff prepare for the meeting, I circulated copies of the draft to all of the physicians, psychiatrists, nurse practitioner, nurses, social worker, dietitian, health education coordinator, and front office staff.

During the meeting, one of the other physicians expressed his concern that I was getting into the 'therapeutics' of depression, and felt that I should only focus on adherence and side effects. Another physician was worried about the duplication of services. Those in favour of the original outline argued that I was providing supplemental care and it would be beneficial for the patients to hear the same message more than once. In the end, we compromised and I collapsed the two pharmacist visits into one – concentrating on assessment of adherence and side effect management (see Appendix XII). I had also developed a patient information handout on managing side effects along with the first draft of the counselling form, and its use was approved by the staff (see Appendix XIII).

As for logistics, it was agreed upon that I would see referred patients approximately one week after they started an antidepressant. Whether a patient was referred to me or not, was left to the discretion of the physician/nurse practitioner and willingness of the patient. After I had seen a patient, the *Antidepressant Counselling* form was completed and placed in the patient's chart, along with additional documentation in the progress notes that I saw the patient.

# Antipsychotics and Metabolic Syndrome

In addition to counselling patients on antidepressants, one of the psychiatrists suggested that I could be a resource for both the staff and patients regarding atypical antipsychotic medications and metabolic syndrome. These agents have been linked to the metabolic risk factors that are associated with the syndrome, such as abdominal obesity, changes in cholesterol and the body's response to insulin, as well as elevations in blood pressure. I agreed that a pharmacist could assist with the monitoring of these changes, and make recommendations for the prevention and treatment of metabolic syndrome. Unfortunately, because of the time constraints of the study, no patients on atypical antipsychotics were referred to me.

# 3.6.2.1.3 Last-Minute Travel Health Information Package

The staff had requested information on travel health, particularly for patients who seek medical advice in close proximity to departure of their trip. It was clearly laid out that the staff did not want to replace or compete with Public Health's International Travel Centre. However, they desired information that would allow them to be better prepared for seeing patients who could not afford, did not have time, or refused to visit the Travel Centre.

I began by sending out an e-mail to the primary care physicians and nurse practitioner to gather ideas for a *Last-Minute Travel Health Information Package*. In addition, I had conversations with the nursing staff to obtain their input on the subject. I took into account all of their suggestions, and added some topics I discovered while investigating the subject and felt would be beneficial. Topics included:

- Malaria prophylaxis
- Last-minute hepatitis vaccinations
- Prevention and treatment of Traveler's Diarrhea
- Economy Class Syndrome (travel-induced thrombosis)
- Recommended over-the-counter medications for travel
- Traveling with medication
- Drug-induced photosensitivity
- High-altitude sickness
- Reputable resources for additional travel health information

Gathering ideas and some preliminary investigation was as far as I got during this "Look" stage of the action research cycle.

#### 3.6.2.1.4 Asthma

The key areas I wanted to focus on for asthma included proper device technique; assessment of drug therapy in terms of efficacy, presence of side effects and patient compliance; and education on differences between medications (e.g. preventer versus reliever), signs that asthma is not controlled and alert symptoms of an asthma attack. I gathered several patient education tools to assist in the delivery of the above information. This included obtaining copies of Health Quality Council's *Asthma Action Plan*; the *30 Second Asthma Test*<sup>TM</sup>; placebo devices of an inhaler, turbuhaler, and diskus; and patient

information sheets demonstrating proper device technique. Because the Student Health Centre provides health services to many international students, I ensured that the information sheets on device techniques included pictures to facilitate a patient's learning process.

# 3.6.2.1.5 Pharmaceutical Information Program

The Pharmaceutical Information Program (PIP) provides authorized health care professionals access to Saskatchewan patient medication records. Prior to me joining the team, the Student Health Centre was not registered with PIP. I had introduced the program to the staff during a meeting, and met with the manager separately to provide additional information. Shortly thereafter, the Centre became a registered site. A few of the physicians, along with myself, were granted approval to access the records. This allowed us to view both current and previous medications histories, identify all of a patient's physicians/nurse practitioners and community pharmacies, assess compliance, and check on exception drug status.

# 3.6.2.2 Drug Information

# 3.6.2.2.1 Contraception

Alesse® and Triphasil® Shortage

Approximately one week after I started at the Student Health Centre, there was a national supply shortage of two oral contraceptives – Alesse® and Triphasil®. Both products are manufactured by the same pharmaceutical company, and problems within the manufacturing plant resulted in the shortage. I contacted the drug company and a few community pharmacies in Saskatoon to assess the situation. The company could not provide an expected date for when new stock would be available. As such, I sent out an e-mail to the entire staff explaining the above, as well as providing a list of alternative oral contraceptives which could be used in the meantime (see Appendix XIV). Prior to sending the e-mail, I discussed what I had prepared with one of the physicians, to ensure all of the information was applicable to the Centre.

# Evra® Transdermal Contraceptive Patch and Risk of Thrombosis

On Thursday, November 23<sup>rd</sup>, 2006, Health Canada released a notice regarding new safety information for the transdermal contraceptive patch, Evra®, and the risk of thrombosis. I reviewed the preliminary, but conflicting studies this new warning was based on, and summarized the information in an e-mail I sent to the primary health care physicians, nurse practitioner and nursing staff. In addition, I included a few statements to keep the warning in perspective, which would hopefully assist the staff in dealing with any questions they may receive from patients currently on Evra® (see Appendix XV). I had showed the senior physician the e-mail before I sent it out, again to guarantee that the information was tailored specifically for the Centre.

# 3.6.2.3 Drug Information Questions

I received a variety of drug information questions, ranging from patient specific scenarios to personal inquires from individual staff members. Depending on the question, I either gave an immediate verbal answer or a written response citing evidence to support my reply. Below is a list of the twenty questions I was asked, broken down into categories.

#### Therapeutic Options:

- 1) What other medications could be used to treat *Clostridium difficile* in a patient currently being treated with Flagyl® (metronidazole), but vomits after each dose?
- 2) What 'as needed' medications can be used to treat diarrhea-predominate irritable bowel syndrome and the associated cramping?
- 3) What kind of iron supplement should a patient take?

# Safety and Efficacy of Medications:

- 4) Why is an allergy to gentamic listed as a contraindication to the flu vaccine?
- 5) What are the safety concerns with energy drinks, like Red Bull®?
- 6) Can the hepatitis A vaccine, Vaqta®, be given to a patient with an egg allergy?
- 7) Does Nexium® (esomeprazole) become inactivated if chewed, as a patient who cannot swallow the delayed release tablet is still suffering from gastro esophageal reflux symptoms?

8) Can ciprofloxacin be safely used to treat a urinary tract infection in a patient with an eating disorder and allergies to penicillin and sulfa drugs? Will the medication be absorbed if she vomits the medication?

# Availability of Medications:

- 9) Does Ovol® (simethicone) come in a pediatric formulation?
- 10) Are immediate release propanolol 10mg tablets still available?
- 11) What combination topical steroid and antifungal agents are currently on the market?

# Drug Identification/Indication:

- 12) Can you tell me what two medications a patient is currently taken, but has mispronounced the drug name and it is unclear as to what she is on?
- 13) What is metocloperamide and what is it used for?

# Drug Coverage/Regulation:

- 14) Is Imovane® (zopiclone) included in the new prescription review program?
- 15) Is Wellbutrin® (bupropion) covered by the Saskatchewan Drug Plan?

#### General Resource:

- 16) What are good references for herbal medications?
- 17) What do you think of the new Human Papillomavirus vaccine?

#### Personal Use:

- 18) Are bioidentical hormones better than conventional hormone replacement therapy?
- 19) What are the goals for cholesterol levels?
- 20) Is it okay to take both Advil® (ibuprofen) and Tylenol® (acetaminophen) for severe muscle spasms?

#### 3.6.2.4 Direct Patient Care Interactions

I met with fourteen patients during the month of November. Taking into account both the initial visits and all follow-up appointments, I had twenty-two interactions with patients.

Two additional patients were referred to me, but unfortunately, they did not show up for their appointments. For each patient I saw, I documented the exchange in the patient's chart and, whenever possible, provided the team member who referred the patient to me with a verbal report of what transpired.

A summary of the patient interactions, sorted by the primary reason for the referral, are as follows:

#### Over-the-Counter Product Selection

1) Suggested a non-prescription product for a patient complaining of nasal congestion and a cough due to post-nasal drip.

#### Gastrointestinal Disorders

- 2) Counselled a patient suffering from an ulcerative colitis relapse on a new prescription for prednisone. Discussed the benefits and side effects of prednisone, recommended to avoid non-steroidal anti-inflammatory agents, and discussed the importance of getting adequate calcium and vitamin D while on a corticosteroid. Suggested a change in therapy to the physician discontinue Cortenema® (hydrocortisone) and increase the dose of prednisone, which was accepted.
- 3) Discussed the benefits of starting Paxil® (paroxetine) for the treatment of irritable bowel syndrome and comorbid social phobia, in addition to providing education on primary prevention for cardiovascular events.
- 4) Compared antidepressants to antispasmodics as therapeutic options for the treatment of pain associated with irritable bowel syndrome.

#### Travel Health

5) Reviewed malaria prophylaxis; recommended vaccinations and over the counter medications for traveling; how to prevent Traveler's Diarrhea; reputable websites for travel health information; guidelines for traveling with medications and travel health insurance with two patients heading to Mexico – one visiting the Mayan Riviera and the other heading to Puerto Vallarta.

# Depression

- 6) Followed the *Antidepressant Counselling* form while counselling a patient on starting Celexa® (citalopram).
- 7) Reviewed Celexa® (citalopram), using the *Antidepressant Counselling* form as a guide, with a patient who had previously been on the medication. The patient had concerns regarding her history of weight gain while on antidepressants and inquired about using herbal weight loss drugs. I warned her of the lack of safety and efficacy with these products, and encouraged her to try lifestyle changes instead (e.g. diet, exercise). This patient already had a referral to the Centre's dietitian.
- 8) Received a phone call from a patient who was concerned about possible antidepressant side-effects. Her complaints appeared to be a mixture of side effects and symptoms of depression. The patient admitted to having suicidal thoughts, and I therefore transferred her onto a physician to address the urgent matter.

#### Chronic Disease Management

- 9) Met with a patient who suffers from depression, hypertension, diabetes, and asthma over three appointments: 1) medication review, assessment of compliance and education on primary prevention for cardiovascular events; 2) review of herbal medications and supplements the patient was previously taking; and 3) recommendations for treating insomnia and constipation.
- 10) Demonstrated how to properly use Pulmicort® (budesonide) and Bricanyl® (terbutaline) inhalers to an asthmatic patient. I also discussed with her the role of each inhaler, the signs of uncontrolled asthma and how to identify an asthma attack.

#### Abnormal Laboratory Results

11) Investigated probable drug-induced hepatotoxicity for a patient who was on Effexor XR® (venlafaxine) and Nexium® (esomeprazole), and had a recent course of Zantac® (ranitidine). I found case reports of elevated liver enzymes that were suspected to be caused by Effexor XR® (venlafaxine). I assisted in the management and monitoring of the patient, and submitted an *Adverse Drug Reaction* form to Health Canada.

- 12) Researched a possible herbal-laboratory interaction for a patient with an elevated vitamin B12 level who was taking several homeopathic medications. Laboratory values returned to normal shortly after the homeopathic mixtures were discontinued. I sent another *Adverse Drug Reaction* form to Health Canada. Overall, I met with the patient for a total of three visits: 1) to gather patient specific information, timelines and a list of the homeopathic agents; 2) to review the information I obtained regarding the possible herbal-laboratory interaction; and 3) to encourage her to take an antibiotic for a urinary tract infection.
- 13) Explored another case of hepatotoxicity potentially linked to herbal products. The patient was taking five different types of herbals, one of which was L-Theanine the major amino acid found in green tea. Green tea has been linked to hepatotoxicity, which may have caused the elevated liver enzymes alone, or in combination with the other products. Again, an *Adverse Drug Reaction* form was submitted. I met with this patient twice. The first visit was regarding his elevated liver enzymes, and the second appointment was to discuss therapeutic options for essential tremor.

# Contraception

14) Counselled a patient who was requesting her third dose of emergency contraception due to non-compliance with her oral contraceptive. I focused on compliance, birth control options, continuous versus cyclical oral contraceptive regimens and the use of multiple emergency contraception doses.

In the first month, I estimated that I spent approximately 55% of my time working on projects, 30% on direct patient care, and 15% answering drug information questions.

# 3.6.3 Think: Explore and analyze as a team

At the end of the first month of clinical service, another meeting was held with the Student Health Centre staff. During this session, I presented a summary to the team of all the clinical activities that had been implemented thus far. In addition, the staff was asked to provide feedback on the pharmacy services that I provided. This allowed the staff and I to reflect on how the project had been received to date.

With action research being a collaborative process, I decided that I would personally obtain the staff's opinions on what I had accomplished thus far, as all key players should be incorporated in the search of solutions to issues, rather than having a third party involved. I had already been working with the team, receiving their comments on what I had developed, throughout the month of November. I also felt that my presence would be needed in case further explanation was required for the summary of activities. In addition, I had worked with the team each step of the way, starting from the initiation of the study. I wanted to maintain that team approach, and felt that I should be involved in any discussion regarding my role. As health care professionals, I felt confident that, as a team, we could discuss any issues in an open and professional manner.

# 3.6.4 Act: Evaluate, plan & implement second month

Originally, my co-supervisors and I were to evaluate the findings from the staff meeting and modify the clinical services based on the team's recommendations. However, the team provided positive feedback on the study and had no suggestions for change. I, therefore, did not alter my role and continued with the responsibilities I had achieved thus far.

# 3.6.5 Look: Gather information to define and describe the situation

During the month of December, I documented all of the clinical activities and interactions in the same manner as I did throughout November.

# 3.6.5.1 Projects

# 3.6.5.1.1 Suppressive Therapy for Genital Herpes Simplex Virus

A discussion surrounding suppressive therapy for genital herpes simplex virus and the recently released Canadian Guidelines on Sexually Transmitted Infections took place during one the staff meetings. The guidelines stated that safety and efficacy data for two of the antiviral agents - acyclovir and valacyclovir, had only been established for up to one year of therapy, and only up to four months of administration with famciclovir. The team expressed their frustration, as the duration of suppressive therapy is often beyond these timeframes. In addition, they admitted to struggling with their patient's inquiries of how safe extended antiviral therapy is.

I was asked by one of the team members if I knew what the side effects were with chronic antiviral treatment. I could not provide an immediate answer, but jumped at the opportunity to offer another example of how a pharmacist could add value to a health care team. Subsequently, I volunteered to conduct a literature review assessing the long-term safety of antiviral agents when used as suppressive therapy to treat genital herpes simplex virus.

My review included the recommendations published in both the Canadian and American treatment guidelines for sexually transmitted infections, as well as safety data from the longest antiviral trials I could retrieve – ten years for acyclovir, and one year for both valacyclovir and famciclovir. The senior physician reviewed and approved my first draft, which was then sent out to the remaining primary health care physicians and nurse practitioner for their input.

While conducting the literature review, I noticed a discrepancy with the duration of one of the famciclovir trials referenced in the 2006 Canadian Guidelines on Sexually Transmitted Infections. The trial was conducted over a period of 52 weeks, however as mentioned earlier, the guidelines stated that no safety and efficacy data was available beyond four months of administration. I sent an e-mail to the Public Health Agency of Canada, who published the guidelines, asking for clarification. My e-mail was returned stating that the duration was printed in error and an erratum would be posted on their website. I forwarded the e-mail to the Student Health Centre to inform them of this change. The erratum appeared on the website this past spring. Despite the fact that I was no longer providing services at the Centre, once the erratum was available, I updated the original document, printed off copies of the erratum and distributed the revised version to the primary health care physicians and nurse practitioner (see Appendix XVI).

# 3.6.5.1.2 Last-Minute Travel Health Information Package

During the month of December, I continued to search for and review literature on the travel health topics to be included in the *Last-Minute Travel Health Information Package*. In addition to the documents I prepared for the staff, I added three information sheets specifically for patients which focused on Traveller's Diarrhea, Economy Class Syndrome and recommended over-the-counter medications for travel. I asked the senior physician to

review the initial draft first. After I made his suggested revisions, I then gave copies to the remaining primary health care physicians and nurse practitioner for their feedback.

The final document was 24-pages, and I wanted to present the information to them in a manner that was practical and could be easily updated. I therefore assembled the package in a thin binder, one for each physician/nurse practitioner, and placed several copies of the patient information sheets in clear plastic binder inserts. A Public Health International Travel Centre business card was also attached to the first page of the document (see Appendix XVII).

# 3.6.5.1.3 Contraception Counselling Program

Since the Student Health Centre already had a Contraception Counselling Program in place, my suggested role was primarily to update and expand the information for the staff. I talked to the nursing staff to obtain ideas for changing their existing resources. They were able to provide me with a wealth of suggestions, however due to time constraints of being at the Centre for a total of only two months; I decided to focus on the topics related specifically to pharmacy. I, therefore, elected to update their information sheets on drug interactions. Their present documents included medications that had since been withdrawn from the market (e.g. clofibrate) and did not contain information on oral contraceptives that had been recently introduced (e.g. Yasmin®).

I created three separate documents on oral contraceptive drug interactions. The first handout included a list of medications, categorized by drug class, whose drug concentrations are altered by oral contraceptives, a description of the effect and recommendations for dealing with the interaction. The second information sheet was similar in terms of content, but outlined drugs that may affect oral contraceptives drug concentrations. The third, and final, section focused solely on the oral contraceptive, Yasmin®, due to the medication's unique pharmacology. The mechanisms, as well as recommendations for both monitoring and managing the interactions were summarized.

Unfortunately, it was near the end of December when I had a draft ready to circulate to the staff. I provided copies of the documents to the nurse practitioner and one of the registered nurses. Since my time at the Student Health Centre was drawing to an end, I was unable to receive their feedback on the information I put together. However, these files,

along with all other projects I created, were saved on a shared computer folder through their network. As such, the staff could access, alter and update any of the documents I developed.

#### 3.6.5.1.4 Antibiotics

### Cross-Reactivity of Antibiotics

Shortly after the mid-point meeting with the staff, the nurse practitioner identified an antibiotic project for me when she reflected back to the summary I presented. She requested information on the cross-reactivity of sulfa antibiotics to assist her in providing care to patients with these allergies. Based on my experience as a hospital pharmacist, I knew that concerns regarding the cross-reactivity between beta-lactam antibiotics are also relatively common, and therefore I decided to include penicillin and cephalosporin antibiotics.

The document I created included a list of questions to help assess if a reaction is a true allergic reaction, the incidence of allergies to the chosen antibiotics, the types of allergic reactions, and recommendations for handling cross-reactivity concerns. Once my first draft was approved by the nurse practitioner, I distributed copies to the rest of the primary health care physicians for their input and subsequently a final version was circulated (see Appendix XVIII).

# 3.6.5.1.5 Sports Medicine

Developing a role in sports medicine was suggested by a physician during one of the September meetings. The physician provided me with the contact information for the Huskie Athletics' head physical therapist. Due to her busy schedule, we were not able to meet until December. At that time, the majority of the athletes were focusing on final exams and then heading home for the holidays. As such, she was able to provide me with several examples of how a pharmacist could collaborate with the sports department, but we were unable to implement any of the suggestions. The following is a list of the examples she provided me:

1) Provide drug information consults – e.g. can athletes take their prescribed medications; how much of a substance can be safely taken; how long will a

- medication stay in their system; if a medication is prohibited, what permitted substance can be substituted.
- 2) Hold in-services for the athletes e.g. asthma education.
- 3) Assist with the paper work for any appeals process when the use of a medication is declined by the Canadian Centre for Ethics in Sport e.g. explaining why a patient needs Ritalin® (methylphenidate) and why using another agent is not an option.
- 4) Review the doctor's kit for sports games to see if anything else should be included.
- 5) Conduct a literature review for efficacy of topical anti-inflammatory agents.
- 6) Answer questions on the safety and efficacy of supplements, as well as checking whether a substance in question has been authorized for use.

# 3.6.5.2 Drug Information

### Aerochamber Insurance Coverage

While counselling a patient on the proper use of an aerochamber, the issue of cost came up. I knew that aerochambers are costly, but was unsure if the health insurance through the University of Saskatchewan Students' Union Health and Dental Plan would cover the expense of the device. I called the insurance plan, but they could not provide me with an answer right away. I had talked to a few of the team members, and they were unsure themselves. Within a week, I had received an e-mail from the insurance plan informing me that the cost of an aerochamber is covered. I forwarded the e-mail to all of the physicians and nurse practitioner to ensure they were aware of the available coverage.

#### Information on Salvia (Legal Hallucinogen)

During one of the last staff meetings I had with the staff, they discussed an article on a legal hallucinogen – Salvia, which made the front page of the Star Phoenix. The team members were concerned about the use of this agent in their specific patient population, and asked if I had any information on it. I could not answer their question immediately, but promised that I would look into it for them. After gathering the information needed to answer their questions, I sent out an email to all of the staff, attached a link to the article for those who had not attended the meeting and a document summarizing what I had found. In addition, I posted the information and article in their staff lunch room.

# 3.6.5.3 Drug Information Questions

The staff had asked me a total of eleven drug information questions during the month of December. A summary of the questions, categorized by topic, is as follows:

# Safety and Efficacy of Medications:

- 1) Can inhaled corticosteroids be used during lactation?
- 2) Can a hepatitis C positive patient take doxycycline for malaria prophylaxis?
- 3) A patient who is taking lithium ran out of refills and her regular doctor is not in today. All of the other physicians are booked for the day. Does the patient need to be seen by a doctor today?
- 4) Can Effexor XR® (venlafaxine) capsules be opened and the contents divided to aid with tapering in a patient who is very sensitive to the medication?
- 5) Which medications interact with alcohol?
- 6) Does the drug interaction between antibiotics and hormonal contraception still occur if you select a non-oral route, like a transdermal patch?

# *Drug Coverage/Regulation:*

7) What are the exception drug status requirements for HP-PAC® (lansoprazole, amoxicillin, and clarithromycin seven day pack), and the process for getting the medication approved?

#### Personal Use:

- 8) What is a good muscle relaxant to take?
- 9) What is the best type of calcium supplement to take?
- 10) Are thyroid supplements interchangeable?
- 11) What antihistamine will not make me drowsy?

### 3.6.5.4 Direct Patient Care Interactions

During the month of December, I had eight new patients referred to me, and only one of whom I met with more than once. In addition, I saw one of the patients I originally met in November, for a follow-up appointment. As such, I had a total of ten direct patient care

encounters. I continued to document the patient visits and provide verbal reports to the referring team member whenever possible, as I did in the previous month.

The following is a summary of the patient interactions I had, sorted by primary reason for referral.

### Depression

- 1) Assessed compliance and the presence and severity of antidepressant side effects with three patients approximately one week after they initiated therapy, as per the *Antidepressant Counselling* form.
- 2) Discussed antidepressant therapy with two patients who requested additional information before they were willing to begin pharmacological treatment. One referral was from a physician, and the other from a clinical psychologist employed at Student Counselling Services.

#### Chronic Disease Management

- 3) Counselled a patient on salbutamol for exercise-induced asthma. I educated her on the purpose of the medication, the signs of uncontrolled asthma, how to identify an asthma attack, as well as proper inhaler and aerochamber technique. The patient belonged to Huskie Athletics, and I began the paperwork required for the prescription to be approved for therapeutic use i.e. the Canadian Centre for Ethics in Sport's *Abbreviated Therapeutic Use Exemption* Form.
- 4) Followed up with a patient I met with in November regarding asthma, at the request of her physician. I assessed the patient's compliance and comprehension of her respiratory disease. Further education was provided on topics as needed.

### Pain Management

5) Reviewed the therapeutic options for migraine prophylaxis with a patient who had not responded to first line therapy. At the patient's request, I focused primarily on efficacy and side effects. A second encounter with the patient was required to discuss additional information I had found for her.

6) Performed a pain management assessment on a patient suffering from uncontrolled pain. In addition, I educated her on proper use of pain medication and the management of side effects, such as drowsiness and constipation. The patient also inquired about the effects of combining alcohol with Tylenol #3® (acetaminophen and codeine) tablets, which I addressed.

As for the proportion of time spent on the clinical services during the month of December, I estimated that approximately 65% of my time was dedicated to projects, 20% to direct patient care activities, and 15% answering drug information questions.

# 3.7 Phase III: Evaluating & Prioritizing the Role of a Clinical Pharmacist

# 3.7. 1 Look: Gather information to define and describe the situation

Upon completion of the two month commitment at the Student Health Centre, focus groups were organized to collect information on how the staff and patients felt about their experiences with a clinical pharmacist. The objectives of the focus groups were to identify what went well, what did not and areas for improvement, surrounding the integration of a pharmacist into an already established primary health care team.

# 3.7.1.1 Focus Groups with the Primary Health care Team

My co-supervisors and I wanted to organize face-to-face focus groups with the Student Health Centre staff in close proximity to the completion of Phase II. We decided on using face-to-face focus groups instead of on-line focus groups primarily because the Student Health Center staff had approached the study as a team from the beginning. To hide their identities from each other for the final evaluation would seem contrived. With their teambased philosophy, I was confident that they would feel comfortable discussing the project in an open group setting.

I estimated that approximately sixteen staff members would participate, and therefore planned to divide the staff into two groups for the focus group discussions.

There were a total of twenty-eight staff members on the team; however several of them filled 0.5 positions – or less. I therefore had minimal interactions with some of the team members. In fact, there were a few employees that I did not have the opportunity to meet

over the two month period. Despite this, we sent invitations to participate in the focus groups to all of the employees, as they had received information on my project since our initial planning stages. My estimate of recruiting sixteen staff members was based on the number of people I had interacted with while providing clinical pharmacist services.

I met with the manager of the Student Health Centre, and she was willing to schedule the focus groups during times set aside for weekly meetings. She felt that the focus groups would have to be conducted during business hours, as the staff had too many personal commitments in the evenings and on weekends. She also could not afford to have the focus groups cut into clinical hours.

I worked closely with the office manager to reserve dates for the focus groups during the month of January. A number of the staff work on a part-time basis, and for that reason, we selected both Monday noon and Thursday morning meeting times to accommodate as many staff schedules as we could. I had originally targeted for two hour long focus group sessions, however staff meetings at the Centre are only allotted one hour. Therefore, the office manager set aside two Mondays for one focus group and two Thursdays for the other. I sent an e-mail to the entire staff inviting them to participate in the evaluation of my study. In the e-mail, I had listed the dates for the staff to choose from. I also asked for those team members who were interested to reply with their preference for either the Monday or Thursday sessions. I knew that some of the team members would be able to attend both days of the week, but wanted to create two groups with relatively the same number of participants and also ensure there was a mix of health care professionals per group.

To reduce bias, an external moderator was recruited to facilitate the focus groups as I was both a researcher and the intervener. The Primary Health care Director of the Saskatoon Health Region provided us with one of their staff members, in kind, to serve as the moderator. I met with the facilitator before the focus groups began to discuss the logistics and confirm dates. In addition, we reviewed the focus group questions for the staff and he offered valuable recommendations for modifying the format and phrasing of the questions. These suggestions were discussed with my committee and revisions made until a final list of focus group questions were agreed upon (see Appendix XIX).

The focus group discussions were conducted in Student Counselling Services' conference room on campus, as the Student Health Centre did not have the space to

comfortably accommodate the sessions. The focus group questions were written on a flip chart for the participants to follow along with. Tables and chairs were arranged ahead of time to create a welcoming and relaxed environment, and to be conducive for a group discussion. The discussions were tape recorded using two separate recorders and microphones. We recruited the Student Health Centre's office manager to attend each of the focus group sessions and record the order of speakers. The purpose of keeping such a record is to assist with the transcription of the tapes, in case the transcriber had any difficulty distinguishing voices. A \$50 honorarium was given to the office manager for her assistance.

A few of the focus group sessions had to be rescheduled for various reasons. The very first Monday session was interrupted by a fire alarm. The facilitator's schedule changed mid January, and the original date for the second Monday focus group was no longer an option. Therefore, two alternative dates were arranged and a total of three focus groups were required to provide the staff with ample time to discuss all of the questions. As for the Thursday group, the first session was scheduled for the day after a blizzard had occurred in the city. Only a small number of the team members were able to make it to campus that morning, and therefore the focus group was postponed for a later date. For the last focus group session with the Thursday group, the facilitator forgot about the appointment and did not show. I knew that the facilitator would be away for half of February, and therefore the final session could not be rescheduled until early March. The staff had been very patient with the rescheduling of so many sessions, but I was concerned about taking up too many of their meeting times, which they needed for other obligations as well. As such, I gave the staff the option of having one of them lead the focus group or to reschedule for another date. The team was willing to discuss the questions on their own, and one of them volunteered to moderate the discussion.

Since I had worked closely with the team for two months, there was a chance that I could recognize individual's voices on the focus group tapes. As such, we hired a transcriber to write out the recorded discussions for us. The transcriber was instructed to leave out the names of the participants, and instead assign numbers to each of the speakers. Before each of the focus groups, the facilitator reminded the staff of this, and assured them that I would be blinded to who made each comment. The participants were encouraged to

be as open and honest as possible when reflecting on their experience with having a pharmacist join their team.

Once the focus groups were completed, I delivered all of the cassette tapes to the transcriber, along with the lists that the office manager kept to record the order of speakers. After the tapes were transcribed, I prepared to have the participants verify the transcripts which would provide them with the opportunity to add, alter or delete any of their statements. As mentioned earlier, each staff member was represented as a number in the transcripts, to separate individual's statements yet preserve confidentiality. Participants may have had a different number for each of the focus groups they attended. In order to send the appropriate transcripts to each staff member, we needed to identify which number belonged to whom, as well as inform each individual of their corresponding number to the quotes. Since I was blinded to this information, we solicited the help from someone who was not directly involved in the study. This removed individual prepared a list of which transcripts should be delivered to each staff member. In addition, every participant received a sealed envelope containing their number(s) for each focus group(s) they were involved with, which was also created by this third party individual.

The focus group transcripts and sealed envelopes were sent to the participants, along with a letter explaining the transcript verification process (see Appendix XX). They were allotted a total of four weeks to review the transcripts and make changes. If they had any changes, we asked that they write the changes on the transcripts and return the documents, anonymously, to us. A friendly reminder e-mail was sent to the staff two weeks into the transcript verification period.

# 3.7.1.2 Collecting Data from the Patients

Primary health care encourages patients to take more responsible for their health and become active members on their own health care team.<sup>6</sup> Action research strives to include all relevant stakeholders. It is therefore beneficial to obtain the opinions of patients who I had direct involvement with.

Mental health concerns are the number one reason why patients seek medical services at the Student Health Centre. Contraception is the second most common cause. Due to the nature and sensitivity of these reasons, particularly with mental health issues, we originally

proposed using an on-line focus group. The anonymity that accompanies on-line focus groups helps create a non-threatening environment for the participants. University students also have demanding schedules, and therefore, the on-line focus group would allow the patients to participate when it was convenient for them. In addition, all University of Saskatchewan students are provided with computer accounts and can access computers throughout campus. See Appendix XXI for a list of the focus group questions.

The same website used for the on-line focus groups with the expert panel of pharmacists was proposed to be used with the patients. All University of Saskatchewan students are assigned Network Services Identification (NSID) numbers. The computer programmer required the participants' NSID numbers, which was used to create pseudonyms to ensure anonymity and confidentiality. As researchers, my co-supervisors and I were to be blinded to the pseudonyms. At the beginning of January, I provided our Information Technology Services department contact with a list of patients I had seen at the Student Health Centre. Pseudonyms were created at that time, to assist with the short timeframe we were dealing with.

As with the on-line focus group with the expert panel, the patient focus group was to run over a period of three weeks. The timelines for the data collection were sensitive, as we wanted to minimize the time span between my interaction with the patient and their evaluation of the experience. In addition, the University's mid-term break began the week of February 12<sup>th</sup>, 2007 and students typically have exams prior to the holiday. As such, we did not want the focus group to interfere with the patients' academic schedules.

We were also concerned with the number of patients we had to recruit from. In total, I only saw twenty-two patients during the months of November and December, 2006. We felt that a minimum of five participants would be required to conduct an on-line focus group. If we could not recruit that minimum, we planned to use an on-line survey instead as a method of collecting data from the patients. Due to the time constraints we were facing, we wanted to be proactive. As such, I submitted a protocol amendment to Behavioural Research Ethics Board outlining this possible change in data collection. The amendment was approved on January 8<sup>th</sup>, 2007.

In early January, we initially planned to have the on-line focus group begin on the morning of Wednesday, January 17<sup>th</sup> and end midnight, Tuesday, February 6<sup>th</sup>, 2007. Once

I confirmed these dates with our Information Technology Services contact, I sent an e-mail invitation to nineteen patients I worked with while at the Student Health Centre (see Appendix XXII). One patient whom I provided care to was my cousin, and as such was excluded from the study to avoid any conflict of interest. In addition, two patients - suffering from borderline personality disorders, were also not sent the e-mail invitation. When I met with these two patients to provide care, both had very negative opinions of the health care system as a whole and a high distrust for health care professionals. Due to the nature of their illness, these patients were very opinionated and I was concerned that they could easily have a negative influence on the focus group discussions, and hence their exclusion from the evaluation.

The e-mail invitation was sent on Tuesday, January 9<sup>th</sup>, 2007, and I requested for those who were interested to let me know by Monday, January 15<sup>th</sup>, 2007. The e-mail was sent to the patient's university e-mail account. Since we could not guarantee that this was their primary e-mail account and therefore receiving the e-mail in a timely fashion, a letter of invitation was also sent to each patient via regular mail. A friendly reminder e-mail was sent on Friday, January 12<sup>th</sup>, 2007.

By the reply deadline, not one patient had contacted me. The following day, I received a phone call from one of the patients, expressing interest in the study as he had just received his letter in the mail. The week I mailed the invitations was the same week a blizzard occurred in Saskatoon. As such, mail delivery was delayed. We, therefore, decided to extend the deadline and set a new start date for the on-line focus group – Monday, January 22<sup>nd</sup>, 2007. I sent an e-mail to the patients on Wednesday, January 17<sup>th</sup> explaining the reason for the delay in receiving the letters, as well as informing them of the extension and new start date.

Despite extending these dates, only one other patient had contacted me stating he would participate in the study. Since our total number of participants was less than five, we carried out our back-up plan of switching to an on-line survey instead. As such, another email was sent to the patients informing them of the change and inviting them to complete the on-line survey (see Appendix XXIII). The survey would only require ten-fifteen minutes of their time, compared to the two-three hour commitment with the on-line focus group. The start date for the survey was January 24<sup>th</sup>, 2007, and was available over a one-week

period. Instructions on how to access the survey were included in the e-mail. The website for the on-line survey was secured, and therefore a username and password were required to access it. In order to maintain confidentiality, only one username and password was provided for the entire group. A friendly reminder e-mail was sent mid-week to the patient group (see Appendix XXIV for the on-line survey questions).

At this time, we decided to revisit the idea of inviting the two borderline personality disorder patients who were originally excluded from the on-line focus group. It was an assumption, and unfair judgment on our part, that their comments would be negative. If, by chance, they did have a negative response to the questions, the on-line survey eliminated the concern of their comments influencing others. Lastly, since mental health issues are a predominant concern with the Student Health Centre patient population; these patients in particular should have the opportunity to voice their opinions on the services they receive. After taking all of the above into consideration, e-mail invitations to participate in the online survey were sent to the two borderline personality disorder patients as well.

Unfortunately, in the end, only one patient took the time to partially complete the online survey. Because of the poor response rate (n=1, 4.8%), the survey results could not be analyzed but have been included as an appendix (see Appendix XXV). There are several reasons which may explain the unsuccessful attempt of obtaining patient feedback.

For the on-line focus group with the patients, we mirrored the steps and timelines we had implemented for the on-line focus group with the pharmacists during Phase I - with the exception of providing a monetary incentive for participation, which has been shown to increase response rates. We provided the pharmacists with a \$50.00 honorarium to partially compensate them for their time. As for the patients, since we wanted to evaluate the relationship I established with them, we felt it was unethical to offer them any financial enticement for their feedback.

Another difference between the pharmacists and the patients could be the motivation to participate in the on-line focus groups. The pharmacists were selected to participate in the focus group based on their own initiatives to expand the role of pharmacists on health care teams. The patients, on the other hand, would not have the same interest to see the profession of pharmacy evolve towards a more clinical focus. An additional factor, which may have contributed to the lack of participation in the on-line focus group, was the time

commitment (i.e. two to three hours over a three week period). However, the on-line survey we opted to use only required ten to fifteen minutes of the patient's time, yet still resulted a in poor response rate.

Looking specifically at the on-line survey, the number and type of emails sent to the patients inviting them to participate may have impacted their interest. To increase survey response rates, it is recommended that at least four separate mailings be sent to participants – an advance-notice letter, a cover letter with more detail and the questionnaire, follow-up postcard, and another letter and questionnaire to non-responders. The goal is to make repeated and well-timed contacts in an inoffensive way. A total of five emails were sent to the patients, however this included messages for both the on-line focus group and on-line survey. We could not follow the recommended contact steps for the on-line survey, as our goal to collect the data before the mid-term back was approaching fast. In addition, we had already sent three emails to the patients prior to switching to an on-line survey, and therefore we wanted to minimize the number of emails we sent to avoid any sense of harassment.

Both the focus group discussion and the survey were Web-based, prompting an investigation as to whether technology had a negative impact on participation. We had used a Web-based data collection method, with the established primary health and ambulatory care pharmacists, during the first phase of our study. The on-line focus group was not a deterrent for the pharmacists to participate, as approximately 80% (n=10) of those invited to contribute to the study agreed to do so. Looking specifically at university students and web-based technology, a study was conducted at the University of Florida to determine if differences existed in response rates, response times, number of items completed, item completion errors and number of sensitive items answered between mailed and web-based surveys. A total of 361 undergraduate students (60% response rate), with free computer accounts and access to computers, completed either the paper or web-based survey which included 99 items focusing on health risk behaviour. The researchers found that there was no difference in the response rates between the two data collection methods. They did find that the web-based survey required fewer days to complete and return the questionnaire. In addition, the web-based participants were more likely to answer sensitive questions than participants in the mail group.<sup>71</sup> Therefore, based on our own experience

with the on-line focus group with the pharmacists and the study from the University of Florida, the use of technology to gather data from the patients should not have contributed to the low response rate. Lastly, we had only a small sample of patients to recruit from which limited the potential number of participants.

# 3.7.2 Think: Explore, analyze, interpret & explain the collected data

I reflected on the information gathered from the focus groups & own personal experience.

# 3.7.3 Act: Report

The data has been analyzed, and the findings reported in this thesis. The results have also been presented to the Student Health Centre staff.

# 3.8 Ensuring Validity with Action Research

Because there are no objective methods to measure validity in qualitative research, establishing trustworthiness is recommended. Trustworthiness is referred to as the extent in which we can trust the truthfulness or adequacy of a research project. Credibility, transferability, dependability and confirmability all help to establish trustworthiness, and are attained through: 42

- Prolonged engagement: The duration of the research process influences the relationship that develops between the researcher and participants. I had only provided two months of full-time clinical service; however I was also previously employed at the Student Health Centre. This previous position was not as a pharmacist, however relationships with several of the staff members had already been established.
- Triangulation: Triangulation refers to the integration of several sources. Using information obtained from the Student Health Centre; the literature view; and input from primary health and ambulatory care pharmacists, staff members and patients; provided a diverse collection of material.
- Member checks: With member checks, participants are given the opportunity to review the data that are produced. For the on-line focus group, the last question

posed for discussion included a summary of the data and the participants were asked to confirm that it was an accurate summation. The transcripts for the on-line focus group were saved verbatim, therefore checking for the accuracy of transcription is not necessary. Participants could read their responses at any time during the on-line focus group time period to confirm that their meaning was captured. As for the focus groups with the Student Health Centre, participants were given a copy of the transcripts to review and an opportunity to add, alter or delete any of their contributions during the focus group discussions. In addition, the focus group findings were presented to the Student Health Centre team members during a staff meeting, to ensure all of the topics which were discussed at length during the focus group discussions were included in the themes extracted from the transcripts.

- Transferability: Thick, that is, rich and detailed, descriptions of the study context and participants were included to allow others to assess the applicability of the research to their own situation.
- Participatory validity: Participation of stakeholders can increase the credibility of a
  project. Stakeholders primary health and ambulatory care pharmacists, staff, and
  patients, were involved throughout the various phases of the study.
- Pragmatic validity: To ensure the utility of the outcomes, the research question was created based on timely issues the profession of pharmacy is currently facing. For this project, the role of the pharmacist was tailored specifically for the Student Health Centre. However, the process provides a template that can be applied to other primary health care teams.
- Participant debriefing: Debriefing is used to review the appropriateness of the
  research procedures and to clarify the participants' interpretation of events. This
  proposal was reviewed by Dr. Jennifer Nicol, my instructor for a graduate level
  course on naturalist research methods. In addition, the project as a whole must meet
  the approval of my committee members. Member checks were used to ensure we
  accurately captured the participants' viewpoints brought forth during the focus group
  discussions.

# 3.9 Ensuring Rigor with Focus Groups

Numerous steps were proposed to help ensure rigor with using the focus groups. Pretesting the focus group questions can increase the validity of the data obtained. All focus group questions, the instructions for using the on-line focus group website – WebCT®, and the WebCT® website were pre-tested during the summer of 2006. This ensured the questions were phrased clearly and the sequence was logical, the instructions for using the website were clear and concise, and to identify and solve any glitches with the website. All four of my committee members were asked to review the questions, two of the members were clinical pharmacists, and the other two have qualitative backgrounds. A faculty member with the College of Pharmacy and Nutrition, who specializes in questionnaire design, was also consulted for his input. In addition, another graduate student who previously was a primary health care pharmacist, along with two non-pharmacist graduate students with the College of Pharmacy & Nutrition, were asked to pre-test the process as well.

An external moderator was contracted to facilitate the focus groups with the Student Health Centre staff. Using the external moderator reduced bias, as I was both the clinical pharmacist and one of the researchers. For the on-line focus group, the software transcribed the interactions verbatim and therefore increased the accuracy of the data. Summary questions were used to end the focus group to confirm the adequacy of the findings. Lastly, two of the researchers – Dr. Neubauer and myself independently coded the data to compare and verify the results.

#### **CHAPTER 4: RESULTS AND DISCUSSION**

# 4.1 Approach to Data Analysis

To preserve confidentiality, I deleted the opening question from the focus group transcripts, which asked the participants to state their position at the Student Health Centre and the number of years they had been employed there. The purpose of this question during the focus groups was to help the participants feel comfortable, as everyone could provide an answer.<sup>52</sup> However, their identity may have been revealed had the question remained in the transcripts during analysis. It should be noted that despite our efforts to protect the participants' identity, we could not guarantee it as some self declared their professional backgrounds during the focus group. For the quotes included in the results and discussion section, the professional designation was removed if the risk of revealing that participant's identity was present.

Since the participants may have had more than one participant number representing their statements within the transcripts; there were five focus group sessions in total, we needed to alter the transcripts in such a way that each person would have one individual identifier for all group discussions they participated in. The purpose of having one individual identifier is to differentiate between one participant repeating a statement several times or more than one person expressing a similar idea. To do this, without compromising confidentiality, the same third party individual who assisted in the preparation of the transcript verification, assigned each participant with a letter of the alphabet and then replaced each participant number throughout the transcripts with the appropriate letter.

Just as was done with the data from the expert panel of pharmacists, thematic coding was the approach used to analyze the data from the focus groups with the staff. Again, I used computer word documents to sort, categorize and rearrange statements, along with different font colours to highlight common themes. While rearranging the transcripts into themes, I left sentences as whole statements to ensure that I would not lose the context of

the original quote. A theme was defined as a topic which was brought forward by two or more participants. Both Dr. Neubauer and myself coded the data individually and then discussed the themes we extracted to ensure they were similar.

Saturation occurs when themes are repeated during the discussions and no new ideas are generated. Saturation was reached on all topics except for the action research process. When saturation is not achieved, additional focus group sessions may be arranged to obtain further data from the participants. However, the transcripts indicated the Student Health Centre team provided as much feedback as they could on the topic, and further probing would not have yielded saturation.

The quotes selected to represent the Student Health Centre staff's opinions are presented in a more polished format – i.e. where necessary the grammar has been corrected/modified, for ease of readability. Only portions of the statements have been altered to ensure that the original meaning behind the quote was not jeopardized. For example, 'umms' and repetition of words with pauses in-between (e.g. "... and I think... I think we all perhaps learned..." re-written as "... and I think we all perhaps learned...") have been deleted. The unique identifier for each participant (i.e. a letter of the alphabet) begins each of the quotes, except when the transcriber was unable to match a statement to an individual. A question mark has been used in place of a letter of the alphabet when the source was unclear.

# 4.2 Student Health Centre Focus Group Participants

A total of fifteen Student Health Centre staff members participated in the focus group discussions. This was a fairly representative sample of health care professionals from the Centre, and included four physicians, three registered nurses, one nurse practitioner, one psychiatrist, one manager, one dietitian, one health educator, one social worker, and two front office staff members. Despite our efforts to create two focus groups of equal size and professional background, the need to reschedule some of the focus group discussions interfered with this attempt. As such, the risk of professional dominance influencing the focus group discussions may have been a possibility. Professional dominance may have occurred had there been an overrepresentation of one of the health professions (e.g. the number of nurses in attendance being greater than any other group) or due to professional hierarchy (e.g. the physicians directing the discussion, as they worked closest with the

clinical pharmacist). However, similar themes arose from both focus groups leading us to believe that this was not an issue. For the Monday focus groups, the number of participants in attendance was as follows: January 8<sup>th</sup>, 2007 – six; January 22<sup>nd</sup>, 2007 – three; and February 5<sup>th</sup>, 2007 – two. As for the Thursday focus groups, eleven staff members attended the January 18<sup>th</sup>, 2007 session and ten for the February 1<sup>st</sup>, 2007 gathering.

It is recommended that a focus group be comprised of six to ten participants.<sup>67</sup> Unfortunately, two of the Monday focus group sessions had less than six participants. Because of the low participant numbers, it is important to recognize that the information collected during these sessions may have mirrored personal dialogues more than traditional focus group discussions.

The low number of participants for the Monday group likely occurred for several reasons. First, the Monday focus group discussions had to be rescheduled twice – once due to a fire alarm, and a second time because of a last-minute scheduling conflict with the facilitator. Second, it could have been the time of day when the discussions were held. The Thursday meetings were scheduled at the start of the day, between 8:30-9:30am – prior to the Centre opening while the Monday meetings are scheduled over lunch. Appointments with patients sometimes extended into lunch breaks and this may have affected attendance.

Although the Thursday meetings may have been more accommodating to some of the staff, it was not ideal for the Centre as a whole since some of the Thursday time slots had been booked for other reasons (e.g. presentations, joint meetings with Student Counselling, etc.). From a researcher's point of view, we wanted to schedule the focus groups soon after the clinical services component of the study. Scheduling the focus groups solely on Thursday mornings would have drawn out the process, left long time lapses between discussions with each group and excluded some of the part-time staff.

#### 4.3 Themes and Sub-themes

### 4.3.1 Major Themes

Seven major themes emerged from the Student Health Centre focus group discussions, as the staff members reflected on their experience of having a pharmacist join their primary health care team. Within each of these seven themes are several sub-themes, which are as follows:

# I. Perceptions

- a. Positive: excited, open to the idea and curious
- b. Concerns: uncertainty with role, degree of utilization and proper utilization

#### II. Content of Role

- a. Staff
  - i. Drug information resource
  - ii. Support to the team
  - iii. Sufficient timeframe to demonstrate support to the staff
- b. Patients
  - i. Drug information resource

#### III. Roles

- a. Role Ambiguity
  - i. Researcher versus clinical pharmacist
  - ii. Previous employee versus clinical pharmacist
- b. Role Overlap
- c. Role Evolution
- d. Impact on the Team Members' Roles

#### IV. Attributes

#### V. Process

- a. Co-located clinical pharmacy services
- b. Full-time versus part-time clinical pharmacy services
- c. Patient referral process
- d. Action research process

#### VI. Communication

- a. Formal and informal discussions
- b. Consultations for medication-related projects
- c. Debriefing after direct patient care interactions

#### VII. Limitations

- a. Duration of the study
  - i. Limited the impact and exploration of the role
  - ii. Generation of patient referrals
- b. Patient population
  - i. Narrow patient demographic
  - ii. Timing of the study
  - iii. Lack of patient buy-in
- c. Funding and Space

#### 4.3.2 Minor Theme

During the focus group sessions, the staff members were asked to provide recommendations to assist with future integrations of pharmacists into primary health care teams. The staff generated several suggestions, based on their experience. Despite having numerous ideas, few of the recommendations were brought forward by more than one individual and are therefore presented as a minor theme.

#### I. Recommendations

#### 4.4 Discussion of Themes

- 4.4.1 Major Themes
- 4.4.1.1 Theme 1: Perceptions
- 4.4.1.1.1 Positive: excited, open to the idea, curious

When the staff members were asked to share how they felt about having a pharmacist join their primary health care team, many responded positively, stating that they felt privileged to have this additional resource co-located with them at the Student Health Centre.

- E) ... it was a surprisingly rich resource that was just right there,... I felt so privileged to have her there, it just made the day go smoother and you felt like you were supporting your clients...
- G) Well I was pleased to have Lynette there and saw it as an opportunity to, you know, ask a lot of questions, get a lot of help, easily, very convenient.
- I) I felt almost a bit privileged to have a pharmacist in our Clinic, and I felt that it was a great resource. A luxurious resource...

In addition to feeling privileged, the staff acknowledged that they were 'excited' and 'intrigued' with the idea of adding a pharmacist to their team. Their interests were particularly focused on whether a pharmacist was suitable for their specific primary health care team and how a pharmacist's expertise would be integrated into their current mix of health care professionals.

C) I was really excited to be able to see if the role of a pharmacist was appropriate for our team.

E) I felt very positive and excited about it. I thought too it would be very interesting to see what role that potentially a pharmacist could play and I found the idea intriguing and interesting... I was very curious to see how it would unfold and just how we could incorporate her skills into our team.

The Centre's team focus also helped, as one participant stated, "...at Student Health we're pretty committed to kind of a team approach to care anyway, so the more the merrier..." when reflecting on the addition of a pharmacist to their team.

This project needed the support of the primary health care team. Integration would have been compromised had the staff not welcomed the initiative or had not been as open to the idea of what a pharmacist could offer. Having a group of practitioners who are willing to discuss difference about roles and responsibilities is a key component for creating effective interdisciplinary team work. 16

4.4.1.1.2 Concerns: uncertainty with role, the degree of utilization and proper utilization

The staff was curious with what I could offer the team as their pharmacist, however, with this curiosity came some uncertainty concerning what my role would be and the degree of utilization, as the staff 'wondered what [I] was going to be able to do for [them]'. Reasons for their concerns included the Centre's unique patient population, a lack of understanding of what a clinical pharmacist can offer and what type of education a pharmacist receives.

- H) I was certainly very open to the idea and I could see some potential positive benefits. I probably had some, not misgivings, but some wonder about especially particularly, you know, with the demographics of students that we're looking after and the nature of concerns that they were coming forward with, etc. as to how fully implemented such a role could be in our setting... And just how well utilized her role would be.
- D) Initial reaction was just wondered what she was going to be able to do for us, because I didn't understand, initially ... I kept asking her, what is a clinical pharmacist? ... just never had exposure to that outside of the [pharmacists] in the community that you see behind the big counter....
- E) ... the role of pharmacy is certainly evolving... it seems to be growing so dynamically and I feel like I don't really understand yet exactly what they do anymore, like I feel stuck in a box where I think of a pharmacy and a pharmacist dispensing medications...

A) I think that physicians don't really know the training that pharmacists get.

The specific patient population is a limitation of the study, and will be discussed in more detail further on. It is expected that the staff would not have a clear idea of what a clinical pharmacist could offer. As mentioned in the introduction, a study involving physicians concluded that they did not know what to expect of pharmacists.<sup>20</sup> One of the participants admitted to being surprised with the knowledge that a pharmacist can have, "She knew more than I thought she would know." Perhaps having an understanding of the training pharmacists receive would help other health care professionals gain a better appreciation for what we do.

The uncertainty with my role lead to some concerns surrounding the proper utilization of a clinical pharmacist. More specifically, the staff wondered if their questions were appropriate for a clinical pharmacist. Along these same lines, they questioned whether they should be asking someone to answer their drug related inquires since they could also carry out those responsibilities themselves.

- G) ... there is always that sort of wondering at first, well, is this an appropriate question to ask, you know. Is it at the right level, is it sort of challenging enough... not wanting to misuse Lynette.... Am I asking a question that she thinks is worth her time, or am I asking her to look up something I could look up ....
- H) ... sometimes becomes a matter of do you feel right asking someone to do that, because I mean, typically if you don't have that resource...

Another concern that the staff members had was whether or not they were keeping me engaged and maximizing the opportunities of having a pharmacist on staff.

H) I would have had not negative feelings but anxieties I guess again about, you know, are we able to appropriately utilize a person in this role? ... I was getting a little anxious at times of, you know, is she just sort of having to find work for herself or are we able to really keep her engaged in everything that's going on, and are we missing opportunities to have some students see her that might have benefited from it....

Inexperience with an expanded role for a health care professional can lead to misinterpretation, as well as under utilization and inconsistent use of the role.<sup>18</sup> As direct contact with a clinical pharmacist increases, physicians' awareness of our scope of clinical services enhances.<sup>73</sup> In the interim, delegating tasks within a health care team enhances the

utilization of each team member's skills and training.<sup>73</sup> Had I provided services for a longer period, over time I would expect that the team would have a better idea of what a clinical pharmacist can offer. Consequently, my responsibilities may change to better suit my expertise and thus increase the utilization of my role on the team.

# 4.4.1.2 Theme 2: Content of Role

When analyzing the content of the pharmacist's role, the role branched into two sections – the role with the staff and the role with the patients.

- 4.4.1.2.1 Content of Role with the Student Health Centre Staff
- 4.4.1.2.1.1 Drug Information Resource

My primary role on the team was as a drug information resource. The staff felt that I was a 'great resource' and 'helped [them] untangle some differences in areas with medications'. Their questions included inquiries pertaining to 'drug interactions' and 'side effects of medications' – which were both general and obscure in nature.

- D) ... The effect for my practice again was that I had this added value resource of someone who could answer all of the obscure questions that I end up having...
- G) ... I found when patients had questions about the medication and it was something a little unusual, I wasn't sure of the answer, I could ask Lynette and she got back to me very quickly and I could get back to the patient.

The team valued the drug information services. One physician went as far as saying that 'having a pharmacist in our team was – for me, it was vital'. Providing the staff with this information allowed them to 'learn more about the medications' and feel 'more prepared' when carrying out their daily functions. In addition, they appreciated my updates on relevant and current medication related issues.

B) ... there was good communication by e-mail from Lynette about changes in drugs... I think we were probably more on the ball with that kind of stuff than we perhaps normally would be.

One staff member was also pleased that I introduced him/her to several reliable drug information resources.

D) I often have questions about medications and interactions and she just set me up with some just wonderful web sites and information... I know it is good sound scientific information that I'm looking at.

The team members were impressed with the quality of the drug information services I provided. Several of the staff made encouraging comments, stating that "the depth of what [I] provided was really excellent clinically", and that the information was 'very detailed' and delivered in a 'very timely manner'. Others described the service as being efficient and effective, and one staff member stated that it 'really did meet [his/her] needs'.

A) I think the research piece that she did for us, I mean if we had questions about some medication... she would take that piece and go and research it and provide all that information to us, and that was very efficient and effective.

Another feature of the drug information service that the team valued was receiving objective information. This was particularly important for them, as they recognize the limitations of receiving information from pharmaceutical companies as '[drug reps] have a huge bias' in terms of the literature they provide the Centre with. The team felt that I 'knew where to go for unbiased information', and felt that I was 'an objective source' for answering their questions related to medications. The team also appreciated that I provided them with literature to support the answers.

- E) ... if you were to ask Lynette a question, you know, in a very short timeframe, she came back with all sorts of information that was printed out... And for every single question we always got a bounty of information.
- ?) ... not only would she be able to give you information right away but she would back it up and she would immediately go and research it and then provide you with that information as well.

By using a thorough approach to investigating their inquiries, I was able to start establishing credibility with the team.

G) ... a positive experience I had was the thoroughness with which she researched the question I had... so that when I answered the patient's question I had, you know, I was very certain that yes, this was a sound answer.

The focus group participants also noted that 'a pharmacist is the expert in drug therapy'. Having access to a health care professional with this 'expertise' provided them with a sense of assurance when dealing with medication related issues.

- ?) ... she was an expert resource, which we could have confidence in what she was advising or in information that she was presenting.
- G) ... Lynette look into it thoroughly and me feel safer in what I was doing...

The staff identified that there was an increase in the efficiency of the team when a pharmacist researched drug information questions. The health care professionals on the team acknowledged that they were capable of answering the same questions. However, this enhanced efficiency occurred when a pharmacist provided the drug information services.

- B) So there is a degree of efficiency maybe as well in utilizing the right person for the job... in looking at side effects, looking at drugs... I think that there is efficiency in utilizing a pharmacist.
- D) ... about the research aspect, having her do some of that legwork for me was very efficient...
- H) ... she might be a little more directed based on her experience in terms of knowing how to hone in on the valuable information.
- J) It was like a lot of the research that, you know, you'd normally do yourself you could just ask her and then she would be able to do the research or answer your question directly.

As a pharmacist, it was not surprising that a considerable portion of my responsibilities was to provide drug information. I felt that it was a logical starting point to establishing credibility with the staff. I hoped that if I could gain their confidence when answering their questions, eventually they would feel comfortable with entrusting their patients to me. Other pharmacists have also found that becoming a drug information resource for physicians was a means of establishing credibility.<sup>26</sup>

Holding a professional license to practice in health care is not indicative of what that person can offer the team. <sup>16</sup> The team appraises the knowledge, skill, experience, performance, reliability, credibility and ability of the new member to apply these attributes to a new clinical setting. <sup>16</sup> The majority of physicians expect pharmacists to be drug therapy

experts.<sup>20</sup> Meeting and/or exceeding the team's expectations can help establish competence, which is the most important determinant of success when joining an already established team.<sup>16</sup>

# 4.4.1.2.1.2 Support to the Primary Health care Team

By having a pharmacist provide drug information services to the team, the staff felt like they had additional support while caring for their patients. It was noted that my presence was a support for both the team and patients, but the impact was greater with the former.

- M) ... support for me and support for the client.
- C) But I think she really did provide some valuable support to staff... and probably less so directly with the patients.

My role complemented what the other health care professionals offered, and one staff member stated, "I found that she was a great ally for what I do." Another participant added that having a pharmacist available to them gave him/her "an overall sense of having backup".

The staff also felt that having a pharmacist on their team was a means for them to offer enhanced care to their patients, as it was "added support to the entire service [they] were able to offer". One participant commented that adding a pharmacist to their primary health care clinic allowed them to offer 'Cadillac care' and that 'it's better care for the patient'. Along those lines, a physician shared with the group that a pharmacist is an 'added resource' – both directly and indirectly, for patients.

H) ... whether it's the resources by the patient actually having direct contact with the pharmacist or by me as a physician going to the pharmacist and using that person as a resource so that I'm better educated, even if I'm the one who'd been, you know, providing that information, by face-to-face with the patient, either way it's a resource overall to for the care that's being given.

Creating a supportive work environment should not be overlooked when trying to integrate a new team member into a health care team. Physicians tend to be more receptive to a wide range of clinical pharmacy opportunities when the services are provided in a

consultative and supportive role.<sup>20</sup> An effective interdisciplinary health care team has the patients' best interest in mind, and being a support to the team helped foster this philosophy.<sup>16</sup>

# 4.4.1.2.1.3 Sufficient Timeframe to Demonstrate Value as a Support to the Team

In spite of the short study duration, one staff member noted that two months was an adequate period for me to make an impact as a support to them, "... the help for staff... she was there enough and did enough that proved itself". Some of the other staff members were impressed with how much I was able to accomplish during my time with them. One participant said, "I think that she did <u>lots</u> for us actually, more than I initially thought that she would".

By the end of the two months, a few of the team members commented that my 'role was almost leveled when [I] left, in comparison to the time [I] started'. In other words, the staff had started to become familiar and knowledgeable with what I could offer. Another participant reinforced this by adding, "... it was just kind of catching on to what she was doing and what she could offer, and then it was done". Their increased understanding of what a clinical pharmacist could do was also portrayed by their ability to generate additional drug information activities to broaden the role of their pharmacist.

- B) Because if you think about the issues we have with Chinese medicine, that would be just a great area to look into. I don't know how many internationals are taking some medicine, Chinese medicine. That would be a great area to really do some big education on...
- D) ... she was such a good resource for us that it would have been interesting to see her work with the health education outreach people, and be able to supply them with some more detailed knowledge and accurate information to go out to the general public.
- L) I think a value that we could have used her for but probably just didn't have enough time is doing some in-services, you know, on new drugs or new areas... inservices for the peer health educators, they also just, you know, to offer to students workshops on different things.

Despite the ability to make some headway with the staff in terms of my role over a two month period, there were several drawbacks with the short timeframe. These will be further

discussed under the limitation theme. To my knowledge, no other action research study investigating the integration of an expanded health care professional role has been conducted over a comparable duration – as similar trials cite one to three years as a study timeframe.<sup>25, 50</sup> Our study showed that a two month period is an adequate timeframe for a clinical pharmacist to demonstrate added value, as a support to the staff, when added to a primary health care team. This benefit was in the form of non-direct patient care activities, as there was insufficient time to develop a direct patient care role.

#### 4.4.1.2.2 Content of Role with the Patients

### 4.4.1.2.2.1 Drug Information Resource

The Student Health care staff also defined my role with the patients as being a drug information resource, as I provided education and counselled on medication side effects and compliance.

- D) I certainly used Lynette as a resource and I did refer a number of people to her which I think really impacted the education that they needed at that time and feel it was positive.
- ?) I used Lynette for people who were having problems with side effects of birth control pills and compliance, and emergency contraception; she did great work with those girls.

The patient population at the Student Health Centre is unique and made up of a narrow demographic. The bulk of the patients are university students, who are – in general, very keen to find out about their medications but often seek information from unreliable sources.

J) ... the students here tended to want to know a lot more about their medications than what a lot of patients in a lot of other situations would want to know...

Part of my role with the drug information service was to provide objective information and correct patient's inaccurate perceptions about their medications.

- A) I think one thing it adds is that, I think maybe especially in this population group, it's a resource that students can come and I think would say okay, I can go to this pharmacist and get an objective assessment of what's with this medication that I'm on.
- D) ... the students come in quite well educated but often misinformed...

- E) Lynette's role in sort of our well population, she was really helpful in reassuring patients about other medications and sort of the fallacies and the misinformation that sometimes patients get stuck on.
- O) Patients want to know everything especially when you start them on psychiatric medication... and they get wrong information from wrong resources. That was a very important part of having a pharmacist on your team.

Another component to the drug information services I imparted to the students was to reinforce what other team members had told the patients. This also strengthened our team approach for providing patient care.

- D) ... Lynette was able to kind of straighten that out and reinforcement of those messages from all three of us I think was very helpful for the patient in the long run.
- J) ... to have her just to reinforce kind of a lot of the things that I said...

The team noted that when I discussed drug therapy with the patients, it assisted the patients with their decision making around medications. One physician reflected on my involvement with counselling patients on antidepressants, and how the information I presented either empowered a patient to make a decision regarding initiating therapy or reassurance that it was appropriate.

H) I don't mean she scared them off or anything, but that they had enough information then that they had some reservations and then felt that perhaps it wasn't absolutely essential for them. I saw that as a positive thing... and then there were other situations where her information to the patient was reassurance to them, when they had serious misgivings about being on the antidepressant, she was able to reassure them to the point that by the time they saw me again they were more comfortable with it, so I would say it definitely affects for patients even in terms of their own decision making about whether this was appropriate for them or not, so that was neat.

Clinical pharmacists have previously provided medication consultations to patients in primary care settings.<sup>17, 19, 37</sup> One advantage of providing counselling in this manner is that patients can receive medication advice in an unhurried environment.<sup>37</sup> This can be particularly important when patients have several questions or misperceptions surrounding medications. In addition, when patients have the opportunity to discuss their medications with a primary health care pharmacist, there is a greater opportunity to achieve medication

concordance – i.e. the health care professionals and patient have established a shared agreement for the rapeutic goals.  $^{37}$ 

#### 4.4.1.3 Theme 3: Roles

Because of my dual role as researcher and clinical pharmacist, some role ambiguity surfaced during the study. This was also confounded by the fact that I was previously employed at the Student Health Centre as a Health Education Coordinator Assistant. In addition to some overlap in the roles I took on, the staff also questioned how their roles would be impacted, in the long-term, when a pharmacist is added to their team.

#### 4.4.1.3.1 Role Ambiguity

### 4.4.1.3.1.1 Researcher versus Clinical Pharmacist

For our research project, I wore two hats – one as a researcher and another as the clinical pharmacist. One staff member noted that during the meetings to discuss the project, my role as researcher dominated over my role as their pharmacist.

B) ... her role at meetings was the [graduate] student... it was more about her research and not of her as pharmacist on the team, so when we had meetings it was more about the research than the pharmacist coming.

Originally, I intended to only be the researcher and the plan was to hire another pharmacist to fulfill the clinical role for the team. However, the staff had requested that I work with them as their clinical pharmacist because of my previous history with the Student Health Centre.

The term 'double-act' has been used to describe scenarios where one person acts as the researcher and another in a clinical role. However, the literature only provides examples of having an 'outsider' – i.e. someone not part of the health care team, taking on the role as researcher and an 'insider' – i.e. someone already part of the team, acting as the intervention. The Galvin et al. (1999) conducted a study using action research to implement change within a primary health care nursing team. They used a 'double-act' approach, but found that the research project manager – as an outsider, had a difficult time with the role. Group boundaries and responsibilities were unclear; therefore maintaining a collaborative approach was sometimes complicated. They recommended that a joint clinical/research role be used to offset these issues. Our project was unique in the sense that I was an

outsider who took on both roles. Seeing that a pharmacist had never been part of the Student Health Centre team, it was inevitable that an outsider would have to fill that role.

# 4.4.1.3.1.2 Previous Employee versus Clinical Pharmacist

As mentioned earlier, I had previously worked at the Student Health Centre as an undergraduate student in health education. The team identified both positive and negative aspects of my prior history with the Centre and subsequent research endeavor. Starting with positive angles, the staff that I had worked with in the past felt comfortable with me joining their team as the pharmacist since a rapport was already established between us.

A) I certainly looked forward to the experiment, whatever difficulties the person might have anticipated, I think were allayed, because we knew Lynette from before, and knew her abilities, her personality, so it was not at all difficult for her to feel part of the group and for us to accept her quickly, and trust her work.... We know from her performance in other roles that she did for us, that she'd perform anything you gave her at an extremely high level.

The staff also saw an advantage to me being familiar with them, "She came in knowing the team, she knows what we do."

My prior connection to the Centre allowed the staff to feel more at ease during the initial stages of the study. However, when they evaluated the role of the pharmacist at the end of the study, some felt it challenging to separate myself from the role. One participant stated, "... to look at it as a position, and divorce it from who the person was, I find it somewhat difficult". This same participant commented that it was also hard to disconnect my previous role as an undergraduate student from their pharmacist, "... because of our experience with Lynette... I viewed her as a [undergraduate] student... she didn't come to us as some unknown clinical pharmacist who was going to set feet in our place...". Other comments included:

- A) ... it's hard to separate Lynette from the position. I'm sure not every person who was filling that role, we would experience the high quality we got from Lynette.
- D) I do wonder though, if a different personality Lynette was known to us and she has a certain ethic or work habit about it that is lovely and I'm wondering if somebody else came into that mix if it would be quite a different affect to a relationship on the team.

Another concern the team had was whether I felt limited with what I could do, due to my previous role with the team.

- A) So maybe in a way having somebody like Lynette who we knew, who we liked, got along with, and she had worked with us and viewed us in some ways as her supervisors over the last couple of years, maybe in some ways she wasn't the ideal person to come and explore... maybe she didn't have the freedom to just say, here's what I think I should be doing. We were telling her what we think she should be doing.
- B) ... I'm not sure we ever really got Lynette's vision 100 percent. I think that there was a relationship that wasn't where she could sit there and give her complete vision, I don't think she felt maybe she could 100 percent do that.

As previously introduced, the action research terms 'outsider' and 'insider' are used to describe the relationship a researcher may have with a health care team. Outsiders can sometimes encounter difficulties with being accepted by the group.<sup>50</sup> Insiders may feel limited in their potential to create change, as they are knowledgeable of the hierarchy within their setting.<sup>74</sup> These power relations may have a greater influence on decision making than the action researcher's project and findings.<sup>74</sup> Again, our study is unique in the sense that I was an outsider who was previously an insider, but contributed to the team in a different role –i.e. health education.

The obstacles I encountered did not involve joining the group, but instead revolved around my attempts at establishing a clinical role for a pharmacist on their team. It was sometimes challenging to gain certain team member's approval for specific direct patient care initiatives I wanted to initiate. A prime example being the original antidepressant counselling format that I developed, but had to simplify based on a few team members' concerns that I was stepping out of the traditional role for pharmacists. During these times, I felt the frustration that insiders often do, as I was aware of the existing politics within the health care team, but felt that I lacked the power to change them.

As the researcher and clinical pharmacist, I did have a strong vested interested and personal commitment to the project. This is not uncommon in action research, even for those who act solely in one capacity – researcher or intervention. When assessing the external validity of an action research project, it is recommended that the notion of transferability is used rather than generalizability.<sup>6</sup> Transferability occurs when knowledge

is transferred from a sending context to a similar receiving context – i.e. another primary health care centre.<sup>6</sup> Every action research project is unique, just as every health care team and health care professional is. We presented some of our results as a list of recommendations in Chapter 5, which we hope will be beneficial for and applicable to other pharmacists and primary health care teams.

## 4.4.1.3.2 Role Overlap

Role overlap occurred between the pharmacist and physicians/nurse practitioner in the area of counselling patients on their medications. Because of this, the debate of whether hearing the same message more than once, from multiple health care professionals, results in a duplication of services or reinforcement of valuable information was brought up. One physician mentioned how a patient may hear similar information from three health care providers – a physician, clinical pharmacist and community pharmacist.

H) ... They'll come into my office, I'll provide them with a certain amount of information about the medication which we were probably are going to be prescribing for them, then potentially they would, if they were to be referred to the in-house pharmacist they would receive some reinforcement of the information. And then when they get the prescription filled at the pharmacy you never know what - either by handout or discussion they might have, so... is it all just sort of duplication or is it all just good reinforcement because, you know, it's better to hear it more than once anyway.

Another participant added that, as physicians, their role in providing standard drug information would likely not change.

J) ... explaining, you know, side effects of the medication or how they work or whatever else, probably shouldn't change from the physician's point.

One explanation of their continued practice, of supplying patients with standard drug information, was to avoid feeling neglectful when providing patient care. However, the following physician also acknowledged that roles would evolve over time.

H) I'm just so used to explaining certain things just to patients about medications and effectiveness and side-effects potential and all that kind of thing. But it's not that I wouldn't trust the pharmacist to do it, but I'm so used to doing it that if I didn't do it I'd feel like I'd somehow been neglectful. I think that's something that would just

gradually change as somebody became more established as part of the team as a pharmacist. Those roles would become better defined...

Role overlap in interdisciplinary teams is sometimes inevitable, however practitioners report less anxiety when a collaborative approach is used.<sup>5</sup> Determining team accountability – i.e. what the team, not an individual, does for a patient, may remove any sense of neglect. However, team accountability takes time to delineate and requires roles and responsibilities to be clearly defined.<sup>16</sup>

In an optimal health care team, each member has the freedom to apply their own unique expertise.<sup>17, 73</sup> Physicians, nurse practitioners and pharmacists are all capable of counselling patients on medications; however the approaches and perspectives of the professions may differ. Task duplication can result in a waste of time and resources if health care professionals do not brief each other after patient interactions.<sup>25</sup> In our study, the Student Health Centre staff members were pleased with the feedback I provided them after meeting with a patient – which will be further discussed under the communication theme.

#### 4.4.1.3.3 Role Evolution

Expanding on the previous quote that team roles would become more defined over time, other participants also identified the likelihood of this – particularly with the role of the clinical pharmacist. To deal with this anticipated change, they suggested that the team re-examine the role as it changes over time.

- J) ... I think that probably with time her role would probably change slightly,... Or how we would use her would change.
- E) ... And I think that if we had a pharmacist on our team that role definitely would evolve and just like all of us would become a dynamic part of our team.
- G) Well this was kind of an innovative thing, so I would think over time, after a certain number of months, it would be important to sort of meet and clarify the roles even further, based on experience as opposed to just what we think the roles should be, you know, how it's worked out...
- M) ... expect the role to keep changing so to keep reviewing so that you can add to or fix or change or whatever you need to do at the time.

Along these lines, one participant used hospital pharmacists as an example of how pharmacists' roles have became more defined over time.

O) ... the first person who decided you have to have a pharmacist in hospital, probably had the same debate ... years of having a pharmacist in hospital-based patient care, everybody knows what is the role of a pharmacist, and it's very much precise... so I guess that's the same problem, we are at the beginning of something...

Using action research as an integrative methodology provides a structure for reflecting on a change in practice and implementing any modifications. As such, it would provide the team with opportunities to revisit and redefine the role as needed.

# 4.4.1.3.4 Impact on the Team Members' Roles

Despite being satisfied with the drug information services, the staff did have concerns with what impact this could have on the team in the long run. In a general sense, one staff member pointed out that their own roles may change when a new health care professional is added to the mix, and this may not be a desired effect.

B) ... but sometimes when you add a new person to the team with a different type of expertise... people might feel that part of their role changes and they're not sure they want to change their role.

More specifically, the physicians discussed their concerns with having a pharmacist provide drug information. For example, one physician wondered if (s)he would become lax, over time, with retrieving drug information when answering patient's questions.

A) ... I wonder if having somebody like Lynette on staff, a person - at least maybe as a physician I would get lax in doing a lot of digging myself on some of the stuff that now she would do.... What affect that would have in the long term I don't know.

Another physician acknowledged that this may be a concern, but added that the concern was attenuated with good communication between the pharmacist and physician. In addition, this physician stated that (s)he learned a lot when I answered their drug information questions.

O) ... it could be like dependency, in fact, if there is no feedback. But if there is a good feedback, I learned a lot... on every single patient I learned a lot.

Tension may result when health care professionals' roles change due to a new team member taking on their responsibilities. However, as clinical credibility of the new member becomes evident, the rest of the team starts to value this additional expertise.<sup>21</sup> Having an increased understanding of what another health care profession brings to the team can heighten other team members' awareness of their own clinical expertise.<sup>5</sup>

#### 4.4.1.4 Theme 4: Attributes

Although the staff questioned whether all pharmacists share the same characteristics, there were several attributes identified by them as being important for a pharmacist to have. The following traits were valued by the team:

- *Knowledgeable*:
  - A) ... I was very impressed with her knowledge. I mean she was pretty good on stuff that she didn't have opportunity to go read up on all of a sudden.
  - D) I was surprised by the amount of knowledge that she did have on some of the questions. I had a question on weight-loss drugs and she provided me with this very indepth piece of information that I found very helpful...
- *Diligent / Thorough:* 
  - A) ... I think a lot of her success was that she got in there and sort of dug and did things, and so I think it was all in all a positive...
  - D) ... she has a certain ethic or work habit about it that is lovely...
  - G) ... she got back to me very quickly and I could get back to the patient... and very detailed, you know, she sent me a very detailed e-mail as answer to my question.
  - H) Ya, I would agree, that her thoroughness in sort of accomplishing whatever task had been asked of her...
  - J) One thing I noticed with her is that, you know, like I said before, she was very keen... I mean I found her very helpful, and even times when I hadn't even asked for her help she would know that I would be seeing somebody who, you know, had a certain problem and she would, you know, spontaneously kind of give me information about, you know, the medications that the person should be on or the side-effects, that sort of thing.

#### • Professional courtesy:

- H) ... it was just a positive experience in terms of the collegiality.... whenever we would have discussions about anything that was even the slightest bit contentious or subject to different opinions or whatever, there was never any kind of a defensiveness on her part, that she would hear me out and I would hear her out and we would come to some middle ground or agree right from the outset and it was just always a very pleasant interchange in that way.
- G) ... she was quite sensitive to, you know, not wanting to have anyone think that she was sort of stepping on their toes...

#### • *Communication skills:*

- I) Lynette was very thorough, very open to questions. She was a really easy person to communicate with, and she put people at ease. I felt really comfortable with patients working with her...
- ?) So she has really good writing skills as well, and like any research that she does, you know, she does a really good job with that, and also any patient visit documentations, very thorough, very legible, you know, just very clear.

All of the aforementioned attributes allowed me to make a positive impact on the team, as they were "very impressed with the nature of the work" I had completed.

Research into developing effective interdisciplinary teams acknowledges that an individual's attributes, experience, and ability to establish competence cannot be controlled for. However, identifying characteristics that have been linked with success can aid future health care professionals who are interested in joining an interdisciplinary health care team. The ability to challenge one's self, willingness to work with others, good communication skills, responsiveness to requests, and clinical credibility are personality traits that have been associated with establishing effective teamwork. Exercising mutual respect for other health care professionals' input, not trying to control situations or competing with the responsibilities of co-workers also facilitate integration of a new team member onto a health care team.

#### 4.4.1.5 Theme 5: Process

In terms of process, four sub-themes emerged from the data: providing co-located clinical pharmacy services, full-time versus part-time services, the patient referral process and using action research.

# 4.4.1.5.1 Co-located Clinical Pharmacy Services

Over the past several years, the staff had developed relationships with community pharmacists in the surrounding area, but noted that having a co-located pharmacist afforded them increased access to and an enhanced level of clinical pharmacy services.

- I) ... we did have some good relationships obviously with other pharmacists in the community and stuff but with having Lynette as part of the team it was just kind of on a whole other level, because I used her more in her role as the resource person... just to have that person at our fingertips to answer our questions and to work on requests that we had...
- M) ... I think that the key of it being part of our health care team is that, I mean we have always had access to pharmacists around the area who students have interacted with or who the team has, but it was very nice to have her right there. And I think that the piece of it, of the flow, and the likelihood that more people that we encourage to go, went, because she was right there as opposed to, you know, having to go on another day or whatever because she's in another building or three blocks away, or whatever.

Integration into a health care team would take longer if the new team member worked primarily off-site. Being present, even during lunch breaks, reminds the staff that a pharmacist is on-site and available to them. In fact, my very first patient referral arose from a discussion on non-compliance between a physician, nurse and myself over lunch. Pharmacists who work in family practice clinics have noted that being co-located promotes greater interaction between them and the physicians, and allows for easier access to patient care areas and medical records. This subsequently results in a more active pharmacy involvement with drug therapy decision-making and direct patient management. 42

Taking a closer look at the advantages for the patients, the on-site clinical pharmacist services offered the patients more time to discuss medications and active engagement than what community pharmacists can provide.

E) And there were times when I identified that the patients just really needed to sit down and talk about their drugs... they saw Lynette to talk in detail about, you know, birth control side effects, or you know pain medication and proper use of it, travel medications,... you would feel like you were being heard and that someone's going to spend the time with you as well. I mean when you're in a pharmacy you always see them scrambling around counting pills and doing the till and people waiting in line and you don't feel valued, particularly.

I) I think too that, you know, as far as myself dealing with pharmacists has always been just sort of a quick review of a patient's medications, a quick question on side effects, and personally just, you know, being handed a piece of paper with a bazillion side effects and things I should know about a medication I'm taking but there's never been, you know, a real dynamic communication with a pharmacist as there was with Lynette...

Along those lines, a physician reflected on a patient (s)he had referred to me who was frustrated when unable to get the information she needed from a community pharmacist.

O)... she was actually going to a different pharmacist in the city and like begging for information. They were busy, they couldn't talk to her. So just referring her to Lynette she was very much happy...

The benefits of a pharmacist-patient interaction in a primary care setting is that is occurs in an unhurried, private, accessible and credible environment.<sup>37</sup> In addition, questions that arise during the interaction, which need to be addressed by the patients' other primary health care providers, can be quickly dealt with when all are operating under the same roof. It is also a convenient means of receiving clinical pharmacy services, as we would often try to schedule patients in close proximity to any other medical appointments they had booked at the Centre.

### 4.4.1.5.2 Full-time versus Part-time Clinical Pharmacy Services

We asked the staff to what extent should clinical pharmacy services be accessible to the team (i.e. full-time versus part-time). As the staff reflected on my two months with them, they noted I provided full-time services 'which made it nice so everybody could access [me]'.

- H) ... whether it was by sort of an official referral, because there was a referral form that was put together that we could use, or probably just as often by kind of casually popping into her office to ask a question or pick her brain about something, I think it was all quite positive in that sense... she had a very open-door policy... we had the luxury of being able to do it just on the fly.
- O) ... it was great that she was available at any time, we just stepped into her office and ask her a question...

Several of the participants agreed that ideally, a clinical pharmacist would be employed fulltime to increase accessibility and foster role development.

- M) And we may think that's always the ideal, that everybody's there full time because then you can interact and consults easiest, when you have access to everyone.
- E) And they would... grow more dynamically if someone was there full time.
- A) ... I mean sure in an ideal world each doctor would have a clinical pharmacist full time...

One of the benefits of having a full-time clinical pharmacist is that urgent issues are addressed in a timely fashion. Although there was some debate as to how often these pressing situations occur.

- H) ... I mean it does raise the issue that if they're not here full time, then there would be times in the week where even if you fairly urgently would like to have use out of the pharmacist, you can't get it... if the total position is less than full time there might be some frustration in, you know, just at the times that you want the person to be available, and they're not even on site.
- J) ... most of the questions don't need to answered right away, and then if somebody was part time, that that could be easily worked around.
- O) ... I could wait for a couple of days until I see her and ask her that question. Or my patients could wait like for one week to get an appointment with her. So I would say part time.

The staff was also quick to point out the hiring a pharmacist for a full-time or part-time position would depend on several variables – such as the responsibilities assigned to the pharmacist, the team structure and volume of patients, resources and space.

- H) ... would generally depend very much on the size of the team and the range of services being provided... the number of physicians, the number of patients... I'm not sure that we could justify a full-time position year round, for a pharmacist to be on staff, but then again I guess it would depend on how widely you describe the essential role...
- M) And I think it would depend on their role, like when she was busy doing kind of research or putting together pamphlets or information for us, then you know maybe half time is good, depending on resources and space and all that stuff. And if her main role were client consultation and us wanting her to be available, you know, I've just seen a patient, can you see them now, well then you'd want her there full time so that you had more ability to do that. So it also I think would depend on how the role is broken down.

Within that same thread of discussion, a few participants drew attention to the fact that not all of the staff utilized my services to the same degree, and the significance of having a pharmacist on the team may only be appreciated by those who are scheduled on the same day – if the position was only part-time.

- I) ... I think some team members felt more of a need, or would use that service more than other team members would.
- L) ... if there were a pharmacist here probably like most of the rest of us she or he would be part-time, and it might just be those who actually work on the same day as that person who will find the value of that person, the others will not...

I agree with the staff that full-time services would assist with the development of the pharmacist's role. This would be particularly important for clinics like the Student Health Centre who employ several part-time staff. However, the reality of having the resources for a full-time clinical pharmacist would vary for each health care team.

# 4.4.1.5.3 Patient Referral Process

One important piece for integrating a pharmacist into a primary health care team, that needed to be further defined, was the referral process. Looking specifically at the comments made by one of the nurses, the study did not provide her with enough time to feel comfortable with the process of referring patients to me. Her concern was based on not knowing the impact a pharmacist may have with direct patient care interactions, as well as working part-time and therefore having less contact with me.

B) ... I don't think it was always long enough for the nurses, anyway, to look at who we should refer and who we shouldn't. .... Sometimes I wasn't sure whether I was creating an extra step if I put the person in with the pharmacist, or straight with the doctor - because of the short period of time not 100% knowing the benefit.... I had some compunction, I think, a little bit about her role and I think she wasn't there very long and because I don't work full time, I think maybe I didn't utilize her or get to understand totally her capabilities, that maybe some of the other people that worked there more days a week would have had.

One team member agreed that the referral process still needed to be fine tuned. However, when it came to mental health patients, (s)he felt more comfortable with a physician deciding whether or not a pharmacist should be involved.

?) ... As far as patients coming out of depression, that's something I still prefer for the physicians to see first and then decide whether that patient is best seen by the pharmacist, so as far as flow goes that still was sort of being established...

Along those lines, one participant pointed out that (s)he viewed me as an adjunct, not a replacement, to a physician visit when referring patients to me.

E) ... the people that I refer to Lynette I used her as an adjunct to also a physician visit. I didn't utilize her separately under them for information on medication, as her role on the team.

In contrast, one of the physicians felt that often the issue was resolved after a nurse had referred a patient to me, and a subsequent physician visit was not always necessary.

O) ... lots of time I saw that the nursing staff they always turn to Lynette, and they ask a question and there is no need for me to see the patient and they get their answer and everything is done.

These differing statements portray the uncertainties that surrounded the referral process. A pharmacist referral form was developed prior to me joining the team to help identify which patients I could provide care to (see Appendix IX), however doubt still existed in some of the staff member's minds. In another study investigating the feasibility and content of clinical pharmacy medical consultations in a primary care setting, nurses did not refer any of the twenty-five recruited patients over a three month period.<sup>37</sup> All primary health care professionals on the team were encouraged to refer patients to the pharmacist; however physicians were the only health care profession to do so.<sup>37</sup>

The team members felt more comfortable with referring patients if they knew the patient would still be seen by their physician. However, as the one physician pointed out, this approach was not always time efficient for the team. A clearly defined direct patient care role and experience with what a clinical pharmacist can offer would alleviate their concerns regarding appropriate patient referrals. The timing of integrated care must also be determined in order to develop effective interdisciplinary teams.<sup>16</sup>

#### 4.4.1.5.4 Action Research Process

Staff members were asked to comment on the approaches we used, as researchers, for integration a pharmacist into their team. One team member recalled that I had consulted primary health and ambulatory care pharmacists at the beginning of the study, and (s)he considered it an appropriate step.

H) ... it made good sense that she would have consulted with whoever that description is available...

Connecting with colleagues who hold a similar background plays a valuable part when developing new roles in multidisciplinary teams. This link can provide professional identity, as well as a resource for support and guidance. <sup>21</sup> For me personally, seeking advice from established primary health and ambulatory care pharmacists was very important. I realized that my role at the Student Health Centre would be tailored to meet the needs of the team and patient population. However, involving other pharmacists allowed me to feel assured that the clinical pharmacist role I would take on would be supported by my colleagues and not jeopardize the direction our profession is taking to expand our presence in health care.

This study investigated the integration of a primary health care pharmacist – a role for the profession which was new to the Student Health Centre staff. Scheduled meetings with the team to define my role, prior to providing clinical services, were deemed a reasonable approach.

H) ... in terms of the discussion with staff,... that was certainly a logical starting point in terms of some consensus between her and us as to how we would define her role for the short time that she was here.

When adding a new member to a health care team, the staff should collaborate to define the role and responsibilities, as well as the logistics, with this new professional before they officially join the team. <sup>16, 17</sup> This philosophy aligns well with action research, which encourages key players to be involved in decision making. <sup>46</sup> We can also learn from nurse practitioners and their experience of creating roles in primary care, as they discovered that if stakeholders are not involved in the planning stages for the new role, role conflicts and resistance from the stakeholders surfaced. <sup>18</sup> In addition, a team approach can help identify

where the current treatment gaps exist - which in turn can help shape the role of the new member.<sup>21</sup> I felt it was critical to have the staff assist with the development of my role, as I wanted them to feel ownership of the project as well.

Despite our efforts of defining my role, as the pharmacist prior to providing clinical services, one staff member admitted to being puzzled with how to incorporate a health care profession that had never been part of the team before.

M) I think the biggest negative is just the confusion of startup process so I don't think that that was specifically her, or specifically a pharmacist added to our team but just trying to figure out how we were going to do that, how we were going to use her, how she would fit in, all of that.

Another team member highlighted that the study was 'exploratory' in nature and 'you kind of almost expect to be a little bit unsure of what's going to be'. This same participant acknowledged that (s)he was unsure, like the others, as to how I would fit into the team, but also pointed out how much they did learn in terms of what a clinical pharmacist can offer.

B) I wasn't sure what she would do, and how she would fit into the team. I think that was part of the process anyway and I think we all perhaps learned a lot more about what a pharmacist did have to offer our team, ... there was a lot more than perhaps I thought a pharmacist might have to offer.

Action research is a flexible process, which does not require a detailed outline at the onset of a research project.<sup>47</sup> Those who are involved can improvise on the preliminary findings, and the study unfolds as the participants learn more about the project at hand.<sup>50</sup> Because the study was exploratory and action research was the selected methodology, some degree of uncertainty may be inevitable.

### 4.4.1.6 Theme 6: Communication

Defining, implementing and evaluating the role of the pharmacist required open communication between the pharmacist and primary health care team.

#### 4.4.1.6.1 Formal and Informal Discussions

It took the staff some time to adapt to having a pharmacist on their team, and they therefore appreciated the opportunities to gather and reflect on my role. They felt that they were provided with a sufficient number of occasions to discuss my contribution to the team, through both organized meetings and casual conversations. The two methods used to exchange ideas – the formal and informal gatherings, were considered 'complementary' to each other.

- M) ... she did lots of discussion with us to define her role... I think it was good that she kept meeting with us along the way to kind of revamp and check in.
- H) ... A medium midpoint, I think that was also useful... I think there was a lot of ongoing kind of discussion and that outside of sort of formal meetings, which was probably just as helpful as the formal meetings.

In addition, since not all of the staff could attend the planned meetings – primarily due to scheduling and the large number of part-time staff employed at the Centre, the team regarded the impromptu discussions as a valuable part of the process.

- I) ... the previous comments about her role, you know, we as the staff have some responsibility in that and we had ample opportunity to have discussion and come up with ideas and stuff and I think one of the negative things -- and it's not anybody's fault, it's just there's a number of part-time staff and to try and get everybody on the same page, everybody reading the same meaning... it never happens, that's not any fault of Lynette's or anybody's, it's just a reality of how our clinic is because we just are never all in one place at one time. It's difficult to communicate I think....
- D) ... conversations with Lynette, I think that informal piece was very helpful. I know that we weren't all present at the formal meetings just because of when they were held.... Somehow those informal things were very important.

When reflecting on roles, it is important to work with the team to identify what needs to be modified versus imposing the researcher's ideals onto them. Action research is a cyclical and dynamic process, and this collaboration should be maintained throughout the study.<sup>25</sup> In our study, allowing the staff to share their views when it was convenient for them (i.e. scheduled meetings or informal discussions) helped convey the message that all feedback on my role was welcomed.

### 4.4.1.6.2 Consultations for Medication-Related Projects

In an effort to involve vital players throughout the process, two approaches were applied and I believe were key to the integration of a pharmacist onto the team. First, I

used a team approach with every task I undertook, and as such, I consulted several staff members throughout the process. The second, was to know when to consult these team members.

A few staff members noted my efforts of consulting key players for initiatives I undertook. Not only did they appreciate being asked for their input, they also acknowledged my strategy of approaching only one staff member, when I had a first draft available, as a logical approach.

- H) ... there were some little initiatives that she was trying to go forward with... and she was very good at consulting... to sort of wanting to run things by me first, rather than just sort of forging ahead with something which may or may not have been entirely a good idea or which may have had some weaknesses to the approach, and so I really appreciated the fact that she was consulting appropriately in terms of things that she was thinking of doing... a lot of that stuff, it just made more sense to happen informally one-on-one with her and me or whoever else she might have consulted, rather than sort of leaving it to a general meeting to go over those things.
- G) ... she checked with me too about an initiative she was looking at in my area...

# 4.4.1.6.3 Debriefing after Direct Patient Care Interactions

From the staff's perspective, they appreciated the verbal debriefing I gave the referring team member after each patient encounter, as well as the documentation I left in the patient's chart. To them, these actions portrayed my efforts of being a team player and also helped establish credibility with the staff.

- I) ... she always debriefed afterwards, after I sent her someone she would say okay, this is what we did, I think that we've covered this, like she was very thorough. So I also felt reassured that the issue had been tackled and I knew it had been documented...and certainly the confidence level of her counseling skills, you know, because it was really good.
- O) But that was the routine that she leaves a very good note on their chart, and before we had time to go take a look at her notes, she comes and gives us a very clear feedback about what she thinks or what she did.
- ?) She always provided a team meeting after she saw clients, like there'd be certain clients and she would always get back to you and describe how it went. And after, you know, if she thought that patient needed follow-up or more education... she was a team member, and nothing was left open-ended. There was closure or follow-up.

?) ... she has really good writing skills as well, and like any research that she does, you know, she does a really good job with that, and also any patient visit documentations, very thorough, very legible, you know, just very clear.

Expanding on the communication piece, I believe it was a key element to the integration process. After working in a hospital setting with a strong team focus, my framework for providing patient care always involved discussions with the patient's other health care professionals to optimize the care they received. From a researcher's point of view, I felt it was essential to continue in this fashion, as it would also assist with the Student Health Centre staff's process of understanding how a clinical pharmacist approaches patient care.

#### 4.4.1.7 Theme 7: Limitations

The limitations from the study included the duration, patient population, funding and space.

# 4.4.1.7.1 Duration of the Study

## 4.4.1.7.1.1 Limited the Impact and Exploration of the Role

Despite demonstrating value as a support to the staff during the study timeframe, as discussed earlier, several of the team members cited the duration of the study as a limitation. One staff member pointed out that the impact on his/her practice would have been greater had I been at the Centre for a longer period of time.

G) I think if she'd been there longer it would have affected my practice more, in terms of, you know, perhaps considering medications I'm not so familiar with or combinations I haven't tried before...

Another team member also highlighted that two months was not enough time for them to fully explore the role of a pharmacist for their team.

B) ... I think there is a lot more of a role for her, and I think that we haven't explored it as much as we potentially could... I don't think we've really got to know 100 percent all that the pharmacist could do in the team... I think what she did was invaluable, I think we learned lots, but I think that there's still a long way to go.

At the end of the two month period, my role as a drug information resource for the staff was far more developed than my direct patient care role. Therefore, the limitations with the study timeframe were more of a barrier for my role with the patients than the staff.

A) ... the piece dealing with individual patients, I really don't think we had enough time to say did that help or didn't it help... in the long term was it effective? Did it help the patient? Did it help efficiency in the clinic? Did it take more resources or fewer resources? I don't see how we could tell at this point...

It was difficult for the staff to evaluate my role with the patients as they did not know how the patients felt about seeing a pharmacist in this unique role. One staff member highlighted the difference of patients agreeing to see me because their physician recommended it versus truly having an interest in meeting with a pharmacist to discuss their medications.

H) ... not that I asked for it, but I didn't get that much feedback from students that had seen her, as to what their perception was of looking at the information that she had provided to them... where I made referrals... I wasn't entirely sure in some cases whether it was something that they agreed to do because they figured well, this is just part of the process, or whether they were really quite keen to have had that opportunity to have spoken with a pharmacist about all those things.

In addition, the team members were still unclear on exactly what my role with the patients, and degree of involvement, should be.

A) ...I found where she did good work, that to my mind the best work, at least the most helpful for me, was the research component... I still don't understand how the clinical pharmacist would work with the care giver in evaluating side effects and giving advice. I think there would need to be a more a closer clinical relationship to prescribe or the patient and the pharmacist, than we developed, for that to work.

Interestingly, the evolution of clinical pharmacy services – pioneered by hospital pharmacists, followed a similar path. <sup>75, 76</sup> Historically, providing drug information to physicians and nurses was a fundamental step in the development of the clinical pharmacist role. <sup>75</sup> The provision of drug information by clinical pharmacists was established prior to the inception of direct patient care services. <sup>76</sup> As the role expanded, health care

professionals – including pharmacists, were not clear on what the direct patient care role would be, but did acknowledge that the role needed to be clearly defined.<sup>76</sup> Today, the roles of clinical pharmacists continue to evolve and have migrated from hospital practice to ambulatory setting,<sup>75</sup> as demonstrated in our study.

#### 4.4.1.7.1.2 Generation of Patient Referrals

The number of patients I saw was dependent on the number of referrals the team made. Of note, the opportunities to answer the staff's drug information questions surfaced more easily and quickly compared to patient referrals.

- D) Unfortunately I never got as far as referring that client to her, but just great resource for me as a professional in that way.
- G) ... Especially their referring patients to meet with her, you know, like I had no difficulty, you know, using her as a resource, and I'd done that before, but I actually hadn't had the opportunity to refer patients to sit down and talk to a pharmacist and that would have taken me longer to make good use of that.

One of the challenges the staff experienced with referring patients to me was remembering that there was a pharmacist on the team. They acknowledged that it 'takes a while for everyone to change practice patterns' and the referrals 'required a conscious thought'. Each participant who brought up this issue noted that had the study been longer, they would have become more accustomed to the idea of having access to a pharmacist.

- H) ... it takes a long time to change your own habits... I even put a sticky on my computer saying, you know, with her name on it, just so that I would constantly remind myself... the longer she was here the more that would have become ingrained....
- J) ... perhaps if I had worked with a pharmacist longer I would in that sort of situation that I would have had a better sense of when I should be, you know, talking with her or referring to her,... and you'd probably, you know, do that more quickly rather than, you know, kind of thinking about that as an after thought.

One of the allied health care professionals added insight to establishing referrals by using her/his own experiences with the team. (S)he commented that the number of patient referrals increased for her/him over time.

D) ... when I first started as a [allied health care professional], there had been someone in place before but referrals weren't quite as easy as they are now. You should see my list! I think that new added step in figuring out when to send them and when not to send them just takes time for the practitioners to get used to.

Other researchers have also noted that patient referrals to primary health care pharmacists were slow to generate, initially. <sup>26, 37</sup> However, an explanation for this delayed acceptance of clinical pharmacists providing direct patient care was not provided. In my introduction, I discussed a survey involving randomly selected physicians from the state of California, which discovered that physicians do not know what to expect from pharmacists. <sup>20</sup> One of their findings was that physicians believe that pharmacists are capable of providing non-patient specific drug information; however they were less confident in our ability to provide information tailored to individual patients' clinical situations. They also concluded that the level of physician acceptance to pharmacy services is related to their degree of exposure. <sup>20</sup>

The Seniors Medication Assessment Research Trial (SMART), which was also highlighted in my introduction, was a study evaluating a collaboration between six expanded role pharmacists and six family physicians. The pharmacists were only brought in for medication consultations in an effort to optimize the patients' therapy. The researchers found that the physicians were reluctant to support the pharmacists in anything beyond a traditional pharmacy role. The need for developing a trusting relationship was identified as an important piece to creating an effective collaboration between the two health care professions. When the physicians were asked for suggestions to change or improve the program, they recommended that the pharmacists provide academic detailing, which would assist the physicians in making informed choices when selecting medical therapy for patients.<sup>19</sup> In other words, the physicians offered ideas for enhancing the drug information they could receive from the pharmacists, as they were not comfortable with the pharmacists providing direct patient care.

In our study, creating my drug information role was a comfortable and natural process for the team. Whereas my direct patient care role was new to them, and required more than two months to develop. Although the above reference to the evolution of clinical pharmacy in hospitals is an interesting link to our current study, the previous progression dealt with hospital pharmacists pioneering direct patient care activities versus our present practice in

which direct patient care activities have been established and successfully implemented by clinical pharmacists in ambulatory settings. If we draw on the findings from the above reported studies on pharmacists' roles, establishing credibility by providing team members with drug information needs to occur before the health care professionals are prepared to refer patients to pharmacists in an expanded role. To facilitate the understanding of what a clinical pharmacist can offer, I feel that the drug information questions should include both general and patient specific inquiries. The latter will increase the team's confidence in our ability to tailor the information to best suit the scenario. Over time, as credibility is formed and the staff is more familiar with a pharmacist's capabilities, the team should be more willing to foster a direct patient care role for the pharmacist – however additional research is needed to confirm this notion.

It should be noted that other patient referral methods, not only those requested by the Student Health Centre health care professionals, were considered prior to Phase II. During the on-line focus group with the established primary health and ambulatory care pharmacists, two options were proposed; a patient referral form and an automatic patient referral process. With the latter, two approaches were used by one of the focus group pharmacists at different practice sites. In one, patients completed a self-administered drug related problem risk assessment questionnaire. In the other, all patients with coronary artery disease or diabetes were referred to the pharmacist for medication reviews. The receptionists at both practice sites were responsible for identifying and contacting the patients and making an appointment to see the pharmacist.

Although this patient referral method would have been beneficial, we felt that the Ethics Board would have rejected our request to incorporate this selection process in our proposal. The pharmacist incorporating the patient referral method in his/her practice was employed by the team to provide direct patient care. In our study, the Ethics Board likely would have reviewed our proposal from a researcher's perspective and not as a practitioner. In addition, one of the focus group participants currently conducting clinical research reported being able to access patient charts only after a referral was made by a physician, which was stipulated by the Ethics Board.

## 4.4.1.7.2 Patient Population

## 4.4.1.7.2.1 Narrow Patient Demographic

The type of patients who seek medical care at the Student Health Centre are 'very specific', and are comprised of a relatively 'young, healthy population'. In addition, 'there isn't as much chronic illness management' compared to other primary health care centres in the city of Saskatoon. Despite these limitations with the demographics, the team still saw benefit in working with a clinical pharmacist, as one participant added, "... but that doesn't mean that there isn't value in having a pharmacist on site".

Primary health care involves a proactive approach to preventing health problems, along with an appropriate management plan and follow-up once a disease or condition has been diagnosed. As I reflected on my patient interactions, as a primary health care pharmacist I focused on how medication compliance can have a favourable impact on a disease or condition. For example, taking an antidepressant for an appropriate duration - even after the symptoms of depression resolves, to decrease the risk of suffering from another episode. Education around the benefits of a medication and management of side effects, along with encouraging patients to take an active role in their health also align with the primary health care philosophy. To my knowledge, there are no published papers assessing clinical pharmacy services with university students. However, the Student Health Centre allowed me to specialize in this particular patient population while maintaining a primary care approach.

The patient population should be taken into consideration when selecting a primary health care centre; however a narrow patient demographic does not preclude the ability to establish clinical pharmacy services. The Seniors Medication Assessment Research Trial (SMART) focused solely on elderly patients. Medication use and the number of medical conditions tend to increase with age, and the pharmacists who participated in the study had more of an opportunity to make several recommendations to optimize the patients' therapy. However, they were unable to secure physician acceptance of expanding the role of a pharmacist. <sup>19</sup> In contrast, pharmacists have been able to successfully develop roles on health care teams which provide care to a specialized group of patients when using action research as an integrative approach. <sup>50</sup> Therefore, the process of establishing patient care is

more important than the patient population itself, when integrating a pharmacist into an already established team.

# 4.4.1.7.2.2 Timing of the Study

As for the timing of the study, the clinical services were provided at the end of the first school term – i.e. November and December. One of the focus group participants noted that December was not an ideal month for recruiting patients.

B) ... December is not a good month, because students start exams practically right off the bat, and that changes whether they're going to turn up for appointments and results.

The direct patient care interactions I was able to obtain decreased during the month of December. University courses ended the first week of December. Students were busy studying for exams, and then often left campus immediately after their last test to head home for the holidays. The drop in patient visits not only declined for me, but the entire Centre.

I feel that the duration of the study was more of a limitation than the months we selected, as the academic calendar is always busy for students. Therefore, I would recommend a period greater than two months when trying to establish and evaluating a direct patient care role. A longer timeframe could compensate for fluctuations in patient volumes.

### 4.4.1.7.2.3 Lack of Patient Buy-in

As mentioned earlier, patients who seek care at the Student Health Centre often want to know a lot about their medications. A caveat to this is that they want to receive the information in a fashion that is quick and convenient for them. Therefore, issues arose regarding a lack of patient buy-in, as booking an appointment with yet another health care professional did not always appeal to them.

H) ... a lot of our student population is sort of rushing in and out looking for a quick easy fix kind of care... there certainly would have been occasions where I did make an offer to a student in my office that they be seen by the pharmacist, where they basically would have said no. And for them it was just too much of a hassle, like it had been

enough of an inconvenience in their life to see me... how do I actually get the student to see her in a way that meets their needs and also meets my needs...

The patients would need to perceive value in meeting with a primary health care pharmacist before they would agree to do so. With the uncertainty the team had surrounding my direct patient care role, conveying the benefit of meeting with a clinical pharmacist to a patient would have been difficult for them. To complicate the situation further, all patients who received a prescription from their physician/nurse practitioner would have an interaction with a pharmacist, albeit a community pharmacist, when the prescription was filled. I admit that at certain points of the study, I feared that the staff would not allow my direct patient care role to evolve beyond the traditional boundaries of community pharmacy. These concerns support the importance of having a clearly defined role when a new health care professional joins an already established health care team.

## 4.4.1.7.3 Funding and Space

Concerns surrounding funding and space emerged from the focus group discussions. The staff recognized that 'funding is an issue' and they may have to reallocate resources in order to add another health care profession to their mix.

A) ... I don't know how the pharmacist would be funded, when you're on a global budget of sorts... you've gotta balance this resource against an additional counselor... I mean you can't just keep adding, adding, adding and getting bigger, bigger and bigger, you end up having to reallocate resources at some point.

In terms of space, as with the majority of buildings on campus – space is a premium. It was noted that the Centre was short one office while I provided clinical services, and the lack of space could be a large enough barrier to prevent the addition of a pharmacist onto their team.

H) ... we were a little shorter on rooms, sometimes when she was here. But we knew that that was going to be an issue and we knew we could work our way around it ... if we were to have someone in that position on a permanent basis as part of our team, I mean it would just accentuate our need for more appropriate space... but that honestly might be a deal breaker... we could all in principle think that this is a great idea and come to the conclusion that no, we can't have a pharmacist because we don't have adequate space, to house one.

The Student Health Centre did not have to pay for the clinical pharmacy services I provided over the two month period. They were unable to dedicate one office solely for a pharmacist; however there was always a room for me to work out of. Nurse practitioners found that a lack of office space and inattention to basic resources marginalized their purpose and legitimacy when they expanded their roles in primary health care. Therefore, funding and office space would need to be addressed by a health care centre prior to a pharmacist joining their team.

#### 4.4.2 Minor Theme

#### 4.4.2.1 Theme: Recommendations

As mentioned earlier, the Student Health Centre staff members provided several recommendations to facilitate future integrations of pharmacists into primary health care teams. The following section includes the suggestions that surfaced during the focus group discussions.

# Bring in established primary health care pharmacists to describe their role.

The roles of health care professionals working in primary health care centres can vary from team to team – based on the needs of the patient population and existing treatment gaps, as discussed previously. For these reasons, I did not provide much detail of what other primary health/ambulatory care pharmacists do. Instead, I presented the Student Health Centre with the results of the on-line focus group with established primary health/ambulatory care pharmacists, during our initial planning phases. These results – i.e. a list of clinical pharmacy activities tailored specifically to the Student Health Centre, is what we used as a base for creating my role.

Unfortunately, the staff appeared disconnected from this expert panel of pharmacists. As a future consideration, the team suggested they be provided with more detail of how clinical pharmacists, already established on other primary health care teams, function within their teams.

A) ... we didn't actually have another clinical pharmacist come in... I wonder if it would have helped if somebody would have actually come in and said here's what we do, first hand...

H) I guess it might have been... nice to have heard a little bit more... of an introductory synopsis of how this does play out in other settings where it has been established, and not necessarily even just in Saskatoon but you know, in other.. in other settings, because it is kind of a newer idea, because evidently Lynette has done some research on that. Maybe there just wasn't time for her to sort of share that with us, and that wouldn't necessarily have helped all that much in terms of the specific setting that we're in but it would have been - to me it would have been interesting.

### Identify the pharmacist's vision to assist with role creation.

When selecting a pharmacist to join your team, ensure you 'interview somebody and look at their vision'. One participant recommended that a team should ask a pharmacist '...what their vision is, what they think that they could ultimately achieve, what would be their idea." This will help establish the role and direction of adding a pharmacist.

IMPACT (Integrating family Medicine and Pharmacy to Advance primary Care Therapeutics), was an initiative to integrate seven pharmacists into primary health care centres in Ontario, Canada. When reflecting on their hiring process, they acknowledged the importance of identifying the each pharmacist's vision for the position. By learning more about the candidates' vision – along with their previous experience and practice settings, the IMPACT team felt they were better equipped to match the job applicant to the available positions. <sup>78</sup>

# As a profession, pharmacists need to market ourselves better to highlight the diverse roles we can take on.

One staff member noted that the profession of pharmacy needs to promote the variety services we can provide.

B) ... I also think that pharmacists maybe haven't done a good job of telling us what they really can do, and maybe that's why I think we kind of have problems thinking about it. Maybe they need to stand up and say, we can offer this so much more.

Pharmacists should not assume that other health care professionals understand our background or capabilities. To facilitate our role expansion in health care, we need to educate other health care providers on the various responsibilities we can take on.

The health care team needs to think big and outside the box when considering what a pharmacist can do for their team.

When forming the role of a clinical pharmacist, one participant suggested the team members open their minds to the possible functions a pharmacist can take on and not to restrict the opportunities based on their traditional view of pharmacy services.

B) I think we have to think out of the box too about what pharmacists do do, and maybe not think about pharmacists who, you know, have their own business and sell drugs and make money... but what they have to offer as a team in doing that, and look at pharmacy in a different way,... I think you have to think about what they can do... I think if you could look at it outside of how these pharmacists function now, to how you think an ideal pharmacist should function... I think you'd have to think big. Think about all the things that pharmacists can do and more, and don't just restrict what you know about pharmacists.

The team's recommendations of bringing in an established primary health care pharmacist to describe their role, along with having the pharmacist who will join the team promoting our diverse services, could assist the staff with this step.

When shaping the role of clinical pharmacist for your team, it is important to identify the treatment gaps that exist in your current service.

It was noted that a team should recognize the areas in their practice that could be improved upon or enhance the level of care patients receive.

A) ... I think you'd sit down ahead of time and figure out that here's areas in our service that are weak, here's the way we can help our patients, our clients, here's needs we see that aren't getting fulfilled. We need somebody to work on those things.

The treatment gaps that also fall under the scope of practice for pharmacists can form the initial clinical activities that the pharmacist takes on.

Create a job description and/or policies and procedures to ensure the role of the pharmacist is clearly defined.

Once the role of a clinical pharmacist has been defined for a team, a few of the team members felt that a job description and/or policies and procedures would be beneficial to ensure the expectations and responsibilities are outlined.

- A) I think it would help if there had been some development of a protocol for how a clinical pharmacist works in a multidisciplinary team... the primary health care teams before going this direction had a clear idea clear statement of what they at least initially intended that the pharmacist to do... I'd think you'd want some more definition of the role rather than just hiring somebody sort of on principle it's a good thing to do, and then let them sort out what they're going to do...
- H) ... important process of having, you know, policies and procedures and very clear sort of job descriptions and what are the ranges of services that can be provided, what are services that require the input of a physician and those that don't require the input of a physician, those kinds of things would need to be pretty clearly delineated...

Because my role as the Student Health Centre's clinical pharmacist was still being explored and defined, we would have been unable to create an official job description. However, as the responsibilities of the clinical pharmacist are solidified over time, I agree with the team that developing a job description – as a next step, would beneficial. In addition, writing a job description may identify areas that need to be further discussed with the team in a proactive manner.

The team members should be aware that their roles may change when a clinical pharmacist joins their team.

As highlighted earlier, a team member noted that their own roles may change when a new team member is added to the mix of health care professionals. Another participant recommended that the staff be aware of this possible change.

I) ... I think all of us at first, you know, you think a little bit about your own role ... and how that may or may not change with the pharmacist on the team, so I think just being aware of that and exploring that and thinking about that a bit would be useful as well.

Ideally, if individual team member's roles were altered, the team would be able to identify how the changes could benefit the team. In other words, how can the services be restructured to increase the level of care the patients are offered.

Consider sharing a pharmacist with another health care clinic or having access to a pharmacist via phone or email and who is available for patient consultations.

The staff suggested that a pharmacist could be shared with another health care centre. To expand on this idea, some of the team members recommended that they should still have access to clinical pharmacy services even if the pharmacist was working off-site.

- A) Would it work if a pharmacist was shared between two clinics?
- H) ... it would be nice to have someone who's more specifically designated to answer my questions... just a phone call away.
- J) Or if she wasn't there all the day all the time... e-mail her with questions if you wanted them answered more quickly.
- O) ... hospital-based work... consult pharmacy... Pharmacist come to the wards, spent one hour, sees your patient, reads the chart, and writes a note for you. If we could have such a thing in our little clinic, not hospital, that you can have pharmacist coming, I don't know, one, two half-days, and seeing your patient, and the same pharmacist or a group of pharmacists, will be available to answer your phone calls... possible there's a group of pharmacists somewhere that they'll be willing to answer, to cover for call sitting, and answering physicians questions...

Having a pharmacist work for a health region, providing both on and off-site services to more than one primary health care clinic could be a solution to the current health care budget constraints.

### Investigate options for a clinical and dispensing pharmacist.

Other options funding issues would be to collaborate with community pharmacists who are located near your centre and expand their role to include clinical activities, or have your clinical pharmacist dispense a certain number of commonly prescribed medications.

- B) ... to have somebody that could dispense, that could be there for students to supply over-the-counter medications and, you know, morning-after pills and stuff, to actually expand their role a little bit so they had a dual role, I think might be as a pharmacist but who also worked clinically, I think would be on campus would be a useful improvement, and maybe utilize them better too. Because lots of our students actually just want over-the-counter medications.
- H) ... I don't know how this would work but in actually having certain medications that could be dispensed right on site, rather than just sort of the consultation at a pharmacist and then they have to go yet again to another place... It just to me that's not a very good integration service... if we ever get our new Student Health Clinic, that it would be immediately adjacent to a pharmacist which might still be separate from

the primary care pharmacist's role. You know, there are just different ways... to minimize duplication of service...

D) Would the idea of having a pharmacy adjacent to the clinic be another way to involve them? You would just get to know that person a lot better, they would be a resource to the doctors as you phone back and forth, or the nurses, and the patients...

In my experience, when the responsibilities of both dispensing and clinical services are combined, there is a risk of dispensing functions taking priority over a clinical role. Therefore, if a community pharmacist was hired by the health care team to provide clinical services, I would recommend that a clearly defined job description be created to ensure that the team receives a certain percentage of hours dedicated solely to clinical services. In addition, if an on-site clinical pharmacist was to dispense medications, the regulations set forth by the Saskatchewan College of Pharmacists would need to be honored to ensure that legal requirements are met.

Interestingly, my role on the team did not include product distribution, yet the staff still associated a clinical pharmacist with the provision of drugs. Despite our attempts as a profession to expand the role of pharmacists, I feel that these efforts are often overshadowed by our most prominent traditional role – dispensing medications. Hopefully, in the future, other health care professionals will acknowledge clinical pharmacists as having a distinct and specialized role.

#### Investigate research opportunities which would involve pharmacists.

One team member recommended that a health care team could create and implement research projects as a means of involving the profession of pharmacy with the team.

H) I mentioned research, and that was a way to involve pharmacists if there was some kind of a research project that could use the involvement of a pharmacist. That would be one way to make it a door into the evolvement.

Conducting clinical research in an existing health care team is a practical option and provides an opportunity to work with other health care professions. However, research projects are only run over a certain timeframe, therefore it does not provide a long-term solution of the lack of funding.

Consider establishing clinical pharmacy services in a primary health care centre that serves a wide patient demographic with need for chronic disease management.

A few of the team members felt that a pharmacist may have more opportunities in a primary health care centre the served an older patient population suffering from more chronic conditions.

- A) ... I'm sure a geriatric unit would make far more use of a pharmacist than a clinic serving well, intelligent, young people that are on any one or two drugs.
- H) Well I think in a more general practice such as the West Winds Clinic, where you've got the full demographic including a good proportion of elderly and I think that that sort of opens up a lot more possibilities or the kind of role that the pharmacist can have. Just sort of a multi system or organ diseases and a lot of probably pharmacy issues and all that kind of thing. And just the availability of clients to be part of that kind of a process... there's a lot of follow-up being provided by the pharmacist to people's chronic illnesses that makes a lot of sense.... we can't pretend that in our setting that we're really in the same situation...
- O) ... But if she could have this study in a place with more elderly population, you could really have a good assessment of her role in community.

The patient population should be reviewed when selecting a primary health care centre, however as already discussed, the process of establishing pharmacy services is more important then the patient demographics.

For our study, we used the two available Student Health Centre needs assessment surveys to identify services required for this patient population. It is suggested that primary health care teams include members of the community on their governing bodies and have processes in place for identifying their need.<sup>1,79</sup> Means for ascertaining patient population health care requirements, in addition to needs assessment surveys, include focus groups or interviews with community members. Working in conjunction with local community programs can also assist in the recognition of essential services.<sup>1</sup>

### Advertise to patients that a pharmacist is on the team and available for them to see.

One focus group participant noted that my services were not advertised to the patients, which could have made a difference in the number and type of referrals I received.

I) ... it wasn't advertised to students... it could have been a different experience had, you know, students known up front somehow that that service was available. It might have brought her a whole different type of referral.

This is a valid point, which unfortunately we did not think of while I was providing clinical services over the two months. The Student Health Centre does advertise some services – such as chiropractor and massage therapy, to their patients in the form of posters displayed in the patient waiting areas inside the clinic, as well as on bulletin boards located throughout campus. As a future recommendation, any advertising should provide examples of what a clinical pharmacist can offer. In addition, it should be clear that the on-site pharmacist does not dispense medications – unless a dual clinical and dispensing role was developed for a particular health care centre, to avoid any confusion with the patients. The team would also have to be comfortable with the idea of patient self-referral, which may be an issue for individual team members who have reservations of inviting pharmacists to participate in the care of their patients.

#### Gather patient input/feedback to help define and optimize the role of a clinical pharmacist.

During the focus group discussions, one participant suggested that feedback should be obtained from the patients.

H) ... I think for future integrations of pharmacy into a primary health care team... getting more info or feedback from the actual patients themselves as to what they see as being important. So kind of like having focus groups of people that are receiving service rather than just all the professional staff talking about what's good.

As mentioned earlier, we did try to organize an on-line focus group and survey to obtain the patient's feedback on his/her experience with a clinical pharmacist, but unfortunately, our efforts were unsuccessful. Nonetheless, it would be valuable to collect this information.

#### **CHAPTER 5: SUMMARY AND CONCLUSIONS**

#### 5.1 Introduction

In this final chapter, the research findings are summarized under the research questions. The major research findings are then presented, followed by the implications of our study for health care professionals. Finally, limitations and areas for future research are addressed.

#### 5.2 Summary of Research Findings by Research Question

The following section uses the results from the Student Health Centre focus group discussions to answer the research questions. Again, the main research inquiry was how to integrate a pharmacist into an already established primary health care team, which was further broken down into three subsequent questions.

#### 1. Can action research be used to assist with this integration process?

Using the integrative process action research, aided the integration of a pharmacist into an already established primary health care team. This exploratory process was new to staff; at the beginning of the study they were unsure of how to incorporate a pharmacist into their team. However, by providing the staff with opportunities, both formal and informal, to reflect on and evaluate the role of a pharmacist, they began to get a sense of what a pharmacist could offer them. Defining my role with the Student Health Centre staff, prior to providing clinical pharmacy services, and consulting appropriate team members for projects I undertook, fostered the collaborative approach which is encouraged with action research.

# 2. How did the primary health care team members feel about having a clinical pharmacist join their team?

The Student Health Centre staff members welcomed the idea of having a pharmacist join their team and overall were quite pleased with the experience. They did, however, have some initial uncertainty with what the role of the pharmacist would be, along with the degree of utilization. As the study progressed and opportunities arose for using a pharmacist, their concern shifted to whether or not they were utilizing the clinical pharmacy services appropriately.

The primary role established for the pharmacist was as a drug information resource for the staff. The team members were impressed with the quality of the drug information provided, in particular, that the information was detailed and objective, as well as conducted in an efficient manner. This aided with building credibility for the new team member. Staff also noted that having a drug expert carry out these responsibilities increased the efficiency of the team. Being a support to the team members was another role that was established, and the staff felt this enhanced the level of care they provided to their patients. By the end of the two month timeframe, the team had a good understanding of what the role of the pharmacist was in the above listed areas. It was suggested, had the study been longer, the role would have been explored in greater depth.

In contrast, the staff members were unsure with what should be the direct patient care role for the pharmacist. They acknowledged the primary health care role with patients was to provide drug information – particularly with correcting patients' inaccurate perceptions about medications, offering reassurance by reinforcing the recommendations of other health care providers, and empowering patients to make decisions around medication use. Yet, the short study duration appeared to inhibit the development of a clearly defined role and there was some uncertainty surrounding the degree of involvement a pharmacist should have with patients. Some staff members were also unable to identify patients to refer to the pharmacist within this timeframe.

There was also some uncertainty surrounding the roles of the researcher, the clinical pharmacist and team members. Role ambiguity surfaced at times, as the researcher was also the clinical pharmacist, as well as a previous employee at the Student Health Centre in health education. Role overlap between the pharmacist and the physicians/nurse practitioner was brought forward in the areas of drug information and medication counselling. The staff members noted that their own roles may change when a new health

care professional is added to their team. However, they also highlighted that roles would evolve over time and the pharmacist's role would become better defined. The generalizability of the study was questioned by the staff, due to the researcher also functioning as the clinical pharmacist. As well, the staff wondered if the attributes they valued in a pharmacist – i.e. knowledgeable, diligent, thorough, professional courtesy and communication skills, were generalizable to other pharmacists.

The staff identified several process related issues during the focus group discussions. Offering co-located and full-time clinical pharmacy services increased the level of service for the patients, along with enhanced accessibility for the staff. The patient referral process, however, needed to be further defined to ensure that staff could identify patients to be referred to the pharmacist.

As eluded above, the duration of the study was a limitation. Another limitation, identified by the staff members, was the patient population. In particular, the narrow patient demographics, the timing of the study in relation to the patients' academic schedules, and the lack of patient buy-in to see a clinical pharmacist were noted by the team. Funding and space were also brought forward as limitations.

# 3. What recommendations can be provided to support the integration of pharmacists onto primary health care teams?

The recommendations provided by the Student Health Centre team, for facilitating future integrations of pharmacists into primary health care teams, are used to answer the third research question. Their comments, along with some of my own – based on my experience, form the following guide for integrating pharmacists into already established primary health care teams. As highlighted earlier, our study involved a specific primary health care team and pharmacist; however, our recommendations are transferable to other pharmacists and primary health care settings.

- 1. Choose a collaborative process to assist with the integration of a pharmacist into a health care team, such as action research. Apply the framework throughout the integration process.
- 2. Select a primary health care team.

- a. Find a health care team that will welcome and support a clinical pharmacist as a new member of their team.
- b. Identify how resources such as funding and space, will be generated for the expansion of the team.
- 3. Define the role of a pharmacist with the primary health care team prior to joining the team.
  - a. Analyze the health centre's patient demographics to identify what pharmacy services are required.
  - b. The pharmacist should share with the team their vision of how they see their role.
  - c. Educate the health care team on the diverse functions a clinical pharmacist can be responsible for. Bring in established primary health care pharmacists to discuss their role and how it compliments their team.
  - d. Encourage the health care providers to think big and outside of the box when creating the role of the pharmacist emphasizing the difference between dispensing and clinical roles.
  - e. Have the team identify treatment gaps within their current services, and identify how a pharmacist could enhance the level of care patients receive.
  - f. Create a list of projects for the pharmacist to work on when not occupied with patient consultations or drug information questions.
  - g. Develop a job description or policies/procedures to ensure the expectations of both the pharmacist and health care team are clearly defined.
- 4. Determine the logistics of the pharmacist providing direct patient care with the health care team. Again, this should be accomplished before the pharmacist joins the team.
  - a. Decide whether the pharmacy services will be available on a full-time or parttime basis.
  - b. Discuss how patients benefiting from a pharmacy consultation will be identified.
  - c. Develop a process for referring patients to the pharmacist. Ideally the pharmacist would be available to patients via appointment or walk-in basis.

- d. Ensure the pharmacist has access to office space and administrative support.
- e. Construct a plan to advertise the clinical pharmacy services to the patients.
- 5. Once the pharmacist officially joins the team, the first priority should be to establish credibility with the health care team. Answering drug information questions and completing medication-related projects for the team will assist with this process.
- 6. Conduct patient consultations as the referrals arise. Be patient as the volume of referrals take time to gain momentum. As you establish credibility with the team as a drug information resource, they will feel more comfortable with inviting you to participate in their patients' care.
- 7. Depending on the integrative approach you selected, follow the framework to revisit and redefine the role of the pharmacist, with the team, as it evolves. In addition, the pharmacist's original vision for their role (refer to step 3c) should be reviewed and evaluated to determine if alignment between the desired and created role exist.
- 8. Gather patient feedback to identify areas that require improvement.

#### 5.3 Major Research Findings

- 1. The primary health care team involved in the study welcomed and supported the idea of having a pharmacist join their team. They were interested and curious as to what a pharmacist could offer them. However, the team was also unsure what the exact role of the pharmacist would be, how well the pharmacist would be utilized and whether the utilization of this new team member was being conducted in an appropriate manner.
- 2. Being a drug information resource for both the staff members and patients was one of the responsibilities for the pharmacist, and aided the pharmacist with establishing credibility with the staff members. The staff was impressed with the quality of the drug information services, as they felt it was conducted in a thorough, objective and efficient manner. However, despite acknowledging the provision of drug information to patients was valuable especially with the Student Health Centre patient population keen to learn about their medications, the staff was unsure to what extent the pharmacist should provide direct patient care.

- 3. Two months is an adequate timeframe for a clinical pharmacist to demonstrate added value, as a support to the staff, when added to a primary health care team. This support took the form of answering drug information questions, completing medication related projects requested by the staff, and being available for patient consults; however it was primarily based on non-direct patient care activities as two months was not enough time to develop a direct patient care role. The amount accomplished by the clinical pharmacist, along with the staff becoming cognizant of what a clinical pharmacist can offer, assisted in this process. However, the team also recognized that the impact and exploration of the pharmacist's role was limited by the study duration. This finding may be a useful benchmark for pharmacists when evaluating their impact on a team, as they can strive to establish a role as a support to the staff within an eight-week time frame.
- 4. Concerns regarding role ambiguity for the pharmacist, as well as role overlap between and role evolution for the pharmacist and primary health care team, surfaced during the project. The staff sometimes found it difficult to separate my roles as clinical pharmacist, researcher and previous Health Education Coordinator Assistant. They acknowledged that the role of the pharmacist would evolve with time, and noted that individual team members' roles may also change when a pharmacist is added to their staff.
- 5. Having a pharmacist who is knowledgeable, diligent, and thorough; extends professional courtesy to co-workers; and displays good communication skills is valued by a primary health care team. These attributes were identified by the staff as being important, however they did question whether all pharmacists have these character traits.
- 6. Offering co-located clinical pharmacy services provided the staff and patients with greater accessibility to a pharmacist and an enhanced level of clinical pharmacy services. As such, the pharmacist was available to answer questions and conduct patient consults as the need arose and in a timely fashion. However,

resources such as funding and office space need to be addressed prior to hiring a clinical pharmacist.

- 7. Using an integrative approach that fosters collaborative relationships and provides opportunities to establish credibility with the primary health care team like action research, has a greater effect on expanding the role of pharmacists than the patient population. The process used to integrate a pharmacist into an already established primary health care team is more important than the perceived opportunities or limitations with the patient population. However, the patient population should be taken into consideration prior to defining the role of a clinical pharmacist and still has the ability to influence the initiative.
- 8. Good communication between the pharmacist and primary health care team was essential for defining, implementing and evaluating the role of the pharmacist. Scheduled formal meetings, along with informal conversations, provided the staff with multiple opportunities to reflect and comment on the role that was created. All project ideas were discussed between the pharmacist and key players during the initial stages, and feedback was obtained throughout the initiatives until a final copy was produced. Having the pharmacist provide debriefing both verbal and written, to the referring staff member after patient referrals was also appreciated by the team.
- 9. Direct patient care opportunities take time to gain momentum. Adding a new health care professional to a primary health care team requires a process change, and the staff needs time to adapt to this additional available service. In addition, the team members were able to generate several drug information questions for the pharmacist, however not all could identify patients who would benefit from a pharmacist interaction within the two month study duration.
- 10. A template outlining a series of steps to facilitate the integration a pharmacist into an already established primary health care team has been proposed. These guidelines are based upon the experiences of and recommendations brought forward

by the primary health care team and clinical pharmacist involved in the study. The suggested framework can be tailored to suit the needs and structure of any primary health care team. Some of the recommendations were not tested during the project (e.g. bringing in established primary health care pharmacist to describe their role, advertising the clinical pharmacy services, etc.) but were based on practical considerations that the staff felt would aid with the integration process.

#### 5.4 Implications for Pharmacists and Primary Health care Teams

The purpose of this study was to provide guidance on how to integrate a pharmacist into a primary health care team. As mentioned in the introduction, pharmacists within the province of Saskatchewan see value in expanding the profession into primary health care. However, limited experience with team establishment and no clear understanding of the role of pharmacists on primary health care teams were identified as barriers. Investigating team establishment is beyond our study, as current literature suggests that a minimum of four months is required for the development. Our results, on the other hand, allow us to propose a template to assist with defining the role of a pharmacist, as well as tailoring the role to suit individual primary health care teams. In addition, the proposed template may also be beneficial to health care teams who are interested in expanding their multidisciplinary service to include clinical pharmacists.

#### 5.5 Limitations

The principal limitation with our study was the timeframe for the pharmacist to provide clinical pharmacy services at the Student Health Centre. The short study duration of two months constrained the possible impact the clinical pharmacist may have had on the primary health care team. In addition, the staff members were unable to fully explore the potential opportunities and roles that could be taken on by a clinical pharmacist. The time period had a definite impact on the direct patient care role for the pharmacist, as there was insufficient time to develop a clear role. Some of the team members were unable to identify patients to refer to the pharmacist over the two month period. As well, time is required for staff to implement a process change – such as referring patients to a health care professional who is new to the team and functioning in a role that is novel to them.

Another limitation was the patient population. The Student Health Centre provides health care services to a fairly narrow patient demographic. The majority of patients are relatively young healthy adults; suffering from few chronic conditions, and requiring minimal medications compared to other primary health care centres. Because the study involved university students, academic schedules and the demands of post-secondary education also affected the number and level of participation by patients. The study was conducted at the end of the first school term – a time when patients are occupied with completing their course work, writing final exams, and possibly heading home for the holidays. In addition, the Student Health Centre patients often want health care to be provided in a quick and convenient manner. Some patients were unwilling to meet with a pharmacist, as that required booking an appointment with yet another health care professional. Despite our best attempts, we were unable to obtain patient feedback on meeting with a primary health care pharmacist.

An important limitation of this study was my dual role as a researcher and a clinician. This may have introduced some bias in my decision making as a researcher. For example, if these roles were carried out by two individuals, the researcher would have likely included the two patients suffering from a Borderline Personality Disorder in our on-line focus group. However as a pharmacist I likely let my biases dictate who would be included in the evaluation of the services I provided. I also had previous working relationships with some of the Student Health Centre staff, and these members were familiar with my work ethic and personality. Concerns regarding the generalizability of the study were identified by the team based on my dual roles and they questioned whether all pharmacists would perform at the same level. Due to this potential role conflict, it was essential to reduce any bias when analyzing the data collected from the focus group discussions. This was achieved by having two researchers, Dr. Neubauer and I, code the transcripts independently and then discussing the results to ensure we agreed on the findings.

There is a large number of part-time staff employed at the Student Health Centre. This made it difficult for some staff to attend the meetings we held at the Centre for the purpose of discussing the project and defining, reflecting on and evaluating the role of the pharmacist. In addition, the part-time staff had less contact time and opportunity to work with the clinical pharmacist. Lastly, resources – such as funding and space, may exist as

barriers for integrating a pharmacist into an already established primary health care team. However, for our study, these issues were not addressed as the clinical pharmacy services were provided in exchange for participating in the project and office space was only required for a two month period.

#### **5.6 Future Research**

Our study offers direction on how to incorporate pharmacists into primary health care; however additional research into other areas would expand on our findings and further assist with the expansion of pharmacy into primary health care. First - due to the study duration, we were unable to investigate or provide guidance on how to achieve team establishment which has been identified as a barrier for pharmacists who are interested in primary health care. 4 Second, our initiative investigated the integration of a pharmacist into a primary health care team – not the sustainability. It would be advantageous to identify how to maintain clinical pharmacy services once they are established. Third, it would be valuable to explore in greater detail whether establishing credibility with a primary health care team via drug information services and support is required before a direct patient care role for a pharmacist can be developed. Fourth, capturing patient feedback on how they felt when meeting with a pharmacist in this relatively novel role would be beneficial. As discussed already, we attempting to gather this data, but unfortunately we were unsuccessful. Insight into the above areas of research could contribute to and promote an expanded clinical role for pharmacists in primary health care, which would be beneficial to the profession of pharmacy as well as the evolution of primary health care.

#### REFERNCES

- 1. Fyke K. Caring for Medicare: Sustaining a Quality System: Government of Saskatchewan; 2001.
- 2. Romanow R. Building on Values: The Future of Health care in Canada: Commission on the Future of Health care in Canada; November 2002.
- 3. Saskatchewan Pharmacy Coalition of Primary Care: Role of the Pharmacist in Primary Health care; 2003.
- **4.** Role of the Pharmacist in Primary Health care: Pharmacy Coalition on Primary Care; 2003.
- 5. Nancarrow S. Dynamic role boundaries in intermediate care services. Journal of Interprofessional Care. 2004;18(2):141-151.
- **6.** Herr K, Anderson GL. The action research dissertation : a guide for students and faculty. Thousand Oaks, California: SAGE Publications; 2005.
- 7. Health Canada. Primary Health care; 2006.
- 8. Primary Health Care. Saskatchewan Government website: <a href="http://www.health.gov.sk.ca/ps">http://www.health.gov.sk.ca/ps</a> phs services over.html. Accessed June 22, 2006.
- 9. Primary Health Services. Saskatoon Health Region website: <a href="http://www.saskatoonhealthregion.ca/print/your health/ps primary health.htm">http://www.saskatoonhealthregion.ca/print/your health/ps primary health.htm</a>. Accessed March 16, 2006.
- **10.** Canadian Pharmacists Association. Pharmacists and Primary Health Care May 2004.
- 11. Robinson JD, Stewart RB, Curry RW, Jr. The pharmacist as a member of the primary care team: experience in a university-based program. Postgraduate Medicine. 1982;71(1):97-103.
- **12.** American College of Clinical Pharmacy. Establishing and evaluating clinical pharmacy services in primary care. Pharmacotherapy. November-December 1994:14(6):743-758.
- 13. Silcock J, Raynor DK, Petty D. The organization and development of primary care pharmacy in the United Kingdom. Health Policy. February 2004;67(2):207-214.
- 14. Hahn N, Weart W. The pharmacist's role in the optimal delivery of primary care in a managed care world. Pharmacy Practice Management Quarterly. January 1996;15(4):36-43.
- 15. American Society of Health Systems Pharmacists. ASHP Statement on the Pharmacist's Role in Primary Care. American Journal of Health Systems Pharmcy. 1999;56:1665-1667.
- **16.** McCallin A. Developing effective interdisciplinary teams. Nursing New Zealand (Wellington). 2003;9(9):21-23.
- 17. Helling DK. Family Practice Pharmacy Service: Part I. Drug Intelligence and Clinical Pharmacy. December 1981;15:971-976.
- 18. Bryant-Lukosius D. DA, Browne G., Pinelli J. Advanced practice nursing roles: development, implementation and evaluation. Nursing and Health Care Management and Policy. March 16th, 2006 2004;48(5):518-529.
- 19. Howard M, Trim K, Woodward C, et al. Collaboration between community pharmacists and family physicians: lessons learned from the Seniors Medication

- Assessment Research Trial. Journal of the American Pharmacists Association. 2003;43(5):566-572.
- **20.** Smith WE, Ray MD, Shannon DM. Physicians' expectations of pharmacists. American Journal of Health Systems Pharmacy. January 1 2002;59(1):50-57.
- 21. Scholes J, Vaughan B. Cross-boundary working: implications for the multiprofessional team. Journal of Clinical Nursing. 2002;11(3):399-408.
- **22.** Canadian Nurse Practitioner Initiative. Canadian Nurse Practitioner Initiative website: http://www.cnpi.ca. Accessed March 17th, 2006.
- **23.** Gibson F, Bamford O. Focus group interviews to examine the role and development of the clinical nurse specialist. Journal of Nursing Management. November 2001;9(6):331-342.
- **24.** Torn A, McNichol E. A qualitative study utilizing a focus group to explore the role and concept of the nurse practitioner. Journal of Advanced Nursing. June 1998;27(6):1202-1211.
- **25.** Galvin K, Andrews C, Jackson D, et al. Investigating and implementing change within the primary health care nursing team. Journal of Advanced Nursing. 1999;30(1):238-247.
- **26.** Sardinha C. Physician groups embrace pharmacists: collaborations that work. Journal of Managed Care Pharmacy. 1997;3(Sep-Oct):526-528, 530.
- **27.** Carter BL, Helling DK. Ambulatory care pharmacy services: has the agenda changed? Annals of Pharmacotherapy. June 2000;34(6):772-787.
- 28. Brown DJ, Helling DK, Jones ME. Evaluation of clinical pharmacist consultations in a family practice office. American Journal of Hospital Pharmacy. July 1979;36(7):912-915.
- **29.** Eichelberger B. Family Practice Clinical Pharmacy Opportunities in the Community Setting. American Journal of Hospital Pharmacy. May 1980;37:740-744.
- **30.** Bucci KK, Frey KA. A description of a pharmacotherapy curriculum in a university-based family medicine program. Annals of Pharmacotherapy. July-August 1992;26(7-8):991-994.
- 31. Haxby DG, Weart CW, Goodman BW, Jr. Family practice physicians' perceptions of the usefulness of drug therapy recommendations from clinical pharmacists. American Journal of Hospital Pharmacy. April 1988;45(4):824-827.
- **32.** Gums JG. Recent advances: ambulatory care and family medicine. Annals of Pharmacotherapy. July-August 1995;29(7-8):716-718.
- 33. Koffler AB, See S, Mumford J, Johnston B. Implementing and Evaluating a Pharmacy Consult Service Within a Family Medicine Residency Program. American Journal of Hospital-Systems Pharmacy. June 15 2002;59:1200-1204.
- **34.** Carter BL, Helling DK, Jones ME, Moessner H, Waterbury CA. Evaluation of Family Physician Prescribing: Influence of the Clinical Pharmacist. Drug Intelligence and Clinical Pharmacy. October 1984;18:817-821.
- **35.** Price SO, Newnham MA. Physician perceptions of clinical pharmacy encounters in a family practice clinic. Topics in Hospital Pharmacy Management. October 1994;14(3):13-20.

- 36. Lobas NH, Lepinski PW, Woller TW. Satisfaction of physicians and nurses with clinical pharmacy services. American Journal of Hospital Pharmacy. June 1991;48:1189-1190.
- 37. Chen J, Britten N. 'Strong Medicine': an analysis of pharmacist consultations in primary care. Family Practice. 2000;17(6):480-483.
- **38.** Farris KB, Cote I, Feeny D, et al. Enhancing Primary Care for Complex Patients: Demonstration project using multidisciplinary teams. Canadian Family Physician. July 2004;50:998-1003.
- **39.** Davis RE, Crigler WH, Martin HJ. Pharmacy and Family Practice: concept, roles and fees. Drug Intelligence and Clinical Pharmacy. October 1977;11:616-621.
- **40.** Perry PJ, Hurley SC. Activities of the Clinical Pharmacist Practicing in the Office of a Family Practitioner. Drug Intelligence and Clinical Pharmacy. March 1975;9:129-133.
- 41. Juhl RP, Paul PJ, Norwood GJ, Martin RL. The Family Practitioner-Clinical Pharmacist Group Practice a model clinic. Drug Intelligence and Clinical Pharmacy. October 1974;8:572-575.
- **42.** Leff RD, Helling DK, Smith FW, Probasco RW, Pfeiffer FG. Profile of a unique community-based clinical pharmacy family practice program. Contemporary Pharmacy Practice. Fall 1981;4(4):223-226.
- **43.** Moore TD. Pharmacist Faculty Member in a Family Medicine Residency Program. American Journal of Hospital Pharmacy. September 1977;34:973-975.
- **44.** Beney J, Bero LA, Bond C. Expanding the roles of outpatient pharmacists: effects on health services utilization, costs, and patient outcomes. Cochrane Database Systematic Review. 2000(3):CD000336.
- **45.** Smith F. Evaluation of pharmaceutical services: Methods and measures. The International Journal of Pharmacy Practice. March 2000;8:60-76.
- **46.** Stringer E, Genat W. Action Research in Health. Upper Saddle River, NJ: Pearson Prentice Hall; 2004.
- 47. Morrison B, Lilford R. How Can Action Research Apply to Health Services? Qualitative Health Research. July 2001;11(4):436-449.
- **48.** Shaw J. Getting integration started: Q methodology action research. Community Practitioner. Sep 2001;74(9):335-338.
- **49.** White M, Verhoef M. Toward a Patient-Centered Approach: Incorporating Principles of Participatory Action Research Into Clinical Studies. Integrative Cancer Therapies. 2005;4(1):21-24.
- **50.** Tanna NK, Pitkin J, Anderson C. Development of the specialist menopause pharmacist (SMP) role within a research framework. Pharmacy World & Science. 2005;27(1):61-67.
- 51. Morse J, Richards L. Readme First for a User's Guide to Qualitative Methods. Thousand Oaks, CA: Sage Publications; 2002.
- **52.** Morgan D. The Focus Group Guidebook. Vol 1: Sage Publications; 1998.
- 53. Smith F. Focus groups and observation studies. The International Journal of Pharmacy Practice. December 1998;6:229-242.
- **54.** Pulliam L. Client satisfaction with a nurse-managed clinic. Journal of Community Health Nursing. 1991;8(2):97-112.

- 55. Kenny A. Interaction in cyberspace: an online focus group. Journal of Advanced Nursing. 2005;49(4):414-422.
- **56.** Moloney M, Dietrich A, Strickland O, Myerburg S. Using Internet Discussion Boards as Virtual Focus Groups. Advances in Nursing Science. 2003;26(4):274-286.
- 57. Kidd P, Parshall M. Getting the Focus and the Group: Enhancing Analytical Rigor in Focus Group Research. Qualitative Health Research. May 2000;10(3):293-308.
- **58.** J.T. Walston RWL. Computer-Mediated Focus Groups. Evaluation Review. October 2000;24(5):457-483.
- **59.** M.K. Campbell AM, C. Carr, et al. Health Behaviour Changes After Colon Cancer: A Comparison of Findings from Face-to-Face and On-Line Focus Groups. Family Community Health. August 14 2001;24(3):88-103.
- **60.** Oringderff J. "My Way": Piloting an Online Focus Group. International Journal of Qualitative Methods. September 2004;3(3):Article 5.
- 61. Singhal PK, Raisch DW, Gupchup GV. The impact of pharmaceutical services in community and ambulatory care settings: evidence and recommendations for future research. Annals of Pharmacotherapy. December 1999;33(12):1336-1355.
- **62.** Klockars SJ, Blair MM, Ragucci K. Survey of Clinical Pharmacy Services in a Family Medicine Clinic. American Journal of Health Systems Pharmacy. March 2003;60:485-486.
- 63. Campbell RK, Saulie BA. Providing pharmaceutical care in a physician office. Journal of the American Pharmaceutical Association (Wash). July-August 1998;38(4):495-499.
- 64. Student Health Centre. University of Saskatchewan website: <a href="http://www.students.usask.ca/wellness/health/shc/">http://www.students.usask.ca/wellness/health/shc/</a>. Accessed March 16, 2006.
- 65. Student Health Centre Needs Assessment Report. Saskatoon: University of Saskatchewan; 2003.
- **66.** Kehoe S. A Needs Assessment of Student Behaviours & Knowledge. Saskatoon: University of Saskatchewan; 1999.
- 67. Morgan D. Planning Focus Groups. Thousand Oaks, CA: Sage Publications; 1998.
- ovan Eyk H, Baum F. Evaluating Health System Change Using Focus Groups and a Developing Discussion Paper to Compile the "Voices From the Field". Qualitative Health Research. February 2003;12(2):281-286.
- **69.** Krueger R. Developing Questions for Focus Groups. Thousand Oaks, CA: Sage Publications; 1998.
- **70.** Salant P, Dillman D. How to conduct your own survey. New York: John Wiley & Sons Inc.; 1994.
- 71. Pealer LN, Weiler RM, Pigg RM, Jr., Miller D, Dorman SM. The feasibility of a web-based surveillance system to collect health risk behavior data from college students. Health Education and Behaviour. October 2001;28(5):547-559.
- **72.** Krueger R. Analyzing & Reporting Focus Group Result Thousand Oaks, CA: Sage Publications; 1998.
- 73. Helling DK. Family practice pharmacy service: part II. Drug Intelligence and Clinical Pharmacy. January 1982;16(1):35-48.
- **74.** Williamson GR, Prosser S. Action research: politics, ethics and participation. Journal of Advanced Nursing. December 2002;40(5):587-593.

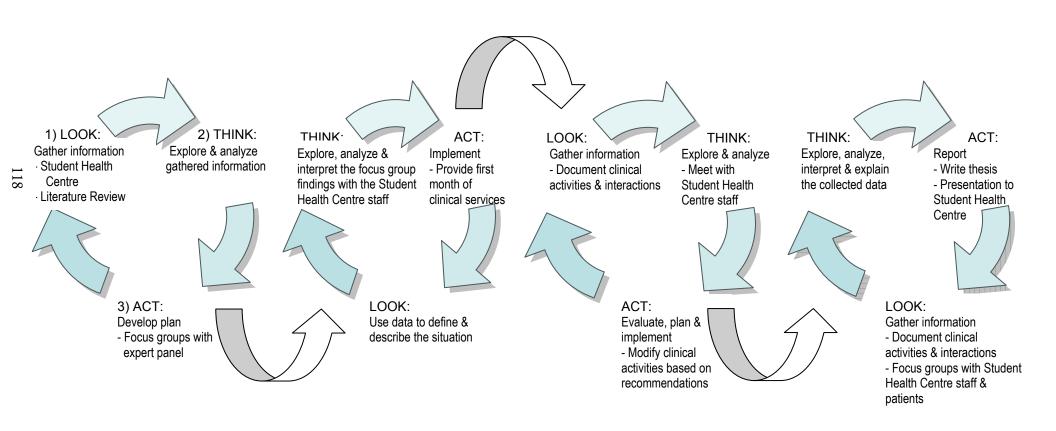
- **75.** Christen C. Clinical pharmacy and medication safety. Annals of Pharmacotherapy. November 2006;40(11):2020-2021.
- **76.** Francke GN. Evolvement of "clinical pharmacy". 1969. Annals of Pharmacotherapy. January 2007;41(1):122-128.
- 77. Branch PHS. Saskatchewan Action Plan for Primary Health care.

  <a href="http://www.health.gov.sk.ca/ph">http://www.health.gov.sk.ca/ph</a> phs publications/phs action plan for primary health care.pdf. Accessed June 22, 2006.
- **78.** K. Babcock BF, L. Dolovich, and C. Sellors. Hiring a pharmacist to work in primary care: Application for ambulatory and hospital pharmacy. Canadian Pharmacists Journal. September/October 2006;139(5):46-48.
- **79.** King A. Primary Health care Strategy. <a href="http://www.moh.govt.nz/moh.nsf/238fd5fb4fd051844c256669006aed57/7bafad2531e04d92cc2569e600013d04/\$FILE/PHCStrat.pdf">http://www.moh.govt.nz/moh.nsf/238fd5fb4fd051844c256669006aed57/7bafad2531e04d92cc2569e600013d04/\$FILE/PHCStrat.pdf</a>. Accessed January 26th, 2008.

#### **Appendices**

#### Appendix I: Action Research Model

#### LOOK-THINK-ACT



#### Appendix II: Email Invitation to Primary Health care Pharmacists

Dear Colleague,

Dr. Fred Rémillard and I are co-supervising a graduate student, Lynette Kolodziejak, working toward her Master of Science (Primary Care). We are investigating how to integrate a pharmacist into an already established primary health care team and require your expertise. There are three phases to the study: 1) defining the role of the pharmacist, 2) implementing the purposed role, and 3) evaluating and prioritizing the implemented role.

For the first phase of the study, we are seeking pharmacists who:

- 1) Have established themselves on Canadian primary health care teams;
- 2) Were the first pharmacist to join their primary health care team;
- 3) Are willing to share their experiences with primary health care teams using an on-line focus group; and
- 4) Are willing to complete a survey regarding the use of an on-line focus group.

Would you be interested in participating in an on-line focus group to help create a prioritized list of possible clinical pharmacy activities tailored specifically for the Student Health Centre at the University of Saskatchewan (the primary health centre chosen for the project)?

The on-line focus group will be accessible for three weeks this summer, likely during the months of August and/or September, 2006. New discussion questions will be posted every week during the three week period. Participants will be asked to log onto the website to read responses and post replies at least once a week.

Pharmacists from across Canada are being asked to participate. Due to different time zones, the on-line focus group will not be live, and therefore you can log onto the website whenever is convenient for you. The total time required to participate is estimated at 3-4 hours over the three weeks. An activity log will be kept electronically to assess how often participants log on and the time spent during each visit. At the end of the three week period, participants would also complete a survey regarding their experience with an on-line focus group. For your participation, we would like to offer you a \$50 honorarium to partially compensate you for your time.

You will be receiving a follow-up letter in the mail regarding this opportunity. If you are interested in learning more about this study, please contact me for additional details. The project has been submitted to ethics for approval from the Behavioural Research Ethics Committee of the University of Saskatchewan.

Thank you for your consideration,

Shannan Neubauer, BSP, PharmD

Appendix III: Information Package for Primary Health and Ambulatory Care Pharmacists Participating in On-Line Focus Group



# Integration of a Pharmacist into a Primary Health care Site

A Qualitative Approach

Information for the Primary Health/Ambulatory Care Pharmacists Participating in Phase I of the Study August, 2006

PRIMARY INVESTIGATORS:
Lynette Kolodziejak, BSP, MSc (Candidate)
Dr. Shannan Neubauer, BSP, ACPR, PharmD, FCSHP
Dr. Alfred Rémillard, BSc (Pharm), PharmD, BCPS

RESEARCH COLLABORATORS:
Dr. Roy Dobson, PhD
Dr. Shawna Berenbaum, PhD

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## Primary Health/Ambulatory Care Pharmacist Consent Form

You are invited to participate in a study entitled: Integration of a Pharmacist into a Primary Health care Centre

#### Purpose of the Study:

The purpose of this study is to identify how to integrate a clinical pharmacist into an already established primary health care team. There are three phases to the study: 1) defining the role of the pharmacist, 2) implementing the proposed role, and 3) evaluating and prioritizing the implemented role. You are being asked to participate in the first phase of this study because of your experience as a primary health/ambulatory care pharmacist.

You have agreed to participate in an on-line focus group to help create a list of possible clinical pharmacy activities tailored specifically for the Student Health Centre at the University of Saskatchewan. In addition, you can also fill out a survey regarding your experience with using an on-line focus group.

#### **Procedures:**

The on-line focus group will be accessible for three weeks during the month of September, 2006. New discussion questions will be posted every week during the three week period. You will be asked to log onto the website to read responses and post replies at least once a week. Since pharmacists from across Canada are being asked to participate, resulting in different time zones, the on-line focus group will not be live. You can log onto the website whenever is convenient for you. The total time required to participate is estimated at 3-4 hours over the three weeks. An activity log will be kept electronically which will assess how many postings are read and the number of responses posted per each participant. Instructions for using the on-line website are providing in this information package (refer to pages 9 & 10).

**Potential Risks:** Due to the fact that the participants for this focus group have been selected from the same professional group, some of whom are known to each other; it is possible that you may be identifiable to other people on the basis of what you have posted. After the focus group discussion, and prior to the data being included in the final report, you will be given the opportunity to review the transcripts from the focus group, and to add, alter, or delete information from the transcripts as you see fit.

**Potential Benefits:** Although not guaranteed, the results of this study will provide guidance to other pharmacists who are interested in joining primary health care teams.

**Storage of Data:** The data, in both electronic/hardcopy formats, will be stored in a password protected computer/in a locked file cabinet in the office of one of the researchers (Shannan Neubauer), 219 Thorvaldson Building, University of Saskatchewan, for a period of five years.

**Confidentiality:** The transcripts will be analyzed for themes and will be reported in aggregate form, so that it is not possible to identify individuals. The researchers may use direct quotations in the publication; however, the speaker will not be identified by name or practice site. The researchers will undertake to safeguard the confidentiality of the discussion, but cannot guarantee that other members of the group will do so. Please respect the confidentiality of the other members of the group by not disclosing the contents of this discussion outside the group, and be aware that others may not respect your confidentiality.

**Right to Withdraw:** You may withdraw from the study for any reason, at any time, without penalty of any sort. If you withdraw from the study at any time, any data that you have contributed will be destroyed. You have the right to refuse to answer any question(s) posed by the facilitator. The \$50.00 payment will be prorated if you choose to withdraw from the study.

Questions: If you have any questions concerning the study, please feel free to ask at any point; you are also free to contact the researchers at the numbers provided below if you have questions at a later time. This study has been approved on ethical grounds by the University of Saskatchewan Behavioural Sciences Research Ethics Board on July 28, 2006. Any questions regarding your rights as a participant may be addressed to that committee through the Office of Research Services (966-2084). Out of town participants may call collect. The results of the study will be used to partially complete the requirements for a Masters of Science (Primary Care) degree through the College of Pharmacy and Nutrition. Furthermore, the results may be published and/or presented at inservices/seminars/conferences.

**Consent to Participate:** Please note that logging on to the website and posting responses to the on-line focus group questions will be considered as providing consent, and as such, you are granting the researchers permission to use the data gathered in the manner described. Retain this document for your own records.

#### **Researchers:**

Shannan Neubauer, BSP, PharmD Associate Professor of Pharmacy College of Pharmacy & Nutrition University of Saskatchewan

Phone: 306-966-6332

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Alfred Rémillard, BSc (Pharm), PharmD, BCPP

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Lynette Kolodziejak, BSP MSc Candidate College of Pharmacy & Nutrition University of Saskatchewan

Phone: 306-966-6346

Email: Lynette.Kolodziejak@usask.ca

Please feel free to contact any of the listed researchers with questions or comments.

#### Background Information on the Student Health Centre

#### CITY OF SASKATOON

Saskatoon is centrally located in Saskatchewan and is the largest city in the province with a population of 206,900. There are approximately 305 family physicians practicing in Saskatoon District, and of those, 25 family physicians are currently accepting new patients. The University of Saskatchewan is situated in the city of Saskatoon.

#### University of Saskatchewan

The University of Saskatchewan's layout is unique in the sense that the entire campus is located in the same area of Saskatoon, versus dispersed throughout the city. Therefore, students can easily access the numerous services which are available to them on campus. In 2004-2005, the total student headcount was 19,763 (15,707 full-time and 4.056 part-time) and of those, 1,825 students self-declared Aboriginal ancestry. Approximately 56% of students are female (n=11,160) and 46% are male (n=8,603). Of the 16,915 undergraduate students, only 5,551 lived in Saskatoon prior to starting school.

Table 1: Age Distribution based on U of S Registration Status for 2004-2005						
Registration Status	N	Mean Age	Minimum	Maximum		
Undergraduate	16,915	23	16	82		
Graduate	1,969	31	20	67		
Post-graduate	221	31	23	52		
Non-degree	658	36	17	69		

#### STUDENT HEALTH CENTRE

The Student Health Centre at the University of Saskatchewan has been selected as the primary health care centre for this project. The Centre received its primary care designation in March 2000 and is one of eight primary care sites within the Saskatoon Health Region. They provide comprehensive health care services to **students** registered at the university **and their families**. The Centre does not offer services to university staff or faculty.

#### Primary Health care Team

The team includes a variety of health care professions including:

- Manager 0.6 position
- Registered Nurses two full-time positions (filled by four part-time nurses)
- Nurse Practitioner one full-time
- Physicians 3.2 positions (filled by two full-time, one part-time and two casual physicians)
- Psychiatrists 0.5 position (filled by three part-time psychiatrists)
- Internal Specialist one half day per week
- Obstetrician/Gynecology one half day per week
- Orthopedic Surgeon one half day clinic each month
- Dietitian one dietitian who works four half days per week
- Social Worker 0.5 position

- Massage Therapist three half days per week from September to April
- Chiropractor two half days per week from September to April
- Health Educator 1.1 position (filled by two part-time Health Education Coordinators)

To date, a pharmacist has not been incorporated onto the primary health care team.

#### **Needs Assessment Survey**

In 2003, the Student Health Centre conducted a Needs Assessment survey to update their data on student health behaviour and knowledge (original survey conducted in 1997), to obtain more demographic data and to evaluate their current services. Students were surveyed on mental health, alcohol and drugs, sexual health, sexual assault, nutrition and physical fitness, and service utilization. Please note that the following information is based on a survey of 1279 University of Saskatchewan students, not solely Student Health Centre patients. However, the results help to identify the needs of the student population. Relevant data are as follows:

#### Mental Health:

- 64.8% of females and 35.2% of males indicated that they were highly stressed or overwhelmed.
- The top sources of stress were academic performance, class load and finances.
- There was a statistical significance between the number of years spent in university and overall stress levels. Those who had spent more years in university tended to have higher stress levels.
- 20% of students stated that they had talked to a health care professional regarding a mental/emotional issue within the past year.
- Approximately 5% had made previous suicide attempts.

#### Sexual Health:

- 72.4% had engaged in sexual intercourse within the past 12 months. 32% had more than one partner
- 16% of students indicated they were not using any method of contraception.
- Of the students using contraception, birth control pills were the most common (38%) and male or female condoms were the second most common (30%)
- 11.3% had used the morning after pill once, and 3.4% more than once.
- 31% stated that they always use condoms.
- 9.5% females & 6.5% males had one unplanned pregnancy. 2.6% females & 2.7% males had more than one unplanned pregnancy. 54.1% of pregnant females either aborted or miscarried.

The Student Health Centre offers several services geared towards the Needs Assessment findings, such as employing three psychiatrists to fill a half-time position, a Contraception Counselling program, and a volunteer group of peer health educators to educate and motivate students towards optimal health.

#### **Summary of Services Based on Billing Codes**

Table 2: Summary of the Number of Physician Visit Services by Diagnosis at the Student Health Centre 2005-2006

**Most Frequent Individual Diagnoses** 

D'	NT 1 CT7 1,			
Diagnosis	Number of Visits			
Depressive Disorder	1056			
Contraception Management	585			
Neurotic Disorders	490			
General Medical Examination	449			
Seeking Consultation without Complaint or Sickness	345			
Affective Psychoses	341			
Acute Pharyngitis	239			
Normal Pregnancy	222			
Disorders of skin & subcutaneous tissue	203			
Acute Nasopharyngitis (common cold)	203			
Most Frequent Blocks of Diagnoses				
Neurotic, Personality and other Nonpsychotic Mental Disorders	1956			
Health Services related to Reproduction & Development	843			
Acute Respiratory Infections	824			
Diseases of the Skin & Subcutaneous Tissue	738			
Symptoms of Ill-Defined Conditions	570			
Injury & Poisoning	536			
Diseases of the Genitourinary System	515			
Persons without reported diagnosis encountered during examination & investigation of individuals & populations	462			

Note: In-province beneficiaries only. Physicians and insured fee-for-service billing codes only.

Table 3: Discrete Patient & Number of Services for 2005-2006					
	In-province	Out-of-province			
Discrete Patients	2,891	793			
Number of Services	13,680	2,559			

Note: Does not include massage therapy, obstetrician/gynecology or orthopedic clinic patients.

#### **Hours of Operation**

From September to April, the Centre is open Monday to Friday from 8:30am-4:30pm, with the exception of starting at 9:30am on Thursday (staff meeting held between 8:30-9:30am that morning). During the months of May to August, the Centre closes over lunch, between 12:00-1:00pm.

#### Health & Dental Plan

All full-time University of Saskatchewan students are automatically covered by a Health & Dental Plan through either the undergraduate or graduate student society. Part-time students have the option of enrolling. Spouses and dependants (under 21 years of age or 25 if still attending school) may be enrolled in the program by paying an additional family coverage fee. The plan includes a list of comprehensive services. Two very relevant services are:

*Prescription Drugs:* The Health plan covers 80% of prescription drugs costs, listed in the Saskatchewan Formulary.

Health Practitioners: The Plan will cover the cost of a physiotherapist, chiropractor, psychologist, naturopath, osteopath, registered dietitian, podiatrist/chiropodist, athletic therapist, speech therapist and massage therapist for a maximum of \$20 per visit, \$400 per category of practitioner per policy year. A referral by a physician or nurse practitioner is required for registered dietitians and a massage therapist.

#### WebCT® On-Line Focus Group for Pharmacists

Thank you for agreeing to participate in our on-line focus group. Below are some key points to review before starting. On the reverse side are instructions for using WebCT®.

- The website will be available starting Sunday, September 3<sup>rd</sup> at 6:00am and will close Saturday, September 23<sup>rd</sup> at midnight (central time).
- You will need your NSID and password to log in to the website.
- Please log onto the website at least once a week to respond to the questions and other postings. The moderator will check the website on a daily basis to facilitate the discussion. New questions will be posted on a weekly basis.
- The focus group discussion is not live, therefore you can log onto the website whenever it is convenient for you, and as often as needed.
- Avoid using the Back button when using WebCT®. Instead, use the breadcrumb trail, Course Menu or Select Topic menu to navigate through the website (see next page for more information).
- You will not be able to change any of your responses; however, you may clarify a statement by posting another response during the one week period.
- To ensure the discussion remains focused, please do not compose your own messages. Instead, only post replies to the questions posted by the moderator and/or other participants' comments.

#### Problems or Concerns with WebCT®

- If you experience any technical problems with the website, please contact the University of Saskatchewan's Information Technology Services Help Desk. You will need to provide them with your NSID.
  - o On campus: Room 70 Arts Building, Monday-Friday 8am-5pm (central time).
  - o Phone: 966-4817 (toll free 1-800-966-4817), Monday-Friday 8am-5pm (central time).
  - o Email: help.desk@usask.ca
- If you have any questions regarding using WebCT®, you can try searching for an answer using the Help menu.
- If you have any questions, comments or concerns regarding the on-line focus group, please feel free to contact Lynette via email: <u>Lynette.Kolodziejak@usask.ca</u>

#### **WebCT®** Icons and Definitions

Section Section Section Section Section Section Read the previous reply
 A message you have not read yet Section Read the next reply

A message you have read

Show all postings for a question

➡ A posted reply to a question or comment▼ Hide all postings for a question

Display: All Displays all of the messages that have been posted. If it appears as though some messages are missing from your list, ensure that Display All has been selected so that all postings are displays.

Only displays messages that you have not read yet.

Threaded Displays postings by question.

Displays postings by date.

Select topic Move to another focus group question.

#### Instructions for Using WebCT®

- 1. Open your internet browser (Internet Explorer preferred).
- 2. Proceed to <a href="http://webct.usask.ca">http://webct.usask.ca</a>.
- 3. Click 'Log In to MyWebCT'.
  - If you are unable to log in, click on <u>Having Trouble?</u> below the log in link.
- 4. Enter your WebCT identification number and password (use your NSID username and password). Click Log In
- 5. Select On-Line Focus Group for Pharmacists.
- 6. Read through the information. When you are ready to view the focus group questions, select the 'Discussions' icon:



#### Discussions

- 7. Click on Question #1. To read the question posted by the moderator and all the responses posted by other participants to date, click on \( \).
  - You can also view individual postings by clicking onto them directly.
- 8. To post a reply, click the Reply button. Type your response in the box, and then click Post. You can post a reply to the focus group question, or to another participant's response.
- 9. After you have posted a reply, click the <u>Update Listing</u> button. If you forget this step, your posting will not be visible during your current visit.
- 10. To return to the other questions, you may use any of the three options:
  - a) Use the breadcrumb trial, along the top of the screen, and click Discussions: Homepage > Discussions > Question #1
  - b) Use the Course Menu, along the left-side of the browser, and click Discussions.
  - c) Use the Select topic pull down menu.



Click the |V| to access the pull down menu options. Select the question you would like to view and click |V|

- 11. Continue to read all of the questions posted for the week and the other participants' responses, and post your own comments.
- 12. Once you are ready to leave the website, please remember to log off (located along top of webpage).

#### Focus Group Questions

#### WEEK #1

#### **Opening Question**

1. Tell us what type of primary health/ambulatory care team you work on (for example: family medicine, women's health, etc) and how long you have been on the team.

#### **Introductory Question**

2. Tell us about your role on the health care team. Think about what you do with or for patients, for the practice or for the team.

#### **Transition Statement**

During the second week, you will be asked to identify clinical pharmacy activities that could be implemented at the Student Health Centre. Once you have created a list of clinical pharmacy activities, you will then be asked to prioritize that same list. Please refer to the *Background Information on the Student Health Centre* section in your information package to help tailor your suggestions for the primary health care team and needs of the patients.

#### WEEK #2

#### **Key Ouestions**

- 3. Based on the Student Health Centre demographics and needs of their patient population, what clinical pharmacy activities do you think should be offered?
- 4. In what order would you prioritize the suggestions you gave for Question #3.

#### **Transition Statement**

During the third and final week, a list of the recommended prioritized clinical activities, based on the focus group discussion, will be posted by the moderator. You will asked be to review the list and ensure it is an accurate representation of what was discussed. Once you have answered the last focus group question, you will then be asked to complete a short online survey based on your experience with using an on-line focus group.

#### **WEEK #3**

A list of the recommended prioritized clinical activities, based on the focus group discussion will be posted.

#### **Ending Question**

5. Do the identified clinical activities capture what was discussed in the focus group?

#### -----FOR YOUR INTEREST ONLY-----

#### Background Information on the Research Study

#### INTRODUCTION

Over the past five years, several government officials – such as Commissioner Fyke and Commissioner Romanow, along with the Saskatchewan's Pharmacy Coalition on Primary Care, have released documents regarding the underutilization of pharmacists on primary health care teams.<sup>1, 2, 4</sup> However, to date, there are no published articles discussing the actual implementation process of a pharmacist into a primary health care site. Until literature is available highlighting solutions to these concerns, as well as guidance on how to successfully integrate a pharmacist into a primary health care site, the profession of pharmacy may be unable to advance towards this opportunity.

There are numerous quantitative studies in the literature which have portrayed the positive impact pharmacists have on patient care, <sup>26, 27, 31-33, 35, 44, 61</sup> the favourable impressions that physicians and nurses have towards clinical pharmacist's interventions, <sup>26, 31, 35, 36, 62</sup> and the satisfaction patients have expressed regarding their interactions with clinical pharmacists. <sup>26, 63</sup> However, no studies have tried to capture the social aspect of how this positive impact on patient care is created or relationships are formed. Therefore, a qualitative approach was selected as the research methodology for this project.

#### Primary Health care Centre

The Student Health Centre at the University of Saskatchewan has been selected as the primary health care centre for this project. The manager of the Centre informally presented the project to the team during a staff meeting. The team welcomed the idea, however because they had never worked with a clinical pharmacist, they were unable to envision how a pharmacist could be incorporated into their team.

Since the Student Health Centre staff is uncertain as to what the role of a pharmacist could be, pharmacists who have already established themselves on primary health/ambulatory care teams will be consulted to help tailor the clinical pharmacy activities for the Centre. Bringing experts together, in this manner, has also been used by nurse practitioners for establishing their role in primary health care.<sup>23, 24</sup> To establish consensus amongst these specialists, focus groups can be used.<sup>53</sup>

#### PHASE I: DEFINING THE ROLE OF A PHARMACIST

To aid with successful integration onto a health care team, the new team member's role, responsibilities, and timing of the care need to be clearly defined prior to joining the team. This process should be a collaborative effort put forth by all members of the team. Role conflict, role overload, and variable acceptance for the new team member can result when there is a lack of role clarity and inconsistent expectations. In addition, dissatisfaction within the team can occur when uncertainty with a job description – i.e. role ambiguity, exists.  $^{18}$ 

To provide optimal care, primary health care teams should assess and evaluate the health needs of their patient population, and subsequently customize their services based on these needs.<sup>3</sup> To tailor the clinical pharmacy activities based on these patient needs, it would seem logical to initiate discussion with those who know the population best - that is, the primary health care team. However, this can be very difficult and frustrating when the team has no clear understanding of the spectrum of activities that a clinical pharmacist can offer.

The Seniors Medication Assessment Research Trial (SMART) is an excellent example of the above. The study evaluated the collaboration between specially trained expanded role pharmacists and family physicians. A major drawback for the pharmacists involved was that physicians did not recognize their full potential. The physicians expected the pharmacists to stick specifically with investigations involving over-the-counter medications. In addition, the pharmacists could not discuss possible alternatives with patients as the physicians felt this would be a criticism on their performance. This inhibited the pharmacists from having significant impact on patients' drug therapy. In addition, the pharmacists were not aware of occasions when physicians had unsuccessfully tried a particular therapy or plan because they were restricted from discussing therapeutic alternatives with patients.<sup>19</sup>

Another study, conducted in California, investigated physician expectations of pharmacists. A questionnaire was used to capture physicians' – office and hospital based, and medical residents' current and future expectations, as well as their current experiences with pharmacists. A total of 463 physicians (19.3% response rate) participated in the study. The authors concluded that physicians do not know what to expect of pharmacists. In addition, there was no correlation between the responses and practice setting.<sup>20</sup>

If health care professionals do not realize the range of clinical activities that can be implemented or know what to expect from pharmacists, integration is jeopardized. Interdisciplinary teams report a increased awareness of each member's role, however difficulties in defining the roles of professional groups may still exist.<sup>5</sup> Another approach for defining the role of a pharmacist involves discussion with those who hold a similar role within another organization. These colleagues can offer their expertise on how to establish activities based on the needs of the patient population. In addition, establishing relationships with these key players can lead to further peer support in the future.<sup>21</sup>

#### METHODOLOGY - PHASE I: DEFINING THE ROLE OF A PHARMACIST

On-line focus groups have been used as a data collection tool in qualitative health services research.<sup>53, 55, 56</sup> Like in-person focus groups, on-line focus groups have the advantages of obtaining a broader range of responses and elicitation of details that are not captured during individual interviews.<sup>57</sup> Despite not having the participants physically in the same location, on-line focus groups are still able to create active engagement and group interaction.

Both provincial and national pharmacists have been invited to participate in this stage of the study. On-line focus groups will be the method used to extract information and formulate ideas from the geographically dispersed panel of pharmacists. Focus groups will allow the

pharmacists to draw on their own experiences and discuss with colleagues a range of possible clinical activities that can be implemented at the Student Health Centre.

#### **RESEARCH QUESTION**

How can a pharmacist be integrated into an already established primary health care team?

#### **OBJECTIVES**

The study objective has been divided into three phases:

Phase I: Define the role of the pharmacist. As discussed in the preceding pages.

Phase II: Implementing the purposed role.

Once the role of the pharmacist is clearly defined, one of the researchers (LK) will be providing two months of clinical pharmacy services for the Student Health Centre at the University of Saskatchewan. All clinical activities and interactions will be documented. After one month, a team meeting will be held to discuss how the role of the pharmacist has been received by the staff to date. The pharmacist's role will be modified based on the recommendations that surface from the meeting.

Phase III: Evaluate and prioritize the role of a clinical pharmacist.

At the end of the two months of clinical services, focus groups will be organized with Student Health Centre staff, as well as with patients who had direct interaction with the clinical pharmacist. Participants will be asked to reflect on their experience with having a clinical pharmacist on the primary health care team. The purpose of the focus groups is to identify what went well, what did not and areas for improvement from all stakeholders' perspectives. The Student Health Centre staff focus groups will be face-to-face and moderated by an external facilitator. The patient focus group will be conducted on-line.

#### **SIGNIFICANCE**

The role of the pharmacist that will be defined, implemented, evaluated and prioritized will be tailored to meet the specific needs of the primary health care centre chosen for this project. However, the process could be generically applied to any other primary health care team. Therefore, this study should provide guidance on how to integrate a pharmacist into a primary health care team or serve as a stepping stone towards other investigations.

#### REFERENCES FOR INFORMATION PACKAGE:

- **1.** Fyke K. Caring for Medicare: Sustaining a Quality System: Government of Saskatchewan; 2001.
- 2. Romanow R. Building on Values: The Future of Health care in Canada: Commission on the Future of Health care in Canada; November 2002.
- **3.** Role of the Pharmacist in Primary Health care: Pharmacy Coalition on Primary Care; 2003.
- 4. Haxby DG, Weart CW, Goodman BW, Jr. Family practice physicians' perceptions of the usefulness of drug therapy recommendations from clinical pharmacists. *Am J Hosp Pharm*. Apr 1988;45(4):824-827.
- **5.** Gums JG. Recent advances: ambulatory care and family medicine. *Ann Pharmacother.* Jul-Aug 1995;29(7-8):716-718.
- 6. Koffler AB, See S, Mumford J, Johnston B. Implementing and Evaluating a Pharmacy Consult Service Within a Family Medicine Residency Program. *Am J Hosp-Syst Pharm.* June 15 2002:59:1200-1204.
- 7. Carter BL, Helling DK. Ambulatory care pharmacy services: has the agenda changed? *Ann Pharmacother*. Jun 2000;34(6):772-787.
- **8.** Price SO, Newnham MA. Physician perceptions of clinical pharmacy encounters in a family practice clinic. *Top Hosp Pharm Manage*. Oct 1994;14(3):13-20.
- 9. Beney J, Bero LA, Bond C. Expanding the roles of outpatient pharmacists: effects on health services utilisation, costs, and patient outcomes. *Cochrane Database Syst Rev.* 2000(3):CD000336.
- **10.** Sardinha C. Physician groups embrace pharmacists: collaborations that work. *Journal of Managed Care Pharmacy.* 1997;3(Sep-Oct):526-528, 530.
- 11. Singhal PK, Raisch DW, Gupchup GV. The impact of pharmaceutical services in community and ambulatory care settings: evidence and recommendations for future research. *Ann Pharmacother*. Dec 1999;33(12):1336-1355.
- **12.** Lobas NH, Lepinski PW, Woller TW. Satisfaction of physicians and nurses with clinical pharmacy services. *Am J Hosp Pharm.* June 1991;48:1189-1190.
- 13. Klockars SJ, Blair MM, Ragucci K. Survey of Clinical Pharmacy Services in a Family Medicine Clinic. *Am J Health Syst Pharm.* March 2003;60:485-486.
- **14.** Campbell RK, Saulie BA. Providing pharmaceutical care in a physician office. *J Am Pharm Assoc (Wash)*. Jul-Aug 1998;38(4):495-499.
- 15. Torn A, McNichol E. A qualitative study utilizing a focus group to explore the role and concept of the nurse practitioner. *Journal of Advanced Nursing*. Jun 1998;27(6):1202-1211.
- **16.** Gibson F, Bamford O. Focus group interviews to examine the role and development of the clinical nurse specialist. *Journal of Nursing Management*. Nov 2001;9(6):331-342.
- 17. Smith F. Focus groups and observation studies. *The International Journal of Pharmacy Practice*. December 1998;6:229-242.
- **18.** McCallin A. Developing effective interdisciplinary teams. *Nursing New Zealand (Wellington)*. 2003;9(9):21-23.
- **19.** Helling DK. Family Practice Pharmacy Service: Part I. *Drug Intelligence and Clinical Pharmacy*. December 1981;15:971-976.
- **20.** Bryant-Lukosius D. DA, Browne G., Pinelli J. Advanced practice nursing roles: development, implementation and evaluation. *Nursing and Health care Management and Policy*. March 16th, 2006 2004;48(5):518-529.
- **21.** Care PCoP. *Role of the Pharmacist in Primary Health care* May 1st, 2003.

- **22.** Howard M, Trim K, Woodward C, et al. Collaboration between community pharmacists and family physicians: lessons learned from the Seniors Medication Assessment Research Trial. *Journal of the American Pharmacists Association: JAPhA*. 2003;43(5):566-572.
- **23.** Smith WE, Ray MD, Shannon DM. Physicians' expectations of pharmacists. *Am J Health Syst Pharm.* Jan 1 2002;59(1):50-57.
- **24.** Nancarrow S. Dynamic role boundaries in intermediate care services. *Journal of Interprofessional Care.* 2004;18(2):141-151.
- **25.** Scholes J, Vaughan B. Cross-boundary working: implications for the multiprofessional team. *Journal of Clinical Nursing*. 2002;11(3):399-408.
- **26.** Kenny A. Interaction in cyberspace: an online focus group. *Journal of Advanced Nursing*. 2005;49(4):414-422.
- **27.** Moloney M, Dietrich A, Strickland O, Myerburg S. Using Internet Discussion Boards as Virtual Focus Groups. *Advances in Nursing Science*. 2003;26(4):274-286.
- **28.** Kidd P, Parshall M. Getting the Focus and the Group: Enhancing Analytical Rigor in Focus Group Research. *Qualitative Health Research*. May 2000;10(3):293-308.

## Appendix IV: On-line Focus Group Questions for the Primary Health and Ambulatory Care Pharmacists

#### WEEK #1

#### **Opening Question**

1. Tell us what type of primary health/ambulatory care team you work on (for example: family medicine, women's health, etc) and how long you have been on the team.

#### **Introductory Question**

2. Tell us about your role on the health care team. Think about what you do with or for patients, for the practice or for the team.

#### **Transition Statement**

During the second week, you will be asked to identify clinical pharmacy activities that could be implemented at the Student Health Centre. Once you have created a list of clinical pharmacy activities, you will then be asked to prioritize that same list. Please refer to the *Background Information on the Student Health Centre* section in your information package to help tailor your suggestions for the primary health care team and needs of the patients.

#### **WEEK #2**

#### **Key Questions**

- 3. Based on the Student Health Centre demographics and needs of their patient population, what clinical pharmacy activities do you think should be offered?
- 4. In what order would you prioritize the suggestions you gave for Question #3.

#### **Transition Statement**

During the third and final week, a list of the recommended prioritized clinical activities, based on the focus group discussion, will be posted by the moderator. You will asked be to review the list and ensure it is an accurate representation of what was discussed. Once you have answered the last focus group question, you will then be asked to complete a short online survey based on your experience with using an on-line focus group.

#### **WEEK #3**

A list of the recommended prioritized clinical activities, based on the focus group discussion will be posted.

#### **Ending Question**

5. Do the identified clinical activities capture what was discussed in the focus group?

#### Appendix V: Project Plan for the Student Health Centre

#### Integration a Pharmacist into a Primary Health care Centre Project Plan for the Student Health Centre Staff

#### Staff Meeting: Introduction of Study & Obtaining Consent

All staff members are encouraged to attend an initial meeting with the researchers. During this meeting, the researchers will introduce themselves to the staff, present the study, outline how the staff can contribute to the research and provide consent forms to those who are interested in participating in the study.

• Meeting scheduled for: Monday, September 11<sup>th</sup> 12:00-1:00pm

#### Staff Meeting: Defining the Role of the Pharmacist

The staff members who are interested in the study will be invited to attend the second meeting. During this time, the researchers will present data collected from a focus group involving primary health/ambulatory care pharmacists, which will highlight a list of possible clinical pharmacy activities that could be offered at the Student Health Centre. A discussion between the researchers and staff members will then occur to identify which clinical pharmacy activities would compliment the existing services the best. As a team, the role of the pharmacist will be discussed and defined, as well as the logistics of providing the services.

• Meeting scheduled for: Thursday, September 28<sup>th</sup> 8:30-9:30am.

#### **Staff Meeting: Midpoint Meeting**

One of the researchers, Lynette Kolodziejak, will provide two months of full-time clinical pharmacy activities during the months of November and December, 2006. At the end of the first month, another staff meeting will be held. During this time, the pharmacist will present a summary of the clinical pharmacy activities that have been implemented thus far. Staff members will be encouraged to provide feedback on the pharmacy services that have been provided. As a team, the role of the pharmacist will be discussed and modified to suit the needs of the primary health care team.

• Meeting scheduled for: Thursday, November 23<sup>rd</sup> 8:30-9:30am.

#### Focus Groups with the Staff

During the month of January, 2007, focus groups will be organized with staff members to evaluate the integration of a pharmacist into an already established primary health care team. The objective of the focus groups is to identify what went well, what did not and areas for improvement. An external moderator will be contracted to facilitate the focus groups.

• Focus groups will be scheduled closer to the date.

## Appendix VI: Cover Letter to Student Health Centre Staff Who Could Not Attend the Initial Meeting

Monday, September 11th, 2006

Dear (name),

Sorry that we missed you on Monday, September 11<sup>th</sup>, 2006, during a meeting we held with your coworkers at the Student Health Centre. The purpose of the meeting was to introduce our study - investigating how to integrate a pharmacist into an already established primary health care team, as well as to obtain consent from those staff members who are interested in participating in the study. Please find attached a copy of the PowerPoint presentation slides, program plan and the consent form. All highlight what your role would be if you agree to participate.

Another meeting, to define what my role on the team would be as a clinical pharmacist, will be held on Thursday, September 28<sup>th</sup> from 8:30-9:30am. If you are interested in participating in our study, you are welcome to join us that morning. Please bring your signed consent form to the meeting.

If you require any additional information or have questions regarding the study, please contact either of my supervisors - Shannan Neubauer (email: <a href="mailto:Shannan.Neubauer@usask.ca">Shannan.Neubauer@usask.ca</a>), Fred Rémillard (email: <a href="mailto:AJ.Remillard@usask.ca">AJ.Remillard@usask.ca</a>), or myself.

Thank you for your consideration.

Lynette Kolodziejak MSc Candidate College of Pharmacy & Nutrition Email: Lynette.Kolodziejak@usask.ca

## Appendix VII: Possible Clinical Pharmacy Activities Generated from On-Line Focus Group with Primary Health & Ambulatory Care Pharmacists

## How to Integrate a Pharmacist into a Primary Health care Centre Phase I: Defining the Role of the Pharmacist

#### POSSIBLE CLINICAL PHARMACY ACTIVITIES

#### 1) Direct Patient Care:

- a) Mental Health Psychiatric Medication Counselling & Monitoring
  - In-depth initial counselling sessions for a new medication or change in therapy.
  - Assist with continuity of care/developing guidelines for follow-up.
  - Follow-up to ensure/encourage compliance, efficacy of the medication, monitor for side effects, review lab data to prevent toxicity, identify & solve drug related problems, assess possible substance abuse issues and address lifestyle issues (proper nutrition, sleep).
  - Make drug therapy recommendations and provide drug information to physicians/psychiatrists.

### b) Management of Acute Illness

- Over-the-counter medications for cough/cold/flu management.
- Optimizing antibiotic use:
  - o Ensuring appropriate choice of antibiotic follow culture & sensitivity and provide suggestions if resistance to empiric therapy.
  - o Provide follow-up phone call to assess how patient is doing and encourage them to complete the full course of antibiotics.
  - o Develop an antibiograms specifically for the Centre.

#### 2) Drug Information

- a) Team members
  - Literature searches on request and answering drug information questions.
  - Drug use in pregnancy & lactation.
  - Therapeutic updates.
  - Forum: presentations at rounds/meetings, email updates, bulletin boards.

#### b) Individual Patient Education Sessions

- To help them understand how their medications are linked with the condition(s).
- Assist with compliance by identifying how medications administration times fit best with their lifestyle.

#### 3) Health Education/Promotion

- a) Group Patient Education Sessions
  - Offer regularly, be consistent with time & place, select convenient times for students (e.g. evenings) and match topics with time of year when applicable (e.g. flu vaccination).
  - Collaborate with other team members and university groups.
  - Topics: sexual health options/contraception, depression & its treatment, weight control issues & agents, herbals, drugs of abuse, smoking cessation, travel information (vaccinations, travelers diarrhea, malaria), flu vaccinations, health/stress management.
  - Develop information materials on common illnesses & medications.

## Appendix VIII: Student Health Centre Staff Memo Summarizing the Meetings

Thursday, October 26, 2006

Dear Student Health Centre staff:

I will be starting at the Student Health Centre, as a clinical pharmacist for my Masters project, on Wednesday, November 1<sup>st</sup>. Through the staff meetings we have had, my role will consist of a mixture of direct patient care and drug information for the staff. For direct patient care, the following main areas have been identified for patient referral:

- Psychiatric Medication Counselling and Monitoring
  - o Examples: Counsel on new medication/change in therapy; follow-up to assess compliance, efficacy of medication, presence of side effects
- Asthma
  - o Examples: Counsel on device use; follow-up to assess compliance, efficacy of medication, presence of side effects.
- Contraception
  - o Examples: Provide supplemental care; discuss risks vs benefits of continuous vs cyclical oral contraception.
- Patient Medication History
  - o Examples: Medications that require therapeutic drug monitoring (lithium, carbamazepine, etc), frequent medication changes (>3 changes in past 12 months), herbal/complementary medications.

Please note the above are examples and other referrals would also be accepted. I have created a Patient Referral form to assist with the referral process. When referring patients, please fill out the form and ask the student to take the form up to the front desk to book an appointment. Walk-ins are also an option, in which case a verbal reason as to why would you like me to see the patient would suffice. You can start referring patients as of today.

Even though this is a study, the patients will not have to a sign consent form or be notified that this is a study prior to seeing me. The relationship I develop with the patients is under investigation, which will be evaluated using focus groups at the end of the project. If the patient agrees to participate in the focus group, they would then be provided with the consent form. This process has been approved by the University of Saskatchewan Behavioural Sciences Research Ethics Board.

As for drug information, the projects will include expanding information for the Contraception Counselling program, last minute travel concerns, medication use in athletes, herbals, and medications and alcohol consumption.

Any comments you have regarding the above and the Patient Referral form are welcome. I look forward to working with all of you.

Thank you,

Lynette Kolodziejak, BSP, MSc Candidate

## Appendix IX: Pharmacist Referral Form

## PHARMACIST REFERRAL FORM

Student Health Centre

☐ Other:

**PATIENT INFORMATION** 

Please place patient identification sticker here.	Date of referral:
	Date of appointment
DEACON FOR REFERRAL	
REASON FOR REFERRAL	
Montal Health Mediantion Co.	uncelling and Manitoring
☐ Mental Health Medication Cor	unsening and Monitoring
o Counsel on new medication.	
o Counsel on change in therapy.	office are of modification process of side officets
0.1	efficacy of medication, presence of side effects
o Other:	
☐ Asthma	
	office as of modication presence of side offsets
<ul><li>Follow-up to assess compliance,</li><li>Other:</li></ul>	efficacy of medication, presence of side effects.
o other.	
☐ Contraception	
	nuous vs cyclical oral contraception.
o Other:	nuous vs cyclical oral contraception.
O Other.	
☐ Patient Medication History	
5	vitic daira monitorina (lithium, carbomazonina, eta)
1	eutic drug monitoring (lithium, carbamazepine, etc)
o Frequent medication changes (>	
<ul><li>Herbal/complementary medicat</li><li>Other:</li></ul>	10115.
O Other:	

Referring Health care Professional Name:

## Appendix X: Patient Documentation Form

## PATIENT DOCUMENTATION FORM Student Health Centre

Patient Information		
Name:	Date of I	Birth:
College & Year:	HSN	J:
Preferred method of contact:		
□ Phone Number:		
□ Address:		
□ Email:		
Allergies/Intolerances:		
Medications (prescription, OTC, he		
Medication	Use	Duration
Additional Medical/Surgical Histo	ry:	
_		_
Referral		
Date:		
Reason for Referral:		<u> </u>
Patient's Primary Concern:		
T- 44		
Follow-up:		

## Appendix XI: Pharmacist Depression Counselling Form – Initial Draft

#### PHARMACIST COUNSELLING FORMAT - DEPRESSION

#### **Student Health Centre Staff:**

Please review the following proposed pharmacist counselling format for patients suffering from depression. Although it may seem very structured, please note that it is also intended to be flexible and each visit could be tailored to a patient's specific needs – based on your recommendations and patient's response during the counselling. All comments and suggestions are greatly appreciated.

### **Objectives:**

- To provide supplemental care to patients suffering from depression, as they often have difficulty with concentration and a poor memory due to their depression.
- To help increase patient compliance by providing education on the illness, how antidepressants work, when to expect an effect, anticipate duration of therapy, the benefits of therapy and an overview of the side-effects, including a proactive approach to manage side effects.
- To develop a collaborative process with other health care professionals at the Student Health Centre via developing the counselling structure and aid future patient referrals.
- To create a clinical pharmacy opportunity for direct patient care.

### **Proposed Process:**

- Work with Student Health Centre staff to develop the counselling format.
- Any health care provider at the SHC could refer patients to the pharmacist. Patients could be antidepressant naïve, previous or chronic antidepressant users.
- <u>Initial Visit:</u> the pharmacist would cover as much information that the patient is comfortable with, following the predetermined format. Depending on the patient, an additional visit may need to be scheduled with the pharmacist to conclude the counselling intended for the initial visit.
- <u>Follow-up visits:</u> the patient would book another appointment with the pharmacist in close proximity to the follow-up appointment with the physician. Logistics of whether the pharmacist would see the patient before the physician or vise versa would depend on staff input. The pharmacist would counsel the patient following the predetermined format.
- Additional follow-up would be at the discretion of the patient, referring health care professional and pharmacist.
- The forms would consist of a series of counselling topics, each with a tick-box to be checked once the topic has been discussed with the patient. At the end of the visit, the pharmacist would sign the bottom of the form indicating that each of the checked topics was reviewed. The form would be placed in the patient's chart to inform the prescriber of what has been discussed.
- The patient would be given the pharmacist's contact information, for any future questions or concerns. If a patient contacts the pharmacist, the issue will either be addressed by the pharmacist (providing within scope of practice) or redirected to the physician. All interactions will be documented in the chart.

## PHARMACIST PATIENT COUNSELING FOR DEPRESSION – INITIAL VISIT

Date:	_			
Patient Information	D (D) 1			
Name:	Date of Birth: HSN:			
Preferred method of contact:	HSN:			
	(best time to cal	1	)	
	(best time to car	.•	/	
□ Email:				
Allergies/Intolerances: (drug, rea				
Mediantians (agreeminting, OTC)	hadrala garacticus ( mutaiticus ()			
Medications (prescription, OTC, Medication	Use	D	uration	
Medication	USC	Di	шаноп	
Other medical conditions:				
Medications possibly linked to de  □ Interferon □ Systemic corticosteroids (chronic use) □ Benzodiazepines □ Narcotics	epression: ( if patient has used the fo Barbiturates Contraceptives/HRT Antihypertensives (BB, methyldopa, diuretics)	□ A □ A □ H	alcohol (ch anabolic st Iallucinogo Other:	
If the patient is on any of the about	ve, does a temporal relationship with	their depress	sion exist?	
Pregnant/breast feeding:		□ Yes	□ No	□ NA
Positive family history for mood d If yes, who, when & what were the			□ No	
Previous antidepressant use:  If we: indicate the antidepressant	dose, duration, when, reason for disc	□ Yes	□ No	
ir yes. moreare me annucpressant,	dose, duration, when, reason for this	commucu		
Current antidepressant:Any contraindication, precaution If yes, discuss with prescriber.	or drug interaction present	☐ Yes	□ No	
Patient's primary concern:				

## PHARMACIST PATIENT COUNSELING FOR DEPRESSION – INITIAL VISIT

How common is depression  One of the most common mental health disorders; 1 in 5 Canadians will be dia mood disorder; in North American ~18% of the population has at least one epidepression (vs 5% affected by diabetes)	•
What causes depression  Exact cause unknown; possible causes: psychological, biological and genetic fa	uctors
Why take your antidepressant (goals of therapy)  Prevent harm to self, relieve symptoms, restore function, & prevent recurrence.  BENEFIT: Taking your antidepressant as prescribed increases your ability to a goals.	
How do antidepressants work  Antidepressants work to restore the correct balance of important chemicals (can neurotransmitters) in the brain that affect a person's mood.  Explain how their specific antidepressant works.	lled
How long will it take before the antidepressant starts to work  Usually within 1 week: insomnia, anxiety, & decreased appetite improve; 3-4 vertices increased libido/energy and depressive symptoms improve.  Minimum trial of 6 weeks at an adequate dose is needed to fully assess efficacy	
What type of side effects may occur  Discuss possible side effects and how to manage.  Serotonin syndrome if SSRI prescribed (signs to watch for, medications to avoid	id).
How to take your antidepressant  Taking your antidepressant as prescribed increases your chances of recovering depression. Create a system to help you remember to take your medication.  Do not skip doses or stop treatment abruptly. Discontinuation syndrome: "FII like symptoms, Insomnia, Nausea, Imbalance, Sensory disturbance, Hyperaron	NISH" - <b>F</b> lu-
Should alcohol be avoided while taking antidepressants	
Alcohol may worsen your mood, increase antidepressant side effects and can not 'off'. If necessary, have the first few drinks at home with people you trust. Do taking your antidepressant just so you can drink.	
'off'. If necessary, have the first few drinks at home with people you trust. Do	not stop
'off'. If necessary, have the first few drinks at home with people you trust. Do taking your antidepressant just so you can drink.  Follow-up appointment:	not stop

PHARMACIST PATIENT COUN Date:	SELING FOR DEPRESSION –	FOLLOW-UP VISIT
Patient Information: Name:	HSN:	
A		
Assessment of Antidepressant Thera  Side Effects  Blurred vision, dry eyes  Dry mouth/thirst Constipation Urinary retention Headache	□ Insomnia/agitation □ Nausea □ Orthostatic hypotension/dizziness □ Sedation	□ Sexual dysfunction □ Weight gain □ Other:
Indicate the severity, course (tolerand management for all side effects.	ce vs worsening), how disturbing	to the patient and
Response to Therapy – has there bee  □ Sleep □ Interest in activities □ Appetite  Additional Information:	en any improvement in the follow  Motivation Concentration Energy	ring:  Feelings of guilt/worthlessness Mood
<ul> <li>What does the patient do wh</li> </ul>	orget to take their medication	
Comments.		

Medication Changes (additions, discontinuation, dose changes for other medications)

## PHARMACIST PATIENT COUNSELING FOR DEPRESSION – FOLLOW-UP VISIT

Pa	tien	t Education							
	Pa	Patient's primary concern:							
	<b>Re</b>	Prevent harm to self, relieve symptoms, restore function, & prevent recurrence.  BENEFIT: Taking your antidepressant as prescribed increases your ability to achieve these goals.  An increase in antidepressant dose or change to another antidepressant may be required to reach goals.							
	<ul><li>Co</li><li>o</li><li>o</li></ul>	Remission: absence of depressive symptoms. Goal of treatment.  • ~1/2 of people suffering from depression will only have one episode.  Response: ~50% reduction in baseline symptoms. Suboptimal.  • ~3/4 of people will have a response to therapy.  Relapse: return of significant depressive symptoms.  • Relapse rates at one year are ~50% for people who discontinue their therapy.  Recurrence: another major depressive episode.  • See your prescriber as soon as possible. The longer you are symptomatic, the lower the likelihood of recovery.							
	<ul><li>Re</li><li></li><li></li><li></li></ul>	Response to Therapy Response may take 2-4 weeks and the dose may have to be adjusted before treatment is successful.  If there is no improvement in your mood after ~6 weeks, there is an excellent chance you will respond more favorably to a different antidepressant.  The most common cause of not responding to therapy is failure to take the antidepressant properly, or even at all.							
	<ul><li>Dt</li><li>o</li><li>o</li></ul>	Depends on the severity & duration of the current depressive episode, and the number of previous episodes.  First episode - minimum of 6-9 months of treatment after symptoms have cleared. Severe first episode or prior previous episodes - 1 year to a lifetime.  Your prescriber will determine the exact duration and never discontinue your antidepressant on your own.							
	Fo	<b>Illow-up appointment:</b> To complete counselling or at the patient's or other health care provider's request.							
Αj		rmacist has discussed the above information with the patient.							
BS	P S:	ignature							

# Appendix XII: Final Version of the Pharmacist Antidepressant Counselling Form PHARMACIST ANTIDEPRESSANT COUNSELLING

Date	··					
	ent Information:		HSN:			_
Curr	ne:ent antidepressant & regimen: _				_	-
Patie	ent's primary concern:					
	<b>ible Anti-depressant Side Effe</b> Blurred vision, dry eyes Dry mouth/thirst		Insomnia/agitation Nausea		Sexual dy Weight ga	
	Constipation Urinary retention Headache		Orthostatic hypotension/dizziness Sedation		Other:	
	cate the severity, course (toleran	ice v	s worsening), disturbance to	the p	atient and	management of
	essment of Compliance:  o Is the patient taking medicat	ion	nronerly	Пν	Zes .	□ No
	How often does the patient f	forge	et to take medication			
C	What does the patient do wl					_
C	What does the patient do to	rem	ind themselves to take their	medic	cation?	

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**Comments:** 

## ANTIDEPRESSANT COUNSELLING

	Why take your antidepressant (goals of therapy)  Prevent harm to self, relieve symptoms, restore function, prevent recurrence.  BENEFIT: Taking your antidepressant as prescribed increases your ability to achieve these goals.	
	Exact cause of depression is unknown; possible causes: psychological, biological and genetifactors.  Antidepressants work to restore the correct balance of important chemicals (called neurotransmitters) in the brain that affect a person's mood.  Explain how their specific antidepressant works.	ic
	Insomnia, anxiety, and decreased appetite typically improve within 1 week. Libido, energy and depressive symptoms typically improve within 3-4 weeks. Minimum trial of 6 weeks at an adequate dose is needed to fully assess efficacy.	
	What type of side effects may occur  Discuss side effects (current and possible) and how to manage them.  Serotonin syndrome if SSRI prescribed (signs to watch for, medications to avoid).	
	Taking your antidepressant as prescribed increases your chances of recovering from depression. Create a system to help you remember to take your medication. Do not skip doses or stop treatment abruptly.	
Αŗ	armacist has discussed the above information with the patient.	
BS	Signature	

## Appendix XIII: Patient Information Handout on Managing Antidepressant Side Effects

## **Antidepressant Side Effects**

All drugs, whether prescription, over-the-counter, herbals, nutritional and/or recreational, can cause side effects. Some people are more sensitive to medications and may experience side effects, where side effects may never occur in others. The key is to know what side effects may occur with the medications you are taking, how to manage them if they occur and when to report them to your doctor.

Side effects caused by antidepressants, if they do occur, are often mild and typically go away with continued treatment. The following side effects may occur when you start your antidepressant or the dose is increased, and is usually temporary. **If a side effect continues for more than a week or worsens, let your doctor know.** Remember - taking your antidepressant is very important and increases your chances of recovering from depression.

Possible antidepressant side effects:	How to manage the side effects if they occur:
Blurred vision	Reading under a bright light, at a distance or with a
	magnifying glass may help.
Dry eyes	Try using eye drops that contain methylcellulose (e.g.
	Artificial Tears®).
Dry mouth	Sugarless lemon drops, sugarless gum and ice chips may
	help. Drink more water and try to avoid sweet, high-calorie
	drinks. Brush your teeth regularly.
Constipation	Increase the amount of fiber in your diet (e.g. fruits,
	vegetables, bran) and drink more water. If that does not help
	to regulate your bowels, try a laxative (e.g. Metamucil®) or
	stool softener (e.g. Colace®).
Headache	Use acetaminophen (e.g. Tylenol®) or ibuprofen (e.g.
	Advil®, Motrin®).
Problems sleeping/agitation	Decrease caffeine intake (coffee, tea, pop) & alcohol.
	Practice good sleep hygiene.
Upset stomach/nausea	Take your antidepressant with a meal or snack.
Dizziness	Get up from lying or sitting slowly. If you feel really dizzy
	or faint, sit or lie down until the feeling passes.
Drowsiness	Avoid other medications and alcohol that can also make you
	drowsy.
Changes in sex drive or sexual	Depression itself can decrease someone's desire to have sex.
performance	Talk to your doctor if your mood improves, yet you still have
	concerns regarding your sex drive or sexual performance.
Sweating	If you sweat more than usual, shower frequently and use
	deodorants.
Weight gain	Some people lose their appetite when depressed. Gaining
	weight when on antidepressants may be a sign that you are
	getting better and your appetite is improving. Eat healthy
	and exercise. Talk to your doctor or dietitian if you are
	concerned about weight gain.

If you have any questions or concerns regarding antidepressant side effects, talk to your doctor or pharmacist. Please refer to the antidepressant information you received when you filled your prescription for further information.

## Appendix XIV: Email Sent to Student Health Centre Staff Regarding the Shortage of Alesse® and Triphasil® Oral Contraceptives

## Shortage of Alesse® and Triphasil®

Alesse® and Triphasil® are both manufactured by the same pharmaceutical company – Wyeth. Recently, due to problems with their manufacturing plant, there has been a shortage of supply throughout Canada for both of these oral contraceptives.

I talked to the drug company today and they have recently distributed a supply of Alesse to Canadian pharmacies. However, I also called a few community pharmacies in Saskatoon and not all have received a new shipment of Alesse®. As for Triphasil®, Wyeth does not have an expected date for when new stock will be available.

In the meantime, here are a few options for patients who are unable to fill their Alesse® or Triphasil® prescriptions:

Alesse® (ethinyl estradiol 20mcg & levonorgestrel 0.1mg)								
If used for acne management only								
Alternative Oral Estrogen Progestin Comment								
Contraceptive								
Tri-cyclen®	ethinyl estradiol 35mcg	norgestimate 0.18-0.215- 0.25mg	Tri-cyclen-Lo® is not on the SK formulary.					
Diane-35®	ethinyl estradiol 35mcg	-	Contains an antiandrogen - cyproterone 2mg. Does not have an indication for contraception and is not on the SK formulary.					
If used for contracep	tion							
Min-Ovral®	ethinyl estradiol 30mcg	levonorgestrel 0.15mg	-					

Triphasil® (ethinyl estradiol 30-40-30mcg & levonorgestrel 0.05-0.075-0.125mg)								
Other available triphasic oral contraceptives								
Alternative Oral	Progestin	Comment						
Contraceptive								
Triquilar®	ethinyl estradiol 30-40-30mcg	levonorgestrel 0.05-0.075-0.125mg	Exact same estrogen and progestin formulation as Triphasil®.					
Tri-cyclen®	ethinyl estradiol 35mcg	norgestimate 0.18-0.215-0.25mg	Tri-cyclen-Lo® is not on the SK formulary.					
Ortho 7/7/7®	ethinyl estradiol 35mcg	norethindrone 0.5-0.75-1mg	-					

## Appendix XV: Email Sent to Student Health Centre Staff Regarding the New Safety Information with Evra®

## New Safety Information on Evra® - Risk of Thromboembolism

Over the past few months, Health Canada has been reviewing the safety of the contraceptive patch, Evra®. An update was released today, informing the public that the product monograph has been revised **based on preliminary, but conflicting, data** concerning a possible increased risk of blood clots. This data comes from two post-marketing studies which compared the patch (releases 20 mcg of estradiol and 150mcg of norelgestromin per day) to low-dose estrogen & norgestimate combination oral contraceptives). One study found no increased risk, while the other on-going and unpublished trial found a 2-fold increased risk for developing venous thromboembolism (VTE).

## **Keeping Things in Perspective**

Back in September, the FDA had updated the product labelling in the States to acknowledge this possible increased risk of blood clots with the use of Evra®. Subsequently, the Star Phoenix featured an article on the topic and will likely highlight Health Canada's decision in the near future. If any of your patients are on Evra® and are concerned with the recent news in the media, the following can be brought to their attention:

- Even if the new & conflicting information is correct, and the Evra® patch has a  $2x \uparrow$  risk of VTE, this risk is still extremely low (would  $\uparrow$  from 1-1.5 per 10,000/year to 2-3 per 10,000/year).
- Reiterate that they should watch for any early signs of VTE (DVT, PE)
- The warning that contraceptives may increase the risk of VTE is not new and is relevant with either the oral or transdermal formulations.

To view Health Canada's warning on this issue, visit <a href="http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/2006/evra hpc-cps e.html">http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/2006/evra hpc-cps e.html</a>.

## Appendix XVI: Literature Review for Suppressive Therapy for Genital Herpes Simplex Virus

## LONG-TERM SAFETY OF ANTIVIRAL AGENTS FOR GENITAL HERPES SIMPLEX VIRUS SUPPRESSIVE THERAPY

#### Introduction

A review of the current literature was conducted to assess the safety of antiviral agents for genital herpes simplex virus (HSV) therapy. The recent guideline recommendations are noted, however further investigation into the side effects reported with continuous therapy was carried out to aid in the decision-making process of initiating and maintaining patients on suppressive therapy. In addition, information from the longest trials was sought to provide a sense of where the evidence lies for length of therapy.

## Canadian Guidelines on Sexually Transmitted Infections

The 2006 Canadian Guidelines on Sexually Transmitted Infections recommends the following for Suppressive therapy:

- Suppressive therapy is intended for patients with frequently recurring genital herpes, generally for those with recurrences at least every 2 months or 6 times per year. In such patients, suppressive therapy is preferred to episode therapy and improves quality of life.
- For individuals with fewer than 6 recurrences per year or one every 2 months, episode therapy is recommended. However, suppressive therapy will probably be efficacious and may be considered on a case-by-case basis.

#### Notes:

- Acyclovir, famciclovir and valacyclovir are approved for suppressive therapy in Canada.
- Safety and efficacy data suggest that acyclovir and valacyclovir can be administered for up to 1 year based on controlled trials, whereas famciclovir has been evaluated only for up to 4 months\* administration.

\* Erratum on duration of famciclovir trials - Public Health Agency of Canada website (<a href="http://www.phac-aspc.gc.ca/std-mts/sti">http://www.phac-aspc.gc.ca/std-mts/sti</a> 2006/updates e.html) (see attached)

Page 151, Table 3 - footnote 2. The new bullet should read: Safety and efficacy data suggest that acyclovir and valacyclovir can be administered for up to 1 year [A-I] based on controlled trials, <sup>47-59, 62</sup> famciclovir has also been evaluated for up to 1 year of administration [A-I]. <sup>60, 61</sup>

Suppressive Therapy for Non-pregnant Patients (all A-1 recommendations)

- Acyclovir 200mg po three to five times daily OR 400mg po bid
- Famciclovir 250mg po bid
- Valacyclovir 500mg po OD (for patients with ≤9 recurrences per year) OR 1000mg po OD (>9 recurrences per year)

## 2006 American Sexually Transmitted Diseases Treatment Guidelines

Of note, the current American guidelines state the safety and efficacy of once daily suppressive therapy has been documented for as long as 6 years for acyclovir and 1 year for valacyclovir or famciclovir. The document also suggests that patients be periodically reassessed (e.g. once yearly) to determine whether therapy should continue, since recurrent genital herpes outbreaks decrease over time.

#### Disclaimer

The recommendations in the Canadian Guidelines on Sexually Transmitted Infections should be applied to daily practice. The trials referenced by the expert panel were included in this review, when possible. Several of the studies were not published in English or in very reputable journals; therefore it was not always possible to obtain the referenced literature. In addition, due to a lack of well designed trails, the Guidelines have limited their evidence based recommendation to one year for safety and efficacy. The following information that is beyond these recommendations is only to supply you with the data that is available – albeit, not always the most sound evidence.

## **Overall Safety**

Suppressive therapy with antiviral agents appears to be well tolerated. With each medication, the nature and incidence of side effects were similar to placebo. In addition, the events that did occur were mild, transient and infrequent. No cumulative toxicity has been reported and resistance rates are very rare. Please refer to the following pages for details.

## Safety Monitoring with Suppressive Therapy

There are no guidelines available outlining the type of parameters that should be monitored, or frequency of follow-up, in patients who are on suppressive therapy. It should be noted that the antivirals have been suspected in case reports of hematological changes (i.e. anemia, leucopenia, neutropenia, thrombotic thrombocytopenia purpura) and hepatotoxicity. It has been suggested that urinalysis, BUN, serum creatinine, liver enzymes and CBC be measured at baseline and periodically with continued therapy.

#### References:

- 1. Public Health Agency of Canada. Canadian Guidelines on Sexually Transmitted Infections. 2006 edition.
- 2. Centers for Disease Prevention and Control. Sexually Transmitted Disease Treatment Guidelines 2006. Available at: <a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5511a1.htm">http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5511a1.htm</a>. Accessed December 4<sup>th</sup>, 2006.
- 3. Micromedex 2006.
- 4. Tyring SK, Baker D and Snowden W. Valacyclovir for Herpes Simplex Virus Infection: Long-Term Safety and Sustained Efficacy after 20 Years' Experience with Acyclovir. Journal of Infectious Disease 2002; 186(Supp 1): S40-6.
- 5. Diaz-Mitoma et al. Oral Famciclovir for the Suppression of Recurrent Genital Herpes. JAMA.1998; 280: 887-92.
- 6. Valtrex® and Zovirax® data on file. GlaxoSmithKline. December 12<sup>th</sup>, 2006.
- 7. Famvir® data on file. Novartis. December 13<sup>th</sup>, 2006.

## Acyclovir (Zovirax®)

- Longest trial: 10 years
- Source:
  - o Data on file (GlaxoSmithKline).
  - o Summary of data: Tyring SK, Baker D and Snowden W. Valacyclovir for Herpes Simplex Virus Infection: Long-Term Safety and Sustained Efficacy after 20 Years' Experience with Acyclovir. Journal of Infectious Disease 2002; 186(Supp 1): S40-6.
- Design:
  - o First year: Randomized, double-blind, placebo-controlled
    - Intervention: acyclovir 400mg po bid or placebo
    - Recurrences: episodic acyclovir 200mg po 5 times a day for 5 days
  - o Second-Sixth Year: open-label
    - Intervention: Patients selected either suppressive or episodic therapy, or discontinued from the study.
  - o Seventh Year: open-label
    - Intervention: episodic therapy with acyclovir 200mg po 5 times a day for 5 days only
    - ≥2 recurrences: continuous suppressive therapy with acyclovir 400mg po bid x 3 years
- Population: N=1175 otherwise healthy patients with frequently recurring genital HSV infection

Table 1: Frequency of most common adverse events (%) among patients receiving continuous acyclovir

suppressive therapy for ≤10 years

Year	Therapy	Nausea	Diarrhea	Headache	Rash	Asthenia	Dizziness	Abdominal	Vaginitis
	(n)							Pain	
1	S (586)	4.8	2.4	1.9	1.7	1.2	1.2	0.9	1.1
	E (589)	2.4	2.7	2.2	1.5	1.2	1.2	1.7	0
2	S (698)	0.7	0.1	1.9	1.1	0.2	1.1	1.1	0.3
	E (85)	1.1	1.1	2.4	0	0	2.4	0	2.3
5	S (430)	0.2	0.2	1.2	0	0.2	0	0.2	1.7
9	S (152)	0	0	1.3	0	0	0	0.7	0

E=episodic therapy (+placebo suppression for year 1); S=suppressive therapy.

#### Valacyclovir (Valtrex®)

• Longest trial: 1 year

#### • Source:

- Below summary comparing valacyclovir to acyclovir and/or placebo: Tyring SK, Baker D and Snowden W. Valacyclovir for Herpes Simplex Virus Infection: Long-Term Safety and Sustained Efficacy after 20 Years' Experience with Acyclovir. Journal of Infectious Disease 2002; 186(Supp 1): S40-6.
- Study 1: Patel R, Bodsworth N, Woolley P, et al. Valaciclovir for the suppression of recurrent genital HSV infection: a placebo controlled study of once-daily therapy. Genitourin Med 1997; 73:105–9.
- Study 2: Reitano M, Tyring S, Lang W, et al. Valaciclovir for the suppression of recurrent genital herpes simplex virus infection: a large-scale dose range-finding study. J Infect Dis 1998;178:603–10.
- o Study 3: Baker DA, Blythe JG, Miller JM. Once-daily valacyclovir hydrochloride for suppression of recurrent genital herpes. Obstet Gynecol 1999; 94:103–6.
- Study 4: Conant MA, Schacker T, Murphy RL, et al. Valaciclovir versus aciclovir for herpes simplex virus infection in HIV-infected individuals—two randomized trials. Int J STD AIDS 2002; 13:12–21.
- Design: 3 randomized controlled trials and one open-label study

Table 2: Trials assessing valacyclovir for suppression of recurrent HSV infections.

Study	Population	Total	# of	Total daily	Variable compared	Trial
		subjects	valacyclovir	valacyclovir	(total daily dose)	duration
			recipients	dose		
1	Immunocompetent	382	288	500mg	Placebo	16 weeks*
2		1479	269	250mg	Acyclovir (800mg)	1 year
			540	500mg	Placebo	
			269	1000mg		
3		127	127	500mg	=	1 year
4	HIV infected	1062	713	1000mg	Acyclovir (800mg)	1year
Total		3050	2206			

<sup>\* 313</sup> patients continued with open-label valacyclovir to complete 1 year of therapy.

**Table 3:** Adverse events reported in patients receiving valacyclovir (250-1000mg/day), acyclovir (800mg/day) or placebo for up to 1 year.

	Immunocompetent			HIV Infected	
Event	Valacyclovir (n=1493)	Acyclovir (n=267)	Placebo (n=228)	Valacyclovir (n=713)	Acyclovir (n=349)
Headache	32	37	25	18	17
Rhinitis	20	25	15	12	12
Infection*	15	21	11	18	13
Nausea	10	12	8	12	14
Pharyngitis	9	11	10	11	13
Diarrhea	8	12	10	20	19
Abdominal pain	8	7	4	11	7
Rash	6	6	7	15	14
Depression	4	4	3	10	11
Fever	2	<1	1	10	11
Any event	82	85	67	77	77

<sup>\*</sup>Infectious illness included influenza, common cold, rhinitis, sinusitis.

### Famciclovir (Famvir®)

- Longest trial: 1 year
- Source:
  - O Diaz-Mitoma et al. Oral Famciclovir for the Suppression of Recurrent Genital Herpes. JAMA.1998; 280: 887-92.
- Design:
  - o Randomized, double-blind, placebo-controlled, multicentre (Europe and Canada), parallel-group study
- Population:
  - N=455, ~48% male, mean age 37 (19-76 years old), mean duration of genital herpes was ~7 years, 85% had experienced at least 10 recurrences in the 2 years prior to study entry, 15% had previously tried suppressive therapy with acyclovir in the 12 months prior to the study, and 40% had received episodic acyclovir treatment.
- Intervention:
  - o famciclovir 125mg po TID, famciclovir 250mg po BID, famciclovir 250mg po TID or placebo
  - o Patients with either 2 virologically confirmed or 3 clinically confirmed recurrences were given the option of open-label famciclovir 250mg po TID for the remainder of the study.

**Table 4:** Adverse events in patients (%) who received at least 10 months of double-blind study medication.

A decome Execut		Placebo		
Adverse Event	125mg tid (n=69)	250mg po bid (n=81)	250mg po tid (n=76)	(n=30)
Patients with ≥1 event	67 (97.1)	75 (92.6)	70 (92.1)	27 (90)
Headache	36 (52.2)	34 (42)	32 (41.2)	14 (46.7)
Viral Infection*	16 (23.2)	29 (35.8)	25 (32.9)	10 (33.3)
Upper respiratory tract infection	26 (37.7)	25 (30.9)	25 (32.9)	10 (33.3)
Injury	15 (21.7)	10 (12.3)	19 (25.5)	7 (23.3)
Back pain	7 (10.1)	9 (11.1)	15 (19.7)	4 (13.3)
Pharyngitis	12 (17.4)	13 (16)	11 (14.5)	6 (20)
Dyspepsia	4 (5.8)	3 (3.7)	7 (9.2)	5 (16.7)

<sup>\*</sup>Viral infection included influenza, flulike symptoms, and symptoms of a cold.

## Appendix XVII – Last-Minute Travel Health Information Package Project

#### LAST-MINUTE TRAVEL HEALTH INFORMATION PACKAGE

**Disclaimer:** all patients should be encouraged to visit the International Travel Health Clinic through Public Health:

Location: #108-407 Ludlow Street

Hours: 8:00am-12:00 noon, 12:30pm-4:15pm M-F

For appointments call: 655-4780

Website: http://www.saskatoonhealthregion.ca/your health/ps itc about us.htm

This information package is intended to provide you with travel health advice for patients who cannot attend the Travel Clinic.

Recommendations for traveling change often and vary according to destination. Once a patient's current health status, travel itinerary (dates of departure and return, stopovers, plans after arrival, type & style of travel) and immunization history is assessed, visit the Centers for Disease Prevention & Control's website (<a href="http://www.cdc.gov/travel/">http://www.cdc.gov/travel/</a>) for the latest recommendations.

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#### **Additional Resources:**

- Immunization Action Coalition (http://www.immunize.org/index.htm)
- World Health Organization (http://www.who.int/ith/en/)
- International Society of Travel Medicine (<a href="http://www.istm.org/">http://www.istm.org/</a>)
- Public Health Agency of Canada Travel Health (http://www.phac-aspc.gc.ca/tmp-pmv/index.html)

#### MALARIA PROPHYLAXIS

#### General Statements 123434349

- Physicians are strongly advised to recommend that all travelers to malaria endemic areas, developing or tropical countries, extreme environments and those travelers with significant underlying medical conditions consult with a certified travel medicine provider or public health international travel clinic well in advance.
- Malaria recommendations change frequently and unpredictably in response to changing drug resistance patterns and the occurrence of malaria outbreaks in low risk destinations including popular tourist destinations. Review of current travel recommendations is essential!
  - +Canadian: http://www.phac-aspc.gc.ca/tmp-pmv/index.html -Travel Clinics: www.travelhealth.gc.ca
  - -Advisories: http://www.phac-espc.gc.ca/lmp-pmu/pub\_e.html +CDC: http://www.cdc.gov/malaria/\_(Pb. 770-488-7788) +WHO: http://www.who.int/topics/malaria/en/
- Travel to a malaria risk zone (MRZ) within the past year is a risk for malaria even if prophylaxis was used, especially if a fever develops within 3 months of return.
- Individuals originally from a MRZ who return back to visit relatives are at high risk for malaria and high risk to not seek prophylaxis. (Immunity wanes over 3+ months.)
- Symptoms: fever & rigors with other flu-like symptoms such as myalgias, headache, vomiting, abdominal pain
- Refer malaria patients to a specialist early!
- Malaria can lead to seizures, coma, organ failure & death. (The time from onset of symptoms to death can be <48hrs; therefore a suspected case is a medical emergency. Blood slides require processing within hours. Prompt treatment / referral should not be delayed even if lab results not available.}
- Epidemiology: Worldwide: >300 million cases/year and >2 million deaths/year (mostly infants & children). {Canada<sup>2</sup>: ~400 malaria cases imported & ~1 death/yr<sup>2004</sup>}
- Malaria is caused by Plasmodium protozoa that are transmitted from female Anopholes mosquito bites. \*Plasmodium falciparum is the most common cause of serious morbidity 8. mortality. P. vivox. P. ovele & P. malarine present with less severe symptoms.

#### Who's at risk?

- Travelers who enter a malaria risk zone (MRZ) in tropical latitudes & some temperate regions. CDC Map
- Those with ↑ risk factors of acquiring malaria;
  - a destination that includes rural exposure
  - camping versus air-conditioned accommodations
  - duration of stay especially high risk season
  - low altitude at destination (< 2000m or 6000ft)<sup>2</sup>; NOTE: low risk at altitudes >1500m, but can exist up to 3000m.

We would like to acknowledge the following contributors and reviewens: Dr. J. Operate (SHP-Pub Health) the Politic Addition Committee. Proposed by Assept Departure Lover Region <sub>Market</sub>, Devot Assets <sub>He</sub> Copyright 2008 - ForTion, Existation of Health Copyring (EMT) - were Coffice. on

#### What can be done to prevent malaria?

- Reduce physical exposure to mosquito bites from dusk to dawn. Wear light coloured, tucked-in, tight weaved, long sleeved shirts, pants & socks.
- Use DEET (30%) insect repellents for all ages while in the MRZ. Reapply every 6 hrs or sooner if necessary. (Microencepsulated slow release forms ↑ duration with a ↓ concentration. Avail in USA. DEET >30% products are not available. in Canada & provide little added protection over the 30% strength.)
- Postpone travel until low risk season, especially for elderly, children & pregnant women who must travel
- Impregnated clothing with insecticide (Instructions at: www.phac-aspc.oc.caloublicat/ccdr-mtc/04pdf/ccdr malaria 0504 e.pdf/
- Impregnated bed netting: {Instructions for replacement \*4 ataré monto & washing at: http://www.healthbridge.ca/malada\_confroi\_e.cfm

#### Malaria Prophylaxis - Chemotherapy

- No chemoprophylaxis is 100% effective in prevention. If patient is concerned with the side effects & tolerability
- of their malaria meds, may start 3-4 wks prior to travel.
- Weekly malaria prophylaxis (MP) has been associated with Tcompliance & maintains sufficient drug blood levels longer than the daily regimen if a dose is missed.
- Purchase MP in Canada before leaving. Agents purchased. or couriered from overseas may not be effective due to insufficient amounts of active drug, contamination, or the wrong drug. Counterfeit drugs are common. 10 (Some agents used overseas are associated with severe toxicities e.g. Halofantrine (HALFAN) - cardiotoxicity.)
- Choice of prophylaxis will depend on resistance trends. Types: chloroguine-sensitive, chloroguine-resistant P. falciparum: mefloquine-resistant P. falciparum; Chloroquine-resistant P. vivax; & case reports of chloroquine-resistant P. malariae.
- Chloroquine is the drug of choice (DOC) for malaria prevention only in regions with solely chloroquinesensitive P. falciparum/ vivax/ ovale & malariae
- Terminal Prophylaxis "post-exposure" with primaquine may be considered if travel for >8wks in a MRZ with exposure to P. vivax or P. ovale

#### PREGNANCY & LACTATION:

- Due to the ↑ risk of both malaria and pregnancy complications it is recommended that women who are or who may become pregnant should not travel to a MRZ
- For those who must travel, consult with travel specialist.
- Risks of malaria considered to outweigh risks of drugs
- All antimalarial drugs listed in chart enter breast milk. Safety of the mother's anti-malarial medication with the infant must be considered. Insufficient levels of drug are obtained in breast milk which may necessitate infant MP.
- DEET is considered safe in pregnancy and lactation

© www.RxFiles.ca Feb 2007 Drug (g=generic avail.) Role, etc. \$ Tx Comments Dose (po) (Major Contraindications, Side Effects, Drug Interactions, etc.) If Chloroquine Sensitive Area (Resistance trends can change rapidly, As of July/06: Chorquire sensitive over: trad to Carbbernind. Hall & rural overs of Dominican Republic, Invesions visiting record areas not generally at fisis, have to Central America (EXCEPT Persona, Mexico, Argentino, & parts of China / Middle cast).) CI: generalized psoriasis, epilepsy; visual field changes obtains for 3 yo & father pophylan region). Chloroquine phosphate (ARALEN),g 250mg tab (500mg = 300mg base) Pediatric: 8.3 mg/kg (5 mg. 4 meets hase/ko) and weekly myasthenia gravis. Caution: pts with hepatic failure, GSPD deficiency, pre- Loading dose: 16.7 mg/kg First-ling: DOC chloroquine sensitive malaria (10 mg/kg base) if not started 2 existing auditory damage. OK in pt with CrCl >10 minutes Consult travel olinios if available!!! wks prior to exposure) 32: N/V/D, pruritus, headache & dizziness. Uncommon: See current listings for majaria risk zones NRZ×. alopecia, hair de-pigmentation, fatigue, skin eruptions, Adult: 500 mg weekly (Area risk changes over time as do resistance patterns.) tinnitus, blurred vision, retinopathy & seizures. (=300 mg base) 10) t Inhibits CYP 2D6, cimetidine, cyclosporine, antacids Loading dose: 1g in two divided • ■ : All Plasmodium except CRPF& P. vivax: Vaccine Interaction<sup>(1)</sup>: Jap Enceph., Typhold, Cholers, Rables<sup>(1)</sup> doses 6 hr apart if not initiated 2 in areas without CRPF Mirred done: Take ASAP then wait 7 days for next dose. • Cost in Pregnancy if chloroquine sensitive wks prior to exposure Take with food; may crush tablets in jam, fruit juice or \*Begin 1-2wk prior to entering May use long term if tolerating well chocolate syrup to mask bitter taste. Capsule compounding MRZ, continue during stay & (Oothalmological & neurological exam every 3-6 option. Recipe for chocolate syrup at: 4 who after leaving MRZ months if used >6months). ttp://www.sickkids.ca/pharmacy/custom/chocolate\_cherry\_syrup.asp

### Hydroxychloroquine PLAQUENILa

#### (DOC: Mefloquine; if mefloquine resistant area DOC: Doxycycline)

Seldom used, alternative to chloroquine if pt already on, or if chloroquine not available. More info on ref page<sup>1</sup>

Mefloquine \*1. 250mg tab LARIAM # Y ⊗ ≥ 95% effective against CRPF First-line: DOC chloroquine resistant

OGC: 2<sup>rd</sup> & 3<sup>rd</sup> trimenter of programmy if CRPF 2.

[1<sup>rd</sup> amenter, prophylatic benefit may outweigh potential risk

If Chloroguine Resistant Area

- of early pregnancy load Neuropsychiatric SEs not common (but noted in meda) Serious (seizura/psychosis) 1 in 10,600. Less severe
- (agriety, degression, irritability) 1 in 250. Increased risk of neuropsychiatric SE in women, firsttime users, and BMI <20; well telerated in males

Atovaguone/Proguanil

- without past history of psychiatric disorders 20 Long-term montrolaxis well tolerated. Good evidence up to 1 yr. CDN Guidelines recommend not to
- >45 kg: 1 tab weekly Adult: 250 mg weekly Begin 1 wk\* prior to entering MRZ, continue during stay, & 4 wks after leaving MRZ

· Pediatric: 5mg/kg weekly.

cS ko no data: assess dak ya henefit

"Begin 3 wk prior if worded about SE 40% of neuropychiatric adverse events occur after arbitrarily restrict use if well telerated & pts at risk. It dose & 75% by 3" dose; 1-4% DC doe to SE (Monitor: Periodic LFT & Ophthalmic exams)

**x** ⊙

- 5 9 kg: Smg/kg weekly 10-19 kg: 34 tab weekly 20-29 kg: 1/6 tab weekly 30-45 kg: 3/4 tab weekly
  - · Caution: work/ recreation involving coordination or in situations where vertigo is life threatening.

    122 (> in \$): (1-10%) NV/D, dizziness, headache, sleep disorders (bad dreams/insomnia), vomiting (can persist
    - after DC); (<1%) anxiety, confusion, paranoia, psychosis depression, hallucinations, seizures, abnormal heart beat 1-4% discontinue due to SE; similar to other antimalarials Vaccine Interaction<sup>17</sup>: Typhold

CI: Epilepsy, history of depression, psychosis, anxiety,

with halofantrine, quinine & quinidine.

schizophrenia & heart conduction problems. Do not use

 Take with food (after main meal) and 3 or of water Missed dose - Take ABAP, however: If almost time for next dase, skip the missed dose & resume normal dosing regimen. anticonvulsants, bupropion, cardiac conduction meds

• CT: children <11 kg & CrCl <30 ml/min; pregnancy lect det • 532: Well-tolerated. 7-15% NV/D, headache; seizures \*\*\*\* Malarone Pediatric:
 11-20 kg: 1 Ped tab OD 250mg/100mg tab MALARONE 21-30 kg: 2 Ped tab OD Take with food or milk. Missed dose: Take ASAP, skip. 62.5mg/25mg tab MALARONE PEDIATRIC 31-40 kg: 3 Ped tab OD dose if <3 hm of next dose & continue normal regimen. > 40 kg: 1 Adult tub OD "If switching from mefloquine or doxyovoline: there First-line: CRPF (although emerging resistance) are special considerations for duration of prophylaxis 'Malarone Adult Second-line: chloroquine sensitive & multi-drug required 9. Since confusing contact local travel clinic or (250mg/100mg): 1 tab OD resistant malaria (e.g Thailand border region). CDC-Malaria Line @ 770-488-7788. Not first-line due to lack of evidence2 10 indinavir, metoclopramide, tetracycline, rifabutin, rifampin,

 Good safety data up to 12 wks. Supportive evidence. up to 26 wks. Use with caution longer than 25 wks8. Doxycycline 100mg with VIBRA-TABS a

 > 95% effective against CRPF nt-line: chloroquine & multi-drug resistant malaria POOr Thailand border region Cimbola, Myson for scuba divers (less SEIs/seizure issues)

- Second-line: chlorocraine sergitive Persons on long-term minocycline & tetracycline for sone should cease 1-2 days prior to travel & commence deceptions until full course of
- Duration: considered safe <3 months; use documented</li> in troops up to 1 year; UK Guidelines suggest safe up to 2 yes". Monitor CBC, CrCl, LFTs with >3mon use.
- Begin 1day prior to entering MRZ, continue during stay, & 1 wk after leaving MRZ
- Pediatric ≥8yrs: 1.5 mg base/kg OD (max 100 mg) 25-35 kg or 8-10 yrs: 50 mg OD 36-50 kg or 11-13 yrs: 75 mg OD ≥ 50 kg or ≥ 14 yrs: 100 mg OD · Adult: 100 mg OD

Begin 1day prior to entering

MRZ, continue during stay,

& 4 wks after leaving MRZ

dexycycline is completed; then restart previous tx.

- Vaccine Interaction 7: Oral Typhold CT: <25kg or < 8yrs, breastfeeding, pregnancy.</li> myasthenia gravis
- •33: Common: nausea, †sun sensitivity (may be less common with 100mg/day dose equilibrium, †vag. candidiasis Prevents leptospirosis
- Take with plenty of water to ↓GI initation. (Food may ↓ absorption by 20%) · Minned done: Take ASAP, skip dose if within 3 hrs of
- next dose and resume normal dosing regime.

  1131 Inhibits 3A4, anticonvulsants, digoxin, warfarin;
- decrease absorption with antacids/ multivitamins Vaccine Interaction<sup>17</sup>: Typhold, Oral Cholera

#### Terminal Prophylaxis / Prevent Relapse due to P. vivax and P. ovale

Primaquine: Terminal Prophylaxia: Effective against P. vivax & P. ovak only. Used for ptb that have had long exposure to malaria endemic areas (>8wks) 2.

 Only therapy to prevent relapse from P, vivax & P, ovale due to dormant hypnopolies in liver (relapse may occur within 5 years of exposure). Also 2<sup>nd</sup> line for CRFP. More info on reference page – online at www.rxfles.ca.

ASAP-varies not possible CBC-complete blood count. CI-contrainded to CPCI-condition desented. CRPF-Chicogoline Resistance P. Religious variety of day. DEET-Met-NA-feetly bisantife insec replact DC-decettes DI-day intensions DOC-day of cities (D-intensional LFT-tenthatical but mon-recetts MP-related pophysis intensional but we replaced to the MVD-reases, writing 5 districts the placed of the second Military of th

#### **Vaccinations for Travel**

Vaccinations for travelling can be divided into three categories: routine, required and recommended.

#### **Routine Vaccinations**

Travellers should ensure they are up to date on their routine immunization, which will help prevent the acquisition of diseases prevalent in other countries. In Canada, the routine immunizations are as follows:

- Influenza
- Tetanus, Diphtheria, Polio
- Pertussis
- Measles, mumps, rubella

If patients are uncertain of their immunization history, ask them to contact their home town Public Health office to obtain their immunization record.

#### Required Vaccinations

Currently, there are only two vaccinations that are required for certain destinations:

- Yellow fever (certain areas for sub-Saharan Africa and tropical South America)
- Meningococcus (Saudi Arabia for travel during Hajj)

Documentation of vaccination may be needed.

#### Recommended Vaccinations

These vaccinations depend on the destination, expected time in rural areas, time of year, age, health status and previous immunizations.

To determine which vaccinations should be administered prior to travel, visit the Centres for Disease and Prevention (<a href="http://www.cdc.gov/travel/vaccinat.htm">http://www.cdc.gov/travel/vaccinat.htm</a>) for current recommendations categorized by region.

#### Hepatitis A & B

TWINRIX® (purified, inactivated hepatitis A and purified hepatitis B surface antigen)

#### **Transmission:**

- Hepatitis A: ingestion of food and water that has been contaminated with human feces and/or oral-fecal contact with an infected person.
- Hepatitis B: blood, saliva, semen and vaginal fluids. Patients should be encouraged to practice safe sex while traveling. Risk of transmission is higher for those providing or receiving medical care in areas with intermediate or high rates of hepatitis B.

**Contraindications:** patients with hypersensitivity to any constituent of the vaccine. Note:

- TWINRIX® does <u>not</u> contain egg, but does have traces of neomycin in the formulation.
- There is not enough data to establish the safety of TWINRIX® in patients who are <1 year old, pregnant or breast feeding.

#### Administration:

- Intramuscular Deltoid muscle preferred in adults. Anterolateral thigh preferred in infants. Avoid the gluteal region due to suboptimal seroconversion.
- May be given simultaneously with other inactivated vaccines, but administration should be at separate syringes and anatomical sites.

#### **Dose & Dosing Schedule**

TWINRIX Junior®: 0.5ml prefilled syringe contains hepatitis A 360 ELISA units & hepatitis B 10µg.

- Standard Schedule: 0, 1, 6 months using TWINRIX Junior® (ages 1- 18 years old)
- Alternate Schedule: primary dose plus a booster (either at 6 or 12 months) using TWINRIX® (ages 1-15 year old)

TWINRIX®: 1ml prefilled syringe contains hepatitis A 720 ELISA units & hepatitis B 20µg.

- Ages  $\geq$  19 years old.
- Standard Schedule: 0, 1, 6 months
- Rapid Schedule: 0, 7, 21 days and a booster at 12 months

**Development of Immunity** (based on studies involving people 18-50 years old)

TWINRIX® Standard Dosing Schedule (0, 1, 6 months)					
% of people who Day 15 Month 1 Month 7					
developed antibodies	(2 weeks after 1st	(1 month after the 1st	(1 month after the 3 <sup>rd</sup>		
	dose)	dose)	dose)		
Hepatitis A	88%	94%	100%		
Hepatitis B	NA	70%	99%		

If the dosing schedule is interrupted, give the next dose as soon as possible. If the second dose is delayed, ensure the third dose is administered 5 months after.

Rapid/Accelerated Dosing (0, 7, 21 days & a booster at 12 months)					
% of people who Week 4 Week 8 Week 56					
developed antibodies	(1 week after the 3 <sup>rd</sup> (5 weeks after the 3 <sup>rd</sup>		(1 month after the 4 <sup>th</sup>		
	dose)	dose)	dose)		
Hepatitis A	100%	99.5%	100%		
Hepatitis B	82%	85%	100%		

The schedule for rapid dosing CANNOT be interrupted.

Protection will likely last for approximately 20 years against hepatitis A and 15 years for hepatitis B.

#### Hepatitis A

VAQTA® (purified, inactivated, whole virus)

**Transmission:** ingestion of food and water that has been contaminated with human feces and/or oral-fecal contact with an infected person.

**Contraindications:** patients with hypersensitivity to the drug or any of its components. For those with contraindications, refer them to Public Health InternationalTravel Health Clinic to receive immune globulin, which will offer protection for up to 3 months. Note:

- VAQTA does <u>not</u> contain egg, but does have traces of neomycin in the formulation.
- There is not enough data to establish the safety in patients who are <2 years of age, pregnant or breast feeding.

#### Administration:

- Intramuscular (deltoid muscle preferred).
- May be given simultaneously with other inactivated vaccines, but administration should be at separate syringes and anatomical sites.

#### **Dose & Dosing Schedule**

Age	Dose (Primary & Booster)	Dosing Schedule
Pediatric &	0.5ml (~25U)	Primary dose & a booster 6-
Adolescents		18 months later
(ages 2-17 years old)		
Adults	1ml (~50U)	Primary dose & a booster 6-
(≥18 years old)		18 months later

If the dosing schedule is interrupted, administer the booster as soon as possible but restarting the series is unnecessary. The booster dose is interchangeable; therefore if the patient's first vaccine was another inactivated hepatitis A vaccine (e.g. Harvix®) they could receive VAQTA® as their booster dose.

## **Development of Immunity**

% of patients with immunity	2 weeks after Primary Dose	4 weeks after Primary Dose
Hepatits A (VAQTA®)	~70%	~94-100%

<sup>\*</sup> A booster shot is necessary to promote long-term protection.

- The incubation period of hepatitis is long (20 to 50 days). Therefore, it may still be beneficial to vaccinate a patient just prior to departure.
- a person may develop immunity if they are vaccinated just prior to departure.
- If travel is within 4 weeks of vaccination, a dose of immune globulin may be given alone or with the hepatitis A vaccine for optimal protection (administered at the International Travel Health Clinic).
- Protection will likely last for approximately 20 years. Additional booster doses or serologic testing, after the primary series has been completed, is not recommended at this time.

#### Hepatitis B

Recombivax HB® (recombinant surface antigen)

**Transmission:** via blood, saliva, semen and vaginal fluids. Patients should be encouraged to practice safe sex while traveling. Risk of transmission is higher for those providing or receiving medical care in areas with intermediate or high rates of hepatitis B.

**Contraindications:** hypersensitivity to any component of the vaccine.

- Does <u>not</u> contain egg, but harvested in yeast.
- Available in two formulations:1) preservative-containing (thimerosal) (10mcg/ml)
  2) preservative-free (thimerosal-free) (10mcg/ml & 40mcg/ml)
- There is not enough data available to determine the safety of Recombivax HB® in patients who are pregnant or breastfeeding.

#### **Administration:**

- Intramuscular Deltoid muscle preferred in adults. Anterolateral thigh preferred in infants. Avoid the gluteal region due to suboptimal seroconversion.
- Can be given concomitantly with DTP (Diphtheria, Tetanus and whole cell Pertussis), oral Poliomyelitis vaccine, M-M-R II (Measles, Mumps, and Rubella Virus Vaccine Live), Liquid PedvaxHIB, Conjugate vaccine (Meningococcal Protein Conjugate) or a booster dose of DTaP (Diphtheria, Tetanus, acellular Pertussis) using separate sites and syringes for injectable vaccines.

**Dose & Dosing Schedule** 

Age	Dose	Dosing Schedule
Birth – 10 years of age	2.5mcg	
11 − 19 years of age	5mcg	0, 1, and 6 months
≥ 20 years of age	10mcg	
Dialysis or immunocompromised	40mcg	
Two-dose regimen: 11-15 years of age	10mcg	Primary dose and then a
		booster 4-6 months later

If the dosing schedule is interrupted, do not restart the series. Instead, give the next dose as soon as possible. If a patient started their series with Engerix-B®, they may continue with the Recombivax-HB® vaccine and schedule.

If the dosing schedule is accelerated, a minimum of one month must pass between injections (e.g. 0, 1, 2 months).

**Development of Immunity** 

Age	% Of Subjects with Immunity		
20-29	98		
30-39	94		
≥40	89		

Note: seroconversion rates and geometric mean antibody titers were only measured 1-2 months after the third dose.

Protection will likely last for approximately 15 years.

#### Traveler's Diarrhea

#### What is traveler's diarrhea?

Traveler's diarrhea (TD) is defined as the passage of 3 or more unformed stools over 24 hours and at least one of the following symptoms – fever, abdominal cramps, nausea, fecal urgency or dysentery. It is self-limiting and can last for about 3-4 days.

#### What causes traveler's diarrhea?

TD can be caused by bacteria, viruses or parasites. Approximately 85% are bacterial in origin and the causative pathogens can vary based on geography.

Table 1: Etiological Pathogens based on Geographic Area

Geographic Area	Important Etiology Pathogens
All regions of the developing world	Escherichia coli (~50% of cases)
	Shigella, Salmonella and Campylobacter spp. (~15%
	of cases)
Mountain areas and recreational waters of North	Giardia spp.
America	
Southern Asia	Shigella, Salmonella and Campylobacter spp.
	(~30%)
	Note: ciprofloxacin-resistant Campylobacter
Russia (especially St.Petersburg)	Giardia and Cryptosporidium spp.
Nepal, Haiti, and Peru	Cyclospora spp.
India, Ecuador, Bali & Indonesia	Vibrio cholerae
Cruise ships	Norovirus (e.g. Norwalk virus)

#### Destination

TD can affect ~30-60% of travelers from industrialized countries who visit developing countries of the tropical and semitropical world. The rate of traveler's diarrhea between regions is as follows:

- One low-risk area to another: ~5%
- Low-risk area to an intermediate-risk area: ~15%
- Low-risk area to a high-risk area: ~40%

Table 2: Risk of Traveler's Diarrhea base on Destination

Degree of Risk	Geographic Region	
Low-Risk	New Zealand, Australia, Northern/Western/Central Europe, US, Canada,	
	Japan	
Intermediate-Risk	Caribbean Islands, Southern and Eastern Europe, Northern Mediterranean,	
	China, Russia, South Africa, Israel	
High-Risk	South & Central America, Middle East, Africa, and Southern & Southeast Asia	

All travelers to high-risk areas should be provided with medication for self-treatment.

#### Who is at increased risk of acquiring traveler's diarrhea?

There is a large variance in individual susceptibility; however the following people may be at greater risk of developing TD:

- Children and adolescents due to a lack of gut immunity
- Immunocompromised patients (HIV or AIDS, chronic corticosteroid and immunosuppressive therapy, common IgA deficiency)
- Those with gastric hypochlorhydria due to H<sub>2</sub>-antagonists & proton-pump inhibitors use, or gastrectomy/vagotomy surgery
- Lack of previous travel to high-risk regions in the past 6 months
- Lack of careful food & beverage selection in hotels, restaurants & homes

### How can traveler's diarrhea be prevented?

• Refer to the patient information sheet.

#### Should medication be used as prophylaxis for traveler's diarrhea?

Prophylaxis with antibacterial agents is not recommended, due to the concerns with systemic adverse events and the increasing rates drug resistance with these agents. Loperamide is not recommended for prophylaxis either. Bismuth subsalicylate offers ~65% protection rate, but requires frequent dosing: 2 x 263mg tablets with meals and at bedtime (8 tablets/day) [2 tablets=2 oz of liquid formulations].

#### How should traveler's diarrhea be treated?

TD is self-limiting; however empirical self-therapy is a valid approach because:

- Travelers may have a restricted schedule (pre-planned tour itineraries or business demands) and the loss of even one day due to illness may be very disruptive.
- Seeking medical treatment may have its challenges, such as inaccessibility, unfamiliarity with foreign health care systems, language barriers, remoteness and time constraints.

Travelers should be reminded that stress, menstruation, changes in diet, and excessive alcohol intake may also cause changes in stool consistency and frequency.

#### Goals for Treating Traveler's Diarrhea

Prevent dehydration, reduce symptoms and duration of diarrheal illness, and prevent cancellation of planned activities.

## **Maintaining Hydration Status**

- Recommend for all patients, regardless of age and severity of diarrhea. Note: young infants should be given breast milk or lactose-free formula.
- Maintain or increase fluid intake.
- Oral Rehydration: drink soup and sugar-flavoured mineral water with salty crackers, or use oral rehydration solution (e.g. Gastrolyte®, Gatorade®).
- Diuretics may need to be discontinued temporarily if substantial diarrhea.

Table 3: Self-Treatment for Traveler's Diarrhea

Severity of Diarrhea	Symptoms	Treatment
Mild:	Mild or none	Oral rehydration (e.g. Gastrolyte®, Gatorade®)
1-2 stools/24hrs		May use loperamide or bismuth subsalicylate
Moderate: >2stools/24hrs	No distressing	Oral rehydration (e.g. Gastrolyte®, Gatorade®)
	symptoms	Use loperamide or bismuth subsalicylate
		Add single dose antibiotic if worsening.
	Distressing	Oral rehydration (e.g. Gastrolyte®, Gatorade®)
	symptoms	Loperamide and antibiotic.
		• Reassess in 12-24hrs:
		<ul> <li>If resolved, stop antibiotic</li> </ul>
		o If not resolved, continue antibiotic for up to 3 days.
Severe:	Fever or bloody	Oral rehydration (e.g. Gastrolyte®)
>6 stools/24hrs with fever	stools	Antibiotic for 1-3 days. Seek medical if unable to keep
or bloody stools		down fluids or food, abdominal pain, persistent or
		worsening diarrhea.
		Avoid antimotility agents.

Refer to chart on next page for additional drug information.

The above chart is based on the fact that  $\sim$ 85% of TD is caused by bacteria. If chronic diarrhea occurs, consider the following pathogens and treatment options (also refer back to Table 1):

- Giardia lamblia, giardiasis: metronidazole 250-500mg po tid x 5 days
- Cryptosporidium spp: self-limiting, no established therapy

Cyclosporia caytanensis: TMP/SMX i DS tab po bid x 7 days

#### **Dukoral® Vaccine**

An oral inactivated vaccine against enterotoxigenic E.coli and Vibrio cholerae is available in Canada, however it only prevents 1 out of every 8 cases of TD.

#### Concern with Antibiotic Resistance

One of the reasons why antibiotics are not recommended for prophylaxis is the concern regarding antibiotic resistance. Resistance has already developed for the following agents:

- Co-trimoxazole, sulfonamide agents, ampicillin and doxycycline, therefore the use of these agents are limited.
- ~77% resistance rates for ciprofloxacin and levofloxacin with Campylobacter spp., especially in Spain and Thailand.
- Azithromycin-resistant strains have also been identified in US troops stationed in Thailand.

#### References:

- Al-Abri SS., Beeching NJ., and Nye FJ. Traveler's Diarrhea. Lancet Infectious Disease 2005; 5:349-60.
- DuPont HL.Travelers' Diarrhea: Contemporary Approaches to Therapy & Prevention. Drugs 2006;66(3):303-14.
- Canadian Pharmacists Association. Patient Self-Care: Helping patients make therapeutic choices. 1st ed. Ottawa, ON. Canadian Pharmacists Association 2002.
- Do Bugs Needs Drugs. Antimicrobial Reference. Available at: http://www.dobugsneeddrugs.org/health <u>care/antimicrobial/Antimicrobial ref.pdf</u>. Accessed December 1<sup>st</sup>, 2006.
- Gilbert DN, et al. Sanford Guide to Antimicrobial Therapy. 36<sup>th</sup> ed. Sperryville, VA. Antimicrobial Therapy Inc 2006. Taylor Robert B. Family Medicine Principles and Practice. 6<sup>th</sup> ed. 2003 Springer New York. Chapter 9: Health care of the International Traveler p77-84.

Medications for Prevention & Empiric Antibiotic Treatment for Traveler's Diarrhea

Drug	Mechanism of	Comments/Contraindications/Side Effects/	Dosing Regimen	
	Action/ Efficacy	Drug Interactions/Pregnancy	Prevention	Treatment
Antisecretory and	v i	uce the number of stools passed by 30-65%		
Bismuth	Antisecretory	Limit prophylaxis to 3 weeks.	2x262mg tabs (or 2	2x262mg tabs (or 2 oz.) q30min x 8
subsalicylate	Antibacterial	CI: ASA allergy, <2 years of age, renal insufficiency or gout	oz.) QID (with meals	doses, may repeat on day 2
(Pepto-	Anti-inflammatory	SE: black tongue/stools, tinnitus	and hs) x 3 weeks	, , , ,
Bismol®)		<b>DI:</b> anticoagulants or salicylates, probenecid, methotrexate.		
	Protection rate of ~65%	Can interfere with doxycycline & fluroquinolones (space by 2		
		hours)		
		<b>Pregnancy:</b> B (salicylate component may inhibit platelet		
		function & ↑ risk of premature closure of the fetal ductus		
		arteriosus)		
Loperamide	Antisecretory	Antimotility DOC. Combined with an antibiotic is superior	Not recommended for	4mg stat then 2mg after every loose
(Imodium®)	Antimotility	to treatment with either agent alone.	prophylaxis	BM. Max 16mg/day
		Avoid if high fever, chills or bloody diarrhea (may worsen		
	↓ number of stools	clinical course)		
	passed by 65%	May cause post-diarrhea constipation		
		CI: <2 years of age (caution: <12 years of age)		
		SE: abdominal pain/discomfort, drowsiness or dizziness, dry		
		mouth, skin rash		
		DI: St.John's Wort, Valerian		
A411		Pregnancy: B		
Antibacterials: <u>si</u> Fluoroquinolones	Antibacterial.	thea by 1-2.5 days versus placebo  DOC for empiric therapy for moderate to severe diarrhea.	Not recommended	Ontiona
riuotoquinotones	Antibacteriai.	CI: pregnancy, <8 years of age	due to \ rates of	Options: 1) Ciprofloxacin 750mg po OD
	Reduce duration of	SE: GI complaints, headache, dizziness, rashes,	antibiotic resistance	2) Ciprofloxacin 500mg po BID
	diarrhea by ~50% with	photosensitivity (ensure adequate sunscreen protection)	antibiotic resistance	3) Levofloxacin 500mg po OD
	relief of symptoms.	<b>DI:</b> warfarin, phenytoin, cyclosporine, theophylline		4) Norfloxacin 800mg po OD
	Three days of therapy as	Pregnancy: C		5) Norfloxacin 400mg po BID
	effective as 5 days.	Tregnancy.		o) Itemenuem leenig pe 212
	Single dose treatment	Not covered by the SK Drug Plan for this indication.		*All regimens for 1-3 days.
	often sufficient.			
Azithromycin	Antibacterial.	An alternative to fluoroquinolones in areas of high incidence	Not recommended	Options:
		of campylobacter infection. Can be used in children.	(no evidence)	Adults
	As effective as	CI: allergy to macrolides		1) 1g po as a single dose
	ciprofloxacin and	SE: diarrhea, abdominal pain, nausea, vomiting, rash		2) 500mg po OD for 1-3 days.
	levofloxacin, but may	<b>DI:</b> aluminum & magnesium containing antacids (space by 2		
	have a slower response.	hours), carbamazepine, phenytoin, theophylline, warfarin,		Children
		cyclosporine, ergots		10mg/kg po od for 1-3 days.
		Pregnancy: B		
		Not covered by the SK Drug Plan for this indication.  a bacteria/capsule) had protection rates of 12-45%. Dose: i cap bid beginning 2-		

**Possible effective:** Probiotic *Lactobacillus GG* (10 billion bacteria/capsule) had protection rates of 12-45%. Dose: i cap bid beginning 2-3 days before travel & for duration of trip. *Saccharomyces boulardii* 250mg (5 billion bacteria) per capsule or packet. Dose: 1-2 capsules daily beginning 5 days before travel and for duration of trip. **Ineffective:** Probiotics *Lactobacillus acidophilus* and *L.bulgaricus*, kaolin-pectin preparations, activated charcoal, and anticholinergics

#### Patient Information Sheet on Traveler's Diarrhea

All patients are encouraged to visit the International Travel Health Clinic through Public Health.

Traveler's diarrhea is the passage of 3 or more unformed stools over a 24 hour period with at least one of the following symptoms – fever, abdominal cramps, nausea, a sense of urgency to pass stools or the presence of blood/mucus in the stool. These symptoms can last between 1 to 4 days. It is important to note that stress, menstruation, changes in diet, and excessive alcohol intake may also cause changes in stool consistency and frequency.

#### Preventing Traveler's Diarrhea

Traveler's diarrhea is caused by ingesting food or beverages which are contaminated with bacteria, viruses or parasites. Careful selection of what you consume will reduce your risk of getting traveler's diarrhea. Below are some tips to follow while traveling:

#### Avoid

- Tap water, bottled water where the seal is not intact, and ice.
- Salads (unless washed in water known to be clean), unpasteurised fruit juices and dairy products, and cold sauces.
- Fruit that you cannot peel and raw seafood.
- Previously cooked foods that have been sitting at room temperature for several hours after initial cooking.
- Items served in buffet tins without effective heating flame below.
- Food from a street vendor.
- Swallowing water while swimming.

#### Do

- Drink boiled water or carbonated beverages.
- Eat freshly cooked, piping hot food.
- Use a portable water filter.

## Medication for Traveler's Diarrhea

It is a good idea to plan ahead and pack medications in case you experience traveler's diarrhea. Medications should be purchased in Canada prior to the trip. Items to consider include:

- Oral rehydration solution (e.g. Gastrolyte®, Gatorade®)
- Non-prescription products like loperamide (e.g. Imodium®) or bismuth subsalicylate (e.g. Pepto-Bismol®).

Check with your physician, nurse practitioner or pharmacist to ensure you can safely take the above medications, as well as to provide you with instructions for using these medications.

If you do develop Traveler's Diarrhea, seek medical treatment if you experience any of the following:

- signs of dehydration, blood in the stools, vomiting, severe abdominal pain, or fever;
- persistent diarrhea lasting longer than 3-4 days;
- unable to keep down fluids because of vomiting; or
- extreme exhaustion.

#### **Economy Class Syndrome**

The Risk of Venous Thromboembolism While Traveling

Venous thromboembolism (VTE) can result in pulmonary embolism (PE) and/or deep vein thrombosis (DVT). PE and DVT can occur in travelers who are seated for a long period of time on a plane, train, car or bus. The event can occur during, immediately after or even weeks after travel. Over the past several years, these thromboembolic events have received a lot of attention in the press, particularly when associated with flying. The term *Economy Class Syndrome* has since been created, referring to the cramped space of an economy section of an airplane which can lead to venous pooling.

#### What is the Risk

The evidence for the link between VTE and long distance travel is controversial. It is estimated that PE occurs in:

- 1/100million passengers who are traveling <6 hours
- 1/700,000 passengers who are traveling >6 hours

As for DVT, eight prospective trials (flights >4 hours), estimated the rate of asymptomatic DVT to be:

- 1.2% for low-risk passengers (i.e. no risk factors)
- 4% for those at high-risk (i.e. one or more risk factors)

A case-control study (n=420) concluded that:

- Air travel itself has a 2-fold increase risk of VTE compared to those who do not travel by air. The risk increased to 3-fold for long-distance flights.
- Women who fly and are on oral contraceptives are 14 times more likely to develop a VTE than those who do not fly and are on oral contraceptives.

Although not investigated yet, it can be assumed that other forms of estrogen therapy (e.g. contraceptive patch, hormone replacement therapy) would carry a similar risk.

#### Assessing Risk of Venous Thromboembolism

The risk factors for VTE can be divided into two categories:

Cabin-related risk factors:	Patient-related risk factors include:
Cramped seating	Estrogen therapy
High-altitude cabin	• Obesity
pressure	• Age > 50 years
• Low cabin humidity	History of VTE and/or risk factors for VTE
	Family history for VTE
	• Dehydration
	• Recent surgery/trauma (abdomen, pelvis or legs)
	Prolonged immobilization
	• Pregnancy
	• Cancer
	• Smoking
	Blood clotting abnormalities (e.g. thrombophilia)

## **VTE Prophylaxis for Long Distance Travel**

The CHEST Guidelines reviewed seven randomized controlled trials assessing active thromboprophylaxis. The flight duration and presence of risk factors varied across all studies, but each used Doppler ultrasound to identify asymptomatic DVT. The pooled analysis revealed the following:

Intervention	Rate of Doppler-screened DVT
No prophylaxis	3.7%
Below-knee graded compression stockings	0.2%
Single dose enoxaparin (100U/kg or 4,000IU) 2-4 hours	0%
before flying	
ASA 400mg po 12 hours before flying & once daily for	3.6%
total of 3 days	

Based on this evidence, the CHEST Guidelines recommend the following:

- 1) For passengers traveling for longer than six hours:
  - Avoid constrictive clothing around the waist and lower extremities.
  - Avoid dehydration by drinking plenty of water and limiting alcohol/caffeine.
  - Do stretch calf muscles frequently (<u>www.continental.com/travel/specialneeds/health.asp</u>)
- 2) For patients at high risk for VTE:
  - Above preventative measures.
  - Use properly fitted, below-knee graduated compression stockings providing 15 to 30 mmHg of pressure at the ankle<sup>(~\$15-30)</sup>, or
  - A single prophylactic dose of low-molecular weight heparin (e.g. enoxaparin 100U/kg or 4,000IU) injected 2-4 hours prior to departure

(Note: pre-filled syringes range from ~\$15-50 & are not covered by the SK Drug Plan for this indication)

3) ASA prophylaxis is NOT recommended.

Note: ASA therapy to reduce the risk of vascular events associated with arterial disease is well established. The difference in venous versus arterial protection is thought to be due to the degree of platelet aggregation in clot development. In VTE, clot development is typically linked to venous status, which involves less platelet aggregation than arterial thrombosis due to vascular wall injury.

#### **Patient Education**

Patients at risk should be instructed to report swelling in one lower leg, swelling or bruising behind the knee, shortness of breath, chest pain and fainting. It is also important for patients to realize that these symptoms can occur weeks after travel. An information sheet, *Practical Tips for Avoiding "Economy Class Syndrome"*, can also be provided to patients.

#### References:

- 1. Geerts WH, Pineo GF, Heit JA, et al. Prevention of venous thromboembolism: the seventh ACCP conference on antithrombotic and thrombolytic therapy. *Chest* 2004; 126:338C-400S.
- 2. Boehringer SK. New Antithrombotic and Thrombolytic Guidelines. Pharmacist's Letter 2005; 21:210650.
- 3. O'Mara NB. Venous Thromboembolism: air travel and oral contraceptive use. *Pharmacist's Letter* 2004; 20(2):200203.
- 4. Public Health Agency of Canada. International note: travel by air and health considerations. Canada Communicable Disease Report 2006; 32(1). <a href="http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/06vol32/dr3201ea.html">http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/06vol32/dr3201ea.html</a> (Accessed November 23rd, 2006).

## Practical Tips for Avoiding "Economy Class Syndrome"

## What Is Economy Class Syndrome?

Economy class syndrome is a condition that can happen after sitting in a cramped space, such as the economy class section of an airplane. This can lead to blood clots in the legs and sometimes the arms, which is called deep vein thrombosis (DVT). These clots can break free and travel to the lungs (pulmonary embolism) and sometimes this can cause death. This can occur during or after a flight or even a few weeks after a flight. Blood clots can also happen when traveling by train or car for a long period of time, or even from sitting at a desk for a long time.

## How Do I Know If I Have a Blood Clot?

Symptoms of a blood clot can be swelling in one lower leg or arm, swelling or bruising behind the knee, difficulty breathing, chest pain, or fainting.

### Who Is At Risk For Economy Class Syndrome?

The risk factors for blood clots in economy class syndrome can be patient-related or cabin-related. Patient factors include smoking, dehydration, drinking alcoholic or caffeinated beverages, obesity, age over fifty years, pregnancy, and history of blood clots and/or risk factors for blood clots. Other risk factors are recent surgery, cancer, heart failure, and women who are taking birth control pills. Cabin-related factors include sitting in a cramped space for a long time and low cabin humidity.

### General Tips For Avoiding "Economy Class Syndrome"

- Drink plenty of water before and during travel to prevent dehydration.
- Do not drink alcohol and caffeine during the flight since they can cause dehydration.
- Wear loose fitting clothing and comfortable shoes when flying.
- Do not sit with your legs crossed for long periods of time.
- Walk around in the airport during layovers.
- Sleep for only thirty minutes at a time while flying.
- Try to sit in an aisle seat so that you can stretch and move more easily.
- Do not sit for a long period of time. Walk (if permitted) or do stretching exercises during the flight (e.g., ankle circles, toe and heel lifts, knee lifts). Specific exercises that can be done in your seat can be found at http://www.continental.com/travel/specialneeds/health.asp.

#### What Should I Do If I'm At Risk For A Blood Clot?

If you are at high risk for blood clots, talk to your doctor about other things you can do including elastic compression stockings or medicines that can be prescribed for you to take before, during, or after flight.





#### TRAVELING MEDICINE CABINET

#### **Patient Information Sheet**

All patients are encouraged to visit the International Travel Health Clinic through Public Health.

Don't let minor ailments ruin your vacation. Plan ahead by packing the following items to treat conditions from abrasions to the zombie-like state caused by jet lag. All are available without a prescription, but check with your doctor, nurse practitioner or pharmacist to ensure there are no concerns with a medical condition or your current medications.

<b>Pain Relievers:</b> Acetaminophen (e.g. Tylenol®) or ibuprofen (e.g. Advil®, Motrin®) for mild to moderate pain, fever or headache.
Antacids: several products available (e.g. Pepto-Bismol®, Diovol®, Zantac®) for relief of indigestion and heartburn.
Antihistamines: for minor allergic conditions. There are two kinds of antihistamines – those that can cause drowsiness and those that are non-drowsy. Sedating antihistamines – like diphenhydramine (e.g. Benadryl®) and dimenhydrinate (e.g. Gravol®) can be used as a sleep aid to help travelers adjust to jet lag. Dimenhydrinate can also be useful for controlling motion sickness and nausea.
<b>Antidiarrheals:</b> loperamide (e.g. Imodium®) or bismuth subsalicylate (e.g. Pepto-Bismol®) for the management of mild-moderate traveler's diarrhea.
<b>Decongestant:</b> Look for a <i>tablet</i> containing pseudoephedrine, ephedrine or phenylephrine. A decongestant is useful for preventing 'ear popping' during air travel descent or underwater diving. If you have previously experienced ear discomfort while flying, take a decongestant 30-60 minutes prior to arriving at the destination to help reduce the pain, blockage and hearing loss. You can also chew gum or suck on candy.
<b>Hydrocortisone 0.5% cream:</b> useful for skin conditions such as mild inflammation and/or itching.
<b>Insect Repellent:</b> insect repellent containing DEET (30%) is effective against mosquitoes, ticks, fleas, chiggers and flies. Protecting yourself from insect bites will reduce your risk of acquiring diseases such as malaria, dengue and Japanese encephalitis.
<b>Laxatives:</b> a stool softener (e.g. Colace®) or laxative (e.g. Senokot®, Metamucil®) can treat constipation, which may result from dietary changes while traveling.
<b>Oral Rehydration Solution</b> : packages (e.g. Gastrolyte®) are added to water to help prevent dehydration due to traveler's diarrhea. Gatorade® may also be used (available in powder form as well).
<b>Sunscreen:</b> broad-spectrum (i.e. both UVA and UVB) sunscreen with at least SPF 15 to help prevent sunburn. If using both sunscreen and insect repellent, avoid applying them at the same time – if possible. Apply the sunscreen approximately 30 minutes before sun exposure and the insect repellent before heading outdoors.
<b>Topical antibiotic cream/ointment:</b> polymyxin B-gramicidin-bacitracin (e.g. Polysporin) for superficial wounds to treat minor irritation or infection.

Make items more accessible by placing them in a self-sealing plastic bag or a plastic box.

#### TRAVELING WITH MEDICATIONS

When preparing for a trip, medications deserve more attention then just ensuring they are packed. Purchasing medications from another country can be a gamble and there is tighter airport security, resulting in special precautions. Patients should be educated on the following:

#### PREPARING FOR THE TRIP

Unfortunately, there is no international body that oversees brand name selection by pharmaceutical companies. Therefore, different medications may have the same brand name in another country. For example, Dilacor is diltiazem in the US but is digoxin in Serbia. This is also a concern with over-the-counter medications, different dosage formulations (e.g. XR, LA, XL, etc) and foreign lookalike or sound-alike drug names.

Patients should be instructed to:

- 1) Pack an adequate supply of medications for the entire trip, with a bit extra in case of unexpected delays.
- 2) Carry a complete list of current medications. The list should include both the brand and generic names, dosage, how often the medication is taken and reason for use.
- 3) Keep an update list of medical problems, along with the phone numbers of health care providers.
- 4) Medications should be kept in their original prescription container. Do not put medications in pill boxes.
- 5) Recommended medications for traveling (e.g. over-the-counter, self-treatment of traveller's diarrhea) and prescription medications should be purchased in Canada prior to leaving.

#### PACKING FOR THE TRIP

Canadian Air Transport Security Authority recommends the following:

#### **Prescription Drugs**

- Medication should be placed in carry-on baggage, in case it is needed while traveling.
- Each prescription needs to be properly labeled (professionally printed label identifying the medication or a manufacturers name or pharmaceutical label);

**Syringes, Hypodermic Needles and Biojectors** for personal medical use can be packed in either carry-on or checked luggage providing:

- Needle guard is in place; and
- The person possesses medication that is to be administered by means of the syringe or needle and biojectors; and
- The medication is in a container that bears the name of the medication and the name of either the pharmacy that dispended the medication or the manufacturer of the medication

## Liquids, Gels or Aerosol

Passengers will be permitted to bring liquids, gels and aerosols through security screening at Canadian airports provided that the items are packaged in containers with a capacity of 90 ml / 90 grams (3 oz.) or less, and that the containers fit comfortably in one clear, closed and resealable plastic bag with a capacity of no more than 1 litre (1 quart). One bag per passenger will be permitted.

**Liquid prescription medicine** labeled with a name that matches the passenger's ticket or boarding pass, and other essential non-prescription liquid medicines continue to be

permitted and are exempt from the container size restrictions. In addition, they are not required to be placed in a plastic bag.

To speed up the screening process, passengers should place all liquids, gels, and aerosols from their carry-on bags into the trays provided at the beginning of the screening process. When possible, passengers should have documentation supporting a medical condition.

Patients should be encouraged to check with the airline they are traveling on for any additional requirements.

#### **References:**

- 1) Woelfel JA. A Different Drug, a Different Country, but the Same Brand Name? Pharmacist's Letter 2005; 21: 210401.
- 2) Airline travel and medications. Pharmacist's Letter 2006; 22(9): 220914.
- 3) Canadian Airport Transport Security Authority. Permitted and Non-Permitted Items. Available at:http://www.catsa-acsta.gc.ca/english/travel\_voyage/list.shtml. Accessed November 15<sup>th</sup>, 2006.

#### Detail-Document #200509



-This Detail-Document accompanies the related article published in-

## PHARMACIST'S LETTER / PRESCRIBER'S LETTER

May 2004 ~ Volume 20 ~ Number 200509

# Drug-Induced Photosensitivity Lead author: Kelly M. Shields, Pharm.D.

Drugs Reported to Cause Photosensitivity Reactions 1-11

Therapeutic Class	Drugs	Comments
Antihistamines	cetinizine (Zyrtec), cyproheptadine (Periactin),	Reactions have been seen
	diphenhydramine (Benadryl), loratadine	both with topical and
	(Claritin), promethazine (Phenergan)	systemic administration of antihistamines.
Anti-infectives	Fluoroquinolones: ciprofloxacin (Cipro),	Lomefloxacin has higher
Anti-infectives	gemifloxacin (Factive), levofloxacin	incidence than other
	(Levaquin), lomefloxacin (Maxaquin),	quinolones, no reports with
	moxifloxacin (Avelox), norfloxacin (Noroxin),	gatifloxacin.
	ofloxacin (Floxin)	
	Tetracyclines: demeclocycline (Declomycin),	Tetracyclines- reactions seen
	doxycycline (Vibramycin), minocycline	most often with
	(Minocin), oxytetracycline (Terramycin),	demeclocycline.
	tetracycline (Achromycin)	
	Others: azithromycin (Zithromax),	Cefazolin reaction was noted
	capreomycin (Capastat), ceftazidime (Fortaz),	in one case report with
	cefazolin (Ancef), cycloserine (Seromycin), dapsone, ethionamide (Trecator-SC), isoniazid	concurrent gentamicin use.
	(Nydrazid), metronidazole (Flagyl), nalidixic	
	acid (NegGram), pyrazinamide,	
	sulfamethoxazole/trimethoprim (Bactrim),	
	sulfasalazine (Azulfidine), sulfisoxazole	
	(Gantrisin)	
Antifungals	flucytosine (Ancobon), griseofulvin (Fulvicin,	
	Gris-PEG), terconazole (Terazol) voriconazole	
	(VFEND)	
Antiretroviral	ritonavir (Norvir), saquinavir (Fortovase,	Reactions seen in less than
A .: 1 : 1	Invirase), zalcitabine (Hivid)	2% of patients.
Antimalarial	chloroquine (Aralen), hydroxychloroquine	Limited reports of reactions
	(Plaquenil), pyrimethamine (Daraprim), pyrimethamine/sulfadoxine (Fansidar), quinine	exist.
	pyrimetriamine/surradoxine (** ansiaar*), quinine	
Antivirals	amantadine (Symmetrel), acyclovir (Zovirax)	About 1% incidence.
Antineoplastics	bexarotene (Targretin), capecitabine (Xeloda),	Incidence varies from 1% to
	dacarbazine (DTIC), epirubicin (Ellence),	5% by agent.
	fluorouracil (5-FU), interferon alfa (Intron A.	
	Alferon-N), methotrexate (Mexate), pentostatin	
	(Nipent), procarbazine (Matulane), tretinoin,	
1 1 1 1 1	oral (Vesanoid), vinblastine (Velban, Velbe)	
Antiplatelet	clopidogrel (Plavix)	Only one case report.
I		

### (Detail-Document #200509: Page 2 of 4)

Therapeutic Class	Drugs	Comments
Cardiovascular	Thiazide diuretics: bendroflumethiazide	Any combination product
	(Corzide), chlorthalidone (Thalitone),	with hydrochlorothiazide has
	hydrochlorothiazide (Microzide),	a risk of photosensitivity.
	hydroflumethiazide (Diucardin), indapamide	
	(Lozol), methyclothiazide (Enduron),	
	metolazone (Zaroxolyn), polythiazide (Renese)	Incidence of photosensitivity
	Diuretics, Other: furosemide (Lasix),	with amiodarone is about
	triamterene (Dyrenium)	10%.
	Antihypertensives: captopril (Capoten),	1076.
	diltiazem (Cardizem, Tiazac), enalapril	
	(Vasotec), nifedipine (Procardia), sotalol	
	(Betapace)	
	, - ,	
	Statins: fluvastatin (Lescol), lovastatin	
	(Mevacor), pravastatin (Pravachol), simvastatin	
	(Zocor)	
	Other: amiodarone (Cordarone, Pacerone),	
	fenofibrate (Tricor), quinidine	
Anticonvulsants	carbamazepine (Tegretol), felbamate (Felbatol),	Incidence is generally low
	gabapentin (Neurontin), lamotrigine (Lamictal),	ranging from 0.1% to 1%.
	oxcarbazepine ( <i>Trileptal</i> ), topiramate	
	(Topamax), valproic acid (Depakene)	
Antipsychotics	Antipsychotics, Phenothiazines: chlorpromazine	Phenothiazines-reactions
	(Thorazine), fluphenazine (Prolixin),	most common with
	perphenazine (Trilafon), prochlorperazine	chlorpromazine (incidence of
	(Compazine), thioridazine (Mellaril),	2% to 3%).
	trifluoperazine (Stelazine)	
	Antipsychotics, Other: clozapine (Clozaril),	
	haloperidol (Haldol), loxapine (Loxitane),	
	olanzapine (Zyprexa), quetiapine (Seroquel),	
	risperidone (Risperdal), thiothixene (Navane),	
	ziprasidone (Geodon)	
Antidepressants	Tricyclic Antidepressants: amitriptyline	In the case of most of these
randepressinis	(Elavil), amoxapine (Asendin), clomipramine	drugs, incidence of
	(Anafranil), desipramine (Norpramin), doxepin	photosensitivity has not been
	(Sinequan), imipramine (Tofranil), maprotiline	definitely attributed to the
	(Ludiomil), nortriptyline (Pamelor),	antidepressant.
	protriptyline (Vivactil), trimipramine	anittepressant.
	(Surmontil)	
	, ,	No venests noted with
	Selective serotonin reuptake inhibitors:	No reports noted with
	citalopram (Celexa), escitalopram (Lexapro),	escitalopram, but included
	fluoxetine (Prozac, Sarafem), fluvoxamine	because structurally related to
	(Luvox), paroxetine (Paxil), sertraline (Zoloft)	citalopram.
	Antidepressant, Other: bupropion (Wellbutrin),	
	mirtazapine (Remeron), nefazodone (Serzone),	
	trazodone (Desyrel), venlafaxine (Effexor)	
Sedative/Hypnotics	alprazolam (Xanax), chlordiazepoxide	Incidence ranges from 0.1%
	(Librium), zaleplon (Sonata), zolpidem	to 1%.
,		





Therapeutic Class	Drugs	Comments
Analgesic Agents	NSAIDs: celecoxib (Celebrex), diclofenac	
	(Voltaren, Cataflam), diflunisal (Dolobid),	
	etodolac (Lodine), ibuprofen (Motrin),	
	ketoprofen (Orudis), mefenamic acid (Ponstel),	
	meloxicam (Mobic), nabumetone (Relafen),	
	naproxen (Anaprox), oxaprozin (Daypro),	
	piroxicam (Feldene), rofecoxib (Vioxx),	
	sulindac (Clinoril), valdecoxib (Bextra)	
	Other: cyclobenzaprine (Flexeril), dantrolene	
	(Dantrium), sumatriptan (Imitrex)	
Hormones	Oral contraceptives, corticosteroids	
Antidiabetic Agents	Sulfonylureas: acetohexamide (Dymelor),	
	chlorpropamide (Diabinese), glimepiride	
	(Amaryl), glipizide (Glucotrol), glyburide	
	(DiaBeta, Micronase), tolazamide (Tolinase),	
	tolbutamide (Orinase)	
Skin Agents	benzocaine (Americaine), coal tar,	Isotretinoin incidence is 5%
	hexachlorophene (PHisoHex), isotretinoin	to 10%.
	(Accutane), methoxsalen (Uvadex, Oxsoralen),	
	minoxidil (Rogaine), tacrolimus (Prograf,	
	Protopic), tazarotene (Tazorac), tretinoin,	
	topical (Renova, Retin-A)	
	Sunscreen agents: PABA, cinnamates,	
	benzyphenones	
Miscellaneous	chlorhexidine (Peridex, Hibiclens), gold salts,	
	selegiline (Eldepryl), thalidomide (Thalomid)	
Vitamins	pyridoxine (Vitamin B6), Vitamin A	Based on case reports.
Dietary Supplements	bitter orange, chlorella, dong quai, gossypol,	Limited reporting of adverse
	gotu kola, St. John's wort	reactions with dietary
		supplements makes this
		listing incomplete.

Many of the drugs listed in the proceeding table were labeled as photosensitizing based on unclear data. Unclear and incomplete reporting of adverse drug reactions lead to this confusion. Chemicals that are planar, tricyclic, or polycyclic absorb ultraviolet light, which lead them to be classified as photosensitizer drugs.<sup>10</sup>

Types of Photosensitivity

Drug-induced photosensitivity may present in a variety of ways. Most reactions are generally classified as either phototoxic or photoallergic. Photoallergy is a relatively rare, immunological response, which is not dose-related. The allergy develops after multiple days of continuous exposure. It occurs when light causes a drug to act as a hapten, triggering a hypersensitivity response. The reaction usually manifests as pruritic and eczematous.  $^{10-13}$ 

Phototoxic reactions are chemically-induced reactions when the drug absorbs UVA light and causes cellular damage. This reaction can be seen with initial exposure to a drug, may be doserelated, and doesn't demonstrate cross-sensitivity. It usually has rapid onset and manifests as an exaggerated sunburn. This reaction will be seen only on skin areas exposed to the sun. 10-13

## Management of Photosensitivity

Prevention of photosensitivity reactions is based on patient education. Patients should be educated to minimize sun exposure. Use of UVAprotective sunscreens and physical barriers such as clothing can provide additional light protection.

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Sunscreens that provide UVA coverage include: avobenzone, dioxybenzone, oxybenzone, titanium dioxide, zinc oxide. Remind patients of the need to frequently reapply while in the sun. Patients should definitely be counseled to avoid sources of high-intensity light such as tanning beds. Additionally, as some reactions may be doserelated, a decrease in dose may be considered to help minimize the reaction or possibly selection of an alternative agent.

An acute attack may be managed in a number of different ways based on severity. A mild reaction may be handled similarly to a sunburn, with skin protectants and topical or systemic analgesics. Patients may also benefit from application of cooling creams or gels. If patients have blisters that are broken, antibacterial creams may be necessary to prevent infection. Severe reactions may be handled by oral or topic corticosteroids. Antihistamines may also alleviate pruritus associated with reactions.

Users of this document are cautioned to use their own professional judgment and consult any other necessary or appropriate sources prior to making clinical judgments based on the content of this document. Our editors have researched the information with input from experts, government agencies, and national organizations. Information and Internet links in this article were current as of the date of publication.

## References

 Anderson PO, Knoben JE, Troutman WG. Handbook of clinical drug data. 10<sup>th</sup> ed. New York: McGraw-Hill; 2002.

- Dukes MNG, Aronson JK. Meyler's side effects of drugs. 14<sup>th</sup> ed. Amsterdam: Elsevier; 2000.
- Cohen HE. Red Book. 2003 ed. Montvale (NJ): Thomson Medical Economics; 2003.
- Wamock JK, Morris DW. Adverse cutaneous reactions to mood stabilizers. Am J Clin Dermatol 2003;4:21-30.
- Wamock JK, Morris DW. Adverse cutaneous reactions to antipsychotics. Am J Clin Dermatol 2002;3:629-36.
- Arana GW. An overview of side effects caused by typical antipsychotics. J Clin Psychiatry 2000;61(supp 8):5-11.
- Dogra S, Kanwar AJ. Clopidogrel bisulphateinduced photosensitivity lichenoid eruption. Br J Dermatol 2003:148:609-10.
- McEvoy GK. AHFS Drug Information 2004 [database on the Internet]. Bethesda(MD): American Society of Health System Pharmacy. C2004 [updated 2004 Jan 1; cited 2004 April 19]. Available from: http://www.statref.com.
- Jellin JM, Gregory PJ, Batz F, et al. Therapeutic Research Faculty. Natural Medicines Comprehensive Database. http://www.naturaldatabase.com. (Accessed April 17, 2004).
- Moore DE. Drug-induced cutaneous photosensitivity. Drug Saf 2002;25:345-72.
- Allen JE. Drug-induced photosensitivity. Clin Pharm 1993:12:580-7.
- Berbardi RR. Handbook of nonprescription drugs. 14<sup>th</sup> ed. Washington DC: American Pharmacists Association: 2004.
- Morison WL. Photosensitivity. N Engl J Med 2001;350;1111-7.





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#### **HIGH-ALTITUDE SICKNESS**

### **Types of High-Altitude Sickness**

High-altitude sickness is a collective term for the following syndromes:

- 1. Cerebral syndromes:
  - a) Acute mountain sickness (AMS)
    - Clinical presentation: non-specific symptoms headache (cardinal symptom but indistinguishable from other causes of headaches), anorexia, nausea, vomiting, fatigue, dizziness, and sleep disturbance. Note: not all need to be present.
    - Typically appear 6-12 hours after arrival at high-altitude.
    - Can be confused with exhaustion, dehydration, hypothermia, alcohol hangover, or migraine.
  - b) High-altitude cerebral edema (HACE)
    - Clinical presentation: end stage of AMS and is preceded by AMS symptoms. Characterized by ataxia and altered consciousness, which may progress to coma or death due to brain herniation.

#### 2. Pulmonary syndrome:

- a) High-altitude pulmonary edema (HAPE)
  - Clinical presentation: dyspnea, cough, cyanosis, sleep disturbances, irritability, and clinical signs of right heart failure.
  - Typically occurs in the first 2-4 days after arrival at altitudes higher than 2500m.

If HACE and HAPE present concomitantly, papilloedema, ataxia, retinal hemorrhage, and occasionally focal neurological deficits may be present.

Table 1: Incidence of High-Altitude Sickness

Type of High-altitude Sickness	Incidence
Acute mountain sickness	25% at moderate altitudes (1920-2957m)
	50% if walking to altitudes >4000m
	84% if flying directly to 3860m
High-altitude cerebral edema	0.1-4%
High-altitude pulmonary edema	

#### **Risk Factors**

Most Important	Others	Potentia1
<ul> <li>Rate of ascent</li> <li>Altitude reached (especially sleeping altitude)</li> <li>Individual susceptibility</li> </ul>	History of high-altitude illness Permanent residence lower than 900m* Exertion (but not physical fitness)	<ul> <li>Age: ≥50 years ↓ risk</li> <li>Gender: women ↑ risk</li> <li>Neck irradiation or surgery</li> <li>Respiratory infections</li> <li>Dehydration</li> </ul>

<sup>\*</sup>The altitude of Saskatoon is 481.5m above sea level.

#### Prevention & Treatment of High-altitude Sickness

#### Prevention

Gradual ascent, allowing time for acclimatization. Rule of thumb: at higher than 3000m, each night should average not more than 300m above the previous, with a rest day every 2-3 days (or every 1000m).

#### Treatment

Avoid further ascent until symptoms resolve, to descend if there is no improvement or if symptoms worsen, and to descend immediately at the first signs of cerebral or pulmonary edema

#### AMS:

- Mild AMS: rest alone may be sufficient. Analgesics and antiemetics for symptom relief. Headaches responds to NSAIDS and steroids; inconsistent results with sumatriptan
- Moderate to Severe AMS: descent (even 400-500m may relieve symptoms), oxygen & acetazolamide and/or dexamethasone

HACE: Immediate descent, oxygen & dexamethasone

HAPE: Immediate descent, oxygen & nifedipine

Drug	Mechanism/	Comments/Contraindications/	Dose
	Effect	Side Effects/Drug Interactions	
Acetazolamide	<b>M:</b> $\uparrow$ ventilation during sleep & O <sub>2</sub>	Drug of choice for prophylaxis.	250mg po bid
(Diamox®)	saturation, with a $\downarrow$ in erythropoietin	CI: adrenal gland failure, angle-closure glaucoma, cirrhosis,	
	& hematocrit.	low Na <sup>+</sup> /K <sup>+</sup> /Cl <sup>-</sup> acidosis, hypersensitivity to	Start 12-24 hours before
		acetazolamide, severe hepatic or renal disease	ascent & continue for 48
	<b>E:</b> Normalize sleep-disordered	<b>SE:</b> tinnitus, metabolic acidosis, sulfonamide reaction,	hours or longer at high
	breathing; ↓ incidence & severity of	paresthesias	altitudes
	AMS.	<b>DI:</b> ASA, lithium, cyclosporine, amphetamines,	
		topiramate, phenytoin, certain cardiac glycosides &	
		hypertensive agents	
Dexamethasone	<b>M:</b> thought to ↓ intracranial pressure	Alternative for prophylaxis in travelers with sulfa allergy	4mg po q6 hours
		CI: hypersensitivity to dexamethasone, systemic fungal	
	<b>E:</b> ↓ symptoms of AMS	infection	Start 48 hours prior to
		SE: \tappetite, nausea, heartburn, nervousness, edema	altitude exposure
		<b>DI:</b> live vaccines, NSAIDs, potassium-depleting diuretics,	
		anticoagulants, estrogens, cyclosporine	
Nifedipine	M: reduces pulmonary artery	For the treatment of HAPE. May be used as prophylaxis if	Prophylaxis: nifedipine XL
(Adalat®)	pressure	history of HAPE (lack of evidence).	20mg po OD 2-3 days
		CI: hypersensitivity to nifedipine, immediate release in	before ascent
	<b>E:</b> ↓ risk of pulmonary edema	patients with CVD	Treatment:
		SE: headache, peripheral edema, dizziness	Nifedipine 10mg IR, then
		DI: digoxin, grapefruit, ranitidine	20-30mg XL OD-BID

Gingko biloba has also been studied due to its antioxidant effect; however there is not enough evidence to recommend using it at this time.

References:Micromedex 2006. Basnyat B and Murdoch D. High-altitude Illness. Lancet 2003; 361:1967-74. Valarde L et al. Consensus Statement on Chronic and Subacute High Altitude Diseases. High Altitude Medicine & Biology 2005; 6(2) 147-57. Spira AM. Preparing the Traveller. Lancet 2003; 361:1368-81. Levien T and Baker D. Travel Medicine. Pharmacist's Letter 1997; 13(7):130713

## Appendix XVIII: Cross-reactivity to Antibiotics Project

#### **CROSS-REACTIVITY TO ANTIBIOTICS**

Patients often report allergies to antibiotics, however the actual incidence of allergic reactions to these medications are much lower than perceived – for a few reasons. First, there are four different types of allergic reactions, and not all reaction types preclude the use of related drugs. Second, patients often mistake antibiotic side effects or intolerances as an allergic reaction. Therefore, a through investigation of the reaction is needed to ensure optimal use of medications.

## <u>Information for Allergic Reaction History</u>

- Age when the reaction occurred
  - o Penicillin-specific IgE decreases over time. After ten years, 70% will not have detectable levels.
- Description of the reaction
  - o symptoms, severity, duration
- Timing of the reaction
  - o after first dose, after the tenth dose
- Route of administration (oral, IV) and duration of therapy
  - o anaphylaxis is more common with parenteral administration
- Use of any other medications at the same time
- What occurred when antibiotic was stopped? Was treatment required?
- History of other antibiotics taken since and tolerability
  - o If patient is not sure what they have taken, check the Pharmaceutical Information Program (PIP).
- Does the patient wear a medical alert bracelet because of the allergy
- Has penicillin skin testing been performed (only indicates Type I reactions)

It is also important to note that patients with allergies are typically at higher risk for being allergic to other, even structurally unrelated drugs. Therefore, an allergic reaction may be due to this increase risk versus cross-reactivity between medications.

#### **CROSS-REACTIVITY BETWEEN BETA-LACTAMS**

Approximately 5-20% of the population will report a penicillin allergy. Of those, only 10-20% will have an actual IgE antibody mediated reaction to penicillins. Anaphylactic reactions to beta-lactams are very rare (penicillins: 0.01-0.05%, cephalosporins: 0.0001-0.1%).

Types of Allergic Reactions with Beta-Lactams

Reaction	Immunologic	Time to Onset	Clinical Syndrome
Type	Mechanism		·
I	IgE antibody mediated	<1 hour	Immediate: anaphylaxis, hypotension, laryngeal edema, angioedema, urticaria, bronchoconstriction, hyperperistalsis
		1-72 hours	Accelerated: laryngeal edema, angioedema, wheezing, urticaria
II	Cytotoxic reactions (IgG, IgM)	>72 hours	Hemolytic anemia, thrombocytopenia, neutropenia
III	Immune complex reactions (IgG, IgM)	>7 days, may occur after drug discontinued	Serum sickness, nephritis
IV	T cell mediated	>72 hours	Contact dermatitis*, exfoliative dermatitis, maculoapapular or morbilliform rash, Stevens-Johnsons syndrome

<sup>\*</sup>Contact dermatitis most common reaction (penicillin: 1-4%, amoxicillin/ampicillin: 5-10%, Epstein-Bar virus: 70-100%). Penicillins can be safely administered in patients with a history of contact dermatitis.

#### Penicillins and Cephalosporins

The true incidence of allergic cross-reactivity between penicillins and cephalosporins is <10%. In general, the rate is highest with the first-generation cephalosporins, and the risk decreases with each subsequent generation.

**Recommendations Based on Reaction Type** 

	Accommendations Bused on Redection Type		
Type of Reaction	Penicillins	Cephalosporins	
Allergy to Penicillin			
Type I	Avoid	Avoid until additional information is available. If unavoidable, administer under close supervision.	
Type II, III or IV	May rechallenge under supervision, unless severe reaction – then avoid.	Considered safe.	
Allergy to Cephalosporia	n		
All types	Recommend a penicillin skin test first.	Skin test to desired cephalosporin first.	

#### Carbapenems

Cross-reactivity between penicillin and the carbapenems (imipenem, meropenem, ertapenem) has occurred, with an estimated incidence of 9.5%. Until further information available, avoid using carbapenems in patients with allergies to penicillin or cephalosporins.

#### **CROSS-REACTIVITY OF SULFONAMIDE DRUGS**

Approximately 3% of the population has a sulfonamide antibiotic allergy. Reactions can occur when the medication is administered via oral, ophthalmic, topical or vaginal routes. Several drugs and additives contain sulfur, which can cause confusion when determining the safety of these agents in patients with a sulfonamide allergy.

#### **Classification of Sulfa Drugs**

Sulfonamide-like agents are divided into three categories based on chemical structure:

- 1) sulfonylarylamines (includes sulfonamide-type antibiotics)
- 2) non-sulfonylarylamines
- 3) sulfonamide-moiety

In general, cross-reactivity between these classes is very unlikely, but it is important to note that the non-sulfonylarylamines and sulfonamide-moiety drugs can cause their own allergic reactions.

Types of Allergic Reactions with Sulfonamides

Reaction	Immunologic	Time to Onset	Clinical Syndrome
Type	Mechanism		
Type I	IgE mediated	1-3 days	Common: maculopapular eruption, urticaria Serious: angioedema, hypotension, anaphylaxis († with repeated exposure)
Type II	Hypersensitivity	7-14 days	Common: fever, maculopapular rash – may progress to erythema multiforme & multiorgan toxicity Serious: anaphylaxis, Stevens-Johnson syndrome, toxic epidermal necrosis

#### Sulfa-Containing Agents that are Safe

The following agents contain sulfur, but are chemically unrelated to the sulfonamides. Thus, these agents may be safely administered to patients with sulfonamide-allergies without fear of cross-reactivity.

**Sulfa-Containing Agents** 

_ Swith College in Science	
Class of Agent	Examples
Sulfur-containing medications	amoxicillin, captopril, omeprazole, ranitidine,
	spironolactone, sulindac
Sulfates	zinc sulfate, morphine sulfate
Sulfites	sulfur dioxide, sodium sulfite, sodium bisulfite,
• used in drugs & foods as antioxidants	potassium bisulfite, sodium metabisulfite, and
• may cause dyspnea, wheeziness and chest	potassium metabisulfite
tightness in asthmatics (not related to	
sulfonamide allergies)	

Please refer to the attached *Sulfa Dugs and the Sulfa-allergic Patient* chart for a list of sulfonamide-containing agents and a summary of cross-reactivity information.

#### References:

- 1. Lesher BA. Allergic Cross-Reactivity Among Beta-lactam Antibiotics. Pharmacist's Letter 2005; 21(12): 211206.
- 2. Zvonar RK. Cross-Allergy Among the β-lactam Antibiotic Agents: A Review of the Risks. Canadian Journal of Hospital Pharmacists 2005; 58(2):90-6.
- 3. Boehringer SK. Cross-Reactivity of Sulfonamide Drugs. Pharmacist's Letter 2005; 21(11): 211113.
- 4. Sulfa Drugs and the Sulfa-allergic Patient. Pharmacist's Letter 2005; 21(11): 211113.

## Appendix XIX: Focus Group Questions for the Student Health Centre Staff

## **Opening Question:**

1. What is your position at the Student Health Centre? How many years have you worked at this centre?

#### **Transition Question:**

1. How did you feel about having a pharmacist join your multidisciplinary team?

## **Key Questions:**

#### <u>Interaction with a Pharmacist</u>

- 1. What type of effect did having a pharmacist on your team have?
- 2. Please describe any positive experiences you had with having a pharmacist as a member of your primary health care team.
  - a. What made these experiences positive?
- 3. Please describe any negative experiences you had with having a pharmacist as a member of your primary health care team.
  - a. What made these experiences negative?
- 4. In what ways, if any, does having a pharmacist add value to your multidisciplinary team?
  - a. How did this effect the patients? Your practice?
- 5. In what ways, if any, does having a pharmacist detract value from your multidisciplinary team?
  - a. How did this effect the patients? Your practice?
- 6. Based on your experience, what suggestions for improvement would you give for having a pharmacist on your team?

#### Integration of a Pharmacist into a Primary Health care Team

- 1. The researchers used several approaches for integrating a pharmacist into your team (consulting established primary health care pharmacists, discussion with the staff to define the role prior to the pharmacist providing care, meeting at midpoint to discuss the study to-date, etc). Please comment on the approaches that were used.
- 2. What would you recommend for future integrations of pharmacists onto a primary health care teams?
  - a. To what extent should pharmacy services be accessible to the team? (i.e. should a pharmacist be available on a full-time or part-time basis). Please provide an explanation for your answer.
- 3. What approaches might be used by primary health care teams to involve pharmacists on their team?

## **Ending Question:** (moderator to give a quick summary)

1. Does this summary capture what was discussed during the focus group?

## Appendix XX: Transcript Verification Letter to the Student Health Centre Staff

Date, 2007

Name Student Health Centre University of Saskatchewan 91 Campus Drive Saskatoon SK S7N 5E8

Dear (name),

Thank you again for participating in the focus groups for my Masters of Science (Primary Care) project. I really appreciate your input regarding the integration of a pharmacist into an already established primary health care team. I have received the transcripts and will be analyzing the data shortly.

Enclosed you will find the transcript(s) from the focus group(s) that you participated in. I would like to give you the opportunity to add, alter or delete any of the information that you provided during the focus group discussions. Please note that the transcripts were transcribed verbatim – but we are interested in your approval of the content rather than grammar.

In order to maintain your confidentiality, names were removed from the transcripts, and each participant is represented by a number. The transcriber did her best to match the statements to the participants, however at times when she was uncertain, she placed a question mark beside the number. You are only responsible for verifying your own responses, and may have a different participant number for each focus group that you were involved with. In your package, you will find an envelope attached to the transcripts. To help facilitate this process, yet preserve your confidentiality, we had someone, who is not involved with the study, write down your participant number for each focus group you participated in and place it in a sealed envelope.

I would like to provide you 4 weeks to review the transcripts. Therefore, if I don't hear from you by April 19<sup>th</sup>, 2007, I will assume that you are content with the transcripts as is. If you would like to make any changes, please write the changes on the transcripts and return, anonymously, to the above address, by April 19<sup>th</sup>, 2007.

Sincerely,

Lynette Kolodziejak, BSP, MSc Candidate College of Pharmacy and Nutrition

## Appendix XXI: On-Line Focus Group Questions & Schedule for the Patients

You have been invited to participate in an on-line focus group to discuss your experience with a pharmacist at the Student Health Centre. Despite each of you having spent time with the pharmacist, please note that the interaction(s) were unique to your needs and would have varied in nature and depth.

#### Week #1:

This week's questions focus on the interpersonal aspects of your interaction with the Student Health Centre pharmacist.

## Transition question:

- **1.** Describe your experience, both positive and negative, with the pharmacist. Subsidiary questions:
  - a. What made these experiences positive? Negative?
  - b. Was the pharmacist able to meet your needs/expectations?
  - c. What was your comfort level like during your interaction with the pharmacist?
- **2.** What suggestions for improvement would you give for having a pharmacist at the Student Health Centre?

#### Week #2:

This week's questions focus on the pharmacist's work activities (what she did) and on the impact of having a pharmacist at the Student Health Centre. Key questions:

- 1. How did you feel about seeing an additional health care professional (i.e. the pharmacist) at the Student Heath Centre? Subsidiary questions:
  - a. How accessible was the pharmacist?
  - b. How convenient was it for you to see the pharmacist?
- 2. In your view, would the addition of a pharmacist to the Student Health Centre valuable? Please elaborate.
  - a. *If the participants feel the addition of a pharmacist would be valuable, then ask:* In addition to the services you received from the pharmacist, in what other ways do you see a Student Health Centre pharmacist helping you in the future?

## Week #3:

A summary of the discussion will be posted for the group.

#### Ending question:

1. Does this summary capture what was discussed during the focus group?

## Appendix XXII: Email Invitation to the Patients to Participate in the Study

I am the pharmacist at the Student Health Centre, who recently worked with you regarding your medication. The two months I spent at the Centre was part of a study that is looking at how a pharmacist can be incorporated into a primary health care centre. Part of the study is evaluating the services I provided during the two months. As a patient, you can offer valuable information on how you felt about having a pharmacist working at the Student Health Centre.

I am inviting you to participate in an on-line focus group. The focus group will allow you, and other patients, to discuss your experiences with seeing a pharmacist in a health centre. Your input will help me create recommendations for other pharmacists who are interested in working in similar health centres.

The on-line focus group will run for three weeks during the month of January, 2007. New discussion questions will be posted every week during the three week period. Participants will be asked to log onto the website to read responses and post replies at least once a week. The on-line focus group will not be live, and is set up similar to a discussion board. Therefore, you will be able to log onto the website whenever is convenient for you. The total time required to participate is estimated at 2-3 hours over the three weeks. An activity log will be kept electronically to assess how often participants log on and the time spent during each visit. If you agree to participate, but change your mind later on, you can end your involvement with the study at any time without any penalty.

If you are interested in learning more about this study, please contact me and more details will be provided. The project received ethics approval from the Behavioural Research Ethics Committee of the University of Saskatchewan on (<u>date</u>).

Thank you for your consideration,

Lynette Kolodziejak, BSP College of Pharmacy & Nutrition University of Saskatchewan Office phone number: 306-966-6346

Email: Lynette.Kolodziejak@mail.usask.ca

## Appendix XXIII: Email Invitation to Students for the On-Line Survey

We understand that not everyone was able to participate in our on-line focus group evaluating the addition of a pharmacist to the Student Health Centre. However, we would still like to give you the opportunity to provide us with your feedback. If you are interested, we have developed an on-line survey consisting of eleven questions and which should take approximately 10-15 minutes to complete.

If you are willing to assist us with our research, please click on the below link (or paste the link into your internet address bar):

https://survey.usask.ca/survey.php?sid=4204

To ensure **confidentiality**, every participant will be assigned the same username and password. When you reach the survey homepage, enter the following:

Username: SHC Password: student

The website includes instructions to complete the survey.

We thank you in advance for taking time out of your busy schedules to fill out our survey.

Lynette

## Appendix XXIV: On-Line Survey Questions for the Patients

Thank you for participating in our survey to evaluate the impact of having a clinical pharmacist at the Student Health Centre. A clinical pharmacist helps to improve patient care by educating patients, optimizing medication use and monitoring goals of therapy. Please take 5-10 minutes to complete this short survey based on your interaction with the pharmacist. Your input will be valuable in assessing the role of a pharmacist in a medical clinic, like the Student Health Centre. Thank you in advance for your time.

	graphic Information Age:
	Gender: ☐ Male ☐ Female
٥.	College and year of study:
Evner	ience with the Pharmacist
	How would you rate your experience with the pharmacist
ъ.	Positive
	a rositive a regative
	a) What made your experience with the pharmacist positive or negative?
5	Did you feel that the pharmacist was able to meet your needs/expectations?
٥.	Yes  No
	<b>1</b> 163
	a) Describe how the pharmacist was able/unable to meet your needs/expectations?
6	How did you feel about meeting with an additional health care professional (i.e. the
0.	pharmacist) at the Student Health Centre? Please consider accessibility and
	convenience.
	convenience.
7	In addition to the services you received from the pharmacist, what other ways would
7.	you like to see a Student Health Centre pharmacist helping patients in the future?
	you like to see a student Health Centre pharmacist helping patients in the future:
8	What suggestions for improvement would you give for having a pharmacist at the
0.	Student Health Centre?
	otacht Heath Centre:
9	In your opinion, would the addition of a pharmacist to the Student Health Centre be
	valuable?
	☐ Yes ☐ No
	_ <del></del>
	a) Please elaborate why/why not a pharmacist is valuable at the Student Health
	Centre.

Thank you again for your participation. We really appreciate your feedback.

## Appendix XXV: On-Line Survey Results

#### PATIENT ON-LINE SURVEY RESULTS

**Survey Time Stats** 

Average Completion Time: 8min 57sec (Min: 8min 57sec, Max: 8min 57sec)

## **Demographic Information**

1. Age: 25
Total answers: 1

2. Gender

Female 0.00% Male 100.00%

Total answers: 1

3. College and year of study: Arts & Science – 4th year

Total answers: 1

## **Experience with the Pharmacist**

4. How would you rate your experience with the pharmacist?

Positive 100.00% Negative 0.00% Total answers: 1

5. What made your experience with the pharmacist positive or negative?

She provided a very clear understanding of a prescribed drug; which I found very insightful. *Total answers: 1* 

6. Did you feel that the pharmacist was able to meet your needs/expectations?

Yes 100.00% No 0.00% Total answers: 1

**7.** Describe how the pharmacist was able/unable to meet your needs/expectations? Making me understand every detail about the prescribed drug; side effects, do's, don'ts etc, which I wouldn't have known without talking to her.

Total answers: 1

8. How did you feel about meeting with an additional health care professional (i.e. the pharmacist) at the Student Health Centre? Please consider accessibility and convenience. Very easy to talk to, very convenient.

Total answers: 1

9. In addition to the services you received from the pharmacist, what other ways would you like to see a Student Health Centre pharmacist helping patients in the future?

Total answers: 0

## 10. What suggestions for improvement would you give for having a pharmacist at the Student Health Centre?

Total answers: 0

## 11. In your opinion, would the addition of a pharmacist to the Student Health Centre be valuable?

Yes 100.00% No 0.00% Total answers: 1

## 12. Please elaborate why/why not a pharmacist is valuable at the Student Health Centre.

There are some details of particular prescribed drugs which a doctor might not have time or enough specific knowledge of the drugs, to advice specific patients on. Pharmacists come in very helpful with that.

Total answers: 1