AN INVESTIGATION INTO DRUG FORMULARY PRIORITY-SETTING WITHIN REGIONAL HEALTH AUTHORITIES IN BRITISH COLUMBIA

by

KRISTY ANNE ARMSTRONG

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ABSTRACT

Growing pharmaceutical demands in communities and institutions challenge healthcare organizations to provide high quality drug therapy within a sustainable budget. Pharmacy and therapeutics (P&T) committees are typically charged with setting priorities through compiling lists of drugs for funding, yet how this transpires within regional health authorities is unclear.

This study examined the practices of two regional health authority P&T committees in British Columbia in order to construct a conceptual model of drug formulary priority-setting which situates the influence of scientific evidence amongst other decision-making factors.

A grounded theory approach was employed. Data sources spanned committee documents, meeting observations (n=4), and semi-structured interviews with committee members (n=15). Standard grounded theory methods for data analysis were employed, including coding using the constant comparative technique and composing analytic memos.

Regional P&T committees engaged in two activities related to drug formulary priority-setting: developing auto-substitution policies and reviewing drug addition requests. The emergent conceptual model encompassed four processes in which committees engaged for the purposes of reaching formulary decisions: i) Negotiating the margins of therapeutic advantage; ii) Seeking value for the resources allocated; iii) Interfacing between community and institutional settings; and iv) Situating decisions within an organizational context.

This model was set against a background of contextual themes including the ways in which committee members balanced their P&T and patient care responsibilities, intra-committee dynamics between pharmacists and other clinical representatives, the defensive stance taken to restrict pharmaceutical industry involvement, and the ways in which decisions made by other stakeholders and decision-making bodies were incorporated into priority-setting.

Study findings raise policy implications for how to assist institutions with systematically integrating real-world considerations into drug formulary priority-setting and improving the
fairness of agenda-setting practices. Methodological and substantive ideas for future research are also advanced.
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1.0 INTRODUCTION

1.1 Background

Drugs are a commonly used modality for treating health maladies, either alone or in conjunction with other treatment regimes. They are typically classified into two broad categories, prescribed and non-prescribed, which may have varying definitions depending upon the legislation instituted in a particular country. In Canada, prescription drugs are defined as those substances considered drugs under the federal *Food and Drugs Act* and which are sold for use by humans pending a prescription provided by a healthcare professional. Conversely, non-prescription drugs comprise over-the-counter drugs and personal health supplies(1) and do not require a prescription.

Drug policy-making is a heterogeneous term that encompasses a spectrum of policy-making activities targeting different processes. Some drug policy-making targets those government processes by which pharmaceutical companies must abide in order to obtain market approval for the drugs they wish to sell. Once market approval is granted, other drug policy-making activities involve groups making coverage decisions about issues such as who is considered a beneficiary, what drugs should be subsidized for beneficiaries, and to what degree. These latter activities are performed by both public and private drug benefit plans.

In Canada, funding responsibility for drug use by citizens is complex because it depends upon whether drugs are used in a community or institutional setting, and whether they are prescribed or non-prescribed. There are, consequently, many payers for drugs(2, 3). In the community setting in the province of British Columbia, prescribed drug therapy can be subsidized to varying extents by: i) one of seven plans offered by BC Pharmacare, which is the provincial public drug benefit program; and/or ii) private drug benefit programs that are typically sponsored by employers(3, 4). Non-prescribed drug therapy in the community setting is typically paid for out-of-pocket by consumers(1). In contrast, medically necessary drug...
therapy for insured patients being treated in a British Columbia hospital is paid for out of the
drug budget of the regional health authority in which the hospital is located. Public payment for
medically necessary services provided to insured patients being treated in a hospital is mandated
by the federal Canada Health Act(5, 6). Yet what drugs are defined as “medically necessary”
can be subject to interpretation.

A trend of total drug expenditure growth (prescribed and non-prescribed) in the
community setting has been observed in recent years in Canada. Annual growth in expenditure
on prescribed drugs in the community has been most dramatic, however, rising from $2.6 billion
in 1985 to $16.5 billion in 2003(1). Consequently, the realm of drug policy-making in the
community setting pertaining to prescribed drugs has attracted considerable scrutiny. Morgan
and colleagues(7) have attributed 80% of the increase in prescription drug expenditure (from
both public and private financing sources) seen between 1996 and 2003 to the use of ‘me too’
drugs: new, patented drug products not offering substantial benefits above less expensive
counterparts. Other authors have focused on mechanisms of price control for prescription drugs
available to federal and provincial governments, such as the outcomes-based approaches
promoted by the federal Common Drug Review and British Columbia’s Reference Drug
Program(2, 3, 8-10).

Drug spending within institutions, such as hospitals, is also considerable and has been
rising in recent years. In 2003, total drug expenditures for all Canadian hospitals reached over
$1.5 billion; British Columbia’s share of this total was $191.6 million(1). From 2001 to 2003,
drug expenditure in hospitals per capita in the province rose from $67.82 to $76.24 (12.4%)(1).

Various mechanisms are available for controlling pharmaceutical prices and/or
expenditure. One such mechanism is a formulary. A formulary constitutes a continually revised
list of drugs (and sometimes also nutritional supplements and blood products) for which a
particular payer reimburses its beneficiaries(2, 11, 12). When the formulary is restricted,
additions typically require that the products under consideration demonstrate some advantage (therapeutic or cost savings) over existing formulary agents(12).

In Canada, the multiplicity of payers for drugs translates into the potential for formularies at many different levels: provincial drug benefit plans; regional health authorities; hospitals; and private drug benefit plans. In British Columbia, the BC Pharmacare formulary is determined by a provincial committee. This committee has at its disposal the recommendations made by the Canadian Expert Drug Advisory Committee (CEDAC), which is an independent national body of health professionals(10), as well as the expert knowledge of the Therapeutics Initiative, which is a drug review collaborative affiliated with the University of British Columbia(13).

Within hospitals, responsibility for making decisions about the standard of drug therapy for inpatients has long rested with pharmacy and therapeutics (P&T) committees(3). The formation of regional P&T committees to make formulary decisions for clusters of healthcare facilities has also been encouraged in British Columbia following the devolution of responsibility for healthcare service planning and delivery from the provincial Ministry of Health to regional health authorities(14). Little is known, however, about the processes that occur when these P&T committees make decisions about what to include on a regional formulary.

1.2 Study Purpose

The purpose of this study was to develop a conceptual model of the processes used by regional P&T committees to set priorities for regional health authority drug formularies; this model would advance understanding of the political and social contexts against which these processes occur, including those factors that affect the use of scientific evidence. Theory development allows for higher-level realization through integrating previously isolated or tenuously linked incidents, and facilitating the anticipation of future consequences(15).
In this study, the research objectives were to:

1. Describe how decision-makers affiliated with two regional P&T committees set drug priorities for their regional health authority’s formulary.
2. Identify what factors influence the use of scientific evidence by decision-makers during regional drug formulary priority-setting.

This study drew primarily on a set of qualitative data collection techniques and analytic principles associated with a grounded theory approach(15-17). Data collection involved gathering committee documents, observing committee meetings, and conducting semi-structured interviews with committee members. Data analysis involved coding using the constant comparative method and composing analytic memos.

The 3-I (Institutions; Interests; and Ideas) analytic framework, which is a tool used widely in political science to analyze policy change, was also employed. In particular, some of the framework’s concepts were incorporated to develop the initial interview guide, which are elaborated upon in the next chapter.

1.3 Study Setting

At the time the study was conducted, there were five regional health authorities in British Columbia (Vancouver Coastal; Fraser; Interior; Vancouver Island; and Northern Health Authorities). These regional health authorities, along with the Provincial Health Services Authority, were formed in December 2001 as part of a provincial plan to devolve some health services planning and delivery to local regions(18).

This study was conducted with a sample of decision-makers belonging to regional P&T committees in Fraser Health Authority (FHA) and Interior Health Authority (IHA). Both regions encompassed non-teaching healthcare facilities. Fraser Health Authority serves approximately 1.46 million people, or about one-third of British Columbia’s total population, and encompasses communities ranging from small and rural to large, rapidly growing suburban centres(19). The
regional health authority’s annual operating budget for 2005/06 was approximately $1.8 billion(20). Interior Health Authority serves approximately 700,000 people over a large geographical area in the southern interior of British Columbia. At the time of study, it had an annual operating budget of approximately $1.2 billion(18, 21).

1.4 Thesis Outline

The remainder of this thesis is organized into five chapters. The second chapter examines the published research about priority-setting in healthcare, drug formulary priority-setting specifically, and the 3-I analytic framework, in order to construct a rationale for the current study. The Methods chapter outlines the reasons for adopting a grounded theory approach and selecting the study setting, as well as the sampling, data collection and analysis procedures that were used. In the Results chapter, study findings are presented; these include a descriptive piece about the regional P&T committees studied, followed by a conceptual model comprising the key processes in which committees engaged in order to make drug formulary decisions. The conceptual model was contextualized against themes that have been denoted to reflect an "interpretive landscape." In the Discussion, study findings are situated amongst existing published literature, strengths and limitations of the study design are identified, and implications for healthcare policy and future research endeavours are presented.
2.0 REVIEW OF THE LITERATURE

2.1 Overview of the Chapter

A formulary is a continually revised list of therapeutic agents (primarily drugs, but sometimes also nutritional supplements and blood products) for which a particular payer reimburses its beneficiaries(2, 11, 12). For example, some regional health authorities in British Columbia have a regional formulary that lists the drugs that are primarily used for treating inpatients inside the health authority’s public healthcare facilities. Formularies can be positive, which list drugs that are reimbursed, or negative, which list drugs that are generally not reimbursed(22). Positive formularies can be open, whereby they include almost all drugs granted market approval, or more restrictive(23). A P&T committee is typically assigned the responsibility for making such policy decisions(6, 24).

In this chapter, the existing research that is most relevant to the processes of drug formulary priority-setting is reviewed in order to identify the rationale for the current study. The review is organized into four distinct sections. The chapter begins with an outline of the fundamental principles behind priority-setting in healthcare, as well as broad lessons that have been learned from prior research conducted about healthcare priority-setting and evidence-based health policy. Second, the focus will narrow to examine the healthcare priority-setting literature pertaining specifically to drug formularies in order to identify gaps in understanding. The literature related to the 3-I analytic framework, which was used to inform development of the initial interview guide, will then be highlighted. Finally, the chapter will conclude with a summary describing the niche that the current study fills in the relevant literature.

2.2 Policy-Making and Priority-Setting in Healthcare

Resource allocation, or priority-setting, in healthcare is a subtype of health policy-making(25). The basic premise underlying the need for priority-setting in healthcare is that demand for healthcare services outweighs the amount of resources at the disposal of decision-
Decision-makers can constitute healthcare practitioners and organizations, as well as governments. In recent years, greater importance has been attached to setting healthcare priorities using an explicit process that is informed by scientific evidence. The impetus for this trend can be attributed to increasing recognition of the concept of scarcity(27, 31) and, in the public sector, growing pressure for programs to demonstrate transparency, accountability and efficiency(19, 32-35).

This section reviews the literature about priority-setting in healthcare at the levels of organizations and governments in order to highlight what is known about how the process generally occurs in practice and what decision-making factors have manifested as important. Lessons learned from some of the research that has been conducted about healthcare policy-making more broadly are also integrated.

2.2.1 Decision-Making Considerations

Empirical studies of how priority-setting and policy-making in healthcare organizations manifests, using participant observation and interview data collection techniques, suggest that policy-makers tend to have broader views than researchers about what constitutes acceptable evidence for decision-making(36, 37). This has been characterized by some as a “mixed economy” of evidence(38). These factors include: alignment with the organization’s strategic direction and existing external directives (government mandates; clinical guidelines); academic commitments; community need; clinical impact (for example, efficacy and safety); existing partnerships with other organizations; physician buy-in; feasibility of implementation; historical allocation patterns; and values of efficiency, equity, justice, democracy, the health of individuals versus communities, and quality of life(25, 27-29, 36, 39-45). Establishing a fair process has also been understood by decision-makers to be important; this could be operationally achieved by making processes transparent and consensus-driven, as well as consultating with relevant stakeholders(30, 40).
The particular set of factors that manifest in relation to healthcare priority-setting depends upon the substantive area and organizational level (i.e. national; provincial; health region; hospital) at which the process occurs. For example, some criteria that guide priority-setting about infectious disease control (staff safety, screening capability, fear of the unknown)(46) are likely to be less relevant to priority-setting for stroke programming(47). Moreover, priority-setting at national or provincial levels in Canada may have electoral implications that are not as salient when it is performed within a regional health authority, where decision-makers are less directly linked to elected officials.

Current ideas about how healthcare priority-setting should be performed are embedded within frameworks such as ‘Program Budgeting and Marginal Analysis’(31, 48), ‘Accountability for Reasonableness’(49) as well as others(28). An emerging paradigm among these economic and ethical approaches recognizes that healthcare priority-setting is likely to integrate various factors, only one of which is scientific evidence as traditionally understood. Other factors to be formally accommodated within the process include local data about outcomes and finances, representation of a comprehensive set of stakeholders (for example, the public and local experts), and fit with organizational culture(48, 50, 51).

This view is echoed in the literature about healthcare policy-making in general, including decision-making models that have recently been advanced which reflect the theoretical underpinnings of research utilisation(19, 25, 35, 36, 38, 43, 52, 53). For example, incremental or interactive models acknowledge that “research is one of several knowledge sources [also own experiences, the press, politicians, colleagues and practitioners] on which policy-makers draw in an iterative process”(38). According to a context-based, evidence-based decision-making conceptual framework(34), a practical-operational orientation to what constitutes evidence defines evidence with respect to a specific decision-making context. That is, the internal decision-making context (for example, the purpose of decision-making, role of participants, and
process) and external decision-making context (for example, disease-specific, extra-jurisdictional, and political factors) influence what constitutes evidence and how evidence is introduced, interpreted and applied. Researchers note that scientific evidence cannot, for example, unequivocally resolve difficult trade-offs between the benefits provided by a particular technology or health service and the acceptability of associated risks – this depends upon stakeholder interests and values(35, 53).

In conjunction with approaches to healthcare priority-setting, these models of policy decision-making reflect a shift in the way that the role of scientific evidence is conceptualized; from decisions being literature-based to literature-informed.

2.2.1.1 The Role of Scientific Evidence

Several roles for scientific evidence – defined here as research published in the scientific literature – have been identified. For example, a direct role may be to provide empirical evidence which suggests a solution to an existing problem(54); this role is observed more frequently in the context of practice policies (i.e. practitioner decisions about individual patients), rather than service or governance policies(25). In contrast, assisting policy-makers with re-conceptualizing a problem may represent a more indirect mechanism of influence(25, 38, 54). Scientific evidence has also been described to have a “fig leaf” capacity, whereby decision-makers use research to reinforce decisions made for other reasons after-the-fact(45), and to independently confirm what they already know(38). Elliott and Popay(38) note that decision-makers themselves operate with models – either explicitly or implicitly - of how research should be utilized.

2.2.1.1.1 Mediating Factors

The degree to which scientific evidence influences policy-making in healthcare is dependent upon various factors, several of which are highlighted in this sub-section. First, there may be a less than optimal fit between the process of generating research evidence and the
evidence needs of policy-makers(36). Policy-makers are constrained by short timelines and often have difficulty negotiating around the complexity and ambiguity that is associated with the majority of research(25, 36, 45). A common complaint reported by policy decision-makers is the abundance of "policy free evidence", which is research that fails to address a relevant policy problem(36, 45) as well as a lack of evidence syntheses(55). Moreover, there are practical limitations to randomized controlled trial and cost-effectiveness data, which have been described in detail elsewhere(35).

Second, the way in which scientific evidence is introduced into the policy-making process can affect whether and how it is incorporated into decisions. The likelihood of its uptake is increased when the research is presented as a good story, by a knowledgeable source, and is timed to coincide with a window of opportunity for change(25, 38, 45).

Third, organizational characteristics also emerge as salient not only to the degree to which scientific evidence can be incorporated into policy decisions, but also to the ways in which the role of scientific evidence can be studied. In practical terms, the capacity of an organization to integrate research may be reduced when there is a substantial turnover of staff and demanding workloads permit insufficient time for engaging in critical appraisal of research(25, 38). In theoretical terms, an organizational culture that is preoccupied with upholding a strictly evidence-based approach can make it challenging to situate the role of scientific evidence in the context of other non-scientific considerations. For example, Norheim(52), notes that reasons for limiting the provision of health services, other than lack of clinical evidence, can rarely be found within participant narratives and official documentation even when it is apparent that cost containment was an important consideration. This may be attributed, in part, to a perceived societal disapproval of healthcare decisions being based primarily on cost(53).

This section about factors that influence healthcare priority setting has provided insight into current knowledge with respect to: i) the range of decision-making factors that may be
considered during healthcare policy-making, specifically priority-setting activities; ii) potential roles for scientific evidence within these processes; and iii) mediating factors that may affect the use of scientific evidence by policy-makers. This overview provides a backdrop against which research findings from the particular priority-setting domain being investigated in the present study (i.e. drug formularies) can be situated. It has also highlighted the need to deconstruct limit-setting rationales appealing to evidence-based medicine, by conducting in situ observations, in order to better capture the range of factors that may influence decisions.

2.3 Drug Formulary Priority-Setting

In this section, a critical review of the literature pertaining to the process of setting drug priorities for a formulary is presented. Research about drug formulary priority-setting that spans across continents (i.e. North America, Europe and Australia), classes of healthcare organizations (i.e. public drug benefit plans, managed care organizations and public hospitals), and methodology (i.e. quantitative surveys and qualitative designs) will be drawn upon. The review is organized into three sections: i) P&T committees; ii) Decision-making considerations; and iii) Theoretical frameworks.

2.3.1 P&T Committees

As previously stated, a pharmacy and therapeutics (P&T) committee makes decisions about which specific drugs should possess formulary status (i.e. for which a particular payer should or should not reimburse its beneficiaries)(2, 11, 12). These committees can manifest across a variety of organizational levels: individual healthcare facilities, regional health authorities, provincial public drug benefit plans, private drug benefit plans, and health maintenance organizations.

2.3.1.1 Membership

Descriptions of the member composition of a multitude of P&T committees have been generated(12, 56-61). Committee membership in the contexts of hospitals and drug benefit plans
typically reflects various healthcare disciplines (i.e. medical specialists, pharmacists, pharmacologists, nurses). Of these members, medical representatives substantially outnumber all other types of representatives(58, 60). Additional types of representatives may occasionally be included: finance officers(57), government employees(60), ethicists, patients, and members of the public(23, 59). Experts in public health and epidemiology are rarely included as members of P&T committees(56), however, they may be consulted on occasion(60, 62).

Physicians often chair P&T committees but pharmacy directors typically possess management responsibility for the organization’s drug budget(23). Moreover, pharmacists are usually charged with collating and presenting formulary review information to the rest of the P&T committee(63).

2.3.1.2 Authority

P&T committees are often confined to an advisory role, whereby recommendations must be subsequently approved by a higher decision-making body such as a hospital Medical Advisory Council or Ministry of Health(58, 60).

2.3.1.3 Formulary Request Procedures

The process of reviewing requests for changes to a formulary typically involves several stages. First, submissions for formulary changes are made in writing by applicants. The jurisdiction of the P&T committee (for example, affecting inpatients of a particular hospital versus all citizens in a particular province) affects who applies for changes to the formulary. For example, applicants to hospital formularies are typically clinicians working within the hospital(57, 58). Applicants to a provincial drug benefit formulary may also constitute pharmaceutical manufacturers(60).

Second, submissions and the relevant scientific literature are reviewed prior to the meeting by one or several individuals who are typically pharmacists(64). The reviews that are created are then circulated to the remaining P&T committee members prior to meeting for their
consideration. Sometimes subcommittees comprised of specialty experts are required at this stage to evaluate complicated, high-niche drugs (for example, cardiac drug therapies)(62).

Third, the P&T committee accepts (with or without restrictions), rejects or defers making a decision about the request for formulary change at a committee meeting(57, 58, 60). Within managed care organizations and some public drug benefit plans, addition decisions can be further categorized into levels of reimbursement that beneficiaries receive (for example, 50% versus 75% of the actual drug cost)(23, 65). Plans for post-decision monitoring of drug utilization may also be made at this stage(62). A quantitative survey of representatives from 138 public hospitals across France, the Netherlands, Germany and the United Kingdom about formulary processes found that decisions were almost always reached by consensus (89%); formal voting occurred only on rare occasions(8%)(56).

2.3.1.4 Reporting Decisions

Finally, in institutional settings, formulary decisions are typically disseminated to medical and pharmacy staff(62). In the case of committees making decisions for public drug benefit plans, decisions may also be posted on publicly-accessible websites with varying degrees of transparency(66). For example, the Common Drug Review (Canada) and Pharmaceutical Benefits Advisory Committee (Australia) display their final decisions as well as summaries of underlying rationales (in Canada, approximately 1-2 pages; in Australia, approximately 3 sentences). In New Zealand, the Pharmaceutical Management Agency posts the minutes of review meetings but does not post decision rationales. Lastly, the National Institute for Clinical Excellence (United Kingdom) posts detailed appraisal documents ranging from 15-25 pages which include information about the sources and evidence that were used, the names and affiliations of reviewers, and implications for the National Health Service. In all cases, however, commercial confidentiality is a barrier to the degree to which committees are able to be transparent.
2.3.2 Decision-Making Considerations

Quantitative survey and qualitative investigations conducted in relation to drug formulary priority-setting have contributed to the development of an extensive list of factors that influence such decisions. These factors can be related to ideas (clinical merit; access to treatment; cost-effectiveness; fairness; public defensibility), activities (political pressure from physicians both within and outside of P&T committees, as well as patients and pharmaceutical companies; negotiating volume pricing discounts with industry), organizational characteristics (historical precedent; unclear committee mandate; closed hospital budgets; facility teaching status); the quality of scientific evidence; decisions of others (other committees; clinical practice guidelines); and the identities of physician applicants(12, 22, 57-61, 66-74). The ways in which scientific evidence is employed within the drug formulary priority-setting process has also been studied, and is outlined below.

2.3.2.1 The Role of Scientific Evidence

What is defined by “scientific evidence” or “evidence” in the formulary priority-setting literature varies – these terms are inconsistently used to reflect data derived from various combinations of sources ranging from pharmaceutical industry studies, published peer-reviewed literature, to in-house organizational data(11, 57-60, 69, 70, 75). However, a distinction is typically made between clinical evidence (for example, safety, efficacy and effectiveness) and economic evidence (for example, cost-effectiveness analysis and cost-benefit analysis). Some have concluded that even though P&T committees consider scientific evidence as the primary data source for decisions, it is recognized to be only one source of information used within the drug formulary priority-setting process(57-61, 68-70). This conclusion mirrors findings from evidence-based healthcare policy and other substantive areas of priority-setting in healthcare.

Participant perspectives captured through both qualitative and quantitative study designs identify clinical evidence of benefit or the “clinical factor” as the principal driver of formulary
decisions(11, 56-60, 63, 75). Formal pharmacoeconomic evidence is used only rarely, although, informal concepts of cost-effectiveness, cost data, and cost-comparisons may be considered(58-60, 62, 70, 75). Other sources of information (i.e. patient demand, clinician excitement, decisions of other committees) are more likely to be drawn upon when available scientific evidence is perceived to be limited, particularly with respect to its ability to anticipate the potential for drug effectiveness under local conditions(57).

2.3.2.1.1 Mediating Factors

The conditions that affect the use of scientific evidence during formulary priority-setting have been discussed primarily in the context of barriers to the use of economic evidence, however many are applicable to clinical evidence as well. Conditions discussed here relate to the organizing framework proposed by Spath and colleagues(70) – that is, they pertain to the decision-making context or the data itself.

Several social and structural factors affecting the incorporation of scientific evidence into formulary priority-setting are related to the decision-making context: a) social factors include the influence of professional culture; b) structural factors include organizational capacity, committee mandate, budget arrangements and government policies. In reference to social factors, Spath and colleagues(70) found that physicians generally demonstrate greater reluctance towards using pharmacoeconomic evidence than pharmacists. They attributed this discrepancy to a distinct medical culture, whereby physicians seek to protect their prescribing autonomy. Other researchers have noted that this behaviour is affiliated with general practitioners but not medical specialists(56).

With regards to structural factors, participants report insufficient time for collecting and analyzing research as well as limited health economics training compared to training in clinical epidemiology for understanding methodology and evaluating study quality(56, 60, 70). Official committee mandates also occasionally send mixed messages about what types of scientific
Evidence should be explicitly incorporated into drug formulary priority-setting processes. For example, the mandate of one P&T committee making formulary decisions for a group of public hospitals was confined to assessing the clinical nature of drugs despite a perceived responsibility for cost management on the part of committee members(58). Closed hospital budgets were also identified as leaving little incentive to account for global costs incurred or resources saved(70). Finally, the type of drug considered (generic; 'me too'; or innovative) affected the relevance of economic evidence in the jurisdiction of Ontario, where the provincial government set the price of generic products substantially lower than brand name counterparts(60).

Related to the data itself, decision-makers have reported a relative lack of formal health economic data as a major barrier to its use(59, 62, 69); for example, a recent study of the degree to which drug benefit plans in the United States reflected value, as assessed by cost-utility analyses, found that such analyses were available for only 6% of drugs on the Florida Medicaid preferred list(62). Other barriers to the use of medico-economic, patient-reported outcomes, and cost-effectiveness studies that have been reported by formulary decision-makers pertain to limited transferability to the local clinical and operational environment, disorganized manufacturers’ submissions, use of inappropriate comparators and, in the case of economic analyses, concerns about the value judgments made(60, 66, 70). Finally, the study design, journal in which the study was published, and perceived independence of the study from the pharmaceutical industry can also affect the credibility of scientific evidence(57, 70).

The literature also alludes to relationships between clinical and economic evidence. For example, PausJenssen and colleagues(60) found that the strength of the clinical claim made by pharmaceutical manufacturers affected how the economic portion of a submission was viewed; if the clinical merit of a drug therapy was questionable, then discussion would not even proceed to consider cost evidence.
2.3.2.2 The Roles of “Other” Factors

Reporting of decision-making factors less closely linked with the evaluation of scientific evidence (for example, political pressure and the broader drug policy context) is typically characterized by insufficient depth and breadth. Yet akin to other substantive areas of priority-setting in healthcare, an emerging paradigm within drug formulary priority-setting views these factors not as contaminants to rational decision-making but rather legitimate considerations (66, 73).

Quantitative studies have made important contributions to the drug formulary priority-setting literature by quantifying the prevalence and directional influences of these types of decision-making factors. For example, Dranove and colleagues (23) surveyed the pharmacy directors of 41 health maintenance organizations (HMOs) in relation to the formulary status of seven high profile drug therapies in order to develop a statistical model to explain formulary decisions. The number of direct manufacturing competitors within a class of therapeutically equivalent drugs was statistically associated with formulary addition (OR = 1.214, p<0.01). This finding was interpreted to reflect the HMOs’ ability to negotiate better pricing discounts with pharmaceutical companies.

In British Columbia, Shalansky and colleagues (63) surveyed Directors of Pharmacy of 164 hospital P&T committees to determine the factors that influenced formulary acceptance of a set of cardiovascular medications. Participants reported that decisions at peer hospitals of comparable size influenced 73% of their formulary decisions. Similarly, Gill and colleagues (76) surveyed hospital Directors of Pharmacy (n=32) in British Columbia with the purpose of assessing the impact of the provincial drug benefit plan’s Reference Drug Program on the management of hospital formularies in relation to four drug categories (H-2 receptor antagonists; nitrates; NSAIDs; and antihypertensives). Participants in this study reported that the
most common reasons for formulary change within these categories was reference-based drug policies or community prescribing patterns.

Despite providing valuable information, quantitative study designs are less well equipped to explore the rationales behind other decision-making considerations (for example, reasons for aligning with community prescribing patterns), or the ways in which these considerations are incorporated into the multi-faceted drug formulary priority-setting rationales constructed by P&T committee members (for example, the ways in which high drug costs affect the desirability of aligning with community prescribing patterns).

It can be argued that qualitative studies, which are not bound by a priori hypotheses and strict study protocols, are better able to capture these nuances of drug formulary priority-setting(6). For example, Martin and colleagues'(59) used interviews (n=11), observations (n=12) and committee documents to study the rationales provided by a disease management organization, Cancer Care Ontario, for adding new cancer drugs to formulary. One of their primary findings is that previous conceptions of drug priority-setting, which involved making trade-offs between individual factors (for example, equity versus efficiency), are too simplistic. Most decisions involve clusters of factors associated with one drug therapy being juxtaposed against clusters of factors associated with one or several other drugs.

An ethnographic study using non-participant observation of P&T committees within two National Health Service hospitals in the United Kingdom provides a rich description of drug formulary priority-setting(57). Decisions of other P&T committees constitute one type of evidence that can shift committee members towards being for or against accepting a drug. Moreover, the conditions which affect the degree to which decisions of other P&T committees were influential also emerged from the data: a site's recognized expertise (for example, a teaching facility), and motivation to have consistency between hospital formularies throughout a given health authority.
Finally, Wirtz and colleagues (73) conducted interviews with key informants (n=20) in the United Kingdom in order to identify dimensions of drug reimbursement decision-making that reflect the social and political context and situate them within the broader process. One dimension was entitled “Personal Experience.” When the interpretation of clinical data for a particular drug therapy was controversial, for example, the personal treatment experiences of patients and clinicians could shift the nature of the drug assessment. Another dimension was entitled “Meaningful Decision-Making Ends.” Maintaining relationships with clinicians, for example, was identified as a desirable end of decision-making and was occasionally performed at the expense of achieving better cost containment.

Qualitative investigations have contributed, in particular, to understanding the role of informal concepts of cost (i.e. unit cost comparisons; impact analysis) within the process of drug formulary priority-setting. Observations and interview narratives from Canada and the United Kingdom demonstrate that P&T committee members do consider issues of cost when setting formulary priorities, despite committee mandates and decision-maker perspectives that occasionally suggest that competing budgetary pressures should be divorced from assessing patient pharmaceutical needs (58, 61, 69).

The concept of cost is intricately associated with budget management strategies used by P&T committees: i) prioritizing clinical benefit and then minimizing expenditures through cost containment strategies; or ii) funding only cost-effective products and doing so at an affordable level (4). Researchers note that although the assumption is made that the latter approach to resource allocation more effectively manages a fixed drug budget, committees often continue to list new products once initial resources are depleted. Moreover, although high cost does not typically determine whether or not a P&T committee decides to accept a new drug, it can lead to “greater scrutiny of other local factors that would predict their future expenditure as accurately as possible” (57).
Jenkins and Barber(57) attribute the phenomenon of inadequate knowledge about what non-scientific considerations are made by P&T committee members during drug formulary priority-setting, even within qualitative investigations, to a culture of scientific rationality:

“One of the reasons why the literature does not record the use of non-scientific forms of evidence is because reports of decisions by DTCs [drug and therapeutics committees] are written so as to account for the decision in terms of scientific rationality (such as evidence-based medicine), rather than the local rationality that was actually employed. This is not a duplicitous activity, but reflects how members of the medico-scientific community have been taught to account for their activities; i.e. an account that forms a linear rational account of scientific process. Further, this is how the members account for their activities themselves; it is their dominant ideology in which they interpret their world view.”

A similar explanation is offered by Wirtz and colleagues(68). They posit that “technical discourses” are used by authoritative bodies making treatment reimbursement decisions. Ethical and political factors operate within reimbursement decision-making as well but are part of a “hidden curriculum,” an analogy they draw from the domain of education (i.e. the norms, values and beliefs that are transmitted to students through mechanisms other than the formal curriculum).

These explanations regarding the ways in which a decision-making culture of scientific rationality may hinder understanding of non-scientific considerations suggest that observation techniques should be used to supplement interview participant perceptions and document review(45, 57, 59, 68, 70). Yet few studies have employed observational methods(77). As such, many other factors involved in drug formulary decision-making may be inadequately captured to date.

2.3.3 Theoretical Frameworks

Only two studies to date have developed theoretical frameworks based upon empirical data, which help to assist with integrating decision-making factors in order to provide a comprehensive explanation of drug formulary priority-setting processes(60, 75). One theoretical framework is developed based upon the experiences of a Drug Quality and Therapeutics
Committee (DQTC), which makes formulary recommendations for a provincial government-subsidized drug benefit plan, whereas the other framework draws upon the experiences of two disease management organizations. In the following sub-sections, an overview of each theoretical framework is provided as well as a brief critique of its strengths and limitations.

2.3.3.1 The Experiences of a Provincial Public Drug Benefit Plan

PausJenssen and colleagues (60) studied the DQTC of Ontario, which advises the provincial Ministry of Health about what drugs should be included on the formulary of the Ontario Drug Benefit Plan (covering Ontario residents who are over age 65, receiving welfare, or whose drug costs constitute a certain proportion of their income). Their purpose was to describe how the committee reached formulary recommendations, with a particular focus upon the influence of economic information. A case study approach to data collection and analysis was employed. Data sources included transcripts of committee meeting proceedings (n=9), and semi-structured interviews with committee members (n=7).

The final theoretical framework consists of seven inter-related factors which influence whether the DQTC agrees or disagrees with a pharmaceutical manufacturer’s submission (Clinical merit; Type of drug; Quality of data; Consistency; Unit cost and impact analysis; Economic analysis; and Value judgments). Inter-relationships between many of these factors are well defined. For example, drug type is a condition for determining the amount and type of clinical and economic evidence required; generic (in contrast to ‘me-too’ or innovative) drugs only need to demonstrate bioequivalence since the price of generics is government-regulated to fall 25-40% less than brand name versions. Yet descriptions about the inter-relationships between the values held by committee members and other decision-making factors are limited.

2.3.3.2 The Experiences of Disease Management Organizations

Singer and colleagues (75) studied two provincial disease management organizations (Cancer Care Ontario and the Cardiac Care Network of Ontario), which made recommendations
to the DQTC about funding intravenous cancer and cardiac drugs administered in public hospitals and non-intravenous cancer and cardiac drugs covered by the Ontario Drug Benefit Plan. The explicit goal of their study was to develop an empirical model of drug priority-setting focused on procedural fairness. A grounded theory approach to data collection and analysis was adopted. Data sources included written committee documents (mandate; minutes; correspondence), semi-structured interviews with committee members (n=21), and transcripts of committee meeting proceedings (n=unspecified).

The final theoretical framework consisted of six interrelated domains (Institutions; People; Factors; Reasons; Process; and Appeals), which were discussed against a conceptual backdrop composed of fairness and legitimacy. "Institutions" described committee origins and their mandates, particularly in relation to budget management. "People" referred to the degree to which a comprehensive range of stakeholder perspectives were included. "Factors" pertained to the individual factors that were considered by committees during priority-setting (for example, benefit, harm, cost, and equity). "Reasons" described the ways in which clusters of factors were used to construct decision rationales and that, occasionally, rationales involved juxtaposing clusters of factors for different drugs against each other. "Process" pertained to characteristics of the process that contributed to fairness such as transparency, acknowledging conflicts of interest, ensuring appropriate agenda-setting and building consensus. Finally, "Appeals" reflected mechanisms by which decisions could be appealed and how committees would respond (for example, revisiting decisions in light of new evidence or arguments).

The authors note that the novelty of the study "lies in integrating these elements on the basis of evidence from case studies and the perspectives of decision makers." Yet linkages between the six domains (Institutions; People; Factors; Reasons; Process; and Appeals) are not thoroughly explicated. For example, it is unclear why "Institutions" are considered to be mutually exclusive from what falls within the jurisdiction of "Factors" when it is plausible that
the feasibility of expanding a drug budget could affect the ways in which drug costs are
considered.

While beginning to clarify linkages between decision-making factors, and providing a
comprehensive view of drug formulary priority-setting processes, neither the disease
management or the provincial framework is characterized by sufficient abstraction to extend
beyond data organization to theory development. Moreover, findings derived from the
experiences of formulary committees making decisions for provincial public drug benefit plans
may not be easily transferred to the context of a regional health authority(75). Regional health
authorities possess different responsibilities, which may introduce additional considerations into
drug formulary priority-setting processes. For example, their formularies pertain to drugs
dispensed and used by inpatients within an institutional environment (i.e. hospital, mental
health, and residential care facilities) whereas drug benefit plans encompass drugs typically
dispensed by community pharmacies for use by patients in community settings. Therefore,
issues related to physically maintaining a drug inventory (for example, purchasing and
monitoring stock) and administering drugs (for example, dosing convenience for healthcare
staff) may not be captured by these models.

2.4 The 3-I Analytic Framework

Other academic disciplines, such as political science, can be drawn upon to inform
understanding of health policy. The 3-I analytic framework, which is widely used in the
academic discipline of political science as a tool for analyzing policy change(78), was employed
in the present study to inform the development of the initial interview guide. This section
summarizes its key tenets before reviewing its previous application in the context of healthcare
policy.
2.4.1 An Overview

The 3-I analytic framework is premised upon the notion that the factors that influence policy decisions can be grouped into four inter-related domains. These domains include: a) Institutions; b) Interests; c) Ideas; and d) External events. Factors from different domains are understood to typically, although not necessarily, converge in order for a policy change to occur.

The theoretical concepts included within each domain are summarized in Table 2.1.

Table 2.1: Summary of the 3-I analytic framework.

<table>
<thead>
<tr>
<th>Institutions</th>
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<tbody>
<tr>
<td>Formal political structures (79)</td>
<td>* Veto points along the legislative decision-making chain set out by constitutional provisions and formal rules constrain the influence of political actors</td>
</tr>
<tr>
<td>Past policies (80)</td>
<td>* Past policies exert feedback effects upon political actors by providing them with resources and/or incentives</td>
</tr>
<tr>
<td>Policy visibility and traceability (81)</td>
<td>* The ease with which voters notice a policy outcome and can link it to a particular governmental action determines the likelihood of a given policy generating a response from mass publics</td>
</tr>
<tr>
<td>Policy networks (82)</td>
<td>* The structural properties of the arrangements between state agencies and organizational interests can facilitate or inhibit the influence of societal interest groups</td>
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<table>
<thead>
<tr>
<th>Interests</th>
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| Societal interest groups (83) | * Influence depends upon three dimensions:  
   1) Type (material interest, identity, general public interest, advocacy coalition or social movement);  
   2) Group characteristics (membership, resources, organizational structure, outputs) and;  
   3) Policy capacity |
| Elected officials     | * Share collective interests in the form of a party platform and/or have individual interests as may be the case with achieving personal goals and seeking re-election |
| Policy entrepreneurs (e.g. researchers or civil servants) | * Ability to advance their ‘pet’ project depends upon the policy capacity they possess |

<table>
<thead>
<tr>
<th>Ideas</th>
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| Knowledge and values (84, 85) | * May serve as road maps to guide political actors under conditions of uncertainty; focal points to define cooperative solutions or facilitate the formation of coalitions; or become institutionalized  
   * Defining the problem can impart significant consequences for agenda setting and policy design (i.e. problem causation, nature of the problem, characteristics of problem population, nature of the proposed solution) |

<table>
<thead>
<tr>
<th>External events</th>
<th></th>
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<tbody>
<tr>
<td>Release of major reports, electoral changes, economic changes, technological advances, emergence of new diseases, media coverage of particular issue</td>
<td>* Open or close “windows of opportunity” to allow the streams of “Institutions”, “Interests” and “Ideas” to converge and culminate in a policy decision</td>
</tr>
</tbody>
</table>
2.4.2 Previous Application

Political science researchers have applied the 3-I analytic framework in order to analyze macro-level policy changes in a multitude of domains such as foreign economic policy, international law, environmental policy, civil service reform, and food safety policy(78).

It has also been applied in the context of health care policy. Researchers have used its tenets to guide their examination of macro-level health policies such as primary care reform(86), employment-related healthy public policy(87), privatization of rehabilitation services(88), changes to the structure of public health insurance and the privatization of health care services(89), as well as health policies related to governance, financial arrangements, delivery arrangements and program content(90). It has not yet, however, been applied in the context of pharmaceutical policy.

Through these varying applications, the 3-I analytic framework has contributed to policymakers’ understanding of the decision-making environments in which they operate. Particular insight has been gleaned with regards to how department philosophies, past policies, and institutional arrangements, such as jurisdictional authority of various departments and levels of government, may interact to affect the likelihood that a particular policy will be implemented. Used to inform the structure of the initial interview guide, it may assist with elucidating the non-scientific factors which P&T committees draw upon during drug formulary priority-setting.

2.5 Summary

Existing research has highlighted the need to set drug formulary priorities given a finite amount of resources. In order to do so, current paradigms demonstrate that factors other than scientific evidence are considered during drug formulary priority-setting, and are integral to making decisions that are applicable to local contexts, timely, and fair. Many of these studies have failed, however, to report non-scientific decision-making factors with adequate depth and breadth. In part, this limitation may be attributed to the tendency to collect data using interviews
and document review, without observing processes in situ, within a decision-making culture that is often characterized by scientific rationality. Moreover, theoretical frameworks of drug formulary priority-setting that have been generated using the experiences of disease management organizations and provincial public drug benefit plans do not thoroughly explicate inter-relationships between decision-making factors, and may not be very generalizable to the experiences of P&T committees operating within regional health authorities which must contend with issues directly related to maintaining drug inventories and administering drugs to inpatients.

The current study addresses both of these methodological and substantive gaps in the literature. The research objective is to construct a conceptual model of the processes used by regional P&T committees to set drug formulary priorities within two regional health authorities in British Columbia. As part of a grounded theory approach, participant observation techniques were employed in conjunction with semi-structured qualitative interviewing and document review in order to better capture the social and political contexts in which drug formulary priority-setting processes occur.
3.0 METHODS

3.1 Overview of the Chapter

This study examined the experiences and perspectives of P&T committees in two British Columbia regional health authorities when making formulary decisions. The study objectives were to propose a conceptual model which would attempt to explain drug formulary priority-setting processes, as well as identify those factors that influenced the use of scientific evidence during these processes. This chapter outlines the methodology that was used to achieve these study objectives and is organized into seven sections. The first section reviews the rationales for adopting a qualitative, specifically grounded theory, study design. The following sections describe the study setting, sampling procedures, and data collection and analysis techniques that were employed. The sixth section highlights the ethical approval processes that the study proposal underwent, as well as measures that were taken to promote informed consent and protect participant confidentiality. In the final section, key issues related to the rigor of this qualitative study are discussed.

3.2 Study Design

3.2.1 Adopting a Qualitative Approach

A qualitative approach was adopted for this study because it is particularly well-suited for investigating relatively under-developed substantive areas(91). Although a body of literature about formulary priority-setting exists, it is marked by a deficit of understanding about the ways in which such priorities are set by regional health authorities against social and political backdrops. This study was afforded the capacity to begin to fill such gaps in the literature by relying upon interpretive practices to examine the phenomenon in situ, which lies at the core of a qualitative study design(92). Rather than being bound by a set of a priori hypotheses and a strict research protocol, a qualitative approach enabled emerging ideas to be explored and, consequently, a more holistic representation of formulary priority-setting to be developed.
All researchers conduct research through a particular paradigmatic lens; that is, from a set of beliefs about the world and how it should be understood (92). This study utilized a constructivist paradigm, which is defined by several assumptions: the existence of multiple realities; researchers and participants co-construct data; and methodological procedures should be used in the natural world (i.e. *in situ*). The paradigmatic lens used in the present study is highlighted here because it informs the methods that were employed and the interpretations that were subsequently made.

### 3.2.1.1 Aligning with Grounded Theory Methods

A variety of data collection and analytic techniques are at the disposal of those researchers practicing qualitative inquiry. These can be tailored to suit the study questions that are posed, anticipated outcomes of the research, available resources, and constraints imposed by the research setting (91, 92). For this study, the rationale for pursuing a grounded theory approach was influenced by both methodological and pragmatic arguments.

Beginning with methodological-based arguments, the procedures of grounded theory are “designed to develop a well integrated set of concepts that provide a thorough theoretical explanation of social phenomena under study” (16). A grounded theory approach was, therefore, well aligned with the objectives of this study: to construct a holistic, yet detailed, theoretical understanding of the ways in which decision-making factors during formulary priority-setting interacted. Ensuring a close fit between the research question and methods was important for attaining methodological coherence, which enhances quality of data in qualitative research (93).

Consideration was given early on to aligning with ethnographic methods, which would produce a detailed cultural interpretation of formulary priority-setting from the perspectives of decision-makers (94). An ethnographic study, however, which typically requires direct participation in participants’ lives for several years, was determined to be infeasible (94, 95). First, the time frame associated with the funding period for the proposed study was only
approximately one year. Second, opportunities for immersion in the culture were limited since the regional P&T committees under study convened only three to four times annually. Third, the highly structured nature of these meetings (i.e. agenda-driven) created an environment that was not conducive to interjection from a researcher.

Grounded theory studies are typically characterized by the following set of data collection and analytic principles: sampling on a theoretical basis; collecting and analyzing data concurrently; coding data in stages (open, axial and selective) using the constant comparative method; and writing analytic memos(17). This study drew primarily upon grounded theory principles. However, it also utilized participant observation techniques from the field of ethnography and incorporated elements of the 3-I analytic framework during the development of the initial interview guide.

When grounded theory was first presented as a formal methodology by Glaser and Strauss(96), it was defined as “the discovery of theory from data”; although this tenet of grounded theory continues to be upheld, other tenets have evolved to become the subject of numerous interpretations. The role of preconceived ideas, including predefined conceptual frameworks and theory, has proven to be particularly contentious(97). Researchers in various substantive fields have promoted a purist approach, arguing that importing preconceptions violates the inductive emphasis of grounded theory(98, 99). Others argue, however, that it is important to acknowledge the role of preconceived theory and ideas in sensitizing the grounded theory researcher and that this is not necessarily inconsistent with the approach(100). Conceptual frameworks can support qualitative inquiry so long as the selected framework is abstract enough to guide the research without constraining it to particular variables(101, 102). Morse & Mitcham(101) describe the nature of these frameworks as one in which concepts may be loosely delineated but have vague internal attributes; this allows an inductive approach to theory generation to be maintained.
The present study required a methodological approach consistent with that of grounded theory that would facilitate an understanding of the perspectives of the people being studied, capture conditions and processes as they developed over time, allow theoretical relationships to emerge from the data in an inductive manner, and explore the very complex process of drug formulary priority-setting without oversimplifying. Yet it also sought to target those decision-making aspects that had proven problematic for previous investigations, which included exploring the influence of committee member values, institutional context and political interests (i.e. of committee members or external stakeholders); borrowing broad ideas from the 3-1 analytic framework was anticipated to assist in this endeavour. Given the lack of consensus on what room exists for preconceived ideas in grounded theory research, either approach was considered legitimate. The decision was made to accommodate preconceived ideas within the present study design, as Strauss and Corbin (100) permit, with full awareness that grounded theorists who reject the use of preconceived theory and ideas may criticize this decision.

Each of the data collection and analysis principles and techniques that were used in the present study are elaborated upon throughout later sections of the chapter.

3.3 Selecting a Setting

During May and June of 2005, requests for the contact information of key personnel involved with drug formulary priority-setting activities within each health authority in British Columbia (Provincial Health Services; Interior, Northern, Fraser, Vancouver Coastal, and Vancouver Island Health Authorities) were submitted electronically via the feed-back form available upon each health authority’s respective website. Once responses were received by e-mail, these personnel were then contacted to inquire about the structure of formulary priority-setting within their health authority. Two regional health authorities were centralizing formulary responsibilities, whereby a regional P&T committee would take over those responsibilities formerly possessed by hospital-based committees (Vancouver Island and Vancouver Coastal).
Three regional health authorities had established regional P&T committees (Fraser, Interior and Northern). In the PHSA, formulary decisions for specialized patient populations (for example, paediatric and cancer) throughout the province were made by disease-specific agencies (for example, the British Columbia Cancer Agency). P&T committees at the regional, rather than hospital, level were selected as the research setting given this observed shift towards centralization.

Regional P&T committees were approached for participation in this study on the basis of accessibility for conducting face-to-face interviews and observing committee meetings. Northern Health Authority was excluded due to more limited accessibility. Fraser and Interior Health Authorities were approached and expressed interest in participating in the study.

3.4 Sampling

Three main data collection techniques were employed during this study: i) gathering committee documents; ii) observing committee meetings; and iii) interviewing committee members. Drawing upon such different types of data were hypothesized to contribute to the richness of study findings in several ways(94), which will be elaborated upon within later sections. The three data collection techniques that were used are mentioned here for the purposes of briefly highlighting the rationales behind their selection, and the ways in which sampling was performed in relation to each of them.

In accordance with a qualitative approach, sampling was conducted purposively. The intent was to gain a deep understanding of information-rich cases rather than to generalize findings to broader populations as is the case when a quantitative approach to sampling is used(103). Sampling in grounded theory is typically performed in relation to concepts and incidents (i.e. properties, dimensions and variations) rather than specific groups of individuals per se(16).
3.4.1 Committee Documents

It was anticipated that written documents would assist with identifying the official mandate of the regional P&T committee (and sub-committees), the sequence of steps involved in requesting and reviewing drugs for addition to formulary, and what ideas related to formulary priority-setting had been explicitly institutionalized (for example, what types of information were formally incorporated into written formulary reviews).

An initial request for documents containing information about the regional P&T and subcommittee terms of reference, general formulary process, conflict of interest forms, and drug addition request forms was consequently made to the appropriate committee contact at the start of the study (in FHA, the Drug Use Evaluation Coordinator; in IHA, the Secretary). Agenda packages for upcoming regional P&T meetings, which contained background reading material, were also requested. A follow-up request was made near the end of the study period to ensure that the collection of documents was comprehensive (i.e. included documents produced or released in the interim). No additional documents were, however, identified.

3.4.2 Observations

Participant observation, which is rooted in ethnographic fieldwork, involves the researcher immersing himself/herself in a culture in order to learn about the beliefs, values, fears, expectations and behavior patterns of participants(94). Grounded theorists also recognize that observation is advantageous for capturing human decision-making behaviour and group dynamics in their natural contexts(104). For this study, supplementing interview and document data with meeting observations was expected to increase the likelihood of capturing nuances of formulary priority-setting that may go unrecognized or be edited out.

Drugs to be reviewed by the committees could expectantly vary on a number of dimensions (for example, the patient population for which the drug was indicated, price, risk profile). It was hypothesized that the dimensions of a particular drug therapy would influence
the way in which formulary priority-setting processes occurred and, subsequently, what decision outcomes manifested(60). In order to capture as much variation about drug formulary priority-setting as feasibly possible, it was planned that all formulary reviews conducted at regional P&T meetings in IHA and FHA held during the period of November 2005 until April 2006 would be sampled.

An executive summary of the study (FHA) or initial letter of contact (IHA), and consent form for observation was inserted into the agenda package for the first meeting observed in each health authority. These packages were distributed to committee members prior to the regional P&T meeting for their review. Written consent for observation was obtained before any observation of formulary review presentations.

3.4.3 Interviews

Interviews are important to qualitative inquiry because they provide a way for researchers to gain insight into the direct and personal knowledge of the target phenomenon that participants are often capable of sharing(103). Semi-structured qualitative interviews were employed to capture the perspectives of committee members about formulary priority-setting in their respective regional health authority and, in particular, how decision-making factors exerted influence(91).

The total number of interviews could not be specified in advance given that theoretical sampling would be performed, which involves seeking additional participants and/or re-contacting participants as data analysis proceeds in order to refine theory development(105). As Glaser and Strauss(96) explain, “the emerging theory points to the next steps – the sociologist does not know them until he is guided by emerging gaps in his theory and by research questions suggested by previous answers.” A sample of 15-30 interviews across both regional P&T committees was estimated in order to develop an encompassing conceptual model.
In accordance with theoretical sampling principles, it was also initially hypothesized that the professional discipline with which participants were aligned (physician; administrator; pharmacist) could shape their perspectives about how formulary priority-setting does and should occur. However, the total number of committee members was relatively small (approximately 40) and it was anticipated that some members would not participate. Consequently, the decision was made to contact as many potential interview participants as possible instead of only a subset who reflected an array of professional disciplines. Yet those whose inclusion would contribute to generating a theoretically diverse range of professional backgrounds were systematically pursued. For example, it became apparent early during the data collection period that physicians were particularly difficult to recruit for interviews. As a result, the follow-up e-mail that was sent to physician committee members in FHA who had not responded to the initial contact e-mail was tailored to emphasize the importance of capturing the views that physicians had about drug formulary priority-setting processes.

Initial contact with potential interviewees was performed differently in IHA than in FHA. This was due to the IHA Ethics Review Committee requiring amendments for granting ethical approval several months after interview recruitment began in FHA. All regional P&T committee members in FHA were e-mailed an initial letter of contact during November 2005. In IHA, however, only a subset of regional P&T committee members who provided permission to be contacted to the committee Secretary during February 2006 were e-mailed. Follow-up measures were performed the same way for both health regions. If a response was not received after two weeks, committee members were re-contacted by e-mail or telephone. The subset of committee members who chose to participate in interviews received, in advance, an electronic copy of the interview consent form and outline of the interview guide.

As analysis of the initial interviews began, other bases on which theoretical sampling could be beneficial were identified. For example, it became apparent that members of the
committee Executive (Chair; Secretary; Reviewers; Drug Use Evaluation leader) who were more highly involved in the process could possess ‘insider’ information and that this could affect their perspectives. The recruitment strategy was subsequently modified to emphasize to potential participants the importance of capturing the experiences of committee members who belonged to the Executive as well as those who did not. As a second example, committee members who abstained from decision-making about TNKase™ (a cardiac drug) in both IHA and FHA were sought. Abstentions were reported to be rare and, consequently, it was hypothesized that abstaining committee members might contribute a rich set of views about the challenges that members encounter and their subsequent reactions.

3.5 Data Collection

In the previous section, sampling in relation to the three main data collection techniques employed in this study was discussed. This section describes the particular techniques that were applied in order to observe committee meetings and conduct interviews with committee members. Field notes were written about both observations and interviews and are described in those two respective sections. Since the gathering of official committee documents did not involve a particular data collection technique beyond what has already been described within the section about sampling, it is not addressed further here.

3.5.1 Observations

What Fetterman(94) describes as nonparticipant observation, and Morse and Field(91) describe as participant observation of the complete observer type, was employed: the researcher passively observed participants, having limited social interaction with them. This approach was adopted after recognizing that the meeting context was not very conducive to participant-observer interaction. The only social interaction that occurred during observation sessions was informal chatting with committee members prior to meetings, during breaks, and after meetings. These discussions were used to elicit new information or test developing concepts, and also
build rapport with future interviewees. Formulary review presentations and discussions were audio-recorded.

Fieldnotes were written about the setting, non-verbal behaviours (for example, cellphones ringing and committee members exiting the meeting room), key phrases, as well as questions and ideas about future directions. These notes, which were synthesized and elaborated upon shortly thereafter, were included in the overall analysis.

3.5.2 Interviews

Interviews were conducted either face-to-face at the participant’s office (n=5) or by telephone (n=10). They were audio-recorded with the consent of participants; a written record of consent was obtained for face-to-face interviews whereas a verbal record was obtained for telephone interviews. Interviews ranged from 30-90 minutes in duration.

The initial interview guide was informed by existing literature about formulary priority-setting and the analysis of policy change using the 3-I analytic framework, which is widely applied within the academic discipline of political science. Elements of the 3-I framework were imported in this capacity since many factors that were identified to influence formulary priority-setting aligned neatly within three of the framework’s categories: Institutions; Interests; and Ideas. For example, the structure of hospital budgets, scope of committee mandates, and appeals to historical policy precedents could be classified as institution-related factors. Since these concepts were sufficiently abstract, the present study could utilize elements of the 3-I analytic framework without resorting to primarily deductive reasoning(102). Understanding how another academic discipline constructed similar kinds of variables enhanced the theoretical sensitivity of the researcher in the present study; that is, the interviewer/observer’s ability to shift analysis upward from identifying individual categories to developing an integrative social theory(15).

After reviewing the interview consent form with participants, participants were asked to provide a brief description of their role on the regional P&T committee and the related
experiences that accompanied them. Later questions solicited their perspectives about a range of formulary-related issues: the most important decision-making factors; the roles of cost, the health authority as an organization, personal interests and values; disagreements that arose; and barriers to using scientific evidence to inform decision-making. Throughout the interview, different types of probes were employed in order to encourage participants to elaborate upon their responses: silence; continuers (for example, "mm-hm"); encouragement (for example, "that's very interesting"); paraphrased responses (for example, "it sounds as though you're saying..."); defining key terms (for example, "what do you mean when you say 'bang for the buck'?"); and inquiring about management strategies (for example, "how does the committee typically deal with that situation?"). As a way of exiting the interview, participants were invited to contribute any additional study-related information that they thought could be helpful. A copy of the initial interview guide is included in Appendix A.

Following each interview, field notes were written detailing impressions of the interview setting, interactions with the participant, non-verbal behaviours, key themes, concerns, as well as operational ideas related to future theoretical sampling. These field notes were included in the overall analysis. They were also valuable for revising the initial interview guide.

The interview guide evolved considerably over the course of the study for the purposes of improving clarity, minimizing redundancy, and conducting member validation but primarily to refine emerging concepts. This is in line with grounded theory methods whereby the researcher focuses the range of interview topics covered during subsequent interviews to address gaps in their theoretical framework. Emerging concepts in this study could be derived from interview, observation and committee document data, as well as field notes. For example, it became apparent during preliminary analysis of the initial interview narratives that the desire to avoid disruptions to community-initiated drug therapy for patients who were admitted to hospital could contribute to rationales in favour of adding a drug to the regional formulary.
Probes were subsequently developed to explore under what conditions participants perceived this approach to be important, and what its consequences were. As another example, several committee members were observed during one of the FHA regional P&T meetings abstaining from a vote about a cardiac drug known as TNKase™. Subsequent interviews provided opportunities to probe participants about how typical an occurrence this was and what they felt would motivate committee members to abstain. Emerging concepts also included thematic discrepancies between interview narratives, observations, and committee documents.

Finally, prepared interview questions were used as a guide, rather than as a strict regimen, for conducting interviews. In some cases, not all of the prepared interview questions were posed due to participants' time constraints or if it was judged that their insights about a particular formulary-related issue were sufficiently rich to merit further exploration at the expense of foregoing other potential insights.

### 3.6 Data Analysis

Continuous interplay between data collection and analysis is one of the fundamental tenets of grounded theory approach; data collection informs subsequent analysis and data analysis guides subsequent collection(100, 105). Without this interplay, the rigor of the emerging theory can be jeopardized since gaps in the conceptual framework are not identified until after-the-fact(101). Analysis began after making the first observations at the regional P&T meeting in FHA during November 2005. Data analysis was performed on an ongoing basis throughout the data collection period, which ended in April 2006, and thereafter. The progress of the analysis was discussed with members of the research team on a regular basis.

#### 3.6.1 Preparing Transcripts

Audio-tapes of both interview and observation data were transcribed verbatim with in-text personal identifiers removed (i.e. names of people and healthcare facilities) in order to protect participant confidentiality. The audio-tapes of the first three regional P&T meetings that were
observed, as well as the first interview that was conducted were transcribed by the observer/interviewer. Audio-tapes of subsequent observations and interviews were transcribed by an independent transcriptionist. For each of these audio-tapes, transcripts in rough form were created so that the analysis could be advanced in the interim before receiving final polished transcripts from the transcriptionist. Electronic versions of completed transcripts were reviewed while listening to the corresponding audio-tapes to check for accuracy and ensure that personal identifiers were removed. These versions of the transcripts were then used for the remainder of the data analysis.

3.6.2 Coding

Coding is an analytic process in qualitative research whereby a researcher develops labels for the purpose of naming concepts that are contained within the data. This study aligned with the coding strategy advanced by Corbin & Strauss, which involves three types of coding described in detail below: i) open; ii) axial; and iii) selective(16, 17). The coding process was performed sequentially to some degree through open, axial and then selective coding; however, there was also interplay between the three types of coding given the iterative nature of qualitative analysis. Moreover, concepts were not all characterized by the same degree of theoretical development at a particular point in time. Regardless of the type of coding performed, the technique of constant comparison(17) was used: the properties of emerging concepts were compared with each other and established concepts in order to classify them.

These procedures were applied to interview narratives, observations, committee documents*, and field notes. Continuous interplay between the codes derived from each type of data occasionally highlighted discrepancies between theory and practice; for example, the FHA

* Documents were analyzed for themes and included in the overall analysis. They were also used to draft a preliminary understanding of the stages involved in regional formulary priority-setting before any interviews or observations had taken place. Whether excerpts or entire documents were coded depended upon how closely the content was related to formulary priority-setting. For example, sections of agenda packages pertaining to drug administration policies were not included as they were simply not relevant.
terms of reference document stated that a Formulary Review subcommittee managed drug addition requests yet interview narratives and observations noted that, in practice, this responsibility lay with only one individual (Drug Information Coordinator). Analyses of observations, committee documents, interviews and field notes were used to stimulate discussion about new ideas with future interview participants, and to enhance theoretical sensitivity during subsequent observations of regional P&T committee meetings.

Throughout the coding process, memos were written about the properties and dimensions of codes, hypotheses about inter-relationships between categories as well as between categories and sub-categories, and ideas about future data collection such as theoretical sampling or interview questions to pose. These memos fulfilled several purposes. Purposes included establishing an audit trail documenting the theoretical and operational decisions made by the research team,(91) moving away from raw data towards abstraction, and identifying concepts in need of refinement(17).

The ways in which open, axial and selective coding were employed are elaborated upon in the following sections.

3.6.2.1 Open Coding

Open coding reflects an initial process whereby researchers "open" data texts in order to reveal the thoughts, meanings, and ideas that are embedded within them(17). The primary purpose of this process is to systematically capture a comprehensive range of emerging concepts with the intent of later grouping them together into more abstract categories. Open coding was performed on observation and interview transcripts, as well as sections of committee documents and field notes.

Operationally, the process of open coding translated into moving line-by-line through data texts while affixing conceptual labels to individual words, phrases or entire paragraphs. These labels were recorded in the margins of the paper transcripts, field notes or committee
documents. At times, code names were the products of researcher abstractions of events, interactions, or ideas. At other times, "in vivo codes" were used, which by definition reflected key words found within the verbatim speech of committee members or the actual text of committee documents(96). A list of emergent codes was maintained and new data was continually compared against existing codes when appropriate in order to refine codes and prevent the list from becoming unnecessarily superfluous. The interview excerpt located in Figure 3.1 highlights some examples of open codes, which are bolded and bracketed in-text.

Figure 3.1: Example of open coding using an interview transcript.

**Interviewer:** I was wondering if you could talk a little bit more about the rationale as to why that decision was made to continue patients on it even though the committee decided not to add it.

**Respondent:** We're coming up against this a lot [frequency] lately. It's just continuity of care [continuity of care]. We'd like to for as much as possible, we really don't want to disrupt a course of therapy [avoiding disruptions]. So someone is stabilized on Lantus™ and it's working for them and they have the dose figured out [being stabilized] and they come in because they broke...they were in a car accident and they broke their arm [unrelated admission]...we don't really want to get into switching them to our insulin and potentially having to adjust the dose and re-titrate patients [avoiding disruptions] when they were stabilized on one thing [being stabilized]. So that's what we were saying, we would never pay for it up front...we don't want to start patients up front on it [declining unrestricted addition] because the cost is so high compared to the incremental benefits [marginal value] over other insulin.

3.6.2.2 Axial Coding

Axial coding is the process whereby a researcher begins relating "categories to subcategories along the lines of their properties and dimensions"(17). A conceptual tool that Strauss and Corbin(17) refer to as the "paradigm" was used in order to assist with sorting out the connections between codes. The basic components of the paradigm constitute the responses that individuals or groups make (actions/interactions), the set of circumstances in which these responses are taken (conditions), and the outcomes of such responses (consequences). Of all the codes that were generated during open coding, it was realized that some did not reflect free-
standing phenomena but rather the conditions for, or consequences of, other phenomena. Direct connections were occasionally apparent because of participants’ language cues (i.e. “since”, “because”) whereas indirect connections required more interpretive work. During axial coding, relational statements were formulated to hypothesize connections between codes. Examples of these statements are illustrated in Figure 3.2.

Figure 3.2: Examples of relational statements formulated during axial coding.

1. When drugs are used for chronic treatment, patients are stabilized on them in the community, there is the belief that switching causes harm, and patients have an unrelated admission, regional P&T committees are more likely to prioritize “continuity of care”.

2. “Continuity of care” is the action through which regional P&T committees go about “avoiding disruptions” to drug therapy as patients move into and out of healthcare facilities.

These statements formed the skeleton of the initial conceptual model of drug formulary priority-setting, which was depicted diagrammatically.

During axial coding, new data continued to be compared against both existing codes and hypothesized relationships in order to refine them; inconsistencies provided valuable opportunities in this regard. For example, examining the narratives of physician committee members who did not suspect a pharmacy bias to the drug formulary priority-setting process revealed insider/outsider status as an additional condition for understanding variation in the contextual theme labelled “Gatekeepers of the Drug Budget.” Codes also continued to be grouped together into more abstract categories. For example, during axial coding the processes labelled “Assessing the Scientific Evidence” and “Making a Niche for Clinical Experience” were identified as components of a broader process which involved trying to determine a drug’s therapeutic merit relative to existing formulary agents (i.e. “Negotiating the Margins of Therapeutic Advantage”).
3.6.2.3 Selective Coding

The process of selective coding involves a researcher integrating and refining categories for the purposes of developing a theoretical framework(17). During selective coding, relational elements of the conceptual model were applied to the raw interview, observation and document data in order to assess how well they fit. Attempts were also made to conceptualize alternative explanations to what had been constructed using the thoughts, ideas, meanings that were perceived to have emerged from the data. By engaging in these activities, inconsistencies in logic within written analytic memos and the diagrammatic conceptual model were identified and revised, and variant cases were accommodated. Finally, conceptual labels associated with the model were refined (for example, shifting away from colloquial code names such as “Bang for the Buck” and “The Cardiology Group Won’t Like This…”).

The results of this study about drug formulary priority-setting are presented as a substantive theory about the processes in which regional P&T committees, and their individual members, engage in order to set priorities for the regional formulary, and the ways in which their use of scientific evidence is affected. The diagrammatic presentation of the conceptual model summarizes these results. Findings are the result of balancing the need to highlight thematic patterns that were encountered repeatedly (i.e. across interview participants; observations; and/or committee documents), with the need to demonstrate the reality of data variation. What weaves throughout the Results chapter are the patterns and variations that the research team deemed most pertinent to meeting the study objectives.

3.7 Ethical Considerations

Ethical approval was obtained from the UBC Behavioural Research Ethics Board (October 2005), FHA (October 2005), and the IHA Ethics Review Board (January 2006). The FHA Office of Research accepted a copy of the UBC certificate of approval in lieu of conducting its own review. However, IHA required an additional ethics application to be submitted. The
variation in the way in which interview recruitment was carried out in IHA was a direct function of the additional requirements imposed by the IHA Ethics Review Board. These amendments to the study protocol were submitted to the UBC Behavioural Research Ethics Board and approved during February 2006. Copies of all certificates of ethical approval can be found in Appendices B-D.

Copies of the initial letters of contact as well as interview and participant observation consent forms are included in Appendices E-H. Audiotapes and consent forms were stored in a locked filing cabinet, and digital files were stored on a password-protected computer at the Centre for Health Innovation & Improvement. Participants were reminded of their rights as a research subject (i.e. refusing to answer questions and/or withdrawing consent at any time without penalty) and provided with the telephone number for the UBC Research Subjects Information Line (or for the Chair of the IHA Ethics Review Committee) should they have any related concerns. Participants were also invited to contact the interviewer/observer or Dr. Craig Mitton with any questions or comments.

3.8 Issues of Rigor

The meaning of rigor in the qualitative paradigm has provoked considerable debate; yet qualitative researchers agree that considering the methodological strengths and limitations of a qualitative study is imperative (107-109). In this section, the major challenges and successes that were experienced in applying the previously outlined methods in practice and the ways in which the study's rigor was affected are reflected upon.

3.8.1 Juxtaposing Observations with Interviews

Integrating observations with interview narratives was a challenge in the context of the present study. The three month delay in obtaining approval from the IHA Ethics Review Committee meant that the first opportunity to observe a regional P&T meeting in that health authority was not until late April 2006, which was nearing the end of the study period. The five
interviews with IHA committee members were conducted prior to this observation session. As a result, interviews could not be used to obtain individuals’ perspectives about decision-making processes that were observed as they were in the case of FHA. Nor could observations be used to ground interviewees’ discussions about formulary priority-setting within specific contexts in order to avoid vague responses. Attempts to overcome this challenge, however, included making more frequent prompts that IHA interview participants share specific decision-making examples.

3.8.2 Recruitment

Scheduling interviews with those committee members who expressed interest in participating in an interview also proved difficult. Cancellations, two-week delays in returning phone calls or pages, or unanswered contact attempts were not uncommon. Efforts were made to accommodate participant scheduling demands and follow-up by telephone or e-mail, while still communicating deadlines by which data collection was to be completed. Despite these efforts, five committee members who had expressed interest were never interviewed. The 15 interview participants recruited, however, were quite insightful which contributed to a rich data set. Moreover, there was sufficient time between interviews to analyze recently collected data and refine the interview guide for subsequent interviews which is critical for theory-building when operating within a grounded theory approach.

3.8.3 Member Validation

Member validation is a technique that some qualitative researchers employ in order to ensure that their interpretation of psychosocial processes fits with participants’ own perceptions of their experiences(107). During later stages of data collection, informal versions of member validation were performed by asking interview participants to comment upon researcher interpretations, or those offered by previous interview participants, about what was going. The
following example in Figure 3.3 highlights how informal member validation was incorporated into later versions of the interview guide.

Figure 3.3: Example of informal member validation.

| Interviewer: Many people have said that the committee does not make formulary decisions on the basis of cost containment, but on therapeutic merit. But, that cost containment ideas become important for drugs sometimes after the decision has been made to add them...in terms of the projected impact on the budget. How does this fit with your experience on the P&T committee? |

This technique was helpful for assessing how well researcher interpretations captured the essence of drug formulary priority-setting according to regional P&T committee members, as well as providing explicit opportunities for dissenting views to be expressed and incorporated into the emerging theory.

3.8.4 Reflexivity and Relationality

In qualitative research, data is co-constructed by researcher and participants; this characteristic makes it important to reflect upon reflexivity and relationality during any discussion about rigor. Reflexivity refers to the influence that interactions between the researcher and participants exerted upon the research process(109). The term “relationality” refers specifically to power and trust dynamics(109).

Participants had their own ideas about the researcher’s identity. Prior to commencing interviews or observations at regional P&T meetings, the affiliation of the researcher as a graduate student with the Department of Healthcare & Epidemiology at UBC was disclosed. The assumption was often made, however, that the researcher must be a pharmacist to be studying formulary priority-setting. In retrospect, this assumption may have been attributed to the researcher’s visible reliance upon the committee Executive, which consisted primarily of pharmacists, in order to obtain access to both committees; pharmacists introduced the researcher at all regional P&T meetings that were attended and, in IHA, a pharmacist was charged with obtaining permission from committee members to be contacted for interviews. The implications
of the researcher’s perceived professional alignment became increasingly apparent as the contextual theme entitled “Gatekeepers of the Drug Budget” revealed tensions between pharmacists and other clinicians on the committee. One physician’s comments made during an interview illustrate this phenomenon: “Oh, even better! So you’re not a spy for pharmacy...[Laughs].” During later interviews, efforts were made to specify the researcher’s non-clinical status in addition to departmental affiliation. Committee members’ perceptions about the alignment or mal-alignment of the professional identity of the researcher with their own may, however, have affected interview recruitment and the data that was generated during interviews.

As Sandelowski(107) articulates, “both researchers and members are stakeholders in the research process, concerned with staking certain claims (to telling the truth, to being right), with maintaining certain personas (as good persons, subjects, scientists).” Many interview participants portrayed themselves and the committee as good practitioners of evidence-based medicine. This may, in part, be a function of their construction of a researcher or scientist as someone upholding notions of objectivity. Responses to open-ended question about the factors that committees considered when setting formulary priorities often appealed to scientific rationality (for example, “well obviously the clinical evidence”). Yet in response to later open-ended questions, participants recounted anecdotes disclosing what they perceived to be less favourable behaviour; these statements were often prefaced by phrases such as “to be honest.”

The research process exposed researcher data collection and analysis skills, as well as assumptions. Throughout this process, it became apparent that some interview participants also conjured new insights into the formulary priority-setting process as a result of complex interview interactions. One of the most striking examples pertained to an allied health professional who, after being questioned about the scope of her voting privileges, re-evaluated her role. This example is illustrated in Figure 3.4 (see next page).
Interviewer: Yeah but the thing is the whole purpose is what YOU see right? You can only speak about your perspective really so that's-

Respondent: And that's why actually now something you said earlier in the interview, you finally put into words something that has been bothering me but I've never really given it enough thought to articulate it, is why am I not restricted on what I can vote on? Because really...I guess it's a very good point. 'Cause I've always felt uncomfortable thinking 'should I be voting on this? 'Cause what the hell do I know about blah, blah, blah'. So I'm going to take that forward and ask the question...so I appreciate that. Thank you.

This participant’s revelation was triggered, as an unintended consequence, by the interviewer seeing some factual information early during the course of the interview.

In terms of relationality, power dynamics as traditionally conceptualized, whereby the researcher is positioned as more powerful, were perceived to be not as salient in this study. The rationale for this perception was that many of the committee members occupied quite senior positions within the regional health authority (for example, Chief of Cardiology at a particular hospital or Regional Director of Pharmacy).

This section about reflexivity and relationality has highlighted the interpersonal dynamics, as they manifested in the context of the present study, which may have influenced the research process: participant constructions of the researcher’s professional identity; participant realizations; and power dynamics which favoured participants. Readers should consider these interpersonal dynamics when interpreting study findings.

3.9 Summary

This chapter has outlined the methodology that was used in order to construct a theoretical framework that explains drug formulary priority-setting processes, including those factors that influence the use of scientific evidence. Rationales were provided for adopting a grounded theory study design, and selecting regional health authorities in British Columbia as the research setting. Procedures for sampling and collecting document, observation and interview data were
described, as were the coding procedures employed during data analysis. Finally, the main
issues related to research ethics and the rigor associated with this qualitative study were
discussed.

The primary product of the application of the aforementioned methods, which constitutes a
conceptual model of drug formulary priority-setting processes at the level of regional health
authorities, is presented in the next chapter.
4.0 RESULTS

4.1 Overview of the Chapter

This grounded theory study sought to use the experiences and perspectives of regional P&T committees in two British Columbia regional health authorities to: i) construct a conceptual model which would explain the processes that committee members engage in during formulary priority-setting; and ii) understand those factors that influenced their use of scientific evidence. This chapter presents the related findings in three sections. The first section briefly describes the data that were collected (for example, drugs that underwent formulary review and basic characteristics of interview participants). The second section constitutes a descriptive background piece about the committees themselves, as well as the chronological steps that were involved in the key activities related to drug formulary priority-setting (i.e. developing auto-substitution policies; and reviewing new drug addition requests). Finally, the third section details the final conceptual model that was constructed in order to theorize how drug formulary priority-setting occurs within regional health authorities.

4.2 Study Participation

For FHA and IHA, committee documents were gathered that included the regional P&T committee (and subcommittee) terms of reference, as well as conflict of interest and formulary request forms. Agenda packages for observed regional P&T meetings were also collected.

The formulary review portions for 3 regional P&T meetings were observed from November 2005 through April 2006 (2 in FHA; 1 in IHA). A planning meeting held by the FHA committee Executive was also observed during January 2006. The drugs that were reviewed at these meetings with regards to formulary status are noted in Table 4.1 on the following page.
Table 4.1: Drugs reviewed for addition to formulary during study period.

<table>
<thead>
<tr>
<th>Generic name</th>
<th>Trade name</th>
<th>Therapeutic classification</th>
<th>P&amp;T Decision</th>
<th>Health authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic care agents</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insulin glargine</td>
<td>Lantus™</td>
<td>Antidiabetic agent-insulin analog</td>
<td>Continue home therapy only</td>
<td>Fraser</td>
</tr>
<tr>
<td>Risperidone orally disintegrating tablets</td>
<td>Risperdal M-Tab™</td>
<td>Atypical antipsychotic</td>
<td>Add</td>
<td></td>
</tr>
<tr>
<td>Salmeterol and fluticasone</td>
<td>Advair™</td>
<td>Bronchodilator-corticosteroid for inhalation</td>
<td>Add</td>
<td></td>
</tr>
<tr>
<td>Formoterol and budesonide</td>
<td>Symbicort™</td>
<td>Bronchodilator-corticosteroid for inhalation</td>
<td>Add</td>
<td></td>
</tr>
<tr>
<td>Tiotropium bromide monohydrate</td>
<td>Spiriva®</td>
<td>Anticholinergic for inhalation</td>
<td>Add, restricted to residential care facilities</td>
<td>Interior</td>
</tr>
<tr>
<td>Erythropoietin/Darbopoietin</td>
<td>Eprex®/Aranesp®</td>
<td>Erythropoiesis stimulating protein</td>
<td>Defer – consult further with requesting doctor</td>
<td>Fraser; Interior</td>
</tr>
<tr>
<td>Gatifloxacin</td>
<td>Zymar®</td>
<td>Ophthalmologic quinolone drops</td>
<td>Decline</td>
<td>Interior</td>
</tr>
<tr>
<td>Acute care agents §</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tenecteplase*</td>
<td>TNKase™</td>
<td>Fibrinolytic agent</td>
<td>Replace another agent</td>
<td>Fraser; Interior</td>
</tr>
<tr>
<td>Bevacizumab/Ranibizumab</td>
<td>Avastin®/Lucentis™</td>
<td>Anti-angiogenic (off-label use)</td>
<td>Defer – consult further with requesting doctor</td>
<td>Interior</td>
</tr>
</tbody>
</table>

* Chronic care agents are used primarily for long-term treatment in the community setting but may also be administered in an institutional setting.

§ Acute care agents are administered only within an institutional setting.

A total of 15 interviews were conducted (10 in FHA, 5 in IHA). The response rates in FHA and IHA were 38%(10/26) and 33%(5/15), respectively. The disciplinary breakdown of interview participants was as follows: physicians (5; FHA 4, IHA 1); pharmacists (7; FHA 4, IHA 3); nursing administrators (2; FHA 1, IHA 1); and nutritionists (1; FHA 1). Five of these interviews were conducted face-to-face; the remaining ten were conducted by telephone.

Participants reported previous involvement with other P&T committees. Although no healthcare facilities located in FHA or IHA constituted academic centres, some members reported teaching affiliations with UBC – Vancouver.
4.3 Background Description

The following sub-sections relate to basic descriptive information about the committees themselves (i.e. membership and mandate) and the drug formulary priority-setting activities which they engage in. This description is fundamental to understanding the general context out of which the themes of the interpretive landscape and abstract processes of the conceptual model, presented later in the chapter, were derived.

4.3.1 The Committees

4.3.1.1 Structure

Although the IHA and FHA regional P&T committees differed in size (15 vs. 26, respectively), their membership compositions were similar. As specified in terms of reference documents, physicians reflecting a comprehensive spectrum of specialties and healthcare facilities dominated membership, followed by pharmacists. Nursing, senior health authority administration and, in the case of FHA, clinical nutrition were also represented. Although pharmacy departments acted as secretariats for both committees, physicians served as Chairs. In FHA, one pharmacist was assigned the task of producing written formulary reviews (Drug Information Coordinator). In IHA, one pharmacist was recently assigned the task of managing the formulary (Formulary Coordinator). There were no epidemiologists or health economists on either committee, although some physicians possessed Masters-level training in epidemiology.

Regional subcommittees were intended to alleviate resource demands on the P&T committees and utilize expertise within the regional health authority. Examples of regional subcommittees included: Cardiac, Antibiotic, Drug Use Evaluation and Nutrition. Their policy recommendations were advisory in nature, and were provided to the P&T committees for deliberation.
4.3.1.2 Mandate

Both FHA and IHA regional P&T committees performed a range of functions as listed in terms of reference documents. In relation to formulary priority-setting, their goals were similar. Fraser Health sought “to develop and maintain a formulary of drugs...based on objective evaluation of therapeutic merit, safety and cost.” Similarly, Interior Health sought “to establish and maintain a safe, evidence-based, fiscally prudent and sound formulary.” Other responsibilities included monitoring drug utilization and medication safety, facilitating the distribution and administration of drugs, and implementing educational programs to ensure the appropriate use of drug therapies by healthcare professionals. The committees spent up to half of their time during observed meetings discussing drug formulary priority-setting issues.

The FHA regional formulary was positive (i.e. included therapies that were approved for routine provision within regional public healthcare facilities rather than those therapies that were not approved). During February 2006, a first draft of the FHA regional formulary was accepted by the committee. The list included an approximate total of 1100 drugs and nutritional supplements (for example, vitamins); each available formulation (i.e. tablet, injectible, ointment) and dosage was recorded individually. Non-formulary drugs, which physicians could request specially, were not included on the FHA formulary list.

The IHA regional formulary, in contrast, was a mixture of positive and negative elements (i.e. included therapies that were approved for routine provision as well as those that the committee had declined). It included an approximate total of 900 approved drugs and nutritional supplements listed in a format similar to the FHA formulary (i.e. individually by formulation and dosage). At the end of the IHA formulary, several categories had been recently added; these categories identified new medications scheduled for review, medications currently being reviewed by subcommittees, and medications that were reviewed but not approved by the P&T committee. The IHA regional formulary had been revised several times as of April 2006. Both
IHA and FHA were in the process of standardizing auto-substitution policies across sites during the study period.

The drug budgets in Fraser and Interior Health Authorities were managed by the regional pharmacy departments. Money was allocated from the provincial Ministry of Health Services to the regional health authority, a portion of which was designated by the health authority Executive to comprise the regional drug budget. At the time of study, the drug budgets in FHA and IHA were approximately $55 and $25 million, respectively. Each budget experienced some degree of annual growth (in FHA, 5-8%; in IHA, 8%).

4.3.2 Formulary Priority-Setting Activities

Two inter-related activities emerged as most relevant to setting formulary priorities. An overview of each activity will follow: i) developing auto-substitution policies; and ii) reviewing drug addition requests.

4.3.2.1 Developing Auto-Substitution Policies

Policies for auto-substitution or therapeutic interchange instructed pharmacists to automatically substitute drugs of a similar therapeutic class prescribed by physicians with one or several formulary agents. Auto-substitution policies were developed, for example, for angiotensin-converting enzyme (ACE) inhibitors, and proton-pump inhibitors (PPIs). An abundance of rationales were advanced for implementing these policies, which contributed to streamlining the formulary. Such rationales included: reducing prescribing, administering, and dispensing errors; minimizing phone calls made by pharmacists to those individuals prescribing drugs; reducing wastage associated with drug expiry; and maximizing cost-effectiveness by enabling the pharmacy department to negotiate volume pricing discounts with pharmaceutical vendors. The impetus for reviewing a therapeutic class in order to develop auto-substitution policies occasionally arose out of reviewing a drug addition request.
4.3.2.2 Reviewing Drug Addition Requests

This process was composed of two stages. A preliminary stage involved prioritizing new drug addition requests for review. The second stage pertained to making formulary decisions about those drug addition requests that had been reviewed. Each stage is addressed in the following sections.

4.3.2.2.1 Prioritizing Requests for Review

Requests for adding drugs to the formulary could be made by any healthcare professional working in regional acute, residential and mental health facilities but, historically, physicians submitted these requests. Requestors were required to submit a drug addition request form to the committee Secretary. This form detailed information such as the proposed indication(s), current formulary drug(s) that could be replaced, conflict of interest declarations, and approval of the department leader. FHA required applicants to reference the scientific literature; no specific guidelines were, however, explicated. IHA followed a two-stage request process, whereby requestors first solicited information about a potential formulary agent and then decided whether to request its addition. Some supporting information was required at the first stage.

At the time of study, new drug addition requests were primarily prioritized according to chronological order (i.e. a ‘first-come, first-serve’ approach) as a courtesy to requestors. Yet exceptions could be made based upon: i) anticipated impact on the drug budget; ii) potential for improving patient care; and iii) lobbying from clinicians. Both FHA and IHA committees were considering formalizing agenda-setting processes so that the committee was better positioned to justify its decisions.

Even though minor requests were dealt with outside the purview of the regional P&T committee, some requestors had been waiting upwards of one year for review. In FHA, there

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5 Minor requests, such as switches to generic brands, were excluded from this process. These formulary changes were determined internally within the pharmacy department.
were approximately 15-20 pending requests whereas in IHA, there were only 7 pending requests. Interview participants ascribed this situation to the limited resource capacity for staff to conduct evidence-based drug reviews, an infrequent meeting schedule (four meetings per year), and the high rate at which new drugs entered the market. The typical consequence was that only 2-5 drug addition requests could be slotted into each meeting agenda, which amounted to approximately 8-20 drug addition requests being reviewed per year.

4.3.2.2.2 Making Decisions About Reviewed Requests

Written formulary reviews were generated by the pharmacy department for all new drug addition requests that were prioritized for review by the P&T committee. This responsibility was assigned to different pharmacists in IHA but primarily the Drug Information Coordinator in FHA.

Reviews contained background information about the drug (for example, the manufacturer, comparative agents, dosing and safety warnings) and the request itself (for example, the requested indications). Also included were comparisons of the cost of the requested drug to that of similar formulary agents, and occasionally the decisions or recommendations advanced by other groups (for example, other health authorities). The majority of the review was dedicated, however, to summarizing and critically evaluating the primary scientific literature. In IHA, the end of the review comprised a particular policy recommendation whereas in FHA, several policy options for consideration were often advanced. These options included adding without restriction, adding with restriction(s), replacing a current formulary agent, deferring the decision until a pre-specified time (i.e. until the next meeting) or declining a request. In the case of declining a request, physicians could still make special requests for access to non-formulary agents to treat specific patients.

Consultation about written formulary reviews was sought to maximize the likelihood that important decision-making elements were not overlooked and to demonstrate buy-in. They were
peer-reviewed by pharmacists and feed-back was solicited from the requester and medical specialty groups. If a drug fell under the jurisdiction of one of the medical specialty subcommittees, the subcommittee’s comments were appended to the review.

Written formulary reviews were distributed to committee members in the agenda package prior to regional P&T meetings. These reviews were presented orally by the Drug Information Coordinator in FHA, and either the primary reviewer or a peer-reviewer in IHA. Additional information covered included the identities of requestors and feed-back provided by those consulted. Subsequent discussion proceeded in an unstructured manner through a variety of operational issues which, at times, were addressed with considerable uncertainty. For example, one committee member inquired about the estimated cost projection for using Spiriva® within residential care facilities to which another member responded: “That is, we could not put a figure on the actual cost for restricted use. But, it is my feeling, in looking at it, I think we are looking at less than our ceiling, which was about $25,000” (Pharmacist – Observation).

Policy motions were put forward by one committee member and seconded by another prior to voting. The Chair counted a show of hands of those members in favour, against or abstaining. As stated in the terms of reference, both committees typically operated on a consensus basis. This was the case for the majority of the formulary reviews that were observed. However, in both FHA and IHA, voting for replacing the formulary thrombolytic agent with the drug TNKase™ only marginally passed, with many abstentions observed. Nonetheless, this was reported to be an anomalous observation historically for both committees.

Deletions manifested in both the contexts of reviewing drug addition requests and developing auto-substitution policies. Conditions for deletion included when an agent was no longer available from the manufacturer, prescribed minimally for inpatients, and/or deemed less
therapeutically sound or cost-effective relative to a comparator agent. Interview participants reported that very rarely were drugs deleted in response to safety warnings.

4.3.3 Reporting Decisions

In FHA, regional P&T meeting minutes and policy decisions were forwarded to the Health Authority Medical Advisory Council (HAMAC) for their information. In the committee’s brief history, participants reported that HAMAC had never reversed a recommendation.

In both FHA and IHA, the agenda and minutes of the regional P&T meeting were forwarded to the Chairs of the Local Medical Advisory Councils at each site. Medical staff was notified of committee decisions by way of summary memos. Details of decisions could be accessed on the regional health authority intranet but not publicly-accessible websites.

Formulary priority-setting was an iterative process. Decisions could be revised based upon: i) additional production of scientific evidence; ii) future drug utilization patterns in the health authority; and iii) comparator agents becoming less expensive due to patent expiry or willingness of drug vendors to offer volume pricing discounts.

4.4 A Conceptual Model of Drug Formulary Priority-Setting

The primary objective of this grounded theory study was to construct a conceptual model capturing the essence of drug formulary priority-setting by utilizing the experiences of regional P&T committees in FHA and IHA. This model is summarized in Figure 4.1 (see next page). Four processes, which overlap and intersect, emerged from the data as central to reaching formulary decisions: i) Negotiating the margins of therapeutic advantage; ii) Seeking value for resources allocated; iii) Interfacing between community and institutional settings; and iv) Situating decisions within an organizational context. These processes pertain both to developing auto-substitution policies and reviewing drug addition requests.

* A note must be made about the preliminary stage of the latter activity, namely prioritizing drug addition requests for review. The outcomes of the model do not pertain to this stage since, by virtue of constituting a preliminary
Several themes emerged as important to drug formulary priority-setting experiences in FHA and IHA that represent the cultural context in which the regional P&T committees operated, rather than conceptual processes integral to reaching formulary decisions. For the stage, outcomes were 'review' or 'do not review' decisions rather than formulary addition decisions. Nonetheless, the conceptual processes of the model are relevant to prioritizing drug addition requests for review; examples are, therefore, included throughout the written theory.
purposes of this study, the cultural context has been defined as an "interpretive landscape," acting as a backdrop against which the processes encompassed by the conceptual model played out. The key themes that emerged as central to the interpretive landscape, which are also noted in Figure 4.1, are reported first.

As previously discussed in the Methods chapter, reported themes reflect those patterns that were encountered repeatedly within the data and assessed to be critical to answering the research questions. Several variations within each theme are highlighted in order to communicate the richness of the collected data to readers.

4.4.1 The Interpretive Landscape

The interpretive landscape consists of four contextual themes which apply across the conceptual processes of the theoretical model. These themes include: i) Commitment to P&T and Patient Care: Realities; ii) Gatekeepers of the Drug Budget; iii) On the Defensive Against "Big Pharma"; and iv) Referencing Others' Decisions. Each theme will be presented in turn. Following this, the grounded theory of regional drug formulary priority-setting as constructed will be described.

4.4.1.1 Commitment to P&T and Patient Care: Realities

The reality of personal resource constraints was noted by all interview participants irrespective of a ubiquitous belief that formulary priority-setting processes were integral to achieving optimal patient care. Yet physicians were perceived to face the most challenges in maintaining a commitment to the regional P&T committee while fulfilling their primary responsibility: providing front-line patient care.

Commitment to P&T activities involved two components: i) pre-meeting preparation; and ii) attendance and participation during meetings. A typical depiction of this struggle as it pertained to the first stage involved relinquishing control over reviewing individual scientific studies: "Because of our own personal time constraints being clinical people that we are, we're
basically relying on those pharmacy people to do a thorough exam of the literature...” (Physician - Interview). Many committee members did, however, consult specialists on their own time and brought information forward during meetings.

During the second stage, this struggle manifested in the form of reduced meeting attendance even when the committee convened only four times annually. Anecdotes about how difficult it was to recruit and retain physician members were also communicated; some positions were vacant and sub-committees described in terms of reference documents were not yet established. At meetings, physician committee members were observed exiting the room to attend to pages and telephone calls about patient care. These behaviours were constructed as manifestations of general busyness rather than the priority attached to committee work.

The aetiology of the commitment challenge faced by physicians was understood in two ways. First, it was understood as an inevitably of the practice environment which presented an insurmountable task of keeping up with advances in treatments, diagnostic tests, and other dimensions of patient care. In FHA, participants also constructed the problem as a function of the voluntary status of P&T activities for physicians but not for pharmacists or other employees of the health authority:

“...that [voluntary status] becomes a problem not so much for participation but for informed participation. I think people often arrive at committee meetings when they're unpaid for things not really having taken the time to maybe look through the 140 pages of information that came to them three days earlier.”

(Physician - Interview)

The perceived consequences of this commitment reality for formulary priority-setting processes were negative. Accordingly, some structural strategies had been implemented in an attempt to minimize these effects. Educational sessions were incorporated into meetings and printed resources were distributed in response to concerns that insufficient time for developing and applying critical appraisal skills led to behaviours such as “rubber stamping” and greater reliance upon the views of opinion leaders. In response to concerns that unfilled positions and
absences jeopardized the quality and legitimacy of decisions, financial enticements were offered in various forms. In both authorities, physicians were compensated for their travel. In IHA, physicians were paid for time spent at regional P&T meetings. Due to the educational sessions provided in FHA, physicians could apply for Continuing Medical Education (CME) stipends provided by the provincial medical association to cover office overhead for the missed day.

Committee members perceived these structural strategies to be somewhat effective. However, concerns about the realities surrounding the capacity for commitment to regional P&T activities remained problematic for all involved. Limited capacity for commitment had implications that pervaded not only assessing the scientific evidence, but all other conceptual processes related to drug formulary priority-setting.

4.4.1.2 Gatekeepers of the Drug Budget

Intra-committee dynamics reflected some perceptions about a power imbalance established along disciplinary grounds. This was made more significant by polarized ideologies. Participants described the committee as “pharmacy-driven” or “the odds [being] stacked in pharmacy’s favour,” with the pharmacists acting as “gatekeepers” or “watchdogs” of formulary priority-setting processes. Discourse pertaining to interactions between medicine and pharmacy was characterized at times using power-laden language such as “fighting”, “push-pull”, and “hijacked”. The pharmacy department was positioned as embodying greater power and financial accountability by virtue of structural factors that conferred upon it formal responsibility for managing the drug budget and related activities, such as conducting evidence-based reviews.

An assumed natural extension of the budget responsibility was for pharmacists to lay greater credence to minimizing drug costs than achieving the best patient care. For other clinicians, the objective was perceived to be the opposite. Despite acknowledging the importance of the gate-keeping role, some clinicians struggled with the degree to which it was performed:
“Yeah, I think um you know pharmacy has legitimate concerns regarding costs of pharmaceuticals. I think that's one of their responsibilities...to spend our limited resources wisely, but not for the sake of limiting patient care outcomes...so sometimes the cost issue becomes all encompassing and seems to nullify any other valid argument for considering an agent.”

(Physician - Interview)

Pharmacists were acutely aware of this characterization. Interview participants proposed that the discrepant ideology upheld by medicine was a manifestation of professional socialization, working in rather than for the health authority, and being less familiar with the administrative operations that follow writing a prescription. These latter reasons were echoed by one physician whose viewpoint had shifted since obtaining insider status as part of the committee Executive: “Well it wasn't until I was on the inside [of the pharmacy department] that I realized that there are reasons for not carrying everything under the sun” (Physician – Interview).

The implications of a perceived power imbalance were complex and varied. Clinicians who identified a pharmacy bias believed that it compromised procedural integrity; suspicions ranged from inadvertent presentation of selected scientific evidence to predetermined voting by pharmacy committee members. Expressions typically arose in the milder form:

“So I'm just wondering if somehow, I've thought about it once or twice as well, are we really getting the full information that we are supposed to be getting? Is this really as objective as it should be? Because I can see from the pharmacist's level, and particularly the upper management of pharmacy, you know they are really being constrained by monetary issues...”

(Physician - Interview)

The clinician who had attained insider status, however, believed that pharmacists took extra care when reviewing the scientific literature and presented a balanced interpretation by virtue of worrying about this power imbalance. In fact, pharmacists reported taking structural measures to bridge the perceived divide between the medical and pharmacy ends of the P&T committee: preventing an obvious physical clustering of physicians and pharmacists from forming at meetings; and ensuring that at least one of the individuals who moved or seconded a policy was a medical practitioner.
4.4.1.3 On the Defensive Against “Big Pharma”

The pharmaceutical industry was typically characterized by participants as an opponent that the committee needed to position itself against due to the potential threat to objectivity and drain on health authority staffing resources. Interview participants recounted anecdotes of pharmaceutical manufacturers trying to directly influence formulary decisions: requesting drug additions, completing drug addition request forms on behalf of physicians, and making coincidentally timed office visits to committee members in advance of P&T meetings. The regional formulary was recognized as an access point through which companies could extend their reach into the community marketplace:

“I mean this is roughly a $38 to 40 million dollar process...is what Fraser Health spends in a year. And if people are started on drug A, they’ll usually continue on drug A and there’s a huge amount of number of people who slide through 12 hospitals in Fraser Health Authority so there’s a fair amount of drug recognition and drug potential here that a company could realize if their drug is accepted on formulary.”

(Physician - Interview)

It was also believed that physician interactions with pharmaceutical companies via even more subtle mechanisms (for example, free samples, conference sponsorship, office lunches) were what lent momentum to prescribing trends and, indirectly, many formulary requests.

The resulting consequences were such that at both collective and individual levels, pains were taken to minimize the influence of the pharmaceutical industry upon most drug formulary priority-setting processes. Both drug requestors and committee members were required to complete written declarations of present and past (previous 2 years) associations with pharmaceutical companies: employment, consulting, and financial benefits in the form of stock options, speaker fees, travel assistance, and research honorariums. FHA gathered financial details pertinent to declared associations, whereas IHA collected only qualitative information (i.e. yes/no responses). Questions about the conflict of interest status of requestors were observed but none were reported. Similar questions were posed about the conflict of interest
status of those involved in making decisions in other jurisdictions, which is addressed in more
detail in the following section.

Each committee's operational definition of “conflict of interest” permitted some
interaction with pharmaceutical industry to accommodate a perceived inevitably in the lives of
active practitioners. A threshold of $5000 of industry-derived income per company per annum
was arbitrarily set by the Executive in FHA. In the instance that a committee member's income
from a particular drug company exceeded this threshold and one of that company's drugs was
being reviewed, it was reported that the Chair would request the committee member to refrain
from participating in the subsequent discussion and voting. This situation was not, however,
observed during the course of the present study.

In contrast, the IHA committee was experiencing difficulty with establishing a threshold
against which to evaluate qualitative conflict of interest information. As one pharmacist from
IHA explained: “...at this point, we don’t know what to do with that [declarations], right? If a
physician is making – you know I mean the thing is do we put a threshold...oh he’s involved
with more than two companies, he can’t be on the committee?” (Pharmacist – Interview). The
consequence was that conflict of interest information was gathered but not utilized.

Lesser profile strategies included noting whether a clinical study was industry-sponsored,
and refraining from posting decision rationales on the publicly accessible portion of the health
authority web-site in anticipation of having to face additional questioning from pharmaceutical
companies:

"We have to be careful not to paint the target circles on our back when we send things out
to the public because that often times give the industry things to base their concerns
about...the concern is not that you wouldn’t be able to win a debate, just that you can
spend all your time trying to answer those questions."

(Pharmacist - Interview)

Accounts of individual committee members disposing of pharmaceutical industry stock, and
refusing to see pharmaceutical sales representatives were also shared. Taken together, these
strategies generally kept the direct impact of pharmaceutical industry activities upon committee members’ objectivity and health authority staffing resources to a relative minimum. Yet the ability of pharmaceutical companies to influence the prescribing habits of individual practitioners and ultimately initiate widespread shifts in prescribing trends in the physician community persisted as a concern for committee members. The impact of this phenomenon will be considered further in the context of regional P&T committees interfacing between drug therapy taken in community and institutional settings, and responding to political pressure.

4.4.1.4 Referencing Others’ Decisions

Decisions or recommendations made by others were salient both to the decision-making processes of individual committee members and those of the committee as a collective. “Others” could be externally or internally situated in relation to the regional health authority. External others included: other jurisdictions providing hospital-based care (for example, health authorities); public drug benefit plans (for example, Pharmacare, Oregon Practitioner Managed Prescription Drug Plan) and associated advisory committees (i.e. CEDAC, which is the Canadian Expert Drug Advisory Committee); disease management organizations (for example, the Canadian Diabetes Association); and clinical specialty organizations (for example, the American College of Cardiology). Drug reviews produced by the Therapeutics Initiative were, interestingly, not cited by either committee during the present study. Internal others included P&T subcommittees, physician specialist groups, and the physician committee members whose specialty a drug therapy was most closely related to.

Others’ decisions served as benchmarks for practice standards with which to guide or assess the correctness of committee interpretations of the scientific literature, the value for resources allocated or overall decision. For example, national trends were sometimes alluded to in order to bolster an argument for drug addition: “Finally, I want to make the point over 80% of fibrinolytic use in Canada is TNK [tenecteplase]. We are – we’re outsiders! One has to ask
ourselves what is it about Fraser Health that has made us stick with RPA [reteplase]?”

(Physician - Observation). The degree to which these decisions served as benchmarks depended upon their: i) accessibility; ii) applicability; and iii) credibility.

The concept of accessibility arose primarily in the context of the formularies maintained by other regional health authorities, and the perspectives of physician specialty groups. IHA structurally incorporated provincial information into the process with a formulary review section entitled “Survey of other health regions.” It was often incomplete, however, due to lack of response from other regional health authorities. The perceived consequence of the inaccessibility of decisions was “re-inventing the wheel” unnecessarily:

“But to know that ahead of time, so when you step into the meeting and P&T says, ‘we’d like to have this drug,’ we can say, ‘did you know that in Halifax they added the drug a year ago and they took it off because of this reason? And, rather than going through all the problems that they went through...’”

(Pharmacist - Interview)

Low response rates from physician specialty groups, or lengthy delays in receiving feedback were also problematic and sometimes contributed to deferring decision-making in IHA to future meetings.

Ascertaining the fit of others’ decisions with the context of regional P&T formulary priority-setting was confined to those external to the organization. Applicability of decisions made by other health authorities in British Columbia and across Canada was assessed by comparing staffing levels, information technology, and provincial funding arrangements. Applicability of decisions made by Pharmacare and CEDAC was determined by comparing organizational mandates: a shared interest in maximizing the value for resources allocated, but divergent interests in adopting a streamlined formulary. As one pharmacist explained: “…Um but for us to carry all ten [drugs from a particular therapeutic class] it sometimes becomes a burden to our system because of shelf space, inventory and all that. Pharmacare doesn’t carry any inventory. The drug stores do” (Pharmacist - Interview).
The perceived credibility of a decision was affected by procedural transparency and the knowledge boundaries of committee members. First, participants wanted access to the steps that others followed, materials they reviewed, their credentials and conflict of interest declarations. Familiarity with the processes of those external to the organization, particularly Pharmacare and other health authorities, was frequently reported as low. Second, committee members were inclined to defer to internal experts when a drug therapy being discussed fell outside of their specialty. The comment made by one physician typifies this rationale:

“That’s when if we’re debating something from anaesthesia, something I don’t know much about, it’s hard for me to argue those points not being familiar with that...It’s kind of hard to question those people [anaesthesia department] ’cause they are basing it on their day-to-day clinical judgment...”

(Physician - Interview)

Given the range of others whose decisions were considered and participants’ varied perspectives about applicability and credibility, the consequences of referencing others’ decisions upon the FHA and IHA formulary priority-setting processes were inevitably complex. The Canadian Diabetes Association’s clinical practice guidelines which advocated the drug Lantus™ were, for example, dismissed due to suspicions about the degree to which they were evidence-based and free of industry interests. Even when decisions made by external others were perceived to be moderately applicable and credible, their influence was marginalized by a preference for taking ownership of review of the scientific evidence:

“...We feel more comfortable in regards to hearing okay the Common Drug Review states that it’s acceptable and you know approved...But in terms of is it you know the hard evidence? No. What we like to see is the randomized controlled trials to give us more hard evidence support, rather than expert opinion, or whatever else...from an external source where we don’t know where the biases are lying.”

(Physician - Interview)

Physician specialist committee members were poised to be very influential figures during discussions given the considerable credibility ascribed to internal experts.
The existence of a continuous feedback loop between the committees' formulary decisions and the decisions of others was also noted. As one participant articulated: "Once one person adds it, if we were to make a decision here, that decision would perhaps carry weight somewhere else" (Pharmacist - Interview). This was one way in which FHA and IHA regional P&T committees were positioned as capable of shaping the broader drug policy landscape.

4.4.2 The Conceptual Model

In an earlier section (pg. 52), a background description was provided regarding the regional P&T committees studied (i.e. membership and mandate) and the drug formulary priority-setting activities in which they engaged. In the previous section, entitled "The Interpretive Landscape," several themes reflecting the cultural context in which the committees operated were identified. The current section presents a theory which integrates the conceptual processes that are central to setting drug formulary priorities (see Figure 4.1, page 59). In drawing upon ideas reported throughout previous sections of the chapter, the theory addresses the objectives of this study: to explain conceptually how regional P&T committees carry out drug formulary priority-setting, with particular attention to understanding what factors affect the way in which scientific evidence is used.

Four conceptual processes emerged from the data as central to setting formulary priorities within regional health authorities: i) Negotiating the margins of therapeutic advantage; ii) Seeking value for resources allocated; iii) Interfacing between community and institutional settings; and iv) Situating decisions within an organizational context. Although the model is characterized by a general sense of temporality (for example, determining the therapeutic advantage offered by a particular drug therapy prior to assessing its value for resources allocated), there was often continuous interplay between the conceptual processes before making decisions to decline, add, replace, or restrict a drug therapy.
Each conceptual process will be reported, along with the key conditions underlying its variation and resulting consequences. Inter-relationships between processes are also depicted.

4.4.2.1 Negotiating the Margins of Therapeutic Advantage

"Superstar" drug therapies that conferred significant therapeutic advantages relative to existing formulary agents were uncommon yet could occasionally arise. More frequently, regional P&T committees were dealing with drug therapies offering marginal, if any, therapeutic advantage. In order to negotiate this muddled territory, committees assessed the scientific literature and made a niche for practitioner clinical experience.

4.4.2.1.1 Assessing the Scientific Literature

Scientific evidence of a drug therapy's relative efficacy and, to a lesser extent, safety was reported as the initial and foremost consideration when making formulary decisions. This was consistent with some committee self-characterizations: "...this committee has always had an obligation to take the high road in terms of evidence-based medicine" (Physician - Observation). Other committee self-characterizations depicted a culture whereby fear of withholding a potentially beneficial therapy from patients led committees to establish insufficient thresholds for scientific evidence:

"We're an evidence-based committee, and 'mm-hm' we'll look at important outcomes and whatever, but I don't think there is buy-in into the whole process, and I think people are willing to take the chance on the belief that there might be a benefit instead of saying that you know, 'We shouldn't jump on the bandwagon too quickly, we should wait if we already have useful alternatives that we know how to use before we start adopting new products with potential benefits until we know more about it.'"

(Pharmacist - Interview)

Authors and presenters of written formulary reviews made strategies for searching (i.e. journal indices, keywords, hierarchy of outcomes) and methodological assessment explicit (for example, ranking study designs). A considerable amount of time was spent during regional P&T committee meetings reviewing summaries of the scientific evidence about efficacy and adverse
events that was retrieved, which were generated by committee reviewers, and debating possible interpretations of results.

Several conditions affected how the scientific literature was assessed. These were related to participant perceptions about: the negative effects of pharmaceutical industry activities, pharmacy department bias, and non-teaching healthcare facility status; the status of the publishing journal; the resource demands of critical appraisal (time, skill, benefit of education sessions, having a point person conduct reviews); and the methodological limitations of the scientific literature. Methodological limitations of the literature included: the absence of head-to-head trials and serious adverse event data; surrogate outcome measures; insufficient power; short study duration; comparator doses inconsistent with standard clinical practice; and inability to capture clinical "gut feelings" and operational considerations. In light of these limitations, participants struggled with the degree to which interpretations of the scientific evidence represented truth: "You can choose any number of people to tear a paper apart or to support it...and there are two sides to every argument. That's what it boils down to" (Physician - Interview).

The decision-making trajectory of drug therapies was guided considerably by assessment of the scientific literature. Occasionally, a drug request would be declined at this stage when it appeared to cause harm to patients. Although this circumstance was not observed in the present study, it was described by an IHA pharmacist in the case of a non-steroidal anti-inflammatory known as Celebrex™:

"And, basically the summary was that 'no, currently there's not a lot of literature to support it being any better, and there are some concerns and questions about its possible side effects'...as most people are familiar with the media over the last year and a half. So the decision was that 'we are not going to add it to formulary at this time for that particular indication.'"

(Pharmacist - Interview)
When the literature identified a drug as either offering substantial therapeutic advantage, or marginal therapeutic advantage, or neutral (offering neither therapeutic advantage nor harm), the regional P&T committee would proceed to assessing its value for resources allocated and operational implications for the regional health authority. This was also the trajectory followed even in the typical scenario, exemplified by Lantus™, whereby the scientific literature was proclaimed to be ambiguous: “...It’s – it’s not only insufficient evidence, it’s poor evidence! Like, really, very little to guide us” (Nurse – Observation). Although IHA participants reported declining requests on the basis of insufficient numbers of high-quality studies, exceptions were reportedly made for ‘breakthrough’ drugs such as an anti-sepsis drug Activated Protein C:

“And because it was a new drug, and it only had the one randomized controlled trial, we felt that we would review it because it had you know a potential benefit for patients who were most sick, and most at risk of dying, or suffering severe sequelae...But generally speaking, if a medication has only had the opportunity to have one robust study done, we would tend to defer it...”

(Physician - Interview)

For all cases in which the scientific literature did not point to demonstrable therapeutic harm, rationales based upon practitioner clinical experience then factored into constructing a more complete understanding of a drug’s therapeutic merit. No formulary reviews were observed during the present study, however, in which discussions about considerable therapeutic harm took place.

4.4.2.1.2 Making a Niche for Clinical Experience

This sub-category reflects the way in which committees accommodated a role for information about therapeutic merit that was derived from clinical experience, which may or may not be supported by the scientific literature. Clinical experience informed issues such as the potential to improve compliance (for example, one combination rather than two individual inhalers), reduce drug dosing errors (for example, frequency of forgetting to administer a second bolus in practice) and overall efficacy (“you may not know why it works but it works”).
Several belief-oriented conditions affected the degree to which practitioner clinical experience was perceived to be an important type of evidence. First, committee members shared the view that there was an art to clinical practice that could not always be captured by research. As one nurse explained:

“For example, drugs that put you to sleep. Some are more expensive...the other ones the patient wakes up euphoric, they get out of hospital in half the time, it’s easy to nurse...like all those things. Those are like soft reasons why I, as a clinician, would promote one drug over another but it’s not something that you could pull out of a scientific study...”

(Nurse - Interview)

Second, many committee members believed that using clinical experience to negotiate deficiencies in the scientific literature was legitimate in order to make timely decisions – acknowledging that it was the “lowest quality of evidence” (Nutritionist - Interview).

Meeting observations illustrated that arguments based upon clinical experience were not typically accepted uncritically, but rather were challenged by committee members to ascertain their validity. Clinical experiences that were deemed legitimate could then revise the committee’s literature-based assessment of therapeutic advantage; legitimacy was generally conferred when asserted by the most relevant physician specialist committee member. For example, TNKase™ was re-evaluated on the grounds that even though the scientific literature was ambiguous, regional cardiologists argued that it could potentially reduce nurse dosing errors and permit earlier assessment of heart reperfusion given its single bolus administration. The committee cardiologist reflected upon his decision-making influence: “I mean it’s fair to say that if for whatever reason I didn’t attend that meeting, it would have been overturned. No question” (Physician - Interview). The therapeutic advantage of adding both Advair™/Symbicort™ was also revised when the committee respirologist responded to an inquiry from another committee member about aligning with the less expensive of the two inhalers: “No but there’s patient preference for type of inhaler and that does play a big role in
whether they'll use it or not...So I think they both have to be available” (Physician - Observation). Finally, the IHA committee was observed to defer a decision about Eprex® until the next regional P&T meeting in order to obtain more clinical input from a group of critical care, haematology and nephrology medical practitioners.

Determining a drug’s therapeutic merit relative to therapeutically comparable formulary drugs was the first conceptual process that regional P&T committees engaged in when considering whether to attribute formulary status to a given drug. This was accomplished by drawing upon the scientific literature and practitioner clinical experience. The nature of resulting judgments about the therapeutic advantage offered by a particular drug therapy determined access to subsequent conceptual processes (for example, judgments of harm or insufficient therapeutic knowledge could signal committee members to decline drug requests or defer making a decision until a specified time).

4.4.2.2 Seeking Value for Resources Allocated

The process of seeking value for resources allocated, characterized by many interview participants using the colloquial phrase “bang for the buck,” reflects the way in which regional P&T committees conceptually juxtaposed the therapeutic advantage offered by a drug therapy against the incremental monetary costs incurred by the health authority for its acquisition. Incremental monetary costs were considered in various forms across formulary reviews and interviewees: projected total cost per annum or, more frequently, cost per dose or per day.

The importance of determining the value offered by a particular drug therapy in light of the resources required for its provision was constructed as important on the basis of a shared belief that relatively finite health authority drug budgets could not and should not accommodate all drugs, especially given recent industry trends towards manufacturing costly ‘me too’ drugs that offer marginal, if any, therapeutic advantage. The consequence of not limit-setting in this way was to sacrifice the comprehensiveness of the formulary: “Can we stretch our dollar and
have more medications if we don’t accept the most expensive medication out there...if we decline the Mercedes and take the Ford we can spend that extra money on other things that we might not otherwise have” (Physician - Interview). In both IHA and FHA, however, permission to expand the drug budget was requested from the Executive of the health authority to reportedly cope with emergency situations such as a hospital-based flu outbreak or, as was observed during the study period, to bring on board expensive drugs offering a perceived therapeutic advantage (for example, an incremental impact of $500,000 to add TNKase™ to the FHA formulary). Awareness of the size and status of the drug budget among committee members in IHA and FHA differed due to variations in whether this information was routinely communicated. For example, interview participants in IHA reported that committee members were regularly updated by the pharmacy department in terms of how much of the annual drug budget had been spent at a certain point in time through memos and during committee meetings.

The conceptual process of estimating the value obtained by adding a particular drug therapy to formulary given the resources allocated manifested as two sub-processes. The first sub-process entails regional P&T committees negotiating with pharmaceutical companies in order to improve the value offered by a particular drug therapy. The second sub-process reflects the phenomenon of navigating informal thresholds with respect to drugs that offer some therapeutic advantage at an increased incremental cost. Each sub-process is explained in further detail in subsequent sections.

4.4.2.2.1 Price-Brokering With Industry

When asked about the way in which committees considered cost, interview participants alluded to value scenarios in which formulary decisions were made simple. Appeals to the obvious, or what participants described as “no-brainers,” were typified by expressions such as: “If it’s costing more and it’s no better, and no more safer, then why bother?” Scenarios where declining a request was clearly merited included: therapeutic harm irrespective of cost, and
similar therapeutic merit for increased cost. Scenarios clearly meriting formulary addition included: similar therapeutic merit for lesser cost, and therapeutic advantage for the same or lesser cost. Risperdal M-Tab™ exemplified the latter situation and was added following minimal discussion by the FHA committee.

The conceptual process labelled “Price-brokering with Industry” reflects the processes in which committees engaged to try to achieve those scenarios clearly meriting formulary addition. Both health authorities were clients of a health services group purchasing organization that tendered out contracts to pharmaceutical companies in order to contain costs. Regional pharmacy departments could sign onto these negotiated group contracts, and/or engage in activities such as tendering and negotiating volume discounts (for example, rebates or educational grants) with particular companies on their own. Deals could involve individual or bundles of drug therapies from the same manufacturer. Tendering out contracts was conditional upon first establishing similar therapeutic merit between drug therapies that were offered by multiple sources. This afforded the regional P&T committee considerable leverage to influence competition between pharmaceutical companies and, consequently, obtain drugs for below list price: “...We let them undercut each other and do whatever they want to each other...Fraser Health is so large that we have the ability to push people to really reduce prices. It’s amazing the kinds of things we have the power to do” (Pharmacist - Interview). Even when volume discounts were negotiated after selecting a drug therapy that offered a perceived therapeutic advantage, the committee could suppress drug prices.

Yet committee negotiating capability could still be curbed by manufacturers. This was observed in FHA with regards to TNKase™: “We do not receive a volume discount on any Roche product at this time” (Pharmacist – Observation). In IHA, similar concerns were also expressed about the uncertainty of reaping negotiated volume discounts:
"...And we hope that we are going to get all the rebates and free gifts, and all this stuff. And, that's going to take some horsepower when it comes to accounting, because we have done that with Roche before. We have been down that road at our hospital, and we never could agree how much they owed us."

(Pharmacist – Observation)

When juxtaposed against the prevailing cultural context outlined in the interpretive landscape whereby committee members made efforts to restrict the involvement of the pharmaceutical companies, the process of price-brokering with industry highlights the complexity which marks the relationship between regional P&T committees and the pharmaceutical industry. Committees exclude the pharmaceutical industry from drug formulary priority-setting processes in order to minimize associated threats to objectivity and staffing resources, yet also actively engage the industry in order to influence competitive market tendencies and, consequently, save money.

4.4.2.2.2 Navigating Informal Thresholds

This sub-process reflects the ways in which regional P&T committees navigated amongst the informal value expectations committee members had for drug therapies that offered a therapeutic advantage at a greater cost (i.e. drugs not classified as value "no-brainers"). For example, a proportional threshold was advanced during discussion about Lantus™ at a FHA committee meeting: “When I look at this comparison of the cost of $12.35 for a vial of NPH versus $55.07 for a vial of this stuff, I’m thinking ‘Does a patient get four times the benefit from you know using insulin glargine?’ And we haven’t had that put in front of us” (Pharmacist - Observation). Conditions for navigating informal value thresholds included the prevalent belief that formulary decisions should be made on the basis of value rather than cost containment: “We are not unwilling to accept very expensive medications if they offer up firm and clear clinical advantage” (Physician - Interview). This was problematic given the difficulty determining a drug’s therapeutic advantage that has been previously described. A structural-oriented condition
for navigating informal value thresholds was the fact that neither IHA nor FHA had institutionalized thresholds against which drugs could be evaluated.

The overall process of trying to maximize the value for resources allocated resulted in regional P&T committees generating initial value assessments of the drug therapies under review. Yet the consequences of these initial value assessments were complex, since they could be revised based upon other conceptual processes that occurred during formulary priority-setting. For example, the decision to pay for Lantus™ for those patients who were started on it in the community highlights the way in which considering the merits of a chronic care drug therapy in the context of patients transitioning between community and institutional settings (i.e. the process labelled “Interfacing”) could make a drug’s initial value assessment more favourable:

“We don’t want to start patients up front on it because the cost is so high compared to its incremental benefits over other insulin...but we are coming up against it a fair bit and not wanting to introduce another variable into the patient’s treatment course by changing drugs.”

(Pharmacist - Interview)

Similarly, the process of situating decisions within the context of the regional health authority organization could also revise initial value assessments. For example, the value offered by the drug TNKase™ was reduced from the perspectives of some committee members in both FHA and IHA who perceived that the aetiology of the health problem, when considered amongst the full scope of service provision within the health authority, could be better rectified by investing in a non drug-related therapy. This thought process was demonstrated by some comments that were made during a FHA regional P&T meeting:

“I thought, you know, if we’re prepared to throw that kind of money at it then why aren’t we looking at improving our centers of primary intervention [angioplasty]?...I’m not sure if I’m prepared to endorse half a million or a million bucks more in our P&T budget that could be used...for that.”

(Physician - Observation)
Although many committee members agreed with this rationalization, TNKase™ was added in both health authorities since making decisions about angioplasty facilities was beyond committee jurisdiction.

4.4.2.3 Interfacing

The third conceptual process reflects the ways in which regional P&T committees considered the formulary merits of a chronic care drug therapy in the context of patients transitioning between community and institutional settings. It comprised two sub-processes that were inter-related yet characterized by different rationales and consequences: i) Minimizing financial barriers to drug access; and ii) Providing seamless care. Both activities could be performed when reviewing drugs for formulary addition and developing auto-substitution policies.

The process of interfacing was conditional upon the agent under consideration being a chronic care drug which, by definition, could be used in the community setting. Patient transitions between community and institutional settings were significant by virtue of a drug policy climate in British Columbia which fragmented responsibility for covering drug therapy on the basis of treatment setting. Regional health authorities paid for inpatients in healthcare facilities whereas payment in the community could rest with Pharmacare, private drug benefit plans, and/or patient out-of-pocket payments.

4.4.2.3.1 Minimizing Financial Barriers to Drug Access

One type of interfacing activity involved regional P&T committees aligning the regional formulary with the Pharmacare formulary for the purposes of reducing the potential financial barriers that patients could face, following their discharge, to continuing drug therapy which was initiated while they were inpatients. The primary condition for doing so was a belief about patients’ responses to out-of-pocket drug payments and their subsequent effects on compliance:
"...They come in say with a heart attack and they get better and they leave and they're going to be put on say an ACE-inhibitor. You'd better choose the one if they're 70 years old, you'd better choose the one that is being paid for by Pharmacare. 'Cause if you chose another one this patient may not take it. They'll go in and they'll say, 'well it's $100!'"" (Physician - Interview)

The importance of minimizing financial barriers to patients being able to access drugs in the community setting was observed during committee meetings and consistently noted within interview narratives.

4.4.2.3.2 Providing Seamless Care

A second type of interfacing activity involved regional P&T committees aligning the formulary with prescribing patterns in the community for the purposes of avoiding disruptions to drug therapy caused by institutionalization. A typical construction of seamless care was as follows: "...Ideally what we like to think is the seamless care where he's [the patient] on say 5 medications, comes into hospital, continues those 5 medications, leaves the hospital on those 5 medications" (Physician - Interview). This equated to aligning with a Pharmacare decision outright, since benefit coverage was perceived to drive community prescribing patterns, or aligning with the most frequently prescribed medication(s) within a therapeutic class covered by the Pharmacare formulary. Conversely, when a drug did not possess Pharmacare status, this equated to aligning with general impressions of community prescribing trends.

Motivations for providing seamless care were constructed in the context of the available alternatives which included switching patient drug therapy using an auto-substitution policy, or permitting patients to bring in their own drugs from home. These motivations were derived from two belief-oriented conditions. Providing seamless care was believed to avoid both unnecessary harm to patients, and staffing workload burdens.

Participants believed that auto-substituting community drug therapy for a patient who was admitted for an unrelated health condition occasionally posed unnecessary risks of physical and/or psychological harm. These beliefs were advanced on the bases of clinical experience and
rational thinking rather than evidence found within the scientific literature. The degree of physical harm anticipated was affected by the perceived difficulty in stabilizing a health condition with drug therapy; for example, discussions about the potential for detrimental physical ramifications were observed in the cases of drugs used to treat diabetes (Lantus™), asthma or chronic obstructive pulmonary disease (Advair™/ Symbicort™, Spiriva®).

Psychological harm was attributed to stress induced by exceeding patients’ capacity to absorb new information or failing to accommodate their ideas about the effectiveness of particular drugs. Interview participants reflected that minimizing this latter type of harm is often the primary motivation for providing seamless care: “Well in this one[Lantus decision] it’s [physical implications are] probably minimal, it’s probably more the patient’s perception of it but potentially they could be either over- or under-controlled for their diabetes when they switch…” (Pharmacist - Interview). Harm could also arise when administering patients’ own medications if they were mislabelled or previously stored inappropriately, although this concern was lessened for inhaler-delivered medications. The belief that patients’ own inhaler-delivered medications posed less risk of harm contributed to the IHA committee’s decision not to fund Spiriva® in order to allow patients to continue community-initiated therapy but rather to encourage patients to provide their own inhalers upon admission to an IHA healthcare facility.

When a drug was widely used in the community, providing seamless care was also able to minimize workload demands on already short-staffed pharmacy departments in two ways. First, pharmacists could avoid the need to assess medications brought from patients’ homes for safety. Second, drug therapy would not need to be switched when patients were admitted and switched back when they were discharged. Participants in both health authorities recounted anecdotes in which staffing levels that were insufficient for reviewing prescriptions upon discharge led to toxicity for patients:
"But in the past there have been situations where patients will get the hospital drug [upon discharge], go home and not realize that the one they have at home is just an alternative for the one that they've been taking in hospital, so they'll take both. It doesn't happen a lot but even the potential for that to happen is something that we don't want to get near."

(Pharmacist - Interview)

Dissenting views about the legitimacy of such rationales were rare.

The consequences of providing a seamless approach to patient drug therapy reflected interrelationships with other processes within the conceptual model. First, providing seamless care occasionally led to a sense of conceding to compromise. Some participants perceived that the process of aligning with Pharmacare or impressions of community prescribing patterns was upheld at the expense of adding drugs that did not demonstrate a sufficiently favourable therapeutic advantage and/or value for resources allocated on the basis of their intrinsic merits:

“One agent [ACE-inhibitor with Pharmacare status] was chosen just because it's a frequently prescribed agent, so there was I guess a concession that even if the science behind it isn’t all that strong, it’s a drug that a lot of patients will end up being on anyway” (Physician - Interview).

This reactive strategy was viewed to permit costly and somewhat illegitimate additions, particularly by those participants who suspected that the pharmaceutical industry significantly influences prescribing patterns in the community for drugs without Pharmacare benefit status.

Second, maintaining a seamless approach to patient drug therapy for those drugs that were not listed on the Pharmacare formulary was by necessity done at the expense of introducing, or at the very least maintaining, financial barriers to patients being able to access these drugs in the community setting. Therefore, a strong rationale for engaging in one type of interfacing activity (i.e. providing seamless care) when drugs were not covered by Pharmacare became a condition for not engaging in the other activity (i.e. minimizing financial barriers to drug access). Concern about the consequences of this inter-relationship was expressed during P&T committee meetings. In the case of Advair™/ Symbicort™, neither of which were a Pharmacare benefit and both of which were relatively expensive but were to be added to the regional formulary, a
strategy was advanced to alleviate financial-related compliance concerns following patient discharge which involved distributing free medication samples from a regional asthma clinic:

"Yeah that's [non-compliance] a huge – particularly in the community around here too. It's a massive issue and hence, asthma clinics – Surrey this is a plug – um one of our mandates is to give out medication so if that's an issue for your patients then definitely send them on to the asthma clinic 'cause we're in a good relationship with the drug companies."

(Physician - Observation)

The overall consequence of considering the formulary merits of chronic drug therapies in the context of patients transitioning between institutional and community settings was, however, the revision of initial value assessments. Moreover, both types of interfacing activities positioned regional P&T committees as being both reactive and generative agents with regards to community prescribing patterns.

4.4.2.4 Situating Within an Organizational Context

The final conceptual process within the model reflects the processes by which regional P&T committees integrated considerations of inpatient applicability, the anticipated political fall-out, and the congruency of decisions with resources available within the institutional network managed by the regional health authority, into drug formulary decisions. Each of these sub-themes will be elaborated upon within subsequent sections.

4.4.2.4.1 Identifying Inpatient Applicability

The primary concept underlying the process of identifying inpatient applicability was that a formulary should include only those drugs that will be administered on a regular basis, where 'regular' constituted an undefined frequency. Committees drew upon various types of information to make this assessment: historical prescribing trends for similar agents, disease-specific admission rates and lengths of stay, community prescribing patterns, and the therapeutic advantage of new starts in an acute care setting. When chronic care agents were being discussed, it became more difficult to identify the applicability of a particular drug therapy to inpatient care
since distinctions could be made between continuing home therapy and commencing therapy. For example, the inpatient applicability of combination products Advair™ and Symbicort™ was initially ranked lower on the grounds that patients admitted with asthma-related problems would be first titrated on individual drug components. Yet this estimate of inpatient applicability was re-evaluated upwards based upon perceived trends in length of stay which would increase the likelihood of new starts:

"You seem to imply that acute care means short stay. And that, you know, nobody would get started on a combination. Well, our acute care beds are filled with patients who are there for months sometimes so you know I think that you could easily have a patient who came in with an acute episode of something and got into the system and couldn't get out of the system and was still in acute care and requiring something like this."

(Nurse - Observation)

The process of identifying inpatient applicability ultimately shaped which policy options were favoured by regional P&T committees by contributing to the perceived feasibility of imposing formulary restrictions. For example, this phenomenon manifested in the context of discussion about the drugs Advair™ and Symbicort™:

"To actually make the calls, check Pharmanet, you know if we're gonna not advocate new starts as option number two suggests then I think reality is that really gonna happen? For how common a medication that is? For other situations where we don't advocate new starts at least the products don't come along very often but in this situation, realistically, I don't think we have the manpower right now to deal with policing that."

(Pharmacist - Observation)

The prevalence of community use of these drugs in conjunction with insufficient pharmacy staff for monitoring adherence to formulary restrictions led participants to perceive that restricting use to only continuations of home therapy was infeasible.

4.4.2.4.2 Political Fall-Out

Regional P&T committees were faced with political pressure from individual clinicians or clinical practice groups within the regional health authority when prioritizing and reviewing drug addition requests. Participants described the actions of such groups using emotionally-
charged phrases such as “rattling the cage”, “all up in arms”, and “who’s making the most noise”. The basic structure of the drug addition request process, and a hospital culture of territoriality, contributed to such lobbying activities. Clinicians were dependent upon an authoritative body (the regional P&T committee) to have their patients’ needs met, at the expense of others’ needs, from a finite amount of resources. Moreover, hospital culture was described by participants from both health authorities as one of territoriality, in which clinical departments fought to protect their respective domains often without positioning decisions in the broader context of patient care.

Several specific conditions were identified as affecting the degree to which political pressure was influential, one of which included the location of medical specialty groups along a spectrum of power. Cardiologists and anaesthetists were structurally advantaged to exert more political pressure compared with diabetologists, for example, because they had larger and more highly networked memberships. In the case of anaesthetists, they were also essential to the provision of many emergency healthcare services (i.e. surgical-related). This contributed to occasionally revising the initial value assessment of a drug in favour of formulary addition for the purposes of diplomacy:

“Well I think maybe that was an example where we were a little bit railroaded. I think the anaesthesia department is a very powerful department and basically if they shut down, the hospital shuts down. Not that they had threatened that and not that they would've done that but there was certainly a sense that there was going to be a backlash from this. And there comes a point where you have to sort of I think back away and say you know, ‘better not to have disharmony in the hospital over something like this.’”

(Physician - Interview)

Other participants noted that in instances where there was limited scientific evidence about a drug’s therapeutic advantage or the drug offered a marginal therapeutic advantage, the regional P&T committee was left with particularly little to leverage against political pressure at the review stage.
At the stage of prioritizing drug addition requests for review, a different structural condition affected the degree to which political pressure was influential. In the absence of a formalized process which detailed when exceptions to a ‘first-come, first-serve’ priority-setting approach could be made, committee members reported difficulty in resisting political pressure. The consequence was that drugs which were strongly advocated for, such as TNKase™, could get advanced ahead of others on the list for review by the committee:

"And to be honest, other times when we stray...like this TNK thing, we have a thrombolytic on formulary, some people on the executive felt as though you know we don't really have a written process to explain why we pick certain drugs ahead in the list compared to others and there's a lot of push from cardiology to get this going and it's a big political mess, so let's just do it and get rid of it 'cause it's not going away."

(Pharmacist - Interview)

Participants noted that committee concessions to political pressure set a “terrible precedent” by encouraging groups to engage in similar actions in the future. This was of particular concern when participants believed that drug industry marketing activities targeting physicians had created the demand that motivated exacting political pressure. Implications for fairness to drug requestors from medical specialties with lesser lobbying capacity were, interestingly, not mentioned.

4.4.2.4.3 Congruency with Resources

A particularly challenging part of formulary priority-setting in the regional health authorities that were studied was assessing the congruency of a decision with the institutional resources that were available. Fit with drug distribution systems, the drug budget, variations in staffing, equipment and service provision across sites, the need for educating medical staff, impact upon length of stay and re-admission rates, and demands associated with administering the drug and/or enforcing restrictions could be considered. Interview participants articulated that the relevance of particular resource concerns was case-specific and that they were “lower down on the list in terms of importance”. With the exception of budget impact projections, resource
considerations were not structurally incorporated into the written formulary reviews in either IHA or FHA but rather raised by individual committee members during regional P&T meetings.

In light of the range of institutional resources for which the congruency of a formulary decision was examined, the consequences of this process were varied. The typical consequence, however, was to effectively revise the initial value assessment with regards to how a drug therapy should be added (i.e. without restrictions, with restrictions and what type, replacing another formulary agent). For example, inability to package the wafer formulation of Risperdal M-Tab™ into unit doses using existing drug distribution mechanisms led the FHA committee to add the drug to formulary but not use it to replace the comparable pill formulation:

"If you were to take them and put them in these pouches – because these pouches are sealed with heat – they would crumble and dissolve...so my concern was if we got rid of all the other tablets and just replaced it with the wafer, we would have big problems on our hands packaging this stuff. So we should only reserve the wafer for the individual patients that really need it. And so the use then would be smaller versus a mass change because we use the tablets quite a bit. So people were saying, ‘well, since it’s cheaper, why don’t we make the big change?’ Well there’s other practical implications of that...”

(Pharmacist - Interview)

Occasionally, poor fit with health authority resources could contribute to a rationale for declining a drug request but was generally understood as an unacceptable rationale in isolation.

Drugs were also added but restricted to certain clinical settings and practitioners in order to maximize patient safety when drug administration and storage was complex, as well as to contain costs. Cost containment emerged as salient when the projected cost of a drug therapy was anticipated to have a significant impact upon the drug budget; this was of particular concern since participants had observed the costs of drugs to surpass initial projections over time due to “indication creep,” which involved clinicians writing prescriptions for indications in addition to those that had been approved. From a regional perspective, ensuring that such restrictions accommodated inter-site variations in resources was difficult:

"So, we could implement a policy here in a big hospital that says, ‘this drug can only be ordered by an infectious disease doctor,’ or, ‘this drug can only be ordered by a
cardiologist,' or, 'this drug can only be ordered by an endocrinologist.' But, when you go to a small hospital, they have none of the above...so how do you write a policy that covers that?"

(Nate, Pharmacist)

Insufficient staffing levels in pharmacy contributed to removing or lessening the stringency of restrictions that had been suggested based upon the initial value assessment, particularly when inpatient applicability was estimated to be relatively high.

The conceptual process of situating decisions within an organizational context was the last stage involved in drug formulary priority-setting. It typically served to guide regional P&T committees regarding how, rather than whether, to add a drug to the regional formulary.

4.5 Summary

This chapter began with a description of the data that were collected for the present study, the FHA and IHA regional P&T committees that participated, and the chronological steps of the key formulary priority-setting activities in which they engaged (i.e. developing auto-substitution policies; and reviewing new drug addition requests). The interpretive landscape or cultural context, against which the conceptual model would be interpreted, was then highlighted. Challenges for committee members in being involved with regional P&T activities while maintaining commitment to direct patient care, intra-committee dynamics between pharmacists and other clinicians, positioning against the pharmaceutical industry, and referring to decisions made by others all emerged as important within this landscape.

Finally, a conceptual model of drug formulary priority-setting was presented which directly addressed the study’s research questions. This model encompassed four inter-related processes that regional P&T committees engaged in for the purposes of making formulary decisions. The first process involved using the scientific literature and practitioner clinical experience in order to determine a drug’s therapeutic merit relative to existing formulary agents ("Negotiating the Margins of Therapeutic Advantage"). The second process involved trying to
maximize a drug's value by negotiating prices with pharmaceutical companies, and informally establishing thresholds with which to evaluate this value ("Seeking Value for Resources Allocated"). The third process involved considering the therapeutic merits and organizational efficiencies offered by a drug therapy in the context of patients transitioning between community and institutional settings ("Interfacing"). The fourth process involved anticipating a drug's applicability to inpatient populations, the political fall-out from making a particular formulary decision, and how well a formulary decision would fit with the resources available within the regional health authority ("Situating Within an Organizational Context").
5.0 DISCUSSION

5.1 Overview of the Chapter

The present study generated descriptions of two regional P&T committees in British Columbia, as well as an overview of the drug formulary priority-setting activities that they engaged in (i.e. developing auto-substitution policies and making decisions about reviewed drug addition requests). Important themes related to the cultural context in which P&T committees operated were identified as part of an interpretive landscape. These themes encompassed the ways in which committee members balanced their P&T and patient care responsibilities, intra-committee dynamics between pharmacists and other clinical representatives, the defensive approaches taken to restrict pharmaceutical industry involvement, and the ways in which decisions made by others (for example, other health regions, disease management organizations, medical specialty groups) were incorporated into decision-making.

A theoretical framework was then advanced which integrated the main conceptual stages through which regional P&T committees passed in order to make formulary decisions. Four conceptual stages were identified: a) Determining a drug’s therapeutic merit relative to existing formulary agents using scientific evidence and practitioner clinical experience; b) Assessing a drug’s relative value by juxtaposing its relative therapeutic merit against its relative incremental cost to the organization; c) Considering the implications of a formulary decision upon patients transitioning between community and institutional settings; and d) Anticipating the applicability of a drug to inpatient populations, as well as the political fall-out and feasibility of decisions given resources available within the regional health authority.

This study contributes to scientific knowledge about drug formulary priority-setting in several ways. First, it explores an organizational level that has been previously under-explored (i.e. regional health authorities) relative to other organizational levels, such as provinces and individual healthcare facilities. Second, it is one of only two qualitative studies in this
substantive area to use grounded theory methods in an attempt to construct a well-integrated theoretical framework explaining how formulary decisions are made. Third, its use of observational techniques to supplement interviewing and document review facilitated obtaining a more thorough understanding of the political and social cultures in which regional P&T committees were embedded.

Discussion about these results is organized into four sections. First, the findings from this grounded theory study are juxtaposed against the existing literature related to priority-setting in healthcare, particularly that pertaining to drug formularies, as well as the 3-I analytic framework. Both similarities and inconsistencies are highlighted. Second, recommendations for healthcare policy are proposed in order to translate the knowledge obtained from the study into operational take-home messages for consideration by decision-makers. Third, the major methodological strengths and limitations of the study design are reflected upon for the purpose of facilitating more informed interpretation of study findings. Fourth, ideas about further research are advanced which draw upon the study’s substantive and methodological contributions, as well as persisting gaps in understanding.

5.2 Situating Results Within Existing Knowledge

Study findings are first interpreted in the context of the literature about priority-setting in healthcare in general. They are then interpreted specifically with regards to priority-setting for drug formularies. Finally, study results are situated in the context of the 3-I analytic framework that was used to inform development of the initial interview guide.

5.2.1 Priority-Setting in Healthcare

The importance of organizational context to priority-setting has emerged not only in the present study, but also through other investigations that have studied priority-setting in regional

* A detailed comparison and contrast of the practices of the FHA and IHA regional P&T committees is not included in this discussion due to insufficient data for this purpose. Differences and similarities that did emerge are, however, noted in the Results chapter.
health authorities with regards to various types of clinical services. For example, major organizational factors that acted as barriers to explicit priority-setting in the present study that have been described elsewhere include: politics (i.e. distrust, territoriality) amongst decision-makers as well as with staff and healthcare professionals working within the larger health region (110); an abundance of other demands upon decision-makers’ time (for example, direct patient care); and insufficient knowledge about critical appraisal(51, 111). Moreover, the importance of leadership, which in the present study involved the committee Executives in IHA and FHA advocating for a priority-setting approach involving rigorous evaluation of claims and acknowledging the inevitable opportunity cost of decisions, has been described by other researchers as facilitating explicit priority-setting(51). These findings together support the statement made by Mitton and Donaldson(111) that “an understanding of the ‘antecedent conditions’ which exist in a given health organization must be obtained and used to strategically plan whether the time and setting are most receptive to explicit priority setting activity”.

In addition, the release of resources to fund new initiatives is an activity that is integral to priority-setting. In healthcare, the release of resources involves seeking operational efficiency gains or service reductions in one or more areas of patient care in order to free up resources for re-allocation to meet the needs of more highly prioritized areas of patient care(27, 51). In the present study, neither FHA nor IHA regional P&T committees appeared to use formulary deletions as a way to release resources from the drug budget in order to fund other drugs. Reasons reported for deleting medications, in fact, often would have limited capacity for curbing expenditures (for example, discontinued by manufacturer, minimal usage). Even the effectiveness of restriction policies, which were occasionally implemented for the purposes of containing costs, was viewed with scepticism due to lack of buy-in from physicians and inadequate pharmacy staffing levels for meaningfully enforcing such policies. These findings confirm findings in other contexts that decision-makers are often less proficient at identifying
resource releases than evaluating service growth options (112). Moreover, the reluctance of committee members to challenge internal experts when considering drugs that fell beyond the purview of their specialty in the present study is analogous to the findings of other researchers that insufficient knowledge about program areas other than their own is often cited as a barrier to identifying potential resource releases (110). Attention is required to develop strategies which would assist decision-makers engaged in priority-setting for new medical technologies (for example, drugs and devices) in particular with releasing resources since these technologies often occupy highly narrow niches.

Regional P&T committee members drew upon a wide range of types of information during drug formulary decision-making. This finding highlights that the concept of a “mixed economy” of evidence was applicable to the decision-making context of the present study, and that decisions are informed by, but not necessarily based upon, scientific evidence (29, 38, 40, 41, 50, 113). Types of evidence included: scientific literature; clinical anecdotes; regional trends in hospital admission and drug utilization; budget data; formularies in other jurisdictions; previous decisions; contracts with pharmaceutical companies; stakeholder input; and the practice environment for front-line healthcare personnel. Moreover, study findings indicate that it is too simplistic to assume that evidence from the scientific literature is always in direct competition with other information sources for predominance within the priority-setting process. Although in the present study clinical experience and stakeholder views about the benefits of a drug therapy occasionally contradicted what was suggested by the scientific literature, many considerations relevant to the organizational context (for example, assessing contracts offered by pharmaceutical companies) could not plausibly be addressed by the scientific literature.

5.2.2 Drug Formulary Priority-Setting

In addition to confirming some findings generated by previous studies, the present study makes several new contributions to the drug formulary priority-setting literature. The six most
significant new contributions will be discussed in detail in the subsequent section. Following that, a sample of confirmatory findings derived from the present study is highlighted.

5.2.2.1 New Contributions

First, the present study provides an integrated theoretical framework for understanding how P&T committees make formulary decisions, and is the first to reflect the experiences of regional health authorities. Second, this study highlights the rationales for why patient movement between communities and institutions is important when setting formulary priorities. Third, the present study identifies the situation of resource variation across healthcare facilities within a regional health authority as a particular policy challenge for regional P&T committees. Fourth, this study provides new insight into the P&T culture with regards to relationships between the pharmacy and medical professions. Fifth, the present study contributes a more detailed description of the agenda-setting practices used by P&T committees from which a critical commentary can be advanced. Finally, this study identifies two contexts in which issues of harm are considered during drug formulary priority-setting. These six contributions are summarized in Table 5.1.

Table 5.1: New contributions made to the drug formulary priority-setting literature.

<table>
<thead>
<tr>
<th>Previous knowledge</th>
<th>Contributions</th>
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<tr>
<td>• Conceptual models that:</td>
<td>• Conceptual model that:</td>
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<td>- organize decision-making factors</td>
<td>- develops theory</td>
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<td>- draw upon experiences of provincial disease management organizations, and a provincial public drug benefit plan</td>
<td>- draws upon experiences of regional health authorities</td>
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<td>• Seamless care is hypothesized to account for decision-makers aligning hospital formularies in British Columbia with the provincial formulary and community prescribing patterns</td>
<td>• Seamless care is reported to be motivation for aligning regional formularies with the provincial formulary and/or community prescribing patterns</td>
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<td>• Resource levels affect the feasibility of imposing formulary restrictions within</td>
<td>• Varying resource levels across regional facilities affect the feasibility of imposing</td>
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<tr>
<td>• Limited description about dynamics within P&amp;T committees</td>
<td>• Pharmacy responsibility for managing the drug budget led to tensions between pharmacists and other committee members</td>
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<td>• Absence of a description of agenda-setting practices</td>
<td>• Description of informal, ‘first-come, first-serve’ approaches to agenda-setting</td>
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<td>• Issues of benefit are considered to a greater extent than issues of harm</td>
<td>• Varying attention to issues of harm</td>
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<td>- Minimal when considering adverse events found within the scientific literature</td>
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<td>- Greater when considering physical and psychological harm in the context of interfacing activities</td>
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5.2.2.1.1 A Process-Driven Model

First, this grounded theory study offers an explanatory scheme that moves beyond simply classifying decision-making factors into substantive categories, as previous models(60, 75) have done, towards depicting active processes. For example, Singer and colleagues’(75) conceptual model of drug formulary priority-setting would suggest that institution-related factors be grouped together under the category entitled “Institutions.” In this study, however, institutional arrangements such as those between the regional P&T committees and health authority Executives, and federal policies such as the Canada Health Act(5) are woven throughout the model to highlight their influence upon higher-level processes that committee members engage in such as those labelled as “Seeking Value for Resources Allocated” and “Interfacing,” respectively. Constructing a more abstract and integrated representation of what regional P&T committees do lends greater explanatory power to a conceptual model than a loosely networked set of individual decision-making factors. Moreover, the present study contributes the first conceptual model of drug formulary priority-setting that is based upon the experiences of regional health authorities.
5.2.2.1.2 Considering Drugs in a Dynamic Context

For chronic care drug therapies, regional P&T committees assess formulary merit not only within a static context (i.e. within an institution) but also in a dynamic context whereby individuals transition between community and institutional settings. The conceptual process labelled “Providing Seamless Care,” which involves minimizing medically unnecessary disruptions to patient drug therapy caused by institutionalization, constitutes a second important contribution to the literature about drug formulary priority-setting. Studies about medication-related seamless care can be found within the pharmacy literature; these studies survey and assess the services provided by hospital pharmacies to facilitate patient drug safety upon discharge (114-116). Within the drug formulary priority-setting literature, the concept of seamless care has been hypothesized to account for the findings of Gill and colleagues (76), which were collected prior to the most recent round of regionalization of healthcare services in British Columbia: “The rationale for the listing of referenced drugs [drugs funded by the provincial government-subsidized drug benefit plan] on hospital formularies may be the promotion of seamless care initiatives by providing the same agents within the community and hospital.”

The present study adds to understanding about seamless care by identifying therapeutic concerns about imposing harm (physical toxicity, psychological stress) upon patients and staffing resource constraints associated with alternatives (i.e. auto-substitutions or patient’s own medications) as underlying rationales. That regional P&T committees heavily weigh both the potential physical and psychological effects upon patients of their formulary decisions reflects their dedication to providing holistic patient care. Since the scientific literature is unlikely to provide insight into, for example, the psychological stress experienced by patients related to switching types of insulin, this finding also highlights another arena in which drawing upon clinical experience is required.
Given that considerations of seamless care were observed to occasionally make more acceptable initial assessments of value, and outweigh the negative consequences of introducing financial barriers to patient drug access upon discharge into the community setting, further investigation into the ways in which ideas about seamless care affect formulary decision-making, including resulting consequences, is needed.

5.2.2.1.3 Coping with Intra-Regional Resource Variations

Similarly, the conceptual process of situating formulary decisions within the context of the regional health authority organization, specifically the ways in which resource constraints can shape the formulary options selected by a regional P&T committee, also constitutes an important contribution. Akin to the present study, other investigations have identified types of drug costs beyond those that are initially acquisition-related which may shift decision-makers towards imposing restrictions upon a formulary decision. Examples include the potential for indication creep or "leakage" (57, 67) and the ability of nurses or medical attendants to administer the drug (58). What the present study adds, however, is a recognition of the unique difficulty faced by P&T committees making decisions for regional health authorities (i.e. rather than individual hospitals or drug benefit plans): developing global restriction policies which account for variations in resources across regional healthcare facilities. This finding suggests that differences in the composition and distribution of staff (i.e. number and expertise) and medical technologies across institutions throughout regional healthcare organizations may translate into variations between regional formulary lists.

5.2.2.1.4 Professional Tensions: Pharmacy and Medicine

Professional tensions between pharmacists and other clinical committee members (i.e. physicians and nurses) on the issue of the importance attributed to costs during formulary decision-making were described within one thematic element of the interpretive landscape labelled "Gatekeepers of the Drug Budget". For many clinicians, this tension contributed to
distrust in the pharmacy-led process; the comprehensiveness of the review of the scientific literature, and its subsequent interpretation, were particularly suspect. This has not been previously described in the drug formulary priority-setting literature. A survey of staff physicians about attitudes towards formularies and pharmacist services conducted by Sansgiry and colleagues(117) reported high satisfaction with interactions with pharmacists even when satisfaction with formularies was poor. However, the response rate to the survey was low (32%) and a comparison of respondents to non-respondents is not documented in order to assess the degree of response bias. Given the detrimental consequences that this social dimension of P&T culture exerted upon some clinical committee members' trust in the written formulary review work performed by pharmacists in the present study, the capacity for these professional tensions to mediate the use of scientific evidence merits further exploration.

5.2.2.1.5 Agenda-Setting Practices

The present study also contributes a more detailed description of the process of agenda-setting with regards to drug formulary priority-setting within healthcare institutions than is currently available within the peer-reviewed literature. That is, how regional P&T committees prioritize submitted drug addition requests for evaluation by the committee. Agenda-setting, which is the rate-limiting step in the drug addition process, is significant because decisions about which drugs will be evaluated have direct implications upon the likelihood of a drug getting funded at the expense of others(118). Singer and colleagues(30) note that formulary decision-makers belonging to disease management organizations in Ontario identify transparent and accessible agenda-setting as integral to a fair process. McMahon and colleagues(119) note that the Common Drug Review (CDR) makes agenda-setting decisions about new chemical entities based upon their capacity to benefit patients or the healthcare system but do not provide further detail(119).
However, a procedural document reports in detail the agenda-setting processes followed by the CDR(10). Submissions to the CDR are prioritized on the CEDAC agenda in the following order: (re)submissions assigned a priority review status; requests for reconsideration; submissions for new drugs or combinations; drug-related reviews; requests for advice; and resubmissions. Priority status is assigned in two instances: i) "a new drug that is effective for the treatment of an immediately life-threatening disease or other serious disease for which no comparable drug is marketed in Canada;" or ii) "a new drug that will have a significant impact in reducing the drug expenditures of the [provincial] drug plans...total combined annual savings to the CDR drug plans must be projected to be at least $2.5 million dollars."

Neither FHA nor IHA possessed explicit agenda-setting procedures to guide the way in which submitted drug requests should be ordered on the regional P&T agenda or what criteria should be fulfilled in order for a request to attain priority status. These findings raise concerns about the degree to which current agenda-setting processes are fair: a) absence of a formal process for prioritizing drug addition request submissions makes it difficult to be transparent to requestors; and b) making exceptions to the ‘first-come, first-serve’ approach on the basis of political pressure may systematically advantage drugs that fall under the domain of medical specialties that are larger and more highly networked.

5.2.2.1.6 Harm Takes a Backseat?

Finally, the present study deepens current understanding about the ways in which issues of harm are considered during drug formulary priority-setting. Similar to the findings of many other studies, committee members reported clinical evidence of efficacy, effectiveness and safety as the principal consideration during decision-making(11, 56-60, 63, 75). Yet akin to what was observed by Singer and colleagues(75), issues of benefit (i.e. efficacy, effectiveness) had a greater role during discussions about the scientific literature than issues of harm (i.e. adverse events). In part, this phenomenon reflected the absence of adverse drug event data; the
problems of under-reporting and poor quality reporting of adverse drug events in randomized controlled trials have been described elsewhere (120). It also reflected a decision-making culture whereby fears of withholding an effective treatment from patients outweighed fears of harming patients.

Yet concerns about imposing physical and psychological harm upon patients factored prominently into rationales for engaging in the interfacing activities that have been described. Therefore, the present study highlights that issues of harm are considered by regional health authority P&T committees in two contexts: i) the administration of a drug; and ii) switching drug therapy. Future investigations may seek to further explore why issues of harm appear to be differentially considered across these two contexts and how they can be more systematically integrated into decision-making.

5.2.2.2 Confirmatory Findings

Elements of the background description generated in the present study confirm structural characteristics of P&T committees that have been described elsewhere such as physician-dominated committee membership (58, 60), pharmacy departmental responsibility for managing the drug budget (23) and conducting evidence-based reviews (23), and the wide scope of committee mandates (24).

Findings from the present study which illustrate some of the ways in which regional P&T committees interact with others (for example, other decision-making groups and clinicians practising within the region) also reflect the results of previous investigations. For example, that evaluations of applicability and credibility influence the acceptance of formulary decisions or recommendations made by other jurisdictions (typically hospitals) has been reported by studies conducted in the United Kingdom (57) and British Columbia (63). As another example, the importance of maintaining relationships with clinicians by occasionally adding a drug to formulary without an abundance of adequate scientific support is analogous to that described by
Wirtz and colleagues(73), which involved making trade-offs with regards to cost containment. The present study goes further, however, to identify the types of clinicians with whom relationships may be more likely to be maintained on the basis of organizational characteristics (i.e. department size, degree of inter- and intra-regional networking).

Regional P&T committee interactions with the pharmaceutical industry, in particular, also reflect previous research. First, the perception on the part of interview participants that regional health authorities serving larger patient populations have greater volume purchasing power has been hypothesized, though not proven, by researchers studying health maintenance organization formularies in the United States(23). Second, the ways in which committees treated clinical guidelines with scepticism is consistent with recent findings which reveal that 70% of panels generating drug guidelines are composed of experts receiving financial benefits from the pharmaceutical company manufacturing the drug under review(121). Further, that the committee in FHA reportedly adopted a policy to exclude committee members declaring an industry-derived conflict of interest from associated discussions and voting at meetings is akin to the more stringent approaches to author conflicts of interest that have been adopted by various medical journals(122). The IHA committee, which did not yet utilize the conflict of interest information that was gathered, will be more susceptible to industry influence until it adopts a similar policy.

In summary, the present study about drug formulary priority-setting within regional health authorities as performed by regional P&T committees has generated a more integrated conceptualization of the processes which are used to make formulary listing decisions. It has also better defined the boundaries of the capacity for recommendations advanced by review agencies (i.e. CEDAC, Therapeutic Initiative), which are primarily based upon clinical and economic evidence, to influence more local processes. The impact of such recommendations is limited since they do not account for additional considerations (for example, related to
interfacing activities and price-brokering with industry) that regional P&T committees view as having a legitimate place within the "mixed economy" of evidence upon which they draw. However, the recommendations advanced by CEDAC and the Therapeutics Initiative could factor more prominently into regional P&T committee assessments of therapeutic advantage and value since members belonging to these review panels often have more expertise in, and time to devote to, critical appraisal of the scientific evidence.

In a later section, policy recommendations for institutional P&T committee decision-makers with regards to several of the contributions that have been described are put forward.

5.2.3 The 3-I Analytic Framework

In the present study, concepts from the 3-I analytic framework were used to inform development of the initial interview guide in order to elicit participants' understandings of the ways in which institutions, interests and ideas manifested in the context of drug formulary priority-setting. The intent was not to apply the framework directly to data collection or analysis. Many of the specific variables outlined within the framework may not have emerged from the data collected because they were less relevant to the decision-making context being studied. For example, decisions made within regional health authorities are farther removed from the arena of elected officials than those made within the provincial Ministry of Health Services, whose activities are immediately overseen by an elected official (i.e. the Minister of Health).

Upon reflection, some concepts represented by the variables encompassed by the 3-I analytic framework did emerge, however, in analogous ways. For example, previous formulary decisions set precedents for future decisions since regional P&T committees sought fairness through consistency; this is akin to the role described for past policies by Pierson (80). Additionally, medical specialty groups, disease management groups, and pharmaceutical companies emerged as actors seeking to influence regional formulary listing decisions. The
group characteristics identified by interview participants as mediating their lobbying capacity (i.e. membership size, tightness of network) are similar to those advanced by Pross(83) affecting the degree to which societal interest groups are able to influence public policy. It was clear that some ideas, such as cost and therapeutic advantage, had been formally institutionalized(84) through incorporation into terms of reference documents and written formulary reviews whereas others had not (for example, interfacing activities and congruency of decisions with non-monetary resources).

These findings suggest that many concepts of the 3-I analytic framework are relevant to the domain of pharmaceutical policy. Direct application of the 3-I analytic framework to data analysis may be advantageous for qualitative case study investigations explicitly seeking to organize decision-making factors contributing to specific formulary decisions along substantive lines. However, applying the framework directly within investigations similar to the present one, which seek to identify abstract conceptual processes that occur across various formulary decision rationales, may be less appropriate than more process-driven approaches to data analysis (i.e. grounded theory).

5.3 Policy Recommendations

Although the purpose of the present study was not evaluative, what has been learned confers several implications for healthcare priority-setting in the context of drug formularies and other dimensions of patient care. These implications, along with possible modes of action where applicable, are outlined in Figure 5.1.

Figure 5.1: Policy recommendations for institutional P&T committee decision-makers.

- Situate drugs under review in the context of therapeutically similar formulary agents as well as other requests awaiting review
- Formalize agenda-setting process and publish procedures
- Improve the information base of regional P&T committees
First, the experiences of the two regional health authorities studied highlight some of the difficulties encountered when attempting to set funding priorities within a relatively fixed budget without a complete list of eligible therapies from which to select. Requests for drug addition are submitted continuously throughout the fiscal year such that lists of drugs awaiting formulary review are ever changing. Although the regional P&T committees assessed the value for resources allocated offered by drug therapies being reviewed by comparing them to therapeutically similar agents already on formulary, it may have also been beneficial to situate them in the larger context of all drugs awaiting review. Current approaches to healthcare priority-setting with regards to clinical services require what has been described as an accurate inventory(29) or ‘wish list’(123) of clinical services, which is then prioritized. How this can be better accomplished in the context of drug formulary priority-setting, especially given participants’ beliefs that drugs being added typically offer only marginal therapeutic advantage at a considerable cost, merits further consideration. In particular, the notion of relative value of competing claims on the limited drug budget must be assessed more directly.

Second, it became apparent that the agenda-setting processes that the FHA and IHA regional P&T committees used could be improved to achieve greater procedural fairness. An important step might be to make the agenda-setting process for drug addition requests explicit by publishing it in committee terms of reference documents. This action would make the process more transparent to those physicians who submit drug addition requests, enabling them to better understand delays in having their drug reviewed by the regional P&T committee. This would also facilitate the committee Executive with making more consistent agenda-setting decisions. Finally, engaging the entire regional P&T committee in discussion not only about what criteria should be associated with allocating a higher review priority to a particular drug therapy but also how to make these criteria operational will capture more stakeholder
perspectives and values. Referring to the published agenda-setting procedures utilized by the CDR may assist in this endeavour(10).

Third, many non-scientific considerations were made during drug formulary priority-setting which were not accompanied by complete information. Incomplete information was most often observed or reported by interview participants to pertain to organizational implications (for example, effects on drug distribution systems and other health services, administering convenience for healthcare staff), interfacing activities (for example, community prescribing trends), as well as the formulary rationales for drug acceptance or rejection and subsequent policy experiences of other health authorities. Uncertainty on the part of many committee members about the size of the annual drug budget and the proportion spent at a particular point in time is a particularly problematic finding that should be addressed. Institutionalizing these ideas by including them as broad headings (for example, similar to what IHA has already done with “Survey of other health regions”) within written formulary reviews may assist P&T committees to operate with a more complete set of information, in addition to clinical and economic evidence, at the time of decision-making. Finally, improving the accessibility of formulary decision rationales made by P&T committees located in different health regions will be imperative to this endeavour, which has been suggested by another investigation conducted with hospitals across Canada(63).

5.4 Strengths and Limitations of the Study Design

5.4.1 Strengths

Adopting a qualitative, specifically grounded theory, approach to conducting the present study about drug formulary priority-setting within regional health authorities was advantageous for several reasons. First, both the broad research questions guiding the investigation and flexible data collection techniques employed (i.e. theoretical sampling, semi-structured interviews) permitted the emergence and exploration of a wide range of relevant concepts,
including some that were relatively new. For example, the importance and nuances of the processes of minimizing financial barriers to community drug access, and providing seamless care could not have reasonably been foreseen by reviewing the published literature. Since research conducted within the qualitative paradigm does not require strict adherence to a study protocol, the initial interview guide could be modified in order to probe interview participants about these processes after observing elements of these two processes during the first FHA committee meeting.

Second, grounded theory was designed for the purposes of theory development based upon empirical data. A grounded theory approach to the present study was, therefore, critical to developing a conceptual model of drug formulary priority-setting that encompasses a comprehensive range of relevant concepts that are well integrated. As previously discussed, the conceptual model represents an important contribution to the drug formulary priority-setting literature in which only two other models exist (60, 75). Moreover, it is the first conceptual model to be constructed from the experiences of P&T committees making global formulary decisions for multiple healthcare institutions dispersed throughout regional health authorities.

By drawing upon the formulary priority-setting experiences of two regional health authorities in British Columbia, rather than just one, the applicability of the conceptual model to other health regions may be enhanced. Many facets of drug formulary priority-setting are shared by both regional P&T committees. However, differences have also been highlighted (for example, the ways in which IHA and FHA committees have defined what constitutes a conflict of interest). Identifying both contextual similarities and differences is intended to assist readers with determining the degree to which other policy contexts may differ from those of the two regional P&T committees studied.
5.4.2 Limitations

Although the broad study questions permitted the emergence and exploration of a range of relevant concepts, they also limited the degree to which each theme could be examined in detail. This was anticipated given that the objective of the study was to develop a comprehensive conceptual model of drug formulary priority-setting. Detail was maximized, however, by instructing interview participants to communicate their reflections and perspectives using real-life examples of decision-making.

Another potential limitation of the present study pertains to the effectiveness of the theoretical sampling procedures that were employed to sample formulary reviews for observation, and committee members for semi-structured interviews. Theoretical sampling seeks to generate a sample of information-rich cases, rather than a sample of cases that is proportionally representative of the population from which it is drawn. The term “theoretical saturation” is utilized to refer to the point at which a researcher is no longer required to perform theoretical sampling(17). Strauss and Corbin(17) identify several conditions which indicate that theoretical saturation has been achieved to a high degree: a) new data related to categories are no longer emerging; b) categories demonstrate variation, and this variation is explained by the theory; and c) relationships between categories have been identified and confirmed.

With regards to formulary reviews, only 3 of the 10 formulary decisions observed were made in relation to acute care drugs (FHA and IHA: TNKase™; IHA: Avastin®/ Lucentis™); the remaining were made in relation to chronic care drugs. Yet both FHA and IHA committee members reported that the committees focused primarily upon drugs confined to an acute care setting (for example, intravenous medications). It is plausible that observing three formulary reviews pertaining to acute care drugs did not provide sufficient opportunity for related decision-making nuances to emerge. Consequently, concepts related to acute care agents may be
under-developed when compared to those themes exclusively related to chronic care agents within the conceptual model (for example, “Interfacing”).

With regards to interview participants, only 15 out of 41 possible participants were interviewed. Most interview participants offered rich data in the sense that their highly reflective narratives were self-critical as well as critical of the priority-setting practices in which the committee collectively engaged. It cannot be ruled out, however, that the subset of committee members who participated in interviews provided responses that differed systematically from how non-participants may have responded. For example, if non-participants tended to be more apathetic towards drug formulary priority-setting processes than participants, the present study would be missing that theoretically important perspective. It is also plausible that interviewing, for example, only five physicians limited the number of theoretically diverse perspectives that could be explored in order to understand differences across professions.

The ability of the present study to achieve theoretical saturation within the study period was limited, in part, due to the agendas of P&T committees being heavily weighted towards reviewing chronic care agents, and difficulties associated with interview recruitment. New ideas did continue to emerge towards the end of the data collection period, such as the perception that P&T committees which drew members from non-teaching healthcare facilities were less pre-occupied with deconstructing scientific evidence. However, the key categories and inter-relationships between categories which are reported were identified repeatedly throughout the study and demonstrate some variation.

5.5 Further Research

Several suggestions for guiding future research conducted in the field of drug formulary priority-setting can be proposed based upon the findings of the present grounded theory study. These ideas are organized in Table 5.2 (see next page) according to whether they can be classified as related to study methodology or the research focus.
Table 5.2: Suggestions for future research.

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<tr>
<th>Methodology</th>
<th>Research focus</th>
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<tr>
<td>• Sample:</td>
<td>• Study processes of interfacing:</td>
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<tr>
<td>- Greater number of meeting observations</td>
<td>- Across Canadian provinces/territories</td>
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<td>- Specialty subcommittees</td>
<td>- Compare institutional and provincial</td>
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<td>- Regions with teaching versus non-teaching</td>
<td>- drug benefit plan formularies on basis</td>
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<td>healthcare facility status</td>
<td>- of chronic care agents</td>
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<td>• Conduct some interviews after meeting</td>
<td>- Across jurisdictions with varying</td>
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<td>observations</td>
<td>- public-private drug payment</td>
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<tr>
<td>• Maintain investigator-participant</td>
<td>- arrangements</td>
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<td>professional alignment</td>
<td>• Survey detailed agenda-setting practices</td>
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<td>performed by variety of P&amp;T committees</td>
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5.5.1 Methodology

Three recommendations related to sampling arose out of the present study. First, future investigations would benefit from observing a greater number of regional P&T committee meetings (i.e. perhaps all meetings held during one year) in order to possess greater confidence that observations have captured examples of drug formulary decision-making that are more theoretically diverse. Second, sampling specialty subcommittees (for example, Cardiac and Antibiotic Subcommittees), where granted access, would add to understanding the ways in which regional P&T committees utilize scientific evidence as well as the influence of non-scientific factors. By advancing recommendations to the regional P&T committee which are advisory in nature, yet most often accepted, subcommittees ultimately represent the primary source of drug formulary priority-setting decisions with regards to high-niche drugs (for example, cardiac drugs and antibiotics). Third, the present study setting was confined to two regional health authorities which encompassed only non-teaching healthcare facilities. The last interview participant, however, expressed a belief that there was less of a commitment to critically appraising the evidence among P&T committee members working within non-teaching, compared to teaching, centres. Future investigations should employ theoretical sampling to select regional P&T committees on the basis of whether their jurisdiction includes
healthcare facilities with academic teaching capacity in order to explore how this variable may affect the use of scientific evidence during drug formulary priority-setting processes.

For studies which seek to juxtapose interview participant narratives against observation data, it is imperative that some interviews be scheduled after observation sessions in order to capture individual perspectives about group processes. This design strategy also reduces the likelihood that researcher interpretations will emerge that fail to resonate with participant experiences.

Finally, the piece about reflexivity and relationality which was included within the Methods chapter highlighted some important investigator-participant dynamics that others could learn from. Future studies about drug formulary priority-setting should avoid the situation of professional mal-alignment between investigators and participants (for example, a physician researcher interviewing a participant who is a pharmacist) in order to maximize trust and comfort. This could be achieved with a lead investigator who has an academic, non-clinical background or by employing interviewers with different professional backgrounds (i.e. medicine, pharmacy) to maintain professional alignment with interview participants.

5.5.2 Research Focus

Ideas about narrowing the research focus to particular aspects of drug formulary priority-setting also arose out of the findings derived from the present grounded theory study. For example, the concept of regional P&T committees engaging in interfacing activities (i.e. providing seamless care, minimizing financial barriers to community drug access) with regards to chronic care drug therapies could be further explored in several ways. First, studies could examine interfacing with members belonging to regional or hospital P&T committees across other Canadian provinces and territories in order to identify provincial variations in such activities. Second, comparing the chronic care drug therapies listed on regional (or hospital) formularies to those listed on provincial drug benefit plan formularies may assist with
quantifying the degree to which dimensions of interfacing are performed by institutional P&T committees. Third, how the concept of interfacing manifests in countries that are characterized by different public-private drug payment arrangements could also be fruitful.

Finally, it has been demonstrated that agenda-setting processes are important for establishing fairness, and that there currently exists a relative lack of understanding as to how these processes are performed by P&T committees. For example, it is not clear whether some P&T committees do not require agenda-setting processes because they are able to maintain pace with submitted drug addition requests (i.e. meet more frequently; have more reviewer capacity) or whether these processes are simply not reported. Future investigations surveying the detailed agenda-setting practices of a variety of P&T committees could facilitate not only a deeper understanding of agenda-setting, but also the development of more rigorous ways in which to conduct this preliminary step to making drug formulary decisions.

5.6 Conclusion

This grounded theory study drew upon the experiences of two regional P&T committees which were charged with making drug formulary decisions for the public healthcare institutions located within each of their respective regional health authorities in British Columbia (Fraser Health Authority, and Interior Health Authority). Semi-structured interviews with committee members, observations of committee meetings, and written committee documents lent insight into their decision-making realms. From these data sources, a description of the committees and the basic drug formulary priority-setting activities in which they engaged was generated. The primary contribution made by the present study constitutes a conceptual model which outlines how regional P&T committees negotiate issues of marginal therapeutic advantage, seek value for resources allocated, interface between community and institutional settings, and finally situate formulary decisions within the context of regional health authority organizations.
In the words of one interview participant, the process of setting drug priorities for a regional formulary is ultimately one that is fraught with complexity:

"Very complex... There are a lot of balls in the air. You have personalities. You've got big agendas. All that kind of stuff. You have studies. You have talks. You have budgets to work with. You have to partner with the physicians and the pharmacists and the drug companies, because the drug companies can be very helpful to bring the costs down."

(Pharmacist - Interview)

The task of unravelling this decision-making complexity will require continued effort. However, the present study has made a significant step towards understanding the rationales behind why decision-makers belonging to regional P&T committees make the considerations that they do, the challenges they face, as well as the strategies they employ to negotiate such challenges in order to implement healthcare policy.
6.0 BIBLIOGRAPHY


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7.1 APPENDIX A:
Initial Interview Guide (October 2005)

Please refer to specific examples of drug decisions whenever possible.

1. Describe the role that you occupy on this committee. Please comment upon the experience you bring to this role.

PROBES:
   a) What are some of your primary responsibilities in this role?
   b) How do your experiences contribute to the formulary priority-setting done by this committee?

2. Based upon your experience, what decision-making factors does the committee consider during this process? Please describe as many relevant factors as possible.

PROBES:
   a) What factor(s) do you consider to be most important? Why?
   b) What factor(s) do you consider to be least important? Why?

3. What is your understanding of the committee's mandate?

PROBES:
   a) How do you think this mandate affects formulary priority-setting in practice?
   b) What changes would you make to the mandate?

4. How do you think the health authority within which this committee operates influences the decisions that it makes?

PROBES:
   a) What regional considerations are made when setting formulary priorities for this regional health authority?
   b) How does formulary priority-setting at a regional health authority level differ from what might occur in individual institutions? At a provincial level?

5. How might personal interests (of committee members and/or external stakeholders) have the potential to influence the drug coverage decisions that this particular committee makes?

PROBES:
   a) What types of interests have you seen involved?
   b) How have each of these types of interest affected formulary priority-setting?
   c) What role do you see for personal interests within the formulary priority-setting process in a regional health authority?

6. How do you think values contribute to the drug coverage decisions that this particular committee makes?
PROBES:
   a) What types of values have you seen involved?
   b) How have each of these values affected formulary priority-setting?
   c) What role do you see for values within the formulary priority-setting process in a regional health authority?

7. What types of disagreements or difficulties have arisen among this committee when making drug coverage decisions?

PROBE:
   a) How were these disagreements/difficulties resolved?

8. Now turning to consider specifically scientific evidence as a decision-making factor, what are some barriers to the use of scientific evidence by this committee?

PROBE:
   a) What forms of scientific evidence are used by this committee?
   b) What consequences do you think the barriers you’ve identified have had on the decision-making process?

9. What are some enablers to the use of scientific evidence by this committee?

PROBE:
   a) What consequences do you think the enablers you’ve identified have had on the decision-making process?

10. Is there anything else that you would like to share that would help us to better understand the priority-setting process that this committee undertakes?
Certificate of Expedited Approval- External Researchers

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<tr>
<th>Principal Investigator</th>
<th>Institution of Primary Association</th>
<th>IH Research File Identifier</th>
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<tr>
<td>Dr. Craig Mitton</td>
<td>UBC</td>
<td>2005-010</td>
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**Research Study Title:**
An investigation into the process of drug formulary priority-setting in BC: what role does scientific evidence play in the context of other decision-making factors?

**IH Contact and Role in Research Study**
Norma Malanowich, Sponsor

**Other Co-Investigators**
Krisy Armstrong
Bruce Carleton
Jean Shoveller

**Sponsoring/Funding Agencies**
UBC – Okanagan grant

**IH Department Impact**
Norma Malanowich

**Documentation received and reviewed**
- IH REB Application for Ethical Review
- Contact letter - committee observation Aug 20/05
- Participant Observation Consent Form Jan 16/06
- Contact letter - interview Aug 20/05
- Interview Consent Form Jan 16/06
- Interview schedule Aug 20.05
- Study proposal
- Certificate of Approvals from Primary REB
  - UBC Behavioural Research Ethics Board Oct 13/05

**Conditions for Approval**
- It is the assessment of IH that this research study is not biomedical in nature and involves minimal risk to human subjects and therefore qualifies for expedited review.
- It is the responsibility of the primary investigator to inform the IH Research Office if the assessment is deemed at any time to be greater than minimal risk for human subjects.
- It is the responsibility of the primary investigator to inform the IH Research Office if there are changes to consents or other materials used with human subjects – these must be submitted to the IH Research Office for review.

**Approval Date**
Jan 16, 2006

**Approval Term**
1 year

**Reporting Requirements:**
Investigators must provide the IH Research Office with a final report.

**IH Authorized Signature**
B. Ann Ferguson Chair, IH Research Ethics Board
Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to participate as a participant. Also, you acknowledge that you have received a copy of this consent form. In no way does this waive your legal rights nor release the investigators, sponsors, or involved institutions from their legal and professional responsibilities.

________________________  _______________________
Participant's Printed Name                        Date

________________________
Participant's Signature

________________________  _______________________
Investigator and/or Delegate's Signature            Date
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Participant's Printed Name ___________________________ Date ____________

Participant's Signature ____________________________

Investigator and/or Delegate's Signature ____________________________ Date ____________