HEALTH CARE RESOURCE UTILIZATION IN NEWFOUDLAND

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by

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Abstract

Health care delivery is not subject to the economic forces which achieve productive and allocative efficiencies in competitive markets. Allocative efficiency is addressed in the context of a methods review for measuring hospital bed utilization. Productive efficiency is addressed by examining the utilization of ciprofloxacin, an expensive antibiotic.

The reliability and validity of several methods of measuring hospital bed utilization were assessed. Nurse (A) prospectively collected data on the clinical condition and care plans of 80 patients at an acute care hospital, and identified and classified inappropriate days using her clinical judgement. In the same way, a second nurse (B), experienced in appropriateness evaluation, independently rated the same cases as did a third nurse (C), using a modified version of the Appropriateness Evaluation Protocol (AEP). Nurse A's data was also independently rated by a panel (P). Agreement for the number of inappropriate hospital days per case as measured using the Intraclass Correlation Coefficient (R_I) was excellent: Nurse A v P = 0.95, Nurse A v C = 0.87, P vs C = 0.88, B v A = 0.87, B v P = 0.79, B v C = 0.72. Reliable and valid judgements of inappropriateness can thus be made by any of these methods.

In the second study, an academic panel and an industry panel used guidelines to assess the appropriateness of 278 ciprofloxacin prescriptions which were generated through chart review and interview of 72 physicians. Ciprofloxacin was considered to be appropriately prescribed in 42% of cases by the academic panel, and in 62% by the industry panel. The only diagnoses where the two panels differed significantly were nursing home-acquired pneumonia ($p < 0.0005$) and acute exacerbation of chronic bronchitis (AECB) ($p < 0.0001$). Agreement between the two panels was fair ($K = 0.36$), but agreement increased to moderate when cases of nursing home-acquired pneumonia and AECB were removed ($K = 0.58$).

Inappropriate prescription of ciprofloxacin inhibits productive efficiency in the health care system and stems from a combination of lack of knowledge of pharmacotherapy for common infections, as well as a lack of knowledge or concern for the cost differential among antibiotic alternatives. Physician education through academic detailing is needed to disseminate price information and appropriate guidelines with the intent of improving physician prescribing behaviour.

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Methods of Bed Utilization

Dr. JoAnne MacIntyre
Dr. Jennifer Hall
Dr. John Pike
Dr. Leo Best
Dr. Brendan Barrett

Ms. Lynn Mullins, R.N.
Ms. Brenda Hicks, R.N.
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Ciprofloxacin Study

Academic Panel	Industry Panel
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Dr. Patrick O'Shea	Dr. Paul Oh
Dr. Chris Turner	Mr. Robin Lawrence

TABLE OF CONTENTS

TABLE OF CONTENTS (continued)

TABLE OF CONTENTS (Continued)

LIST OF TABLES AND FIGURES

List of Tables:

List of Tables (Cont'd)

List of Figures

SECTION I

CURRENT STATE OF THE

CANADIAN HEALTH CARE SYSTEM

1.0 BACKGROUND

Canadians have become accustomed to a very high level of health care service and believe that it is one of the major advantages of being a Canadian resident (Newfoundland, Economic Recovery Commission, 1994, p.3). Canadians are now faced with growing pressures to reduce government expenditures, the most significant being the debt crisis in Canada (Tholl, 1994). While there are a number of factors which contribute to the Canadian debt and budget deficit problems, the rate of growth of the cost of Canadian health care is one of the most significant. In real 1986 dollars spending on health care increased from approximately $1828 per capita to $2010 per capita from 1987 to 1991 (Tholl, 1994). Spending on health care is often assessed relative to Gross Domestic Product (GDP) since it represents Canada's ability to pay for the services it provides (Tholl, 1994). During the 1990's, Canada has come very close to spending 10% of its Gross Domestic Product (GDP) and employing 10% of its labour force in the health services sector. As recently as 1980, Canada spent only 7.5% of its GDP on health (Blomqvist, 1994; Evans, 1984, p.9). In addition, health care spending increased almost 5% annually in real terms during the 1980's (Blomqvist, 1994). This growth, while having the goal of enhancing human welfare, has a

substantial opportunity cost. This means that the labour and other resources consumed to produce health services are not available to produce other worthwhile goods and services that might be exportable and which could contribute to the economic well-being of the country (Blomqvist, 1994). Thus, the growth of expenditures threatens the very wealth that is needed to support the system Canadians value.

In order to determine why Canada faces this situation, it is necessary to turn to the field of economics. The following section briefly reviews some economic issues relevant to the health care industry.

1.1 OVERVIEW OF HEALTH ECONOMICS

The underlying problems in Canadian health care delivery relate to the economic concepts of productive efficiency and allocative efficiency (Newfoundland, Economic Recovery Commission, 1994, p.3). *Productive efficiency* occurs when a particular level of health care service is provided at lowest possible cost. *Allocative efficiency* occurs when the optimal level of health care service is provided. In a competitive market productive and allocative efficiency are theoretically achieved because of the underlying forces of the price system. Firms in a competitive market will achieve

productive efficiency because they have underlying profit-maximization motives which encourage them to operate at the lowest possible cost. Allocative efficiency is achieved over the long run in the competitive market because the market structure allows for the free entry and exit of commodities and firms in the marketplace. Therefore, the price paid by consumers for a commodity will reflect the value of the resources used by the firm to produce it (Newfoundland, Economic Recovery Commission, 1994, p.3).

In the health service sector productive and allocative efficiencies are difficult to achieve. Physicians account for a large proportion of health spending through direct payments for their services, as well as the resources they control, such as lab tests, prescription medications, admission to hospitals, surgical procedures, and the use of various diagnostic tests (Newfoundland, Economic Recovery Commission, p.9; Culyer, 1988, p.38). In Newfoundland, 15.1% of the 1995 budget was allocated for direct payments for physician services through the Medical Care Commission (Newfoundland, The Budgeting Division of Treasury Board, 1995, p.233), and approximately 6% of the provincial government's health budget is spent directly on prescription medications (Newfoundland, The Budgeting Division of Treasury Board, 1995, p.232-233). In addition, when one

considers that physicians control approximately 70% the dollars spent on inpatient care (Restuccia et al, 1987), and that 65% of the Newfoundland health care budget is spent on hospitals and nursing homes (Newfoundland, The Budgeting Division of Treasury Board, 1995, p.224), one can estimate a further 45.5% of spending under the control of physicians. Without considering physician contributions to the cost of delivering Community Health programs (9.5% of the budget), one can obtain a rough estimate the value of health resources controlled by physicians at about 66% of the budget, or approximately $580 million. Since physicians are guaranteed a fixed fee for their services regardless of the number of providers, and since the cost of over-utilization of resources is not born by these physicians, there exists little incentive to produce at the lowest possible cost. Productive efficiency is therefore not achieved. An example of productive inefficiency would be the over-utilization of expensive drugs, such as ciprofloxacin, a focus of this thesis. Since the incremental cost of a ciprofloxacin prescription over a cheaper alternative does not impact directly on either the consumer (when covered by a government drug plan or other insurer) or the physician, it is prescribed more often than it should and productive efficiency is compromised.

Since patients do not directly pay the market value for the services they receive, and since physicians feel no personal pressure to allocate resources in the most cost-effective manner, there tends to be an excess amount of service demanded and provided, resulting in allocative inefficiencies as well (Newfoundland, Economic Recovery Commission, 1994, p.4). Blomqvist (1994) contends that there is an implicit tendency toward allocating too many resources to health, even in competitive health care markets. Further, in the health services industry the gap in knowledge between provider and consumer is unparalleled in any other market. This impairs allocative efficiency, as consumers do not know the true value of the commodity (Blomqvist, 1994; Evans, 1984, p.123). An example of allocative inefficiency is inappropriate utilization of hospital beds. In 1990-91, Newfoundland's hospital occupancy rate was only 70.59%, lagging behind the Canadian average of 79.9% during that period. The lower occupancy rate provides more room for discretionary and precautionary use of services (Newfoundland, Economic Recovery Commission, 1994, p.6). Reporting on a bed utilization study at the General Hospital in St. John's, Barrett et al (1994) found that almost one third of hospital days were potentially avoidable through such measures as improved discharge planning, utilization of a Preadmission Clinic (PAC), and

more efficient medical management. Another example of allocative inefficiency and subsequent increase in cost to health care is the development and use of new technologies (Evans, 1984, p.95; Newfoundland, Economic Recovery Commission, 1994, p.12). Unlike the market economy, new technologies are not introduced to lower cost, but instead to improve quality of care, and costs often actually increase due to increased skilled labour requirements (Newfoundland, Economic Recovery Commission, 1994, p.12). However, the net impact of technological change is really unknown since the it is unknown whether the expenditure-increasing effects of high technology outweigh the expenditure-decreasing effects (Culyer, 1988).

1.2 CONTROLLING HEALTH CARE EXPENDITURES

In Canada, the public sector is largely responsible for carrying out health care functions, with public spending accounting for 72-73% of all health care spending (Tholl, 1994, p.61; Newfoundland, Economic Recovery Commission, 1994, p.4). The administration of these health services is under provincial jurisdiction as provided by the Canadian constitution, but the provinces must operate within the national principles of universality, comprehensiveness, accessibility, portability and non-profit administration if they are to receive the federal financial transfers critical to the ability to offer these programs (Culyer, 1988, p.47; Newfoundland, Economic Recovery Commission, 1994, p.2). The Newfoundland government spends approximately 23.3% of its budget on health care (Newfoundland, The Budgeting Division of Treasury Board, 1995, p. viii), which is less than the Canadian average (approximately 31.6% in 1991). However, Newfoundland's position of being heavily dependent on federal financial resources means that it faces extreme pressure to rationalize its spending when federal transfers are frozen or reduced. In its 1995 budget, the Canadian government indicated it would be reducing combined transfer payments for all provinces by $7 billion over three years (Naylor et al, 1995). Since the province is in effect a

single paymaster and is not faced with a multitude of financial intermediaries (as in the United States), it retains the ability to exercise discretion over its spending. This does not ensure expenditure constraint, but at least provides the opportunity to do so (Culyer, 1988, p.48). So while the Canadian system introduces some unique challenges to control costs and effectively allocate resources among consumers of health care, provinces have the ability to control those expenditures. Accomplishing this requires careful study of where the inefficiencies are occurring if one hopes to design proper strategies to deal with wasted resources. Once identified, strategies must be developed to curtail the problem. A number of such intervention strategies including physician education, feedback, and academic detailing are discussed in Sections II and III.

1.3 SUMMARY

Given the economic and fiscal pressures to reduce health care costs and the assumption of productive and allocative inefficiencies in the Canadian health care system, it is essential that cost-effective and accurate tools for measuring utilization of health care resources are developed. Studies must be carried out which identify and

quantify the problem areas, and suggest strategies and tactics to reduce inappropriate utilization of health care resources.

Section II addresses the evaluation of allocative efficiency in the hospital sector by assessing the reliability and validity of several methods of measuring bed utilization in acute care hospitals. Section III addresses productive efficiency through a drug utilization review of an expensive antibiotic, ciprofloxacin. Both sections discuss some intervention strategies which might be employed to reduce over-utilization of these health care resources, thus improving allocative and productive efficiency in the system.

SECTION II

METHODS OF MEASURING BED UTILIZATION

2.0 INTRODUCTION

Bed utilization review can be used by hospitals to measure and understand reasons for inappropriate utilization of hospital beds (Restuccia et al, 1987). Administrators can then identify areas of potential cost reduction while maintaining the ability to meet patient needs. The method(s) used to carry out bed utilization review must be valid and cost as little as possible in order to maximize the return on the research investment. Traditionally, most methodological studies on appropriateness have not been able to produce reliable measurements (Rishpon et al, 1986;Gertman and Restuccia, 1981). A major barrier to development of a tool to measure appropriateness of hospital stay is that there is no gold standard against which to compare results.

The Appropriateness Evaluation Protocol (AEP) is an objective, criteria-based instrument used to identify the extent of, and reasons for inappropriate admissions and hospital days (Restuccia et al, 1987). It has been shown to be reliable and valid, and has been used effectively in a number of hospital settings in North America and abroad (Payne et al, 1991;Strumwasser et al, 1990;Siu et al, 1986;Restuccia et al, 1987;Rishpon et al, 1986;Gertman and Restuccia, 1981). Demonstration of reliability and validity has been achieved by comparing the assessments of several

nurses and physicians who independently assessed patient hospital stay using the AEP, and then calculating the agreement between observers generally, and correcting for chance using the kappa statistic (Strumwasser et al, 1990;Siu et al, 1986;Rishpon et al, 1986;Restuccia et al, 1986;Restuccia et al, 1982;Gertman and Restuccia, 1981). Thus, in the absence of a gold standard, the AEP can be considered an excellent tool upon which to compare other measurement tools being developed.

Barrett et al have previously reported studies of bed utilization at the General Hospital in St. John's, NF (Barrett et al, 1994; Barrett et al, submitted). In these studies, appropriateness of hospital stay was assessed by a multi-disciplinary panel of social workers, nurses and physicians. The panel review process was burdensome, costly and led to delays in obtaining results. In addition, the subjective decision making employed by the panel allowed the possibility of biased decisions.

This section of the thesis tests the reliability and validity of methods used to identify and classify inappropriate hospital stay in a subsequent bed utilization review. The specific objectives of this study were to: 1) examine the feasibility and reliability of having a trained nurse prospectively abstract information relevant to

determining appropriateness of bed utilization from medical records and charge nurses; and (2) validate the data collection and decision making of the individual nurses as well as the decisions of a review panel against a modified version of the AEP.

2.1 METHODS

2.1.1 Patients and Recruitment

For the overall bed utilization study, 203 patients admitted to the General Surgery, Urology, Plastic Surgery/Burns, Ophthalmology, Haematology, Radiotherapy, Gynaecology/Oncology, and Infectious Disease services at the General Hospital were studied. In order to get a representative sample from each service, admissions to General Surgery and Urology were studied for 2.5 weeks, and those to other services for 5 weeks. The sample size was one of convenience, taking budget and time constraints into account.

A nurse (Nurse A) with considerable clinical experience, but with limited training in utilization review identified and followed all 203 study patients on a daily basis. To test the reliability of the data gathering process, 80 patients were selected (by coin toss) and followed prospectively by a second nurse (Nurse B), using the same methods as Nurse A

(Nurse B trained Nurse A for this study). In the same way, these 80 cases were further studied by a third nurse (Nurse C), using the AEP. Finally, a panel of nurses and physicians retrospectively evaluated the same 80 patients using the data collected by Nurse A. The 80 cases were selected to be representative of the population from which they were drawn in the same way as the 203 patients for the overall study (see table 2.2 in Results section). All recruited patients were followed to discharge with the exception of those transferred to a non-study service. Such patients were followed up to the time of transfer.

Nurses A and B used a standardized form (Appendix A) to record clinical and demographic data, a daily profile of the patients' medical condition, medical and nursing interventions, and the plan of care from hospital admission to discharge. Unit charge nurses were regularly consulted about the patients' condition and plan of care.

2.1.2 Identification and Classification of Inappropriate Hospital Days

Nurses A and B independently identified and classified inappropriate hospital days using a structured form which classified reasons for these days (see Appendix B). This classification system was generated using the AEP and the "Delay Tool" (Selker et al, 1989). The Delay Tool was

developed to detect, quantify and assign causes for unnecessary hospital stay in tertiary teaching hospitals. Using this same classification system, a panel of 3 physicians and 3 charge nurses from the study services also identified and classified inappropriate days from data presented by nurse A. In making their decisions, the panel followed some pre-agreed guidelines. These stated that: a pre-admission clinic should be used for stable elective surgical cases not needing extensive pre-operative work-up; consults, tests and operations should be done within 24 hours of request; patients should be discharged as soon as their medical and social circumstances permit; early discharge planning should be undertaken for identifiably difficult cases; and that a thorough admission assessment should identify all existing problems and result in a coordinated medical care plan. The panel was blind to patient identity, and to the decisions of the other raters.

Nurse C used a modified version of the AEP to perform the same task and was blind to the data collection and decisions of Nurses A and B. The AEP was developed in the United States, but was modified to reflect local market differences in health delivery. The AEP was modified to require the use of a preadmission clinic where suitable, and by eliminating a criterion that allowed for a post-operative day for several invasive diagnostic procedures, such as angiography

and myelography. An additional modification was to require home care when only intramuscular and/or subcutaneous injections or dressing changes were needed. These modifications did not change the way in which the AEP was administered, so subsequent validation of the modified tool was not deemed as necessary.

2.1.3 Ethics

This study was approved by the Human Investigations Committee at Memorial University of Newfoundland. No patient consent was required as there was no intervention which might impact on patient stay or health outcome. Patient information was obtained through chart abstraction without any patient contact. Confidentiality was maintained by not using patient identifiers on any study documents or reports to be seen by anyone other than those providing care or who were directly involved in the study.

2.2 ANALYSIS

The degree of agreement between nurses A and B is a test of inter-rater reliability of the non-criteria-driven method. The degree of agreement between A and the panel was studied to see whether panel review could be avoided in future studies. Strong agreement between A and C provides a validity check on the data collection and judgement ability

of Nurse A. Strong agreement between any of A, B or the Panel with the AEP provides some validation of the partially subjective judgement methods. Decisions about appropriateness cannot be tested for criterion validity because there is no gold standard "criterion" method for judging appropriateness.

Inter-rater agreement was assessed for: 1) appropriateness of admission; (2) reasons for inappropriate admission day; (3) total number of days inappropriate; and (4) number of inappropriate days due to a specific reason. The kappa statistic (K) was used to assess agreement for nominal data such as appropriateness of the admission day and reason for inappropriate admission day (Kramer and Feinstein, 1981; May, 1994). Intraclass correlation coefficients (R_I) were used to assess agreement for continuous data, including the total number of inappropriate days and the number of inappropriate days due to a specific reason (Kramer and Feinstein, 1981; May, 1994). Landis and Koch's (1977) guidelines for interpretation of kappa were used to evaluate strength of agreement between raters. These guidelines (table 2.1) are also applicable for evaluating R_I (Kramer and Feinstein, 1981). The strength of agreement necessary to validate the method of concurrent data collection and decision making by nurse A was considered to be substantial or better using these guidelines.

Table 2.1 Guidelines for Interpreting Kappa (K) and Intraclass Correlation Coefficient (R_I)

Value of K or R_I	Strength of Agreement
< 0	poor
0.00 - 0.20	slight
0.21 - 0.40	fair
0.41 - 0.60	moderate
0.61 - 0.80	substantial
0.81 - 1.00	almost perfect

Baseline characteristics were evaluated using students t-test and chi-square test with Yates correction where applicable.

2.3 RESULTS

As shown in table 2.2, there were no significant differences at baseline between the 203 patients in the overall bed utilization review and the patients in this sub-study.

Table 2.2: Patient Baseline Characteristics in the Utilization Study and the Methods Sub-study

	Utilization Study (N=203)		**Agreement Study (N=80)**		
Mean Age (yrs)	52		57	(p=0.13)	
Male (%)	59		55	(p=0.62)	
Area of Residence	N	%	N	%	
St. John's	107	53	40	50	
Eastern Avalon	64	32	27	34	
Central NFLD	14	7	4	5	(p=0.94*)
West/St. Anthony	10	5	4	5	
Northern NFLD & Lab.	4	2	3	4	
Outside Province	4	2	2	2.5	
* St. John's and Eastern Aval. vs. Pts from Remainder of Province					
Type of Admission					
Elective	59	29	26	33	
Urgent	55	27	25	31	(p=0.30)
Emergency	89	44	29	36	
Admitting Service					
Surgery	59	29	24	30	
Urology	52	26	24	30	
Plastics/Burns	19	9	4	5	
Haemat/Infect. Disease	20	10	9	11	(p=0.89)
Radiotherapy	20	10	7	9	
Gynecology/Oncology	14	7	4	5	
Ophthalmology	19	9	8	10	

Table 2.3 describes the pattern of agreement between raters for appropriateness of admission day and the reason cited when inappropriate. As reflected by almost perfect agreement between nurses A and B, inter-rater reliability of the nursing data collection and judgement was very high.

Table 2.3: Agreement on Appropriateness of Admission Day

Agreement Using Kappa (95% CI)		
Pairwise Comparisons	**Appropriateness of Admission Day (N=80)**	**Reasons for Inappropriate Admission**
A vs P	0.69 (0.47, 0.91)	0.90 [N=26] (0.59, 1.21)
A vs C	0.68 (0.47, 0.89)	0.33 [N=33] (0.08, 0.58)
A vs B	0.92 (0.70, 1.14)	0.79 [N=34] (0.52, 1.06)
P vs C	0.49 (0.29, 0.69)	0.30 [N=27] (0.01, 0.59)
B vs P	0.75 (0.53, 0.97)	0.72 [N=26] (0.39, 1.05)
B vs C	0.62 (0.40, 0.84)	0.41 [N=36] (0.14, 0.68)

* Numbers in square brackets are sample sizes for analysis

The validity of nurse A's assessment is supported by the substantial agreement between A and both the panel and nurse C using the AEP. There was a lesser degree of agreement

between the panel and nurse C using the AEP for the appropriateness of admission day. Eighty-six percent of the disagreements involved the panel declaring the admission day appropriate while the AEP declared it inappropriate. This resulted from the panel being influenced by patient status and the distance travelled to reach the hospital, leading them to declare a greater number of preoperative admission days appropriate.

The values of K in table 2.3 for Reason for Inappropriate Admission Day only include cases where the two raters agreed on the inappropriateness of the admission, removing the effect of that disagreement. Again, agreement was high for reason for inappropriate admission. One may argue that the agreement may have been upwardly biased by the fact that comparisons were only made where there was already agreement on appropriateness of admission day. However, this was necessary to get a clear picture on the reliability of classification. A lower degree of agreement was found between nurse C and all other raters for reason for inappropriate admission day. This was mainly due to the AEP indicating a premature admission when most others felt that the scheduled procedure could have been performed in an ambulatory setting.

There was substantial disagreement between the panel and other all other raters regarding one case (case #7). In this instance, following a lengthy debate, the panel decided that all 27 days of hospital care were appropriate. The panel were aware of the ultimately fatal outcome of the patient, while the nurses rating the stay in a prospective manner, did not know the outcome until day 27. Nurses A, B and C all rated all 27 days inappropriate on the basis that the care could potentially have been provided in a non-acute setting. Since this single case of long duration had a major impact on the agreement analysis, the data was analyzed again excluding case #7. Table 2.4 provides intraclass correlation coefficients (R_I) the number of days inappropriate and the percent of stay inappropriate for each pair of raters overall, and excluding case #7. Excellent agreement exists between all rater pairs when case #7 is excluded and persists for all comparisons not involving the panel when case #7 is included. This again indicates the reliability of the data extraction process and judgement of nurses A and B. In addition, as a test of convergent construct validity, the data also support the validity of each of these methods to identify the degree of inappropriate bed utilization.

Table 2.4: Agreement between pairs of raters by intraclass correlation coefficient (R_I) for Number of Inappropriate Hospital Days including and excluding case #7.

Pairwise Comparison	R_I excluding case #7 (95% CI)	R_I including case #7 (95% CI)
A VS P	0.95 (0.92, 0.97)	0.40 (0.20, 0.57)
A VS C	0.87 (0.8, 0.91)	0.94 (0.91, 0.96)
A VS B	0.88 (0.82, 0.92)	0.36 (0.15, 0.54)
P VS C	0.87 (0.8, 0.91)	0.98 (0.97, 0.99)
B VS P	0.79 (0.69, 0.86)	0.30 (0.09, 0.49)
B VS C	0.72 (0.59, 0.81)	0.86 (0.79, 0.91)

The strong agreement between nurse A and the panel (table 2.3 and table 2.4) means that panel review for the remaining 123 patients reviewed by Nurse A could be avoided. Table 2.5 describes the pattern of inappropriate bed utilization for all 203 patients as determined by nurse A.

Table 2.5: Description of Hospital Stay for all 203 patients reviewed by Nurse A.

	Patients	Days	% of Total Hospital Days
Total Hospital Days	203	1261	
Median Length of Stay		5	
Total Inappropriate Days	109	317	25
Potentially Avoidable days with New Services*	5	64	5
Potentially Avoidable Days within existing services:			
Awaiting Surgery	48	59	5
Awaiting Diagnostics	21	38	3
Awaiting Consults	0	0	0
Awaiting Results	1	1	0.1
Medical Management	19	77	6
Discharge Delays	40	78	6

* New services include supervised hostel-type facilities, community support services in liaison with acute care and easier access to convalescent and palliative care units.

Raters A, B and the panel could be meaningfully compared with regard to the proportion of inappropriate bed days due to a given reason (table 2.6). The analysis includes case number 7 as all raters agreed that he/she did not have any inappropriate days due to these reasons. There was substantial agreement between raters with regard to the major reasons for inappropriate bed days further supports the reliability and validity of the partially subjective processes employed.

Table 2.6: Comparison of R_I (95% CI) values for Raters A, B, and P for Reasons for Inappropriate Stay.

	A vs P	A vs B	B vs P
Awaiting Diagnostics	0.91 (0.86, 0.94)	0.87 (0.80, 0.91)	0.83 (0.75, 0.89)
Awaiting Surgery	0.59 (0.42, 0.72)	0.47 (0.28, 0.62)	0.35 (0.14, 0.53)
Awaiting Discharge	0.86 (0.79, 0.91)	0.77 (0.66, 0.85)	0.79 (0.69, 0.86)
Inefficient Medical Management	0.94 (0.91, 0.96)	0.97 (0.95, 0.98)	0.92 (0.88, 0.95)

Inappropriate days were classified differently by the AEP except for days awaiting surgery and diagnostic tests. Nevertheless, there was very little agreement beyond chance between the AEP and all other raters about the number of days awaiting diagnostic tests (R_I 0.06 to 0.07). All raters other than the AEP felt that case #29 had 7 to 8 inappropriate days awaiting a diagnostic test that could have been performed on an outpatient basis, while the AEP did not detect any such inappropriate day for this case. If this case is ignored, the intraclass correlation coefficient rises to about 0.25, reflecting modest agreement. Similar levels of agreement were observed between each rater and the AEP for the number of days awaiting surgery.

2.4 DISCUSSION

2.4.1 Reliability and Validity of Methods Assessed

This study supports the reliability and validity of having a nurse collect data to judge the appropriateness of bed utilization using partially implicit criteria. The use of standardized data collection forms and an inappropriateness classification system may have increased the reliability of the process.

Nurse A had not been previously involved in a hospital bed utilization review, but was clinically experienced and had held a nursing supervisor position in critical care. The strong agreement between Nurse A and Nurse B suggests that utilization review can be successfully performed by a nurse in this way after limited training. However, nurse B trained nurse A and both interviewed the same charge nurses about the same cases for this study. It would have been preferable to compare two completely independent nurses to gauge the reliability, however that would have required Nurse B to train another nurse, increasing the cost of the study beyond the resources available. Since the method employed may have contributed to the extremely high level of agreement between these two raters, a further study with new nurses would be necessary to confirm the reliability of this method.

The substantial to excellent agreement between nurse A or B and the panel with regard to appropriateness of admission day and reasons for inappropriate admission suggests by this test of convergent construct validity that both nurses and the panel are capable of judging appropriateness of admission. There was also substantial to excellent agreement between nurse A or b and the panel for the number of inappropriate days and the reason for inappropriate hospital stay, when excluding a single exceptional case. The disagreement that resulted from this long stay may have been due to the difference in perspective of the panel versus the nurses. That is, because the nurses evaluated the case prospectively, they likely had a better account of the clinical uncertainty surrounding the case, and their decisions therefore might be considered to probably be more valid. The panel considered the entire stay (27 days) appropriate after much debate, giving "benefit of the doubt." Overall results suggest that there may not be a need to use the costly and cumbersome panel review process employed in prior studies as long as the disagreement is considered acceptable (Barrett et al, 1994; Barrett et al, submitted).

The partially subjective method of judging appropriateness of stay developed by Barrett et al are validated by the strong observed agreement between nurse C using the AEP and

the other raters. It is instructive to examine the instances where there was a lesser degree of agreement between the AEP and the other raters. Disagreements on the appropriateness of admission days were mainly due to nurse A, nurse B and the panel taking greater account of the patient status and distance from the hospital. Whether slightly sicker patients travelling longer distances should be admitted the day prior to an elective procedure is an aspect of institutional policy that is likely to differ from place to place and over time. In this regard, the implicit judgement system developed by Barrett et al may offer the advantage of being more responsive to such local factors, but in being so will not allow unambiguous comparison between hospitals.

As explained in the results section, the version of the AEP employed was less sensitive to the possibility of having procedures performed in an ambulatory setting. It does not specifically guide the user in judging whether a given patient requiring a procedure should be managed in an ambulatory setting. Nurse C had the option of overriding the AEP criteria in this regard, but did not do so, possibly due to an absence of cuing by the instrument.

Although there was very good agreement between the nurses and the AEP for the number of inappropriate days, there was

much lower agreement when classifying inappropriate days. This may be due to differences in the classification options available to the judges. It would be interesting to study the pattern of agreement between the partially implicit rating system employed by the nurses and the criteria-based AEP while having classification of the reason for inappropriate days done in a common fashion.

2.4.2 Deciding Which Method to Employ

While this study focused on having a nurse carry out concurrent utilization review, exactly who should carry out these utilization reviews could be a point of debate. Linton and Peachey (1989) argue that physicians should develop systems of utilization review, and should supervise data collection and analysis. Indeed, physicians as reviewers might be more knowledgable about the complexities of the medical care required, while also having knowledge of hospital systems and processes. In addition, detailed patient review might result in enhanced care, and being involved in the review might facilitate change. This would be especially true if the attending physician were carrying out the review. However, physician utilization review has disadvantages. If physicians were judging their own cases, a significant bias would exist, and one might thus question the validity of the assessments. The process is also time-consuming and might therefore detract from patient care.

Physician time is also quite expensive in comparison to nursing or clerical time. Using nurses or non-clinical staff provides a cost advantage, greater objectivity, and probable equivalency regarding knowledge of hospital systems and processes. The results of this study suggest that trained nurses can carry out bed utilization review either using guidelines and clinical judgement, or by using a criterion-based approach, such as the AEP. One advantage of the criterion-based approach is the possibility of having initial reviews carried out by non-clinical staff, thereby further reducing the cost of the process. However, rigid criteria may be too inflexible for the complexities of individual patient care and may not consider local market differences in health care delivery as would a panel or nurse using guidelines. Furthermore, a criterion-based method such as the AEP does not question the need for a procedure, but instead judges appropriateness of stay given that the procedure itself is warranted.

Both methods of bed utilization review tested here appear reliable and valid, and the choice of one over the other will depend on resources available, the size of the institution, and the speed at which the review must be done. Ongoing bed utilization would be facilitated by primary computerized input of data, allowing clinical teams and administrators to analyze the data on an ongoing basis

(Payne et al, 1991). Whichever approach is used, the system should have a feedback mechanism so that clinical teams may comment on the results, and develop plans of action to correct any systematic problems identified.

2.4.3 Limitations of Study

There are some points of possible criticism in this study. Nurse A was once a supervisor in critical care, and one might argue that freeing the time of such a resource might prove difficult. It might also be argued that a staff nurse might not provide the same level of assessment as someone with supervisory nurse experience. Furthermore, while Nurse A did not have previous experience carrying out a bed utilization review, she was in contact with nurses who were involved in the original study by working within the same group of people, thus there may be some contamination in that she could possibly have learned about the AEP through casual conversation, or by overhearing conversations relating to the topic. Finally, this study was carried out in a teaching hospital with a focus on research, and in which a similar study was conducted in the previous year. Therefore, the reaction of physicians and charge nurses may have been influenced by these two factors, although the impact on reliability is unclear. Further study could define the importance of these concerns. Such a study should be carried out using a non-teaching acute care or

sub-acute facility using a staff nurse with a significant amount of clinical experience to test the generalizability of these results.

2.4.4 Intervention Strategies

While this study did not focus on the actual utilization of hospital services, studies by Barrett et al (1994; submitted) have demonstrated that between 25 and 33% of hospital bed days in the General Hospital were avoidable. This is similar to other studies which have found that between 20-30% of total patient days are inappropriate (Wickizer et al, 1989; Siu et al, 1986). Given the inefficient use of hospital resources, it is useful to examine some intervention strategies to reduce unnecessary hospital admissions and length of stay. Such interventions include education, financial incentives and penalties, feedback, and administrative changes.

Education

Continuing Medical Education (CME) refers to the education of practising physicians. CME can alter physician behaviour when the curriculum is designed to change specific types of behaviours (Greco and Eisenberg, 1993). Thus, among items to be included in CME for bed utilization would be use of the preadmission clinic for elective surgeries and information on effective early discharge planning.

Feedback

Feedback involves giving physicians information about how their practices or patient outcomes compare with other physicians or with some standard (Greco and Eisenberg, 1993), such as the AEP or any method of bed utilization review. While feedback has not generally been effective at changing physician behaviours (Greco and Eisenberg, 1993), it has been shown to be useful in reducing hospital stay (Greco and Eisenberg, 1993; Billi JE et al, 1992; Manheim et al, 1990). Thus, simply reporting the results of the study to hospital physicians might reduce utilization.

Administrative Interventions

Administrative interventions can mean restrictions, such as requiring a second opinion before surgery (Greco and Eisenberg, 1993), however the intervention might also be facilitative, such as offering increased flexibility for diagnostic procedures by increasing the hours that they are available. Administrative interventions must balance the possible (and generally unsubstantiated) benefits with the possible negative patient outcomes and the increased burden on physicians and others (Greco and Eisenberg, 1993).

Financial Incentives and Penalties

Due to the Canadian fee-for-service system hospitals do not have much flexibility with regard to financial incentives or penalties. There is some evidence that physicians are less likely to hospitalize their patients if they are paid a salary, or if they are put at personal financial risk for their treatment decisions (Hillman et al, 1989).

2.5 CONCLUSIONS

It can be concluded that data collection and judgements of appropriateness of hospital stay can be similarly made by any of the methods discussed, and that they are likely to be reliable and valid. Ongoing concurrent utilization review by a trained nurse provides timely information and reduces the expense of panel review. It provides the data necessary to identify problem areas so that well targeted intervention programs to improve utilization (and allocative efficiency) can be created. Feedback would probably be an effective intervention to reduce inappropriate hospital stay.

Further work using a larger sample is needed to measure the extent and reasons for disagreement, and to determine whether the differences in classification of inappropriate days between the AEP and Nurses A and B result from differing classification systems.

SECTION III

CIPROFLOXACIN UTILIZATION REVIEW IN THE COMMUNITY

3.1 INTRODUCTION

Ciprofloxacin Hydrochloride (Cipro) is an expensive antibiotic that was released in the U.S. in 1987 and has rapidly become one of the most frequently prescribed oral antibiotics in that country (Frieden and Mangi, 1990). It is a fluorinated quinolone carboxylic acid derivative with a wide range of activity against both gram negative and some gram positive aerobic bacteria. In initial clinical trials, oral ciprofloxacin was shown to be effective in eradicating susceptible bacteria in the urinary tract (UTI), skin and soft tissue (SST), respiratory tract (RTI), and in bone and joint infections (BJI) (Grasela et al, 1991).

Ciprofloxacin offers better absorption, wide distribution in tissues, and a broad spectrum of in-vitro activity against enteric gram-negative bacilli compared to other quinolones, such as nalidixic acid, norfloxacin, ofloxacin, and enoxacin (Louie, 1994). It is bactericidal by inhibiting the activity of the bacterial enzyme DNA gyrase, which is required for DNA replication and transcription (Hooper, 1988; Shen and Pernet, 1985). It is also the first oral antibiotic with effective anti-pseudomonal activity (Frieden and Mangi, 1990).

Paladino et al (1991) compared oral ciprofloxacin to intravenous antibiotics in a controlled study of 105 hospitalized adult patients who had each already received 8 or more days of intravenous antibiotic treatment for serious infections. The patients continued for three more days of conventional intravenous antibiotics, and were then randomly assigned to continue parenteral antibiotics (n=53) or switch to oral ciprofloxacin (n=52). Ninety-nine of the 105 patients were evaluable for assessment. The clinical and bacteriologic outcomes and adverse reaction frequency with oral ciprofloxacin were comparable to those of the continued intravenous antibiotic regimens. Ciprofloxacin thus allows physicians to treat orally several infections that previously required parenteral therapy. This provides two real advantages: patients with certain infections no longer need to be admitted to hospital for parenteral therapy, and in certain cases, patients already receiving such therapy in hospital may be discharged earlier on oral therapy (Louie, 1994). This can translate into significant cost savings and free-up hospital beds.

Grasela et al (1991) studied the effects of patients switching to ciprofloxacin from parenteral antibiotics for Respiratory Tract Infections (RTI), Skin and Soft Tissue (SST) infections, Bone and Joint Infections (BJI), and

Urinary Tract Infections (UTI). A total of 766 patients from 54 institutions were monitored. It was estimated that 16,732 doses of parenteral antibiotics were avoided and total drug plus hospital cost savings of approximately $980,000 (U.S.) were realized. Paladino et al (1991) also found that ciprofloxacin provided substantial cost savings.

With such benefits to both patient and taxpayer (in the case of the Canadian Health Care system), there is little wonder why ciprofloxacin has attained its apparently high popularity with physicians. In 1989, ciprofloxacin was the fourth most commonly prescribed antibacterial product in the U.S. (Frieden and Mangi, 1990). Ciprofloxacin is covered by the Government of Newfoundland and Labrador's Social Services Drug Plan and the Senior Citizens Subsidy Drug Program. The number of prescriptions for ciprofloxacin grew quickly since its addition to the formulary, now representing approximately 10,000 prescriptions annually at a cost of about $600,000 per year (Newfoundland, Department of Health, 1994). Unfortunately, there is growing evidence that this popular drug is being inappropriate prescribed.

Frieden and Mangi (1990) discussed four cases of inappropriate use of ciprofloxacin, but did not address the prevalence of inappropriate prescribing. Pickering et al

(1994) conducted chart reviews on patients in a long-term care setting and used criteria to assess appropriateness of prescription. They found that only 25% of prescriptions were appropriate. Rovers and Bjornson (1994) applied published drug use evaluation criteria to the Iowa Medicaid database and found that only 43.8% of ciprofloxacin community prescriptions met the criteria for appropriateness. However, only 26% of patients identified as receiving ciprofloxacin were included in the rating of appropriateness, and there appears to be substantial bias with respect to the proportion of nursing home patients included in the results.

There is, then, some evidence that ciprofloxacin is being inappropriately used, although there has been no comprehensive study performed in the community setting. The effect of such mis-prescribing has consequences beyond the cost issue. Inappropriate prescribing of ciprofloxacin can lead to an increase in ciprofloxacin-resistant strains of enteric gram-negative bacilli (Louie, 1994). Just three months after ciprofloxacin became available in the United States, the first positive culture for ciprofloxacin resistant methicillin-resistant S. aureus (MRSA) was isolated in a New York City health care facility. The level of ciprofloxacin-resistant MRSA skyrocketed from 0% to 79%

within one year of its introduction in one particular hospital (Blumberg et al, 1991). Even more disturbing is evidence that this ciprofloxacin-resistant strain can spread from patient to patient (Pickering et al, 1994). Trucksis et al (1991) found that two thirds of patients infected with fluoroquinolone-resistant S. Aureus had never used a fluoroquinolone before. These reports indicate that it will become increasingly difficult to treat patients with serious staphylococcal infections in the future (Pickering et al, 1994).

Given the concerns of inappropriate prescribing of ciprofloxacin, the fact that no study has comprehensively assessed appropriateness of ciprofloxacin utilization in the community, and that there are no data available for ciprofloxacin prescribing amongst Canadian physicians, this study was undertaken. It was designed to collect clinical data on patients prescribed ciprofloxacin by community doctors in Newfoundland, and to assess appropriateness of prescription using an academic panel of experts. To identify areas of controversy in the prescription of ciprofloxacin, a panel representing the manufacturer of ciprofloxacin assessed the same prescriptions, and their opinions were compared to those of the academic panel.

Before discussing this study's methodology, it is useful to review some general concepts of Drug Utilization Review.

3.1 OVERVIEW OF DRUG UTILIZATION REVIEW

Appropriate use of drugs in the community has been of concern for decades, and this concern has increased as medications have proliferated. Measurement of appropriate drug use may be accomplished through a drug utilization review (DUR).

The DUR in its many forms has existed for over twenty years. Through the 1970s, it tended to focus on drug interactions and overuse of controlled substances. In recent years, however, DUR has expanded to include not only such factors as excessive dose, redundancies, and drug-induced diseases, but also cost and the ability to measure the DUR's impact on use and morbidity verses historic controls (Jones, 1991). DUR can be population-based, studying trends in the aggregate community, or clinically-based, studying a sample of subjects and making generalizations to the broader community. Up until recently, relatively little attention has been given to micro-level DUR in Canada (Melnychuk et al, 1993). In the last few years, however, increasing scrutiny has been placed on rising costs in the publicly

funded health care system, especially in the presence of shrinking budgets. A sharp increase in drug costs to provincial formularies has focused attention on the appropriate use of drugs, and has thus increased DUR activity.

3.1.1 Definition of DUR

Various authors have put forth definitions of what DUR encompasses. In general, DUR seeks to measure and improve quality control and quality assurance of pharmaceuticals, and can be an integral component of a cost containment strategy (Erwin, 1991). Novitch (1991), asserts that the goal of every DUR be first and foremost improved patient care. In the majority of circumstances, increasing quality of care will, in fact, be the primary motivation for doing DUR. However, cost control in itself can be a legitimate reason for carrying out DUR. Indeed, one may argue that saving money on inappropriate drug use in a publicly funded health care system would ultimately preserve funding in other areas which might directly impact on quality of care, such as diagnostic technologies, or money to retain specialists within the system. Knapp (1991) defines DUR as "a flexible and broadly applicable process used to assess the quality and economy of drug prescribing, drug use by patients, and drug dispensing by pharmacists." This

definition is purposely broad, since DUR can be carried out for various health and cost related goals. This section of the thesis specifically reviews the "quality and economy" of prescribing of ciprofloxacin by Newfoundland physicians.

3.1.2 Retrospective verses Prospective DUR

DUR can be approached retrospectively or prospectively. *Prospective DUR* typically occurs at the time of prescription or dispensing of a drug. A computer screen provides patient histories regarding prescription medicine, so drug therapy problems can be detected before prescriptions are dispensed (Erwin, 1991). They can be based solely on the professional judgements of pharmacists (or physicians), or can be aided by computer-assisted alerts (Lipton and Bird, 1991). The advantage is an immediate impact on individual patient care. Historically then, prospective DUR puts the onus on the pharmacist for patient health. This is attractive in that it more actively involves professionals specially trained in pharmaceuticals in the care of the patient. There are, however, several disadvantages to relying solely on this approach. First, such a system by itself would likely only flag obvious medication problems such as overdosage, drug interactions, and allergies. It has no ability by itself to identify whether a certain drug is being appropriately prescribed. The pharmacist has no clinical data with which

to determine appropriateness of use, and would be unable to quantitatively analyze aggregate trends with respect to a specific drug's utilization. Furthermore, even for those areas where the pharmacist can intervene, there may be a lack of the private space and the time necessary to conduct proper patient counselling (Lipton and Bird, 1991). Soumerai and Lipton (1995) recently raised a number of concerns regarding computer-based drug utilization review, including questionable validity with respect to screening criteria, the inability to detect the under-use of certain drugs (such as anti-hypertensive agents), and the possibility of adverse health outcomes from denying prescribed drugs. Finally, there are questions as to the technological integration of pharmacies and physicians, and related questions of confidentiality to consider. By itself, prospective DUR is unable to identify inappropriate prescribing behaviour in the greater community, and may result in adverse outcomes for individual patients. In addition, one of the key aims of DUR is to focus physicians on their prescribing behaviour so that they exercise prudence when issuing prescriptions. This goal could be seriously undermined when focusing at the dispensing point.

Retrospective DUR is a systematic process that captures, reviews, analyzes, and interprets data on aggregate

medication use within a specific health care environment (Erwin, 1991). The data is archival in nature, and is usually focused on prescription drugs. However, over-the-counter remedies may also be the focus of DUR, or may be a variable measured in the DUR of a prescription medication.

Retrospective DUR compares drug use against predetermined criteria to identify aberrant patterns or trends, and providers are usually notified of the results through written communication. Some analysts criticize retrospective DUR because it does not bring about an immediate impact on patient health, so even when inappropriate prescribing behaviour is determined, it is often too late to benefit the patient (Lipton and Bird, 1991). However, retrospective drug utilization review provides a relatively inexpensive way to assess appropriateness of use of a drug, and can be used to identify problem areas where well-targeted interventions may be implemented.

In practice, one might consider using prospective DUR as an extension of retrospective DUR. That is, retrospective DUR could be used to identify and measure the extent of a perceived problem, and prospective DUR could be used to proactively deal with the problem. Retrospective DUR

continually focuses physicians on their prescribing, increasing awareness of their behaviours. When inappropriate behaviours are found, it might be possible to program checks and balances into pharmacy computers to proactively address the problem. In a sense, prospective DUR can be an intervention strategy necessitated by a retrospective study, and made possible by the technology of integrated pharmacy computer systems.

3.1.3 Process of DUR

Erwin (1991) suggests a number of steps in the process of drug utilization review. Included in these steps are preliminary data gathering, establishing resource requirements, designing the basic structure of the study, setting criteria, and data collection and analysis.

Brater et al (1991) suggest the data collection process in a DUR should provide the following information:

i) **Patient Characteristics**:

- Age, sex and birth date
- Weight and height
- Drug allergies
- Specific clinical signs and symptoms and diagnosis for the prescription of the drug

ii) **Drug Data:**

- Chemical entity
- Dose - strength and frequency
- All other medications patient known to be taking
- Longitudinal history of drug intake
- Appropriate indications for the drug
- Inappropriate indications for the drug

iii) **Health Care Utilization:**

- Patient hospitalizations/nursing home use
- Office visits
- Emergency Room Visits

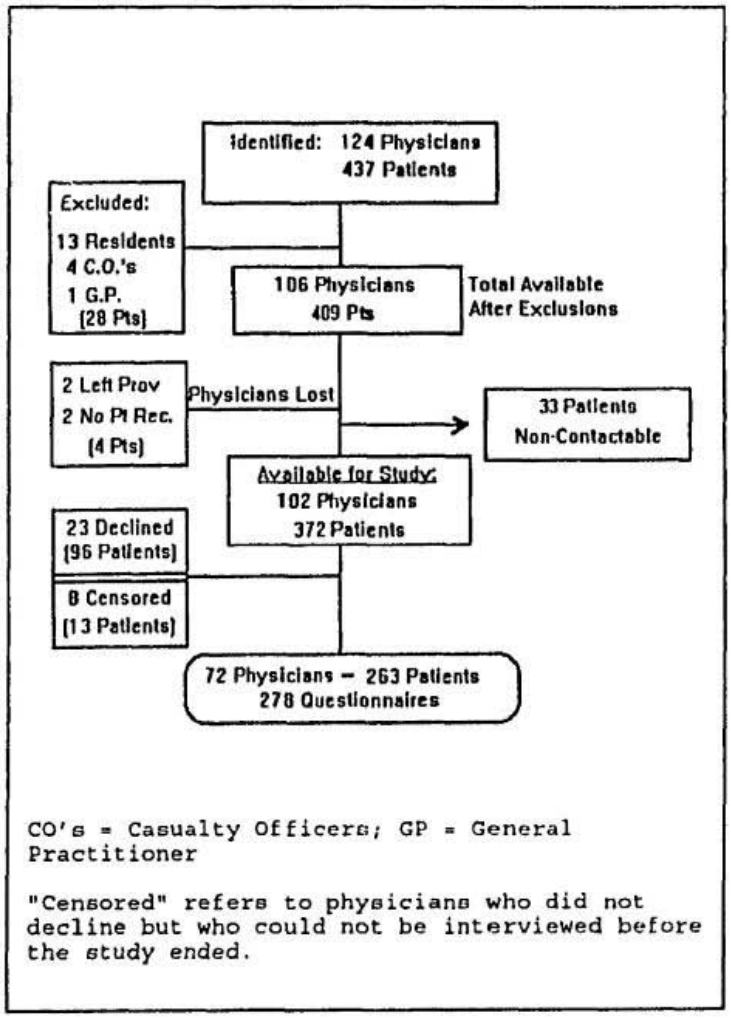
While there is likely no one database in existence which includes all the above data, combining several sources can result in the accumulation of a great deal of clinical data on the patient. The process of chart review and interview employed in this study captured virtually all of the data suggested above. The questionnaire administered by the interviewer is provided in appendix C. Beyond these steps, one must consider intervention strategies for any identified problem. Several possible intervention strategies will be addressed in the discussion section. Let us turn now to the methodology employed in this study, and subsequent data analysis.

3.2 METHODS

3.2.1 Subject Selection

The Department of Health (DOH) flagged all ciprofloxacin prescriptions claimed to its drug plans in the St. John's region between December 1993 and February 1994, generating a list of 559 prescriptions by 124 physicians for 437 patients. Figure 3.1 summarizes the physicians and patients included and excluded from study. Thirteen resident (trainee) physicians were excluded because the antibiotic was prescribed in a hospital setting, and because they may not

Figure 3.1:Summary of Physicians and Patients Included in the Study



CO's = Casualty Officers; GP = General Practitioner

"Censored" refers to physicians who did not decline but who could not be interviewed before the study ended.

have made the decision on drug choice. Four emergency room (ER) casualty officers (CO's) were excluded as it was questionable whether ER physicians were indicative of community physicians. The primary care physician who served on the academic review panel was also excluded in order to avoid potential bias. Two physicians were lost who had left the province, and two physicians could not be included because there was no record of the single patient on their respective lists. Thirty-three (33) patients were lost during the interview process, mostly due to the physician either having no record of the patient or no record of the particular visit. There were also two charts unavailable as they were in use as evidence in a court case.

Physicians were interviewed by one of two people: a research nurse and a research assistant with patient charts present. The interviewers used a questionnaire designed to extract patient demographic data, medical history, clinical signs and symptoms of infection, and diagnosis (See Appendix C). Physicians were asked what their treatment choice would be if ciprofloxacin was unavailable for use. If the choice was to continue treatment on an outpatient basis, the alternative drug choice was recorded. Only seven of the 278 questionnaires were completed solely from chart review. Physician and/or institutional consent was obtained prior to

chart review. In total, 72 of 102 (70.5%) available physicians were studied. Through interview of these doctors, 263 of 372 (70.7%) available patients were studied. A second questionnaire was completed for eight patients who had an additional prescription from the same physician for a second separate infections (not re-fills). An additional questionnaire was also completed for 7 patients who visited and received prescriptions from two different physicians. Thus 278 questionnaires were completed for review. Since these additional questionnaires represent prescriptions for separate infections or separate and independent physician decisions, they were reviewed by the panels and included in the analysis. Physicians were compensated at the Newfoundland partial assessment rate of $15 per patient for each chart reviewed.

The decision to study almost 300 cases was not based on a sample size estimation. Instead, all prescriptions during a set period were identified for study. A post-hoc estimation of the sample size was performed, expecting an approximate appropriateness level of 40%. This was estimated using results from other studies (Rovers and Bjornson, 1994; Pickering et al, 1994), taking into consideration differing methods of data collection and analysis. A 95% confidence interval between 30% and 50% appropriate was desired.

Ninety-two (92) questionnaires were required using these conditions. The final sample size of 278 questionnaires thus provided enough data to be confident about the proportion of inappropriate cases overall, and allowed for analysis of appropriateness according to infection-type.

While a solid proportion of physicians participated in the study, one might question whether the physicians declining to participate represent a possible source of bias. One way to compare the physicians who declined to participate to those who did is on the basis of the number of prescriptions per physician. The participants prescribed ciprofloxacin an average of 4.23 times during the 3 month period, whereas the non-participants prescribed ciprofloxacin an average of 4.35 times over the same period. The difference was not significant ($t=0.017$, $p=0.987$). In addition, the median number of prescriptions for both groups was 2 prescriptions over the 3 month period. It is thus unlikely that there is any significant bias between the prescribing practices of those physicians who participated and those who did not.

3.2.2 Patient Characteristics

Table 3.1 provides baseline characteristics of the 263 patients for which the 278 questionnaires were completed. There was a substantial amount of co-morbid illness in this group, with an average of 2.8 comorbidities and 3.6 concomitant medications per patient. Twenty-four percent (24%) had heart disease, 32% had COPD, and 13% had diabetes. Sixty-five patients (25%) resided in a nursing home.

Table 3.1: Selected Baseline Characteristics for all 263 patients Studied.

Patient Baseline Characteristics (N=263)		
Age		
Range	16-103	
Mean	62.8	
Sex (F/M)	161/102	(61%)
Residence		
At Home	194	(74%)
Nursing Home	65	(25%)
Other	4	(2%)
Current Smoker	92	(35%)
Avg Co-morbidities	2.8	
Heart Disease	63	(24%)
Diabetes	34	(13%)
COPD	84	(32%)
Allergies		
Penicillin	61	(23%)
Sulfonamides	17	(7%)
TMP/SMZ	7	(3%)

3.2.3 Ethics

This study was approved by the Human Investigations Committee, Memorial University of Newfoundland. Patient consent was not required, as no procedure was performed on patients. All patient information was kept confidential, with numerical identifiers for both the patients and physicians that were known only to the investigators.

Physicians were the focus of this study, and initial contact was made by the DOH. Investigators only contacted physicians after the DOH provided a list of physicians who did not decline to be contacted.

3.2.4 Panel Review

Two panels assessed the 278 questionnaires: an academic panel and an industry panel. The academic panel consisted of an infectious disease expert, a professor of pharmacy, and a general practitioner from the community. To highlight areas of agreement and disagreement on appropriateness of ciprofloxacin use between academics and industry, an industry panel also assessed the cases. This panel consisted of a physician who is a research fellow in clinical pharmacology and epidemiology; a product development manager in anti-infectives from Bayer, the manufacturer of ciprofloxacin; and a group health care

manager in anti-infectives from Bayer.

The academic panel used guidelines from the *Committee on Antimicrobial Agents, Canadian Infectious Disease Society* (1994). Decisions were made by panel consensus, using the guidelines and clinical judgement. The academic panel was guided by the premise that efficacious, less expensive alternatives should be used where available. Where there is suspicion of gram positive or anaerobic organisms ciprofloxacin should not be used, or should be used with additional coverage. Appendix D summarizes the academic panel's guidelines for appropriate use of ciprofloxacin.

Once the academic panel had completed its evaluation, the industry panel, blind to decisions made by the academic panel, assessed the same cases. The industry panel made its decisions using the academic panel's guidelines and incorporated the *Anti-infective Guidelines for Community-acquired Infections* published by the Ontario Anti-infective Review Panel (1994), and the *Recommendations on the Management of Chronic Bronchitis* from the Proceedings from the Canadian Bronchitis Symposium (1994).

Both panels first decided whether the choice of ciprofloxacin was appropriate for the particular infection,

and if so assessed the appropriateness of the dose and duration of the prescription. Classification of the rationale for inappropriate prescription was developed post-hoc, working with a panel member and using the recorded comments of the panel members from panel meetings (See table 3.2 for the academic panel's rationale).

Table 3.2: Classification of Academic Panel Decisions on Inappropriate Use of Ciprofloxacin

1.	**Not Appropriate for 1st-line Treatment of Respiratory Tract Infections**: Acute bronchitis, acute exacerbation of chronic bronchitis and community-acquired pneumonia.
2.	**Appropriate Indication/Cheaper Alternatives**: First-line use for lower urinary tract infections and nursing home-acquired pneumonia.
3.	**Inadequate Coverage**: Infections where gram + and/or anaerobic organisms are suspected. e.g. Cellulitis, abscesses, wound infections and aspiration pneumonia.
4.	**Wrong Indication and Cheaper Alternatives**: Cases where there are few data to support ciprofloxacin use and where cheaper alternatives exist. e.g. otitis and sinusitis.
5.	**Previous Quinolone Failure**: Prior failure of a quinolone for the infection, or use of ciprofloxacin just prior to the current infection.

3.4 STATISTICS

Yates-corrected chi-square and Fisher's exact test were used to compare two categorical variables. The kappa statistic was used to assess academic and industry panel agreement.

3.5 RESULTS

3.5.1 Appropriateness of Prescription

Overall, ciprofloxacin was considered to be appropriately prescribed in 42.1% of the 278 cases (95% CI = 0.36 to 0.48) by the academic panel and in 62.2% (95% CI = 0.57 to 0.68) by the industry panel (see table 3.3).

Table 3.3: Appropriateness of Ciprofloxacin Prescription for each panel, Overall and by site of infection.

Site of Infection	% of all Cases	Academic Panel	Industry Panel
All Sites	100%	42.1%	62.2%
RTI	66%	38.3%	66.1%
GUTI	18%	72.6%	72.6%
SST	16%	22.7%	34.1%

* RTI = Respiratory Tract Infection; GUTI = Genitourinary Tract Infection; SST = Skin and Soft Tissue Infection

Respiratory tract infections (RTIs) accounted for 66% of the 278 prescriptions reviewed. For cases of RTI, ciprofloxacin was considered to be appropriately prescribed 38.3% of the time by the academic panel and 66.1% of the time by the industry panel. Prescriptions for skin and soft tissue (SST) infections were considered to be appropriately prescribed least often by both panels (Academic, 22.7%; Industry, 34.1%), while ciprofloxacin was appropriately prescribed most often for genitourinary tract infections (GUTI) (72.6% by both panels).

Table 3.4: Academic Panel Rationale for the 161 Cases of Inappropriate Ciprofloxacin Prescription

Not Appropriate 1st-Line for RTI	66 (41%)
Appropriate Indication, but Cheaper Alternatives	40 (25%)
Inadequate Coverage	36 (22%)
Wrong Indication & Cheaper Alternatives	16 (10%)
Previous Quinolone Failure	3 (2%)

Table 3.4 summarizes the academic panel's reasons for inappropriate prescription of ciprofloxacin. In 41% of prescriptions, it was inappropriately prescribed as first-

line for RTI. In 25% of cases ciprofloxacin was prescribed for infections that it is indicated to treat, but cheaper alternatives could have been used. In a further 22% of cases ciprofloxacin provided inadequate coverage for the infection. Of the 36 cases that were inappropriate due to inadequate coverage, 20 (55.6%) would have been appropriate had the treatment been augmented with a second agent providing anaerobic coverage, such as clindamycin or metronidazole. Infections requiring added coverage included post-operative wound infections, cellulitis secondary to diabetes or peripheral vascular disease (PVD), diverticulitis, and several abscesses.

Table 3.5 presents the rationale used by the industry panel for inappropriate ciprofloxacin prescriptions. Sixty-eight percent (68%) of the cases considered inappropriate by the industry panel were due to cheaper

Table 3.5: Industry Panel Rationale for Inappropriate Ciprofloxacin Prescription (N=105)

Cheaper Alternatives	71 (68%)
Inadequate Coverage, Wrong Drug	15 (14%)
Inadequate Coverage, Needs 2nd Agent	14 (13%)
No Indication for Use	4 (4%)
Recent Ciprofloxacin failure	1 (1%)

alternatives being available, and 27% were due to inadequate coverage. The industry panel indicated that 48% of the inadequate coverage cases were due to need of a second agent. Infections cited as needing additional coverage included cellulitis (3), wound infections (2), diverticulitis (2), aspiration pneumonia (1), and a number of other soft tissue infections with a high suspicion of anaerobic organisms. The industry panel considered prescriptions of ciprofloxacin for diabetic cellulitis appropriate using the Ontario Anti-infective Review Panel (1994) guidelines, which indicates that ciprofloxacin is appropriate first-line (plus or minus clindamycin) for cases of cellulitis complicated by diabetes.

Table 3.6 provides appropriateness data by physician diagnosis. Acute exacerbation of chronic bronchitis (AECB) was the most common diagnosis and prescriptions for it were considered appropriate in 34.9% of cases by the academic panel and in 88.9% by the industry panel. Pneumonia comprised 21% of cases and prescriptions were considered appropriate in 40.7% of such cases by the academic panel and in 74.6% of cases by the industry panel. Of 59 cases of pneumonia, 31 were acquired in a nursing home. The academic panel considered prescriptions for nursing home-acquired pneumonia to be appropriate in 38.7% of cases, arguing that

cheaper alternatives should have been used first. The industry panel considered 96.7% of such prescriptions appropriate on the basis of the Canadian Infectious Disease Society's guidelines used by the academic panel.

Table 3.6: Appropriateness of Prescription for Common Diagnoses for each Panel.

Diagnosis	% of all Cases (N)	Appropriateness of Rx	
		Academic	Industry
AECB	23% (63)	22 (34.9%)	56 (88.9%)
Pneumonia	21% (59)	24 (40.7%)	44 (74.6%)
Acute Bronchitis	14% (38)	13 (34.2%)	12 (31.6%)
Cystitis	8% (22)	16 (72.7%)	14 (63.6%)
Cellulitis or Abscess	8% (23)	3 (13.0%)	6 (26.1%)
Prostatitis or Pyelonephritis	7% (19)	15 (78.9%)	18 (94.7%)
Otitis or Sinusitis	6% (17)	8 (47.1%)	6 (35.3%)

In patients with cellulitis and abscesses ciprofloxacin was considered to be appropriately prescribed in only 13% of such cases by the academic panel. The industry panel was higher (26.1%), but still considered ciprofloxacin inappropriate for most prescriptions for SST infections.

Pyelonephritis and prostatitis were appropriate indications for ciprofloxacin, and were considered so in 78.9% and 94.7% of cases by the academic and industry panels, however these infections only comprised about 7% of the total reviewed.

A key factor differentiating appropriateness of prescription was whether ciprofloxacin was used as a first- or second-line agent. When the drug was used as a first-line agent, ciprofloxacin was considered to be appropriately prescribed in 28% of cases by the academic panel. If prior antibiotic therapy was used, appropriateness rate rose to 68.8% ($p < 0.00001$), and if there was an antibiotic failure, appropriateness rose further to 74%.

Another area of difference was between specialists and general practitioners. The academic panel found specialists to prescribe ciprofloxacin appropriately 60% of the time, compared to 40% for general practitioners ($p = 0.035$). This difference was mainly due to the effect of 3 urologists in the specialist group using ciprofloxacin for prostatitis.

There were 25 cases where the patient had two or more antibiotic allergies, and this appears to have influenced the decision on appropriateness. The academic panel considered 76% percent of prescriptions appropriate when

there were two or more allergies ($p < 0.001$).

Dosing was usually appropriate (76%), with the most common dose 500 mg BID for 10 days. When the dose was inappropriate it was mainly due to the dose being too low (75%). The academic panel did recognize, however, that it was difficult to judge the dose without comprehensive renal function data and patient body mass. The panel noted that TID dosing with ciprofloxacin is inappropriate, and there were 25 such cases (9.0%) in the study sample.

3.5.2 Panel Agreement

There was a significant difference in ratings of appropriateness between the two panels for AECB ($\chi^2 = 36.65$, $p < 0.00001$) and pneumonia ($\chi^2 = 12.53$, $p < 0.0005$). The difference in appropriateness of prescription for pneumonia can be attributed to the difference of opinion regarding pneumonia acquired in the nursing home, with the appropriateness rates being 38.7% and 96.7% for the academic

Table 3.7: Academic and Industry Panel Agreement

Comparison	Agreement
Overall (N = 278)	P' = 0.67 K''= 0.36
Excl. Nursing Home Pneumonia (N = 247)	P = 0.70 K = 0.41
Excluding AECB & N.H Pneumonia (N = 184)	P = 0.79 K = 0.58

* P = percent agreement
** K = kappa

and industry panels respectively ($p < 0.0001$). Comparisons for all other diagnoses yielded no significant difference between the panels ($0.478 < p < 1.00$).

We also tested panel concurrence using the kappa statistic and applying Landis and Koch's (1977) guidelines for interpretation. Kappa values for agreement between the two panels are provided in table 3.7. Overall agreement was fair ($0.21 < K < 0.40$), but agreement improved to moderate ($0.41 < K < 0.60$) when cases of nursing home-acquired pneumonia were removed. When cases of AECB and nursing home-acquired pneumonia were removed agreement remained moderate, but was higher and bordered on substantial ($0.61 < K < 0.80$).

3.6 DISCUSSION

3.6.1 Panel Decisions on Appropriateness

Where the two panels agree on inappropriate prescribing, there is little doubt that the prescriptions were in fact inappropriate. Where they disagree, one can present arguments for both sides.

The panels tended to agree that first-line use for

community-acquired pneumonia, acute bronchitis, lower urinary tract infections, sinusitis and otitis media are inappropriate. They also tended to agree that ciprofloxacin provides inadequate coverage for most abscesses, post-operative wound infections, aspiration pneumonia and other infections where there is a strong possibility of gram positive and/or anaerobic organisms (Hooper and Woolfson, 1991).

There are two clear differences of opinion regarding appropriateness for nursing home-acquired pneumonia and acute exacerbation of chronic bronchitis (AECB). The Canadian Bronchitis Symposium Recommendations on the Management of Chronic Bronchitis (Proceedings from the Canadian Bronchitis Symposium, 1994) separates patients with Chronic Obstructive Pulmonary Disease (COPD) into several severity groups depending on lung function, age, number of exacerbations, and number of symptoms present. Those recommendations cite several antibiotics, including quinolones, that could be used empirically as first line agents if patients fall into severity categories designated as "group 3" or "group 4". Group 3 patients would have one of the following attributes: 1) age over 65; (2) FEV_1 < 50% of predicted level; or (3) four or more acute exacerbations per year. Group 4 patients have reasonable

lung reserve, but have other risk factors that increase the likelihood of a poor outcome from an acute exacerbation, including age, poor lung function, and comorbid illness such as congestive heart failure, chronic renal failure, or chronic liver disease. The argument is that first-line use of second-line agents is justified if such treatment is expected to prevent a hospital admission, a second course of therapy or further diagnostic tests. The industry panel considered ciprofloxacin to be appropriate for AECB patients who can be classified as "group 3" or "group 4" patients, since the guidelines provided an indication for quinolones. However, since co-trimoxazole was also included in the list of acceptable first-line agents, it could be used first where available as an alternative.

The difference between the two panels regarding nursing home-acquired pneumonia was mainly a cost issue. The industry panel considered all but one case of nursing home-acquired pneumonia appropriate, the inappropriate one being aspiration pneumonia. Of the 19 cases of nursing home-acquired pneumonia considered inappropriate by the academic panel, 79% were due to the availability of cheaper alternatives. Of the four remaining inappropriate cases, three were coverage issues (2 aspiration pneumonia and 1 streptococcal pneumonia), and one was due to ciprofloxacin

use just prior to the infection.

Another area of disagreement between the two panels related to 4 cases of diabetic cellulitis that the industry panel considered appropriate based on the Ontario Anti-Infective Review Panel guidelines (1994) which indicate ciprofloxacin may be used first line for diabetic foot ulcer, plus or minus clindamycin. The guidelines do recommend, however, that metronidazole or clindamycin be used concomitantly if anaerobes are an issue. The academic panel considered all 4 cases inappropriate, due to the suspicion of anaerobes and need for additional coverage, such as clindamycin or metronidazole.

3.6.2 Rationale for Inappropriate Physician Prescribing

Primary care physicians have few practical diagnostic aids to rationalize therapy during the initial consultation. It usually takes several days for bacteriological investigation, which is of limited benefit, except for retrospective analysis of the treatment (Grob, 1992). Cultures were sent in only 24 cases (8.6%) in this study. Treatment is therefore usually empiric, based on likely pathogens and the severity of the disease state (Grob, 1992). Joel Lexchin (1993) points to the large influence of detailing by pharmaceutical firms on physician prescribing

behaviour, stating that 85% to 95% of Canadian physicians see pharmaceutical detailers, and that British and Canadian general practitioners ranked detailers as either their first or second most frequently used information source (Lexchin, 1993). Pharmaceutical firms spend over $220 million on detailing (Lexchin, 1989), so it is little wonder physicians rely on this readily available source of information. Furthermore, many physicians attend company-sponsored CME courses (Lexchin, 1993). It is interesting to note that physicians were found to have a low opinion of these sources of information, even though they tend to rely on them (Lexchin 1993). This means that there is a need on the part of physicians for readily available, digestible and non-biased information.

Prescription decisions are also influenced by drug availability and cost (Heppler et al, 1982; Howe, 1976). An apparent problem with the cost factor is that many physicians seem unaware of the cost of the drugs they prescribe. Hux and Naylor (1994) surveyed 1072 physicians regarding a hypothetical case of acute exacerbation of chronic bronchitis. They asked the physicians how they would diagnose and treat the patient, and provided a list of six antibiotics from which to choose treatment. Two of the six medications were expensive (ciprofloxacin and cefaclor),

and four were inexpensive (co-trimoxazole, amoxicillin, erythromycin, and a choice of tetracyclines). One group of physicians was given drug prices with their list, the other group was not provided drug prices. The group without the prices chose an expensive antibiotic 38% of the time, while the group which were shown prices only chose the expensive antibiotics 18% of the time ($p < 0.001$). Hux and Naylor highlight the inadequacy of physician knowledge of drug prices, citing a study by Safavi and Hayword (1992) which found that less than 40% of clinicians were able to come within $10 U.S. of the price of a one month supply of their preferred NSAID or H_2-receptor antagonist (Hux and Naylor, 1994; Safavi and Hayword, 1992). So while physicians are influenced by cost, their lack of knowledge regarding relative pricing may lead to inappropriate prescribing of expensive agents.

In this study, two issues arose with respect to inappropriate prescribing. First, there was substantial inappropriate prescribing on the basis of etiology of infection and the expected pharmacokinetic properties of the selected medication. The fact that 13% of ciprofloxacin prescriptions were for acute bronchitis, a predominantly viral infection (Brown, 1989; Gwaltney, 1985; Phair, 1991), raises concerns about the utilization of antibiotics in

general. The use of ciprofloxacin for infections requiring anaerobic coverage raises concerns about physician knowledge of the etiology of these infections and/or the antimicrobial spectrum of the antibiotic being chosen. The second issue relates to the lack of consideration given to the acquisition cost of the chosen drug. Ciprofloxacin costs approximately $5.14 per day for a 500mg BID prescription, yet there are a number of cheaper first-line alternatives, including tetracyclines ($0.06/day), erythromycin ($1.00/day), amoxicillin ($0.66/day), co-trimoxazole ($0.34/day), and cephalexin ($0.69 per day).

3.6.3 Limitations of the Study

While the questionnaire collected data on concomitant medications, a longitudinal drug history was not recorded. Recording such information would have made it impossible to conduct the interview within a 10-15 minute period. Physicians expressing recent antibiotic use or other factors which may have contributed to their decision to prescribe ciprofloxacin had their comments recorded.

Physician interviews were conducted six months to one year after the patient visit discussed. This may have resulted in some recall error, however it is difficult to ascertain whether this error would resulted in recall bias. Recall

bias is a systematic departure from the truth resulting from imperfect recall of an event, and not simply inaccuracies due to recall (Coughlin, 1990). It is likely that some recall error occurred, however, the chart review combined with personal interview should have mitigated such error, and there is no evidence or reason to suspect that the time period between the initial patient visit and the interview resulted in a biased sample.

Seasonality may have also played a role in this study. Lower respiratory infections have a higher incidence in winter (Brown, 1989; Gwaltney, 1985; Phair, 1991), which was the period for this study (December-February). In a study of 129 subjects presenting to St. John's pharmacies with prescriptions for ciprofloxacin, Butler (1995) found a lesser percentage of lower RTIs than in this study (47% versus 66%). This may reflect seasonal differences, since Butler's study was carried out in March. Another possibility, however, is that Butler's study captured a slight improvement in the appropriateness of prescription, possibly due to interview of 71 St. John's area physicians just prior to that study. This is supported not only by the fact that there were relatively fewer RTIs (generally inappropriate) and relatively more GUTIs (which were generally appropriate) in Butler's study, but also because

only 42% of prescriptions in Butler's study were first-line, compared to 64% in this study. Since first-line use of ciprofloxacin was associated with a lower level of appropriateness, it is conceivable that physician prescribing improved during the course of the DUR.

Another possible criticism may lie in the external validity of the study, since all patients were covered by the two government drug plans. In the study of patients presenting to pharmacies with ciprofloxacin prescriptions, however, Butler (1995) found that in 103 of the 129 cases (80%) of ciprofloxacin prescription, the patients were not covered by these government drug plans. More importantly, there was no significant difference between government insured patients and those without insurance or covered by privately insurance companies with respect to the general indication for use ($p=0.80$).

Another limitation of this study lies in its inability to provide an estimate of the economic impact of inappropriate ciprofloxacin prescription. The retrospective study design makes it impossible to assess what the true alternative actions and occurrences would have been if ciprofloxacin was avoided in inappropriate circumstances. The alternative actions and therapy cited by physicians are hypothetical and

open to substantial bias. Do physicians cite expensive alternatives to make the case seem serious, warranting the use of the ciprofloxacin? Alternatively, do they cite inexpensive medications to show that they are cost-conscious, and that ciprofloxacin was chosen because of its perceived superior efficacy? In 5% of inappropriate cases, the physician indicated that the patient would be hospitalized if ciprofloxacin was unavailable for use. Some might argue that the large incremental cost of hospitalization over oral ciprofloxacin may provide a cost advantage in using the drug. However, the number of avoided hospitalizations is unknown, since outcome data was not collected. Some patients may have required hospitalization despite the ciprofloxacin prescription. Alternatively inappropriate prescriptions for serious SST infections may have led to a hospitalization that may have been avoided had a more appropriate oral antibiotic been chosen. The only way to truly assess the economic benefit (or cost) of ciprofloxacin is to conduct a pharmacoeconomic study which comprehensively monitors all health care consumption by the patient, including visits to other physicians, hospitalizations, other prescribed medications, laboratory tests, etc. (Bootman et al, 1989). While this can be retrospectively achieved, a prospective trial which measures clinical outcome and alternative costs is preferred. Such a

trial would be of particular interest for the cases of AECB and nursing home-acquired pneumonia, as these are areas that the industry panel feel that ciprofloxacin may provide a net economic benefit.

Finally, panel concordance was limited by a number of factors, including differing clinical backgrounds, implicit judgements using guidelines as opposed to criterion-based decision making, and the possibility of bias on the part of the industry panel. The agreement was quite good considering these factors.

Despite these limitations one can confidently conclude that ciprofloxacin is being inappropriately prescribed, contributing to the productive and allocative inefficiencies which increase the overall cost of delivering health care in Newfoundland. If one wishes to increase efficiency in the system, intervention strategies must be devised which provide correction without subjecting the health care system to pure market forces. The following section discusses several possible intervention strategies to deal with the problem of over-utilization of drugs.

3.6.4 Intervention Strategies

The literature suggests a number of possible methods of reducing over utilization and inappropriate use of pharmaceuticals. The effectiveness of these interventions depends on the level of desired reduction in prescriptions, the level of adverse effect on the availability of certain medications to patients, and society's acceptance of such "side-effects." Several interventions designed to change physician behaviour are discussed here, including clinical practice guidelines, triplicate prescription programs, and academic detailing. In addition, overall utilization can be reduced through prescription limits or copayments.

Clinical Practice Guidelines

Clinical practice guidelines are educational in that they attempt to inform practitioners about optimal strategies for diagnosis and management of various conditions. Practice guidelines have been relatively unsuccessful at changing physician behaviour, however, possibly due to difficulty of application to specific cases, distrust of the "experts" writing the guidelines, or because they are not written in an applied fashion (Greco & Eisenberg, 1993). These guidelines might be more successful in changing behaviour if disseminated through opinion leaders (Greco & Eisenberg, 1993).

Triplicate Prescription Programs

Triplicate prescription programs have traditionally been used to target controlled substances such as narcotics or benzodiazepines (Schwartz, 1992). A list of medications is provided to physicians for which they must complete a three-copy prescription form in order for the pharmacy to fill the prescription. The physician retains one copy and gives the other two to the patient to present to the pharmacy, which in turn retains a copy and forwards the third copy to the department of health or other regulating agency (Schwartz, 1992). Physicians can thus be monitored with respect to their prescribing of these medications. This approach reduces the utilization of the targeted medications, but studies have raised concerns over less efficacious alternatives being substituted to avoid scrutiny (Schwartz, 1992; Weintraub et al, 1991). Further, sophisticated computer programs such as the Island Health Information System (IHIS) recently implemented in Prince Edward Island integrate government agencies, pharmacies and physicians (West, 1994) make the triplicate prescription idea obsolete. Newfoundland currently does not have such a system in place, but the Newfoundland DOH now requires pharmacies to report physician identification codes with each prescription claim in order to be reimbursed. High prescribers of certain drugs can easily be tracked anyway, eliminating the need for

a triplicate prescription pad.

Academic Detailing

Also known as educational outreach (Soumerai et al, 1989), academic detailing is a process whereby individual physicians are targeted for education on proper use of drugs and other therapies (Greco & Eisenberg, 1993; Frazier et al, 1991). The efficiency and effectiveness of such an approach is suggested by the resources dedicated to this approach by the pharmaceutical industry (Soumerai et al, 1989). There is also literature supporting the effectiveness of this approach. In a randomized controlled trial, Avorn and Soumerai (1983) assigned 435 physicians to one of three groups: two intervention groups and a control. One of the intervention groups met one-on-one with a trained pharmacist on two occasions and were provided educational material designed for positive reinforcement. The other intervention group only received printed materials. The one-on-one group demonstrated a reduction in prescriptions of the target drugs of 14% ($p = 0.0001$). Importantly, 92% of physicians approached agreed to meet with the academic detailers (Avorn & Soumerai, 1983).

Hux and Naylor (1994) noted that physicians were largely unaware of the cost differential among various therapeutic

alternatives, but they did note that physicians significantly reduce their selection of expensive drugs when they are provided with a pocket price manual (Hux and Naylor, 1994; Frazier et al, 1991). This suggests that a significant difference in prescribing practices might be achieved through academic detailing with price information (Frazier et al, 1991; De Santis et al, 1994). This might even be accomplished through direct mail to physicians, which would be inexpensive and relatively easy to monitor. However, Soumerai et al (1989) suggest that using printed materials alone does not significantly improve prescribing.

Academic detailing offers several advantages, including a strong track record for success (Greco & Eisenberg, 1993), the possibility of net cost savings while at the same time enhancing physician knowledge, and presumably, improved quality of care (Soumerai et al, 1989)

There are several concerns with academic detailing, however. No studies of the effectiveness of academic detailing have been done outside the academic settings and there is some concern about the lasting effect of such an intervention (Soumerai et al, 1989). The latter point might not be a great concern if academic detailing were an ongoing process, as opposed to a time-limited exercise as in the study

environment. A final concern rests with the reach of academic detailing. Butler (1995) found in an exit survey of pharmacists that cefuroxime, an expensive broad spectrum cephalosporin, was increasing in use in the St. John's area. It is even more expensive than ciprofloxacin at the same dosage level. One might question, then, whether academic detailing for ciprofloxacin alone would provide sufficient information to avoid the use of other expensive alternatives. Furthermore, antibiotics actually represent a small proportion of drugs prescribed in an office practice (Frazier et al, 1991), so one would optimally like to see a broad scope for academic detailing, or instead consider macro-level intervention strategies which can reach a broader range of drugs (e g. copayments). However, there is a great deal of literature supporting academic detailing, and the advantage of increased physician knowledge cannot be understated.

Prescription Limits

Prescription limits represent a severe cost containment strategy in which limits are placed on the number or total value of prescriptions reimbursed on a monthly basis (Soumerai et al, 1993). While the restriction itself may force physicians to prescribe the most necessary and appropriate medications for their patients, it is not a

measure which is designed to reduce inappropriate prescribing. In a study of the impact of a Medicaid prescription limit of 3 prescriptions per month in New Hampshire, Soumerai et al (1991) detected a 35% decline in the use of study drugs after the cap was applied, with no change in the comparison cohort. However, limiting reimbursement for effective drugs was found to put frail, low-income, elderly patients at increased risk of institutionalization in nursing homes, increasing the cost to the Medicaid program (Soumerai et al, 1991). Prescription limits, while reducing the utilization of non-essential medications, also reduced the utilization of essential medications, such as insulin (-28%), thiazides (-28%), and furosemide (-30%) (Soumerai et al, 1987). While this approach seemed effective in lowering the number of prescriptions reimbursed, the negative health outcomes and questionable net economic payback make this approach undesirable.

Copayments

Copayments are a method of cost sharing between the insurer and the patient. They can take the form of a percentage of the prescription cost (often 10 to 15 percent of prescription cost), or a fixed fee of one to three dollars per prescription (Soumerai et al, 1993). Copayments as low

as fifty cents U.S. have been found to reduce prescriptions by 20% (Soumerai et al 1993; Nelson et al, 1984; Smith, 1993), although accounting for inflation, that value is actually just over $1 U.S. (Smith, 1993). Medicaid programs that have introduced such copayments have all observed declines ranging from 5 to 10 percent in overall drug utilization, however, there is also some evidence that even modest cost sharing can result in the reduction of "essential" agents as well as less essential agents (Soumerai et al, 1993). In addition, some economists argue that the effectiveness of any user charge in the health services market is inherently limited by the information asymmetry between patient and doctor (Blomqvist, 1994).

Despite these shortcomings, the increase in the elderly population qualifying for drug program benefits coupled with the production of newer, more expensive drugs that have extended patent protection will likely further strain the provincial drug plan (McIsaac et al, 1994). While specific interventions aimed at reducing inappropriate physician prescribing are preferred, governments may be forced to consider macro-level interventions, such as co-payments, in order to counteract these pressures. Given the heightened social and political sensitivity surrounding the application of such an intervention to needy Canadians, provincial

governments should search for innovative variations which attempt to capture the benefits of market correction, without undue hardship. If a generalized co-payment seems too draconian a measure, than one might wish to consider selectively applying a copayment to drugs which are expensive and over-used, and where efficacious and cheaper alternatives exist. This would provide a lower net benefit to the program, but would inject some market forces where they are needed most. Other options exist, such as tighter administrative control on the government formularies. This might include de-listing drugs, or requiring written justification for the use of certain agents. Of all the alternatives academic detailing appears to have the most promise of the existing alternatives. Of course another alternative is the status quo. However, that is unacceptable, since the growth in the cost of these drug plans will divert funds from other health services in a relatively fixed aggregate health care budget.

3.7 CONCLUSIONS

One can conclude that ciprofloxacin is being inappropriately prescribed for a number of infection types, including first-line for community-acquired upper and lower respiratory infections and certain skin infections, such as abscesses and cellulitis. Inappropriate prescriptions seem to stem from a combination of lack of knowledge of pharmacotherapy for common infections, as well as a lack of knowledge or concern regarding the cost differential among antibiotic alternatives. Some differences in opinion exist between academics and industry regarding the appropriateness of ciprofloxacin use for acute exacerbation of chronic bronchitis and nursing home-acquired pneumonia. A prospective pharmacoeconomic study is required to answer broader questions regarding ciprofloxacin use in these two areas. Where inappropriate prescribing is due to the existence of cheaper alternatives one can conclude that productive efficiency is being compromised. One might consider inappropriate prescribing due to infection-type to be a form of allocative inefficiency. Given the high degree of inappropriate prescribing by physicians, education on proper microbiological and cost-effective use of ciprofloxacin and other antibiotics is needed. The literature supports using academic detailing to educate physicians and reduce utilization of over-used drugs. There

are some indications that other expensive antibiotics are increasing in use. Given the broad range of pharmaceutical therapeutic choices available, it is reasonable to conclude that mis-prescribing of drugs is not restricted to ciprofloxacin or even antibiotics for that matter. A broad-based approach, such as co-payments, may be necessary to address this systematic problem. A co-payment that focuses only on problem areas could be useful, but requires study. Since co-payments are not politically expedient, academic detailing should be employed to address current over-use of ciprofloxacin and antibiotics in general.

SECTION IV

SYNOPSIS

The delivery of health care resources in Newfoundland has been sub-optimal due to allocative and productive inefficiencies. This thesis has examined measurement of allocative efficiency in the context of bed utilization review. It has demonstrated that trained nurses can reliably and validly collect data on inpatient stay and decide whether each hospital day is appropriate using partially subjective techniques. Nurses may also make such judgments using a modified form of the Appropriateness Evaluation Protocol.

The area of greatest disagreement was for classification of the inappropriate hospital stay. Hospital administrators might thus be somewhat concerned about their ability to interpret the data, and thus take corrective actions when inappropriate stay has been identified. Future research should use a larger sample to measure the extent of and reasons for disagreement, and to determine whether the differences in classification of inappropriate stay between the AEP and Nurses A and B result from differing classification systems.

Inappropriate utilization of ciprofloxacin is but one example of productive inefficiency within the health care system. Antibiotic overuse seems to be endemic, thus future

research should quantify the extent of the problem, as well as identify reasons for this behaviour. Research should also be conducted in the area of academic detailing to reduce inappropriate physician prescribing as one means of reducing the productive inefficiencies in the Newfoundland health care system.

REFERENCES

Avorn J, and Soumerai S. **Improving Drug-Therapy Decisions Through Educational Outreach: A Randomized Control Trial of Academically Based "Detailing."** The New England Journal of Medicine, 1983;308:1457-1463.

Barrett BJ, McDonald J, Parfrey PS. **Concurrent Utilization Review to Identify Determinants and Potential Interventions.** Annals RCPSC 1994;27(3):140-144.

Barrett BJ, Parfrey PS, McDonald J, Haire R, Peachey G. **A Controlled Trial of Concurrent Utilization Review to Reduce Inappropriate Hospital Stay** (Submitted).

Billi JE, Duran-Arenas L, Wise CG, Bernard AM, McQuillon M, Stross JK. **The Effects of a Low-Cost Intervention Program on Hospital Costs.** Journal of General Internal Medicine, 1992;7:411-7.

Blomqvist A. "Economics Issues in Canadian Health Care." In A Blomqvist and DM Brown, eds. **Limits to Care.** Toronto, Ont.: C.D. Howe Institute, 1994. pp. 3-50.

Blumberg HM, Rimland D, Carroll DJ et al. **Rapid development of ciprofloxacin resistance in methicillin-susceptible and - resistant Staphylococcus aureus**. Journal of Infectious Disease 1991;163:1279-1285.

Bootman JL, Larson LN, McGhan WF, Townshend RJ. **Pharmacoeconomic Research and Clinical Trials: Concepts and Issues**. DICP, The Annals of Pharmacotherapy, 1989;23:693-697.

Brater D et al. Panel I. **Drug Utilization Review: Criteria.** Workshop on drug utilization review - Rockville, Maryland, U.S.A., November 26-27, 1990. Clinical Pharmacology Therapeutics, 1991;50 (Suppl):626-628.

Brown RB. **Acute and Chronic Bronchitis: A Practical Management Strategy**. Post Graduate Medicine, 1989;85(8):249-254.

Butler, JS. **Demographic and Clinical Patterns of Use of Ciprofloxacin in the General Community.** A paper submitted to Dr. Sharon Buehler in partial fulfilment of course requirements for M6270, Memorial University of Newfoundland. Unpublished, 1995.

Committee on Antimicrobial Agents, Canadian Infectious Disease Society: **Ciprofloxacin: an Oral Quinolone for the Treatment of infections with Gram Negative Pathogens**. CMAJ, 1994;150 (5):669-676.

Coughlin SS. **Recall Bias in Epidemiologic Studies**. Journal of Clinical Epidemiology, 1990;43(1):87-91.

Culyer AJ. **Health Care Expenditures in Canada: Myth and Reality; Past and Future**. Toronto: Canadian Tax Foundation, 1988.

De Santis G, Harvey KJ, Howard D, Mashford ML, Moulds RFW. **Improving the Quality of Antibiotic Prescription Patterns in General Practice: The Role of Educational Intervention**. Medical Journal of Australia 1994;160(18):502-505.

Erwin GW. **The definition of drug utilization review: Statement of issues**. Clinical Pharmacology Therapeutics 1991;50 (Suppl): 596-599.

Evans, RG. **Strained Mercy: The Economics of Canadian Health Care**. Toronto: Butterworths, 1984.

Frazier LM, Brown JT, Divine GW, Fleming GR, Philips NM, et al. **Can Physician Education Lower the Cost of Prescription Drugs? A Prospective, Controlled Trial.** Annals of Internal Medicine, 1991; 115:116-121.

Frieden TR and Mangi RJ. **Inappropriate Use of Oral Ciprofloxacin**. JAMA, 1990; 264: 1438-1440.

Gertman PM and Restuccia JD. **The Appropriateness Evaluation Protocol: A Technique for Assessing Unnecessary Days of Hospital Care**. Medical Care, 1981;19(8):855-871.

Grasela TH et al. **Clinical and Economic Impact of Oral Ciprofloxacin as Follow-Up to Parenteral Antibiotics**. DICP, The Annals of Pharmacotherapy, 1991;25: 857-862.

Greco PJ, Eisenberg JM. **Changing Physicians Practices**. The New England Journal of Medicine, 1993;329(17):1271-1273.

Grob PR. **Antibiotic Prescribing Practices and Patient Compliance in the Community**. Scandinavian Journal of Infectious Disease, 1992;83 (Suppl):7-14.

Gwaltney JM Jr. **Acute Bronchitis**. In Mandel GL, Douglas RG Jr, Bennett JE, eds. Principles and Practice of Infectious Diseases. 2nd edition. New York: J. Wiley, 1985: 385-7.

Heppler CD, Clyne KG and Donta ST. **Rationales Expressed by Empiric Antibiotic Prescribers**. American Journal of Hospital Pharmacists, 1982;39:1647-55.

Hillman AL, Pauly MV, Kertstein JJ. **How do Financial Incentives Affect Physicians' Clinical Decisions and the Financial Performance of Health Maintenance Organizations?** The New England Journal of Medicine, 1989;321:86-92.

Hooper DC and Wolfson JS. **Fluoroquinolone Antimicrobial Agents**. The New England Journal of Medicine 1991;324(6):384-392.

Hooper DC, Wolfson JS. **Mode of action of the quinolone antimicrobial agents**. Reviews of Infectious Disease 1988;10 (Suppl 1): S14-21.

Howe JG. **Clinical Judgement and Antibiotic Use in General Practice**. British Medical Journal, 1976;11:1061-1064.

Hux JE and Naylor CD. **Drug Prices and Third Party Payment; Do they Influence Medication Selection?** Pharmacoeconomics, 1994; 5(4):343-350.

Jones J. **A View From the Drug Utilization Review Management Organization Sector**. Clinical Pharmacology Therapeutics, 1991;50 (Suppl): 620-625.

Knapp DA. **Development of criteria for drug utilization review**. Clinical Pharmacology Therapeutics, 1991;50 (Suppl): 600-602.

Kramer MS, and Feinstein AR. **Clirical Biostatistics; LIV The Biostatistics of Concordance**. Clinical Pharmacology Therapeutics, 1981;29(1):111-123.

Landis RJ and Koch GG. **The Measurement of Observer Agreement for Categorical Data**. Biometrics, 1977; 33:159-174.

Lexchin J. **Interactions Between Physicians and the Pharmaceutical Industry: What does the Literature Say?** CMAJ, 1993;149(10):1401-1407.

Lexchin J. **Doctors and Detailers: Therapeutic Education or Pharmaceutical Promotion?** International Journal of Health Services, 1989;19(4):663-679.

Linton AL and Peachey DK. **Utilization Management: A Medical Responsibility**. CMAJ, 1989;141:283-286.

Lipton HL and Bird JA. **Drug Utilization Review: State of the art from an academic perspective**. Clinical Pharmacology Therapeutics, 1991;50 (Suppl): 616-619.

Louie, TJ. **Ciprofloxacin: an oral quinolone for the treatment of infections with gram negative pathogens**. CMAJ, 1994;150: 669-676.

Manheim LM, Feinglass J, Hughes R, Martin GJ, Conrad K, Hughes EF. **Training House Officers to be Cost Conscious: Effects of an Educational Intervention on Charges and Length of Stay**. Medical Care, 1990;28:29-42.

May, SM. **Modelling Observer Agreement - An Alternative to Kappa**. Journal of Clinical Epidemiology, 1994;47(11):1315-1324.

McIsaac W, Naylor D, Anderson GM, and O'Brien BJ. **Reflections on a Month in the Life of the Ontario Drug benefit Plan**. CMAJ, 1994;150(4):473-477.

Melnychuk D, Moride Y, and Abenhaim L. **Monitoring of Drug Utilization in Public Health Surveillance Activities: A Conceptual Framework**. Canadian Journal of Public Health 1993;84:45-49.

Naylor CD, Fooks C, Williams JI. **Canadian Medicare: Prognosis Guarded**. CMAJ, 1995;153(3):285-289.

Nelson AA JR, Reeder CE, and Dickson WM. **The Effect of a Medicaid Drug Copayment Program on the Utilization and Cost of Prescription Services**. Medical Care, 1984;22(8):724-736.

Newfoundland. Department of Health. Drug Plan Summary, 1994.

Newfoundland, Economic Recovery Commission Health Strategy Working Group, **Economics of Health Care**. 1994.

Newfoundland, The Budgeting Division of Treasury Board, **Estimates 1995-96**. March 23, 1995.

Novitch M. **Drug Utilization Review in the 1990s**. Clinical Pharmacology Therapeutics 1991;50 (Suppl): 614-615.

Ontario Anti-infective Review Panel. **Anti-infective Guidelines for Community-acquired Infections**. Publications Ontario 1994.

Paladino J et al. **Clinical and Economic Evaluation of Oral Ciprofloxacin After an Abbreviated Course of Intravenous Antibiotics**. The American Journal of Medicine, 1991;91: 462-470.

Payne SMC, Restuccia JD, Ash A, Shwartz M, Tarr L, Williams B. **Using Utilization Review Information to Improve Hospital Efficiency**. Hospital and Health Services Administration, 1991;36(4):473-90.

Phair JP. **Infections of the Lower Respiratory Tract: General Considerations**. In Shulman ST, Phair JP and Sommers HM, eds. The Biologic and Clinical Basis of Infectious Diseases, 4th edition. Philadelphia: W.B. Saunders Company, 1992:158-163.

Pickering TD, Gurwitz JH, Zaleznik D, Noonan JP, and Avorn J. **The Appropriateness of Fluoroquinolone Prescribing in a Long-Term Care Setting**. JAGS, 1994;42:28-32.

Proceedings from the Canadian Bronchitis Symposium. **Recommendations on the Management of Chronic Bronchitis.** CMAJ, 1994;151(10) (Suppl):8-23.

Restuccia JD, Payne SMC, Lenhart G, Constantine HP, and Fulton JP. **Assessing the Appropriateness of Hospital Utilization to improve efficiency and competitive position.** Health Care Management Review 1987; 12(3):17-27.

Restuccia JD, Payne SMC, Welge CH et al. **Reducing inappropriate use of inpatient medical/surgical and pediatric services**. Baltimore: Health Care Finance Administration, 1986.

Restuccia JD, Gertman PM, Dayno S. **A Method to Determine Inappropriate use of Hospital Resources: Final Report.** Baltimore: Health Care Finance Administration, 1982.

Rishpon S, Lubacsh S, Epstein LM. **Reliability of a Method of Determining the Necessity for Hospitalization Days in Israel**. Medical Care 1986;24(3):279-282.

Rovers JP and Bjornson DC. **Assessment of Methods and Outcomes: Using Modified Inpatient Ciprofloxacin Criteria in Community-Based Drug Use Evaluation**. Annals of Pharmacotherapy, 1994;28:714-719.

Safavi KT and Hayward RA. **Choosing between apples and apples: Physician's choices of prescription drugs that have similar side effects and efficacies.** Journal of General Internal Medicine, 1992;7:32-27.

Schwartz HI. **An Empirical Review of the Impact of Triplicate Prescription of Benzodiazepines**. Hospital and Community Psychiatry, 1992;43(4):382-385.

Selker HP, Beshansky JR, Pauker SG, Kassirer JP. **The Development and Use of a Tool that Detects Unnecessary Hospital Days**. Medical Care, 1989;27(2):112-29.

Shen LL and Pernet AG. **Mechanism of inhibition of DNA gyrase by analogues of nalidixic acid: the target of the drugs is DNA**. Proceedings of the National Academy of Science, 1985;82 (suppl 4A): 2-11.

Smith DG. **The Effects of Copayments and Generic Substitution on the Use and Costs of Prescription Drugs**. Inquiry, 1993;30:189-198.

Soumerai SB and Lipton HL. **Computer-Based Drug-Utilization Review - Risk, Benefit, or Boondoggle?** New England Journal of Medicine, 1995;332(24):1641-1645.

Soumerai SB, Ross-Degnan D, Fortress EE, and Abelson J. **A Critical Analysis of Studies of State Drug Reimbursement Policies: Research in Need of Discipline**. The Milbank Quarterly, 1993;71(2):217-252.

Soumerai SB, Ross-Degnan D, Avorn J, McLaughlin TJ, and Choodnovskiy I. **Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes**. The New England Journal of Medicine, 1991;325(15):1072-1077.

Soumerai SB, McLaughlin TJ, and Avorn J. **Improving Drug Prescribing in Primary Care: A Critical Analysis of the Experimental Literature**. The Milbank Q, 1989; 67(2):268-317.

Soumerai SB, Avorn J, Ross-Degnan D, Gortmaker S. **Payment Restrictions for Prescription Drugs Under Medicaid**. The New England Journal of Medicine, 1987;317(9):550-556.

Siu AL, Sonnenberg FA, Manning WG, Goldberg GA, Bloomfield ES, Newhouse JP, Brook RH. **Inappropriate Use of Hospitals in a Randomized Trial of Health Insurance Plans**. New England Journal of Medicine, 1986;315(20):1259-1266.

Strumwasser I, Paranjpe NV, Ronis DL, Share D, Sell LJ. **Reliability and Validity of Utilization Review Criteria: Appropriateness Evaluation Protocol, Standardized Medreview Instrument, and Intensity-Severity Discharge Criteria**. Medical Care 1990;28(2):95-111.

Tholl, WG. **"Health Care in Canada: Skating Faster on Thinner Ice."** In A Blomqvist and DM Brown, eds. Limits to Care. Toronto, Ont.: C.D. Howe Institute, 1994. pp.53-89.

Trucksis M, Hooper DC, and Wolfson JS. **Emerging Resistance to Fluoroquinolones in Staphylococci: An Alert**. Annals of Internal Medicine, 1991;114(5):424-6.

Weintraub M, Singh S, Byrne L, Maharaj K, Guttmacher L. **Consequences of the 1989 New York State Triplicate Benzodiazepine Prescription Regulations**. JAMA, 1991;266(17):2392-2397.

West P. **Island Health Information System Established: Informatics Plays Big Role in PEI Health Reform.** Canadian Medical Informatics, May/June, 1994:48-49.

Wickizer TM, Wheeler JRC, Feldstein PJ. **Does Utilization Review Reduce Unnecessary Hospital Care and Contain Costs?** Medical Care, 1989;27(6):632-647.

APPENDIX A

CONCURRENT BED UTILIZATION REVIEW

Standardized Data Collection Form

Initials

Case Number:

Age:

MCP:

Gender:

Hospital:

Residence:

Type of Admission: _____

1. Routine
2. Urgent
3. Emergency

Service: _____

Ward: _____

Physician: _____

Room: _____

Date and Time of Admission: _____

Reason for Admission: _____

Confirmed Diagnosis: _____

Medical Status on Admission: _____

_____

_____

Social History and Functional Status on Admission:

Lives Alone: _____ 1. Yes 2. No Comments: _____

Ambulatory Status: _____

1. Independent
2. Requires some Assistance
3. Bedbound/Bed-Chair

Comments: _____

Incontinent: Bowel _____ Bladder _____

1. Yes
2. No

Comments: _____

Oriented to: Time _____ Place _____ Person _____

1. Yes
2. No

Comments: _____

_____

Discharged: _____ 1. Yes 2. No Comments: _____

Date of Discharge: _____
D M Y

Length of Stay: _____

APPENDIX B

Categories for Assessment and Classification of Inappropriate Days

AWAITING SURGERY

1. Premature admission - O.R. date booked, but patient admitted more than 24 hours prior to surgery.
2. Elective Surgery - Specific procedure should have been admitted through same-day admission clinic.
3. Admitted for surgery; Delay in scheduling
4. Awaiting Surgery - post-diagnostic procedure > 24 hours; patient condition is stable - should be discharged and readmitted.
5. Scheduled for surgery, 'bumped' because of emergency
6. Delay in surgery due to "40-hour week" problem.
7. Delay because of indecisiveness of patient/family.
8. Delay due to equipment failure.

AWAITING DIAGNOSTICS

1. Admitted day before a diagnostic procedure that should have been a same-day procedure.
2. Booked for that day, cancelled and rescheduled.
3. Ordered, but > 24 hours waiting for procedure to be done
4. Delay Due to "40 hour week problem."
5. Delay due to indecisiveness of patient/family.
6. Admitted day before chemotherapy - Blood work should have been done the day before.
7. Diagnostic procedure could have been done as outpatient procedure.

AWAITING CONSULTS

1. Ordered but not sent.
2. Awaiting > 24 hours for assessment by consulting physician.

AWAITING RESULTS

1. Results not available (>24 hours)

Appendix B - Continued

DISCHARGE PROCESS

1. Delay initiating discharge plan, ie. sending appropriate consults or contacting Community Hospital.
2. Delay in discharge home - no longer requires inpatient services in an acute care hospital for Dx and/or Rx.
3. Delay in discharge to hostel or other local accommodations for remainder of care.
4. Delay transfer to Community Hospital - for further convalescence at lower level care; long term care (plan had been initiated).
5. Delay in transfer to Long Term Care - has been identified as requiring long term care.
6. Delay in discharge because of other assessment required outside the institution (enriched needs, Veterans Affairs assessment, etc).
7. Delay in discharge because family/patient not in agreement with plan.
8. Delay in discharge because of unhealthy home environment, and unable to return to same.
9. Discharge/transfer delayed because physician wrote discharge orders too late in the day.
10. Delay in transfer to Convalescence; identified as appropriate for Conval.
11. Other

MEDICAL MANAGEMENT

1. Inadequate preadmission assessment, causing delay in completing procedure/treatment.
2. Inefficient test sequence after admission causing delay in diagnosis and/or treatment.
3. Overly conservative treatment (nothing much done for three day observation).
4. Admitted post surgery for observation; could have gone to hostel, returning for recheck in a.m.

REQUIRING SERVICES OTHER THAN ACUTE CARE HOSPITAL - CURRENTLY NOT AVAILABLE:

CONVALESCENCE/REHABILITATION

1. Patient post surgery - needs additional convalescent period for frequent dressing changes or IV antibiotics.
2. Post CVA - stable, requiring skilled nursing, Physio- and Occupational Therapy intervention.

PALLIATIVE/SUPPORTIVE CARE

1. Terminally ill, only supportive care is required which can be given outside an acute care setting.

EXPANSION HOME CARE SERVICES - IV TEAM, MEDICAL DAY CARE

1. Receiving IV antibiotics, usually for long term treatment, with Hickman Catheter in place, is medically stable, and lives within the boundaries of the Home Care Program.
2. Requires complex dressing changes, but with intervention/supervision of a professional, could be managed at home - geographically within the boundaries of Home Care.

Appendix B - (Continued)

REASONS FOR INAPPROPRIATE ADMISSION DAY

A. Patient needs no institutional care - diagnosis and treatment can be handled on an outpatient basis.

B. Patient needs institutional care at a lower level than an acute care hospital - general (unspecified).

C. Patient needs care in a chronic disease hospital.

D. Patient needs care in a skilled nursing home.

E. Patient needs care in a non-skilled nursing home.

F. Premature admission (eg. on Friday for a procedure booked for the following Tuesday).

G. Patient does not need acute institutional care for Rx - requires facilities providing minimal supervision (ie. min ass. ADL and supervision).

APPENDIX C

Questionnaire used for the Ciprofloxacin Drug Utilization Review

CIPROFLOXACIN IN THE COMMUNITY

Patient No._____ Sex:____ 1. Male 2. Female Age:_____

Physician No:_____ Residency: ☐ At Home ☐ Nursing Home ☐ Other

Smoking status: ☐ Current ☐ Ex-smoker ☐ Non-smoker ☐ Don't Know

CASE DESCRIPTION: _____

_____

_____

_____

_____

_____

_____

CLASSIFICATION OF CURRENT INFECTION:

Severity	Acuity
☐ Mild	☐ Acute
☐ Moderate	☐ Chronic
☐ Severe	☐ Acute on chronic

INDICATIONS: Was the infection:

Respiratory	☐ Yes	☐ No
Genito-urinary	☐ Yes	☐ No
Skin/soft tissue	☐ Yes	☐ No
Other	☐ Yes	☐ No

Current indication for which CIPRO was prescribed:

___ RESPIRATORY TRACT INFECTION

___ Upper Respiratory Infection:

☐ Sinusitis
☐ Otitis
☐ Laryngitis
☐ Pharyngitis
☐ Other: _____

___ Lower Respiratory Infection:

- ☐ Acute bronchitis
- ☐ Acute exacerbation of chronic bronchitis
- ☐ Pneumonia
- ☐ Acute exacerbation of cystic fibrosis
- ☐ Acute exacerbation of bronchiectasis
- ☐ Other: _____

___ URINARY TRACT INFECTION

- ☐ Cystitis
- ☐ Prostatis
- ☐ Pyelonephritis
- ☐ Orchitis, epididymitis or epididymo-orchitis
- ☐ Other: _____

___ SKIN/SOFT TISSUE/OTHER INFECTION

- ☐ Abscess
- ☐ Cellulitis
- ☐ Foot ulcer
- ☐ Decubitus ulcer
- ☐ Post operative wound infection
- ☐ Infectious diarrhea
- ☐ Bone/joint infection
- ☐ Other: _____

CHECKLIST OF CLINICAL SIGNS AND SYMPTOMS

Respiratory Tract Infections

- ☐ Fever
- ☐ Rigors
- ☐ Chills
- ☐ Cough
- ☐ Sputum
- ☐ Haemoptysis
- ☐ Dyspnea
- ☐ Tachypnea
- ☐ Rales/crackles
- ☐ Rhonchi/wheeze
- ☐ Pleuritic chest pain
- ☐ Other: _____

Urinary Tract Infections

- ☐ Fever
- ☐ Rigors
- ☐ Chills
- ☐ Dysuria
- ☐ Urgency
- ☐ Frequency
- ☐ Flank pain
- ☐ Suprapubic pain
- ☐ Urologic abnormality
- ☐ Other: _____

Other infections/conditions:

_____

_____

_____

_____

Does the patient have known antibiotic allergies? ☐ Yes ☐ No

COMMENTS: _____

_____

_____

_____

Had there been previous occurrences of this condition in the prior 12-24 months? ☐ Yes ☐ No

If yes, specify how many previous occurrences there had been: _____

_____

Had this condition been persistent for longer than a one week period prior to the prescribing of CIPRO? ☐ Yes ☐ No

If yes, total duration of condition: _____ days

CULTURE REPORTS:

Was a culture sent? ☐ Yes ☐ No

Type of culture sample (ie. sputum, urine):

	Type of Culture	Date Sent	Suspect Viral/Bacterial
1.			
2.			
3.			

REPORTED CULTURES:

NO.	ORGANISIM	SENSITIVE TO	RESISTANT TO

Non pharmacological action:

Referrals:

- ☐ Emergency department
- ☐ Radiology
- ☐ Out patients department
- ☐ Admitted to hospital
- ☐ Other:_____
- ☐ No Referral

Confinement:

- ☐ Confined to bed
- ☐ Confined to house
- ☐ Not confined
- ☐ Don't Know

CIPROFLOXACIN PRESCRIPTION:

Date CIPRO prescribed: ____ ____ ____
DD MM YY

Intention: Shortterm Rx:_____ or Longterm Prophylaxis:_____

Dose prescribed: _____ mg Frequency: _____ Duration: _____ Days Route: _____

Is this present prescription continuing treatment previously prescribed by a specialist? ☐ Yes ☐ No

Pt. REQUEST ☐ YES ☐ NO

Previous Antibiotic Treatment:

Was the patient on any previous antibiotic therapy for this current episode? ☐ Yes ☐ No

Date prescribed: ____ ____ ____
DD MM YY

NAME: (Generic) _____
(Trade) _____

Dose prescribed: _____ mg Frequency: _____ Duration: _____ Days Route: _____

Did this antibiotic fail to treat this condition?

☐ Yes ☐ No

What measure(s) would you have taken AND what medication would you have prescribed if CIPRO had NOT been available to treat this patient?

Measure taken:

- ☐ Still treat as an outpatient
- ☐ Refer patient to a specialist
- ☐ Hospitalize patient
- ☐ No different measures

What medication/s would you have prescribed as a substitute for CIPRO:

1. NAME: (Generic) _____
(Trade) _____

Dose: _____ mg | Frequency: _____ | Duration: _____ Days | Route: _____

2. NAME: (Generic) _____
(Trade) _____

Dose: _____ mg | Frequency: _____ | Duration: _____ Days | Route: _____

ACCOMPANYING OR UNDERLYING DISEASE/CONDITION	

CONCOMITANT MEDICATIONS:

TRADE NAME	GENERIC NAME

RESEARCH NURSE INTERVIEW NOTES:

Appendix D

Summary of Guidelines used by the Academic Panel

DEFINITE INDICATIONS FOR CIPROFLOXACIN

Moderate to Severe Infections

Have previously required 3rd generation cephalosporins or aminoglycosides and the patient can be switched to oral medication. e.g.

- Pneumonia
- AECB with resistant organisms
- A.E. of bronchiectasis - known resistance
- Upper UTI with resistant G - organisms
- Intra-abdominal sepsis (+ anaerobic coverage)
- Non-fungal superinfections

Mild to Moderate Severity

- Cystic fibrosis and bronchiectasis exacerbations
- COPD not responding to other antibiotics
- Recurrent UTI with resistant organisms
- Acute and Chronic Prostatitis
- Sinusitis not responding to less expensive antibiotics
- Diabetic foot ulcer if used with anaerobic coverage
- Traveller's diarrhea and prophylaxis
- Chronic recurrent and resistant otitis media

CIPROFLOXACIN NOT INDICATED FOR:

- Influenza and other respiratory manifestations
- Acute bronchitis, pharyngitis and laryngitis
- Pelvic Inflammatory Disease
- Community-acquired pneumonia
- Acute otitis media or sinusitis
- Skin Abscesses
- Monotherapy for aspiration pneumonia and cellulitis