# Diffusion of Innovation I: Formulary Acceptance Rates of New Drugs in Teaching and Non-Teaching British Columbia Hospitals– A Hospital Pharmacy Perspective

Mel M. D'Sa, David S. Hill and Timothy P. Stratton

## ABSTRACT

Lag times in the diffusion of new drugs in the hospital setting have both patient care and pharmaceutical industry implications. This twopart series uses diffusion theory to examine differences in the adoption rates of new drugs in British Columbia teaching and non-teaching hospitals. Formulary addition of a new drug by a hospital's Pharmacy and Therapeutics Committee was considered the adoption indicator. Time for adoption was defined as the difference between a drug's Canadian market approval date and the date of formulary addition. Surveys were mailed in September 1990 to 41 hospital pharmacies (response rate=88%), asking respondents to provide formulary inclusion dates of 29 drugs marketed between July 1987 and March 1990. A significant difference (Mann-Whitney U Test, p<0.0358) in median adoption time was observed between the six teaching and 25 non-teaching study hospitals, with the former adopting a new drug in 7.5 months versus the latter adopting a new drug in 12.1 months.

**Key Words:** British Columbia, Formulary, Hospitals

## RÉSUMÉ

Le délai d'apparition des nouveaux médicaments dans les milieux hospitaliers a des conséquences à la fois sur les soins aux patients et sur l'industrie pharmaceutique. Cette série en deux volets expose la théorie de la diffusion pour expliquer les différences dans les taux d'adoption des nouveaux médicaments dans les hôpitaux universitaires et non universitaires de Colombie britannique. L'ajout d'un nouveau médicament au formulaire par le comité de pharmacologie a été considéré comme l'indicateur d'adoption. Le délai d'adoption a été défini comme l'intervalle entre la date à laquelle le médicament a reçu une approbation de commercialisation au Canada et celle à laquelle il a été ajouté au formulaire. Les sondages ont été postés à 41 pharmacies d'hôpitaux en septembre 1990 (taux de réponse = 88 %); on demandait aux répondants de préciser les dates d'ajout à leur formulaire de 29 médicaments commercialisés entre juillet 1987 et mars 1990. Les résultats ont révélé une différence notable (Test U de Mann-Whitney, p < 0.0358) dans le délai moyen d'adoption entre les 6 hôpitaux universitaires et les 25 hôpitaux non universitaires faisant l'objet de l'étude; le taux d'adoption d'un nouveau médicament pour les hôpitaux universitaires était de 7,5 mois comparativement à 12,1 mois pour les hôpitaux non universitaires. Mots clés : Colombie britannique, formulaire, hôpitaux

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## **INTRODUCTION**

The existence of thousands of drugs on the Canadian market requires a rational and organized approach for drug selection by hospitals. Drug cost, efficacy, and safety are among the criteria considered in determining the suitability of a drug for inclusion in a hospital's formulary– a continually revised compilation of pharmaceuticals that reflects the clinical judgment of an institution's

medical and pharmacy staff.<sup>1</sup> A formulary limits the use of ineffective or marginal drugs and drugs with undesirable adverse effects.<sup>2</sup> A well-controlled formulary can contribute to a decrease in

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hospital drug expenditures.<sup>3</sup> The objectives of a hospital formulary system are to control drug use, decrease drug cost, decrease duplication of similarly acting drugs, improve drug inventory control, maintain a current list of drug products stocked in the pharmacy, and lastly, meet accreditation standards.<sup>4</sup>

The Pharmacy and Therapeutics Committee plays a pivotal role in developing and maintaining a rational and organized approach to new drugs. It has an advisory role in the implementation of policies regarding evaluation, selection, and therapeutic use of drugs in hospitals. It also has an education role in the development of programs to meet the needs of physicians, nurses, pharmacists, and other health care practitioners for complete current knowledge on drugs and drug use.5 In a national survey of a random sample of U.S. health maintenance organizations, it was found that the role of the Pharmacy and Therapeutics Committee as the final decision maker was significantly associated with limits on the availability of new drugs in responding institutions.<sup>6</sup>

## **Diffusion and Adoption**

The process by which a new technology is introduced and accepted by users is complex. For any potential user a sequence of events occurs involving exposure to a new technology, gathering of information leading to an interest in the new technology, evaluation of the new technology that sometimes involves small scale trial use and peer advice, and finally acceptance or rejection of the technology.7 The concept of Pharmaceutical Care has even been noted to display the characteristics of a diffusing innovation.8 Wide adoption of a new technology depends upon

diffusion from the innovator to end users, relying on communication of the innovation features through a social system of adopters. Rogers describes a classification system which characterizes market users by the speed with which they accept a new technology: 1) innovators; 2) early adopters; 3) early majority; 4) late majority; and 5) laggards.<sup>7</sup> Rejection or discontinuance may eventually occur after adoption. Disenchanted discontinuance results when adopters become dissatisfied with a technology's performance. Replacement discontinuance occurs when a new technology supersedes an adopted technology.<sup>7</sup> This latter type of discontinuance has been observed with antibiotics.9

# Implications for the Hospital Pharmacist and Drug Manufacturer

Pharmacy and Therapeutics Committees, representing the interests of practitioners in the hospital, normally are given responsibility for approving drugs for use in the institution. Consequently, the speed of formulary approval of a new drug will depend on the interest and urgency expressed by the professional staff in a drug combined with the nature and outcome of the Pharmacy and Therapeutics Committee's evaluation process. Excessive haste in approving drugs may lead to overuse by physicians resulting in added drug costs, as well as a higher risk for adverse drug reactions. Demand for ancillary services such as laboratory tests, changing patterns of usage of related drugs, and in-service education requirements may also be influenced by new drug formulary approvals. Conversely, delays may deny patients drugs essential for optimal therapy. The potential for successful patient care outcomes should represent the benchmark by which the appropriateness of the adoption of a new drug is measured.

From a pharmaceutical manufacturer's perspective, a new drug represents future revenue for the company and its shareholders. Stakes are high, since research and development costs of a new drug from discovery to bringing the drug to market can exceed hundreds of millions of dollars.<sup>10</sup> Consequently, a lengthy delay in acceptance by potential users or the complete lack of acceptance will result in lost revenues. When introducing new drugs, firms in the industry establish marketing strategies to reduce acceptance lag time by key markets such as influential hospitals, practitioners, pharmacy leaders, and government drug plan managers.<sup>11, 12</sup>

Intuitively, adoption differences should exist between teaching and non-teaching hospitals by virtue of their different health care and educational roles. It is expected that a greater spectrum of clinical problems exist in the teaching hospital setting versus the nonteaching setting. Therefore, different technology adoption patterns between these two hospital types may exist. For example, in Canada, cardiac catheterization labs, shock wave lithotripters, and magnetic resonance imagers are technologies which are more prevalent in the teaching hospital setting.13 Arguably, a greater cost efficiency can be attained by centralizing expensive technologies in teaching hospitals, where specialized personnel are more likely to be found to operate this equipment. Furthermore, high usage demands placed on new technologies usually require substantial resources, which are typically more available in the teaching hospital setting. Thus, this study asserts that formulary approval rates should significantly differ between teaching and nonteaching British Columbia acute care hospitals.

## **METHODS**

In Canada, a Notice of Compliance (NOC) issued by the Health Protection Branch of Health Canada signifies that a drug may be released by a manufacturer for general distribution to the Canadian market. Drugs receiving a NOC during the period July 1987 to June 1990 were selected to be surveyed. To be included in this study a drug had to be a new chemical entity released on the Canadian market for human therapeutic use only, or had to be an existing drug which had received approval for a new therapeutic indication. In addition, a study drug had to be adopted by at least two study hospitals to be included in the analysis. Appendix A lists all study drugs that met the inclusion criteria. The 29 study drugs will be dealt with in greater detail in Part II of this series.

At the time of the survey in October 1990 there were a total of 64 pharmacies in hospitals licensed by the College of Pharmacists of British Columbia.14 This total would represent all hospital pharmacies in the province. Entry criteria for the survey required that the hospital operate a licensed pharmacy department and have at least 125 beds. Hospitals with licensed pharmacies and having fewer than 125 beds (13 hospitals), serving as extended care or rehabilitation facilities (four), or specialty agencies (seven) were excluded from this study. This was to ensure that study hospitals would have sufficient patient care scope to likely use most of the study drugs. With these exclusions the total number of eligible British Columbia hospitals was reduced to 40. One pharmacy department provided services to two hospitals, thus requiring a separate analysis of each site. Teaching or non-teaching hospital status was confirmed with the Canadian Hospital Association Directory (1992 Edition).<sup>15</sup>

A survey instrument was developed and subsequently mailed to the 41 hospitals in October 1990. Respondents were given two months to reply. To maximize the response rate, each survey was accompanied by a personally addressed letter eliciting support, and a stamped, addressed return envelope.<sup>16</sup> A second mailing to non-responders was conducted one month after the initial mailing. Confidentiality was assured for all hospitals.

The survey instrument was a fivepage questionnaire addressed to the Pharmacy Director. The first page dealt with routine hospital and departmental questions such as the total number of hospital beds, the hospital teaching or non-teaching status, the existence of a Pharmacy and Therapeutics Committee, and the existence of a formal formulary system. Respondents were then asked to indicate their opinions regarding the strength of the hospital's formulary system (strong, moderate, or weak), the strength of the Pharmacy Department's voice in influencing formulary decisions (strong, moderate, or weak), the frequency of acceptance of Pharmacy recommendations by the Pharmacy and Therapeutics Committee (always, usually, or rarely), and lastly, the most recent three-year pattern of budget performance in drug expenditures and overall hospital expenditures (over, on, or under budget).

The remaining four pages questioned directors with respect to the following information about the 29 study drugs: hospital consideration of the drugs for formulary addition; month and year of drug approval; any conditions, restrictions, or time limits placed on the formulary approval of the drug; and whether the drug had been subsequently removed from the formulary and the date of such removal.

A second mailing of individualized surveys was conducted in April 1993 to ensure all study drugs initially surveyed in October 1990 had received at least 36 months on the Canadian market for formulary consideration. Hospitals responding to the original survey were asked about the formulary status of study drugs which had received NOC after September 1988, but had not been approved for use by the time of the initial survey. The nonparametric Mann-Whitney U Test was used to determine if teaching and nonteaching hospitals exhibited differences in formulary adoption of new pharmaceuticals.17

#### **Assumptions and Limitations**

This study assumed that the formulary decision process was a proxy measure of drug technology adoption. However, formulary approval does not necessarily imply usage within the hospital. It was also assumed that drug manufacturers were prepared to aggressively market their new drugs to study hospitals upon receiving NOC. However, a manufacturer may intentionally delay introduction of a newly approved drug due to marketing, sales force deployment, or seasonal considerations. Lastly, the following factors were not addressed in this study: physicians' influence on the formulary decision process, individual hospitals' ethical or pharmacoeconomic standards, and the individual hospitals' drug budget level of flexibility.

An important limitation concerns the study sample size. As the sample essentially represents the entire population of British Columbia acute care hospitals that met the eligibility criteria, the findings should be an accurate reflection of the true experience of formulary management for the province of British Columbia. However, conclusions drawn may not be generalizable to hospital pharmacy practice outside of the province.

## RESULTS

Thirty-six responses representing an 88% response rate were received from the 41 surveys mailed in September 1990. On further review of the responding hospitals, five were deleted from the study. Two of these reported having fewer than 125 beds and thus failed to meet the original inclusion criteria. The remaining three hospitals were classified as extended care facilities. This reduced the number of eligible hospitals to 31. Analysis of eligible non-responding hospitals revealed that all five were non-teaching hospitals, located in different geographic regions of the province. Of the 31 responding hospitals, six were teaching and 25 were nonteaching and were characterized by a small number of large teaching hospitals (five hospitals with greater than 500 beds) and a large number of small non-teaching hospitals (18 hospitals with fewer than 500 beds).

All hospitals reported having a Pharmacy and Therapeutics Committee as well as a functioning formulary. Table I represents responses regarding hospital characteristics. Both hospital types were of the opinion that they had moderate to tight control over their formularies. A majority of both hospital types felt their pharmacy departments had a strong voice in influencing formulary decisions. In general it was felt that the pharmacist's recommendations to formulary decisions were usually accepted by the rest of the Pharmacy and Therapeutics Committee; however, one non-teaching hospital felt that its recommendations were rarely accepted. A majority of

Table I: Responses to survey of hospital pharmacies in British Columbia.

Opinion of Pharmacy Director on Hospital's Control of Formulary					
Teaching (n=6):	Strong: 16.7%	Moderate: 83.3%	Weak: 0.0%		
Non-Teaching (n=25):	Strong: 32.0%	Moderate: 68.0%	Weak: 0.0%		
Opinion of Pharmacy Director on Pharmacy Department Voice in Influencing Formulary Decisions					
Teaching (n=6);	Strong: 66.7%	Moderate: 33.3%	Weak: 0.0%		
Non-Teaching (n=25):	Strong: 68.0%	Moderate: 28.0%	Weak: 4.0%		
Opinion of Pharmacy Director on Acceptance of Pharmacist's Recommendations to Formulary Decisions by Pharmacy and Therapeutics Committee					
Teaching (n=6):	Always: 0.0%	Usually: 100.0%	Rarely: 0.0%		
Non-Teaching (n=25):	Always: 16.0%	Usually: 80.0%	Rarely: 4.0%		
Pharmacy Drug Budget Status September 1987 to September 1990					
Teaching (n=6):	Over: 66.6%	On: 16.7%	Under: 16.7%		
Non-Teaching (n=25):	Over: 64.0%	On: 16.0%	Under: 20.0%		
Total Hospital Budget Status September 1987 to September 1990					
Teaching (n=6):	Over: 66.7%	On: 0.0%	Under: 33.3%		
Non-Teaching (n=25):	Over: 84.0%	On: 8.0%	Under: 8.0%		

pharmacy departments were over budget in drug expenditures for the September 1987 to September 1990 period surveyed. For the same time period, a majority of total hospital expenditures were also over budget for both hospital types. The nonparametric Mann-Whitney U Test revealed that the aforementioned hospital characteristics did not significantly influence formulary adoption of new drugs between teaching and non-teaching hospitals.

Six of the original 29 study drugs were not approved for use in any eligible responding hospitals. Therefore, the number of study drugs for final analysis was reduced to 23. For analytical purposes, a consistent time frame was utilized to minimize underestimation or overestimation of lag times in hospitals. Although respondents were requested to provide the month and year of formulary addition, the date reported was assigned by the researchers to the 15th day of that month. The lag time was then calculated to be the duration of time from the actual NOC date to the 15th day of the month of formulary

addition.

Figure 1 shows the median formulary approval lag time for adoption of 23 study drugs by the six teaching and 25 non-teaching British Columbia hospitals. A discernible bell curve for the adoption of study drugs by nonteaching hospitals is evident. Due to the small sample size of teaching hospitals, a similar curve is not readily apparent.

Table II summarizes individual hospital formulary median approval lag times. Of the 31 study hospitals, the median time to approve study drugs was 11.2 months (range: 4.9-27.5 months). The six teaching hospitals adopted a new drug in a median time of 7.5 months (range: 5.5-15.3 months), compared to the 25 non-teaching hospitals with a median time of 12.1 months (range: 4.9-27.5 months). The nonparametric Mann-Whitney U Test (two tailed, corrected for ties) revealed a significant difference between teaching and non-teaching hospitals in terms of drug adoption  $(z=2.10, \alpha=0.05, p<0.0358)$ . Lastly, during the study period, teaching



Figure 1. Median formulary approval lag time in six teaching and 25 non-teaching British Columbia hospitals for study drugs (n=23)

Table II. Ho	spital formulary	y median appr	oval lag time	for study dr	ugs (n=23) <sup>a</sup>
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Hospital Code (drugs adopted)	Hospital Type	Range (months)	Location <sup>b</sup>	Median (months)
Н (16)	non-teaching	1.5-38.0	urban	4.9
W (16)	teaching	1.8-29.1	urban	5.5
AA (17)	teaching	1.5-30.0	urban	6.5
I (17)	non-teaching	1.5-22.0	urban	6.8
V (19)	non-teaching	2.3-37.1	urban	7.1
BB (13)	teaching	1.5-39.5	urban	7.2
T (17)	non-teaching	1.2-40.1	urban	7.8
R (20)	teaching	2.3-22.1	urban	7.8
D (12)	non-teaching	2.3-22.1	other	8.4
CC (17)	teaching	1.2-40.0	urban	8.5
<b>B</b> (11)	non-teaching	2.5-39.5	other	10.1
C (10)	non-teaching	5.1-42.5	other	10.4
L (11)	non-teaching	5.0-23.8	urban	11.1
Y (17)	non-teaching	1.5-33.3	urban	11.3
EE (14)	non-teaching	1.5-38.1	other	11.4
F (8)	non-teaching	4.3-26.5	urban	11.4
N (14)	non-teaching	1.5-26.0	other	11.8
P (18)	non-teaching	3.3-50.3	other	11.8
X (9)	non-teaching	2.5-16.5	urban	13.8
DD (13)	non-teaching	5.5-32.0	other	14.3
E (10)	non-teaching	4.5-35.1	other	14.4
S (8)	non-teaching	1.5-41.5	other	14.7
Z (17)	non-teaching	3.5-34.5	other	15.3
Q (8)	teaching	6.1-39.5	urban	15.3
O (8)	non-teaching	1.5-22.3	other	15.4
G (19)	non-teaching	6.8-51.0	other	15.5
U (10)	non-teaching	3.5-34.5	other	15.7
K (4)	non-teaching	13.8-18.3	other	15.9
M (13)	non-teaching	11.5-31.0	other	20.2
J (9)	non-teaching	7.3-38.1	other	24.5
A (13)	non-teaching	1.2-41.5	urban	27.5

<sup>a</sup> Lag time measured from NOC date to 15th day of the month of formulary approval.

b Urban refers to the metropolitan Greater Vancouver or Greater Victoria areas. Other refers to cities in any other areas of British Columbia.

hospitals adopted an average of 15 of the 23 study drugs versus 13 drugs for the non-teaching hospitals.

## DISCUSSION

There was a significant difference observed between teaching and nonteaching hospitals in terms of formulary approval times. However, the effect of the small sample size (six teaching and 25 non-teaching hospitals) in determining significance must be considered when interpreting the results of this study. Also, the classification of a teaching hospital versus a non-teaching hospital is somewhat arbitrary. Although a hospital's teaching or non-teaching status was established from information provided by the Canadian Hospital Association Directory (1992 Edition), the actual scope of services provided by certain non-teaching hospitals may be comparable to those of certain teaching hospitals. The distinguishing trait identifying a teaching versus a non-teaching hospital is often simply the presence or absence of medical residency programs within the hospital.

Using Figure 1 and Roger's diffusion theory, four teaching and four non-teaching hospitals could be classified as early adopters (4.1 to 8.0 months), one teaching and nine non-teaching hospitals could be classified as the early majority (8.1 to 12.0 months), one teaching and nine non-teaching hospitals could be classified as the late majority (12.1 to 16.0 months), and the remaining three non-teaching hospitals could be classified as laggard hospitals (> 20 months). The existence of any innovator hospitals was judged to be absent.

According to Roger's diffusion theory, adopters can be distinguished by traits based upon standard patterns of adoption of other innovations.<sup>7</sup> For example, it is believed that the distinguishing trait between early adopter hospitals and early majority hospitals is that the former are often looked to as the opinion leaders in a community; they adopt new innovations early but with discretion. The latter group deliberate for some time; these hospitals like to adopt new innovations before the average hospital does, although they rarely are leaders. The late majority hospitals may be characterized by their skepticism, since they may not adopt an innovation until the weight of majority opinion seems to legitimize its utility. Lastly, the laggard non-teaching hospitals had a median time of approximately two years to adopt any study drugs. These hospitals may be traditionalists. They could be suspicious of any changes, mix with other tradition-bound hospitals, or adopt the innovation only because it has now taken on a measure of tradition itself.7

Hospital H, a non-teaching hospital, is an example of an early adopter. It adopted 70% of the study drugs with a median formulary approval time of 4.9 months. In stark contrast is hospital A, a nonteaching hospital, which is an example of a laggard hospital. Although it did approve 57% of the study drugs, it had a median formulary approval time of 27.5 months.

Analysis of study hospitals revealed that all six teaching hospitals as well as hospitals in the top 25% with shortest median formulary approval times were located in urban areas. Conceivably, the decisions of hospitals concentrated in urban areas may influence the approval process of hospitals in farther outlying areas.

The marketing implications for pharmaceutical manufacturers to market to different hospitals or to a core group of select innovator hospitals should be apparent. Firms marketing to innovators, early adopters, or the early majority will have the most success in getting pharmaceuticals on board. Marketing efforts to laggard hospitals will prove less fruitful. Conversely, the expense associated with aggressive marketing to proven innovator hospitals may also be questioned.

The fact that all British Columbia hospitals operate under a provincial global budgeting system differs somewhat from hospitals in the U.S. where the adoption of the Medicare prospective payment systems and the rapid growth of managed care insurance plans have created markedly different incentives for providers to adopt and use new technologies.<sup>18</sup> Thus, one might expect to see that different incentive mechanisms in Canada may influence the diffusion of new drugs in hospitals. Ongoing and future study of the formulary approval patterns of new drugs in Canadian hospitals will be necessary to ensure that the formulary evaluation process is occurring in a consistent and effective manner among all hospitals.

In conclusion, hospitals approve new drugs based upon review of several factors by a hospital's Pharmacy and Therapeutics Committee. This study revealed a significant adoption difference between teaching and non-teaching hospitals. Hospitals must assess their position on the approval process of new drugs. As health care institutions give greater scrutiny to cost and patient care outcomes of new drugs, it should be anticipated that formulary approval lag times in many organizations may also be affected.

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	Appendix A. Study Drugs	
alfentanilhydrochlofide	cisapride monohydrate	nimodipine
alpha <sub>1</sub> -antitrypsin (human)	dronabinol <sup>a</sup>	nizatidine <sup>a</sup>
alteplase	enalapril maleate	omeprazole
bacampicillin hydrochloride <sup>a</sup>	flecainide acetate	procaterol hydrochloride <sup>a</sup>
buserelin acetate <sup>a</sup>	fluoxetine hydrochloride	propafenone hydrochloride
buspirone hydrochloride	flurbiprofen sodium (ophth.)	selegiline hydrochloride
cefixime	imipenem-cilastatin sodium	terazosin hydrochloride
cefotetan disodium	lovastatin	ticarcillin-clavulanate
ceftizoxime sodium	mecillinam <sup>a</sup>	vancomycin hydrochloride
ciprofloxacin hydrochloride	midazolam hydrochloride	(oral capsules)

<sup>a</sup> Study drugs not adopted by any study hospitals.