

**Improved Organizational Performance through the
Interdisciplinary Provision of Services:
A Case Study of an Economic Evaluation of
Pharmacist Dosing of Warfarin**

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Abstract

The New Public Management is a paradigm which seeks to enhance organizational accountability and performance by focusing on outcomes rather than process. In the case of health care, implementing this new model may require a shift from the status quo, which tends to focus on a process characterized by physician control of patient care, to a more interdisciplinary approach where the responsibility for patient care is determined in large part by identifying which health care professionals or teams achieve the most efficient and effective outcomes. This paper describes a study in which the cost effectiveness of traditional physician-directed Warfarin therapy or “usual medical care” (UMC) is compared to that of “pharmacist dosing of Warfarin” (PDW) which is an interdisciplinary approach in which a pharmacist determines the precise dose of Warfarin to be administered. The results of the study demonstrate improved patient outcomes and a reduction in the cost of care when pharmacists play a key role within a team approach to providing this type of patient care. This case provides support for the notion that performance based public management requires new and interdisciplinary, approaches to the effective delivery of services.

Key Words new public management, health care, economic evaluation

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Introduction

The New Public Management has been defined as “a new paradigm for public management ... aimed at fostering a performance-oriented culture in a less centralized public sector” (OECD, 1995). One of the key components of the New Public Management is “demanding, measuring and rewarding improved organizational ... performance” (Borins, 1999). We believe that this emphasis on performance requirements has accelerated the use of interdisciplinary approaches to public management. In this paper we provide a health economics case study to demonstrate the importance of measurement to successful public administration.

Warfarin is an anticoagulant drug that has been the mainstay of oral anticoagulant therapy for more than 50 years (Ansell and Hirsh *et. al.*, 2004). The effectiveness of Warfarin has been established for prevention of venous thromboembolism, for the prevention of systemic embolism in patients with prosthetic heart valves or atrial fibrillation, and prevention of stroke, recurrent infarction, or death in patients with acute myocardial infarction.

Providing warfarin drug therapy is challenging since 1) it has a narrow therapeutic window (small range between toxic and sub-therapeutic doses); 2) it exhibits considerable variability in dose response among subjects due to genetic and environmental variation; 3) it is subject to interactions with drugs and diet; and 4) there are problems in dosing as a result of patient non-adherence and miscommunication between the patient and physician (Ansell and Hirsh *et. al.*, 2004).

Warfarin response is commonly monitored by a blood test called the Pro-thrombin Time. The Pro-thrombin Time is then standardized and an International Normalized Ratio value is reported. The therapeutic International Normalized Ratio ranges are 2.0-3.0 for prophylaxis and treatment of uncomplicated thromboembolic disease, and 2.5-3.5 for patients with mechanical heart valves or failure with previous Warfarin treatment.

There are serious consequences of mismanaged Warfarin therapy. If a patient's International Normalized Ratio is below 2.0, the patient is not properly anticoagulated and thus at risk of thromboembolic events (“clots”) such as deep-vein thrombosis or pulmonary embolism. If a patient's International Normalized Ratio is above 4.0, there is a much greater possibility of bleeding complications such as gastrointestinal hemorrhage or intra-cerebral hemorrhage.

The objective of the study reported here was to perform a cost-effective evaluation of the Pharmacist Dosing of Warfarin (PDW) versus usual medical care (UMC) or physician dosing of Warfarin for inpatients at an urban hospital in southern Ontario from May 10, 2004 through December 31, 2004.

Background

While patient drug management is traditionally thought of as a physician responsibility, there are many reports of interdisciplinary approaches to the management of patients' drugs, including the utilization of pharmacist-directed drug management protocols. For instance, Hammond *et. al.* reviewed 54 separate studies involving pharmacist collaborative drug management, and found that 85% showed improvements in patient care as compared to physicians managing drug therapy in the absence of a collaborative team approach which provided a significant role for pharmacists (Hammond and Schwartz *et. al.*, 2003).

One example of pharmacists playing a key collaborative role along with physicians is in the management of Warfarin therapy. Specifically, there have been descriptive reports in the clinical literature of the formation of *anticoagulation clinics* (AC) where pharmacists are responsible for the management of Warfarin and heparin dosing. A review of U.S. Medicare hospitals identified that 122 hospitals in the United States had a pharmacist-managed Warfarin program (11% of sample) (Bond and Raehl, 2004). In addition, comparative trials between *anticoagulation clinics* (AC), in which pharmacists were involved in dosing, and *usual medical care* (UMC), in which physicians were responsible for dosing, have been reported in the medical literature.

One study described how the temporary closure of an established pharmacist-led clinic allowed them to compare AC to UMC in patients during two sequential periods (Hammond and Schwartz *et. al.*, 2003). The patient groups in the two study periods were similar except that congestive heart failure was a more frequent anticoagulation indication in the AC groups and a history of stroke a more common risk factor in the UMC group. Overall, the AC groups showed a statistically significant decrease in significant bleeds (decreased 77%), and major or fatal bleeds (decreased 50%). There was an 80% decrease in thromboembolic complications with three life-threatening or fatal occurrences in the UMC group compared to zero in the AC group. The AC group had a combined two-thirds reduction in complications (Chiquette and Amato *et. al.*, 1998). Most striking was that bleeding and thromboembolic complication rates which increased during UMC were reduced following the re-opening of the pharmacist-led AC.

Cortelazzo *et al* (1993) reported similar decreased rates of complications associated with the use of an AC clinic, with reduction of major bleeds by 80% and thromboembolic events by 90%, compared to UMC with general practitioners and cardiologists managing the Warfarin therapy.

Long term assessments of anticoagulation clinics have reported that the low rates of complications are sustainable for longer study periods. One pharmacist-led anticoagulation clinic evaluated six years of data and reported similarly low rates of major bleeds (1.6%) and blood clots (3.3%) (Willey and Chagan *et. al.*, 2003). In addition, both physicians and patients reported they were very satisfied with the AC service.

Evaluations of pharmacist-led ACs have also gone beyond the assessment of clinical outcomes to consider economic impacts. One of these studies found that “if pharmacist-managed Warfarin were available for all Medicare patients who received Warfarin therapy in U.S. hospitals, we could expect 9,862 fewer deaths, 1,120,699 fewer patient-days, and \$829,293,770 in reduced charges, 1,519 fewer patients with bleeding complications and 31,827 fewer units of whole blood used.” (Ansell and Hirsh *et. al.*, 2004) Another study found that for in-patient management of anticoagulation, the median costs were 21% less for pharmacist managed groups compared to usual medical care (Mamdani and Racine *et. al.*, 1999). They were able to decrease length of stay by 2 days (from 7 days to 5 days) with no bleeding episodes (Mamdani and Racine *et. al.*, 1999). The outpatient anticoagulation clinic study found that there were also reduced hospitalizations and Emergency department visits which resulted in savings of \$1,600/patient/year (Chiquette and Amato *et. al.*, 1998).

Methodology

When it comes to UMC (usual medical care) for Warfarin therapy, there are no prescribing guidelines to assist physicians aside from a “sliding scale” for some post-operative surgeries. The

purpose of the analysis was to conduct a cost-effectiveness analysis to determine whether PDW (pharmacist dosing of Warfarin) might represent a cost-effective alternative to UMC while providing equivalent or improved patient outcomes.

The UMC group was composed of a random sample of 50 of the more than 200 surgical patients and all general medicine patients who received Warfarin between May 10, 2005 and December 31, 2005. Since this trial is designed to compare physician dosing to the pharmacist dosing, only surgical unit patients who were dosed by physicians, rather than those on a “sliding scale,” were used. There were 36 general medicine patients and 13 surgical unit patients included in the study for a total of 49 patients in the UMC group.

Patients were assigned to the PDW (pharmacist dosing of Warfarin) group when a physician’s order authorized a pharmacist to manage a patient’s Warfarin therapy within a specified International Normalized Ratio target range. Each pharmacist who participated in the program was experienced and passed a special certification program for Warfarin management. As part of the program, the pharmacist was responsible for prescribing the dose of Warfarin, monitoring the laboratory tests, and educating patients. There were provisions for the pharmacist to consult with the physician if certain criteria were not met. The PDW group consisted of all 54 patients referred to PDW during the trial period of May 10, 2004 to December 31, 2004.

There were some physicians at the hospital, specifically the cardiologists, who decided not to refer patients to the PDW program. These patients are drawn from the same patient population as the PDW patients, however they had their Warfarin therapy managed by the cardiologists. This group has been included to ensure that PDW program will result in outcomes at least as good as this cardiac control group in the same patient population. The Cardiac Control group consisted of all 40 patients who were admitted to cardiology and had a cardiologist as the Most Responsible Physician between May 10, 2005 and December 31, 2005. Only patients on Warfarin therapy for greater than 2 days were included in the study.

Results

Important and Relevant Costs and Consequences

Costs Not Included for Study

Fixed hospital costs such as laboratory equipment were assumed to be equal in each treatment group and they will not be affected by the type of treatment ordered. Other costs such as utilities were also assumed to be similar for both patient groups. Non-medical costs such as pain/suffering, opportunity cost of patient’s time, and lost work productivity were not included in the study.

Variable Medical Costs

The variable medical costs considered for this studied are summarized below.

Item	Cost
Lab costs for International Normalized Ratio	\$7.00
Pharmacist time – see below	\$129,456.32
Transfusion Costs	<\$50.00
Adverse event “Clot”	\$3090.00
Adverse event “Bleed”	\$4531.59

From these variable costs, it was decided that laboratory costs and transfusion costs would not be included in the study since they are several orders of magnitude smaller than the costs of the PDW and the clot and bleed adverse events. Therefore, only the cost of pharmacist time and the cost of adverse events of clots and bleeds were examined. True transfusion costs are significantly greater than \$50.00, however, the hospital receives the product at no charge from the blood bank and the \$50.00 therefore only reflects hospital labour costs.

Explanation of Costs

Incremental Costs of PDW program – Pharmacist Cost

A summary table of the calculation of the pharmacist cost is presented below along with an explanation of each line item.

1. Cost of pharmacist wages	\$80,542.41
2. Cost of benefits, pension, vacation	\$16,913.91
3. Opportunity Cost, pharmacist	\$32,000
Total cost of PDW with 1 full-time equivalent	\$129,456.32

- 1) Pharmacist costs were based on the maximum salary of \$41.30 per hour for a 1,950 hour year. One full-time-equivalent was chosen as it was estimated that this would be sufficient to provide PDW for the entire hospital Warfarin patient population.
- 2) The extra costs of a full-time employee (e.g. pension, benefits) were estimated to be 21%.
- 3) There is opportunity cost of a pharmacist since pharmacists would normally be making clinical interventions that would result in cost-savings for the hospital. A value of \$16.41 per hour was found in the literature and the opportunity cost was calculated to be a \$32,000 (\$16.41 x 1950 hour) per year.

Cost of (Usual Medical Care) UMC

Since UMC represents the “status quo” alternative, there are no extra costs to the hospital to continue with UMC. The hospital does not pay physicians for management of in-patient care. In fact, physicians receive only a flat-fee for management of in-patients. Physicians do not receive increased fees for providing Warfarin management.

Adverse Event “CLOT” (Thromboembolic event)

To estimate the extra cost to the hospital of a thromboembolic event (the formation of a clot), a list of patients with the “Case Mix Group” (CMG) of Deep Vein Thrombosis was created. The expected cost to the hospital for this CMG is \$3090.00 based on the intensity of treatment, and an average length of stay of 7 days. To verify this cost is reasonable, a list of patients in 2003/04 was generated with an ICD-9 code of 451 (Thrombophlebitis popliteal vein) and direct costs were examined. This included treatment of other diseases, but the average direct cost to the hospital was \$16,605.03. Patients with an ICD-9 code of 451 had greater costs than similar CMGs without the ICD-9 code (range of approximately \$2,000 to \$10,000). Therefore, a cost per thromboembolic event of \$3090.00 is a reasonable estimate since it falls within this range.

Adverse Event “BLEED”

A summary of the calculations is listed below.

Cost of Bleed Event

1. Actual average Cost, cardiac admission with GI bleed in 2003/2004	\$6844.00
2. Expected Cost, cardiac admission without GI Bleed	\$2884.00
3. Cost to hospital of GI bleed for cardiac patient	\$3960.00 (1-2)
4. Cost, Adverse Event, hemorrhage due to circulating anticoagulants	\$5103.18
5. Average cost of bleed adverse event	\$4531.59 (5)

- 1) A GI hemorrhage is the most common manifestation of acute Warfarin toxicity. A list of cardiac patients with the ICD-9 code of 578.9 (Hemorrhage, gastrointestinal) was generated. However, this patient group includes costs that are not all related to Warfarin therapy. Therefore, this line looks at patient costs for a cardiac admission that also had a GI bleed.
- 2) This line item looked for the expected cost of a CMG of a cardiac patient who did not have a GI bleed and found the average cost of treatment of these patients.
- 3) Patients that had a GI bleed were compared to similar cardiac CMG without a GI bleed, and an average difference of \$3960.00 was found. Therefore, the cost of a GI bleed for cardiac patient in hospital could be estimated at \$3960.00.
- 4) An ICD-9 code of 286.5 (hemorrhage due to circulating anticoagulants) was used to look for patients with bleeds (not necessarily GI. In 2003/04, these patients had a direct cost to the hospital of \$5103.18. However, this will include hemorrhages that are usually more serious than those seen with Warfarin therapy.
- 5) Since the true cost to the hospital is likely between these two values, an average of line item 3 and 4 was the estimate of the cost of an adverse bleeding event. This cost was also used for surgical patients with bleeds.

Patients

Demographic information was collected on the patients' weight, age, and gender. Other information collected was the length of stay in hospital and number of days on Warfarin therapy. This is reported as the median since the length of stay data was not normally distributed and the mean was not a good measure of central tendency. There was no difference found between the Cardiac Control group and the PDW group. This was to be expected since during the trial period, the pharmacists only managed Warfarin therapy for cardiology patients.

Comparing the UMC group and PDW, there was no significant difference between the patient groups with respect to age ($P>0.5$), weight ($P>0.5$), or gender. However, in the UMC group, there was a longer length of stay and significantly fewer new Warfarin patients. This likely reflects the fact that the UMC patients were admitted for medical diagnoses, but had a pre-existing condition that required Warfarin. PDW patients are often admitted for a condition for which Warfarin is the primary therapy and thus initiated during their hospital stay. For example, this might include a patient who is admitted to PDW or Cardiology with a new diagnosis of "atrial fibrillation" for which the patient would start Warfarin therapy and may require life-long therapy. If this patient is later admitted for another condition such as pneumonia, they would then be admitted to general medicine, which would treat the pneumonia primarily, but would also treat the atrial fibrillation as a co-morbid illness and thus maintain the patient's Warfarin therapy.

Patient Demographics

	USUAL MEDICAL Care	Cardiac control	PHARMACIST DOSING
Number of patients	49	40	54
Length of Stay, median	14	11	12.5
Age	77.89	73.55	72.40
Weight	73.96	74.91	72.95
Male (%)	42.86%	47.5%	47.17%
New or Post-Op Warfarin	40.82%	65%	69.81%
# of Warfarin days, median	9	6	6

In comparing the reasons the patients were taking Warfarin, there were no significant differences among the groups. However, the UMC patients included surgical patients, which accounted for the higher number of fracture/post-operative patients in the UMC group.

Reason for Warfarin

	Usual medical care	Cardiac control	Pharmacist dosing
Atrial Fibrillation	55.10%	65%	68.52%
Clots	18.37%	20%	16.67%
Stroke	10.2%	5%	9.26%
Mechanical Valve	6.12%	5%	5.66%
Fracture/Post-Op	6.12%	5%	0%
Other	4.08%	0%	0%

Therapeutic End Points

Since patients will eventually reach a state where their Warfarin dosage is within a therapeutic range (i.e. patients are unlikely to experience an adverse event of either producing clots or experiencing excessive bleeding), final outcomes for the patients are expected to be equivalent. This finding is well supported in the literature that links therapeutic dosages of Warfarin to patient outcomes. The results of the study are summarized below.

Therapeutic End Points

	Usual medical care	Cardiac control	Pharmacist dosing
If new or post-op, days to therapeutic levels	5.56	4.11	4
Total % International Normalized Ratio's outside therapeutic range	50.37%	26.57%	29.09%
Clots	4 (8.16%)	1 (2.5)	0 (0%)
Bleeds	5 (10.20%)	1 (2.5%)	0 (0%)
Hemoglobin drop > 15	6 (12.24%)	2 (5%)	1 (1.85%)
Vitamin K given	6 (12.24%)	3 (7.5%)	1 (1.85%)
Units of blood given	12 units to 13 patients	2 units to 1 patient	0
Deaths	3, however unrelated to Warfarin therapy	0	0

There were no statistical differences between the Cardiac Control group and PDW group. However, there was a statistically significant difference in the primary end points of the number of clots (P<0.05) and bleeds (P<0.05) between the UMC and PDW groups. There was also a clinically significant difference in the secondary end points of days to therapeutic levels, total % International Normalized Ratio outside therapeutic range, number of hemoglobin drops > 15, vitamin K given and units of blood given. There was a significant difference in the number of deaths, but the cause of death was not deemed to be related to Warfarin therapy.

	Clot	Bleed
Rate of adverse event in UMC	8.16%	10.20%
Rate of adverse event in PDW	0%	0%
Absolute Risk Reduction of PDW	8.16%	10.20%
Numbers Needed to Treat (NNT)	12.25	9.80
Relative Risk Reduction of PDW	100%	100%

There was a large relative risk reduction (100%) due to the absence of any adverse events in the PDW patients. The NNT was calculated as the reciprocal of the Absolute Risk Reduction. This may be interpreted that there needs to be 12.25 patients treated under the PDW program to prevent one clot event and 9.80 patients treated to prevent a bleed event.

Economic End Points

Since there were no significant differences between the Cardiac Control group and PDW, this section will only focus on the comparison between PDW and UMC.

	Clot	Bleed	Total
Absolute Risk Reduction with PDW	8.16%	10.20%	
Estimated number of medical/surgical patients per year based on extrapolation of June-Dec 2004 statistics.	600	600	
number of adverse events averted with PDW	48 clots/year	61 bleeds/year	109 events/year
cost per event	\$3090.00	\$4531.59	
cost to hospital	\$148,320.00	\$276,426.99	\$424,746.99
cost of adverse events per patients per year			\$707.91
cost of PDW	\$129,456.32	\$129,456.32	\$129,456.32
cost per event averted	\$2697.01	\$2122.23	
cost of PDW per patient per year			\$215.76
Total savings to hospital			\$295,290.67
Savings per patient per year			\$492.15

The implementation of PDW for medicine and surgical patients will result in a total yearly savings to the hospital of \$295,290.67 based on a decrease of adverse events. This is a savings of \$492.15 for every patient prescribed Warfarin per year.

Conclusions

PDW is both economically and clinically beneficial for the hospital. PDW closely monitors Warfarin therapy by using specially trained pharmacists and showed a dramatic (100%) relative risk reduction in adverse events compared to UMC. PDW did not show any statistical differences with the Cardiac Control group. It should be noted that the physicians who did not refer to PDW during the trial period were expertly trained and motivated to maintain target International Normalized Ratio levels. These physicians would often come in on weekends to dose the Warfarin for the patients 7 days per week.

PDW also showed a statistically significant difference in all the secondary end-point compared to UMC but not to the cardiac control group. It should be noted that the cause of death for UMC could not be directly attributed to Warfarin therapy. The secondary end-points provide supporting evidence that this difference in adverse event rates is real. For example, as the time outside the therapeutic International Normalized Ratio increase, the risk of an adverse event also increases. In the UMC, patients had a 50.37% chance of being outside therapeutic range when there is an International Normalized Ratio ordered compared to 29.09% with PDW. The economic analysis only calculated values if PDW is expanded to include the medical and surgical patients. It showed that PDW will result in cost savings of \$295,290.67 to the hospital from averted adverse events. The sensitivity analysis shows that the economic analysis can be varied within a wide range and still show that PDW is a cost-effective solution for the hospital. This pilot project has shown that PDW should be implemented throughout the hospital. PDW is as effective as Warfarin managed by cardiologists, and more effective than UMC. These findings are supported by the medical literature which shows that pharmacist-led anticoagulation clinics are effective in the long term.

Discussion

There may be several reasons for the difference between UMC and PDW adverse event rates. One of the key reasons may be that there is a different patient population. The patients who were admitted to medicine and surgery services had a co-morbid medical condition that required Warfarin in addition to their reason for admission to hospital. In addition, the physician who was assigned to care for the patient may not have been familiar with the patient's medical history. Therefore, the physician may not have been focused on maintaining proper Warfarin therapy. A PDW pharmacist only has one responsibility and is therefore focused on the patient's Warfarin therapy. This specialization in one aspect of care also allows the pharmacist to become more expert in Warfarin management. By removing responsibility from the family physician or surgeon for maintaining Warfarin therapy, there may be improved patient care as physicians are able to focus on the patient's primary diagnosis. However, due to the different patient populations, the difference in adverse events may have been due to the fact that cardiac patients may have been less likely to have adverse events since the therapy was initiated at the beginning of their care.

Another factor which complicates the delivery of Warfarin therapy is related to the high number of drug interactions. In the PDW patients, there were 2.78 drug interactions per patient. When dealing with medical and surgical patients, there may be more drug interactions since the patients have at least one other co-morbid illness (the patient's reason for admission). Drug interactions greatly affect Warfarin therapy and need to be considered when starting or stopping other

medications. Again, the specialization of PDW allows the pharmacist to track these interactions more closely than the physician who is required to manage multiple medical problems.

There may also be a difference between UMC and PDW due to the mandatory patient education provided as part of the PDW program. It is likely that the PDW pharmacist spends more time educating the patients. This may result in a decrease in adverse events or readmission to hospital.

New Public Management Implications

Former United States Vice President, Al Gore, described New Public Management as “government that works better and costs less” (Gore, 1993). While this focus on efficiency through the adoption of more business-like behaviours is a recurring theme in the New Public Management literature, other important themes are also evident. The New Public Management movement seeks to achieve efficiency and greater financial control within the public sector by collecting costing information, monitoring performance rather than inputs, and shifting power away from the most dominant professions to weaker professions and management. Evolution towards the New Public Management paradigm has revealed efforts to make changes to both organizational processes and roles.

In this paper we present the case of pharmacist dosing of Warfarin as an example of how high quality services may be delivered in a more cost effective manner by altering the traditional role of physicians and implementing a more collaborative process in which pharmacists take on responsibility for directing and monitoring patients’ Warfarin therapy. This case demonstrates how reorganizing who is responsible for the delivery of a particular service, in order to take advantage of untapped expertise, can be an effective approach to improving organizational performance.

In this case, enhancing the role of pharmacists was shown to have both financial and quality benefits to the hospital. Although this study did not evaluate the indirect impact of PDW it is reasonable to expect that the decrease in complications associated with PDW would lead to decreased pain and suffering and thus a higher quality of life for patients. In addition, a bleed or clot will generally lead to a longer length of stay in hospital which would have financial implications for the patient related to a loss in productivity and income. Furthermore, the number of medication errors in the hospital may be reduced.

Despite the potential benefits of New Public Management-type reforms, they may be met with skepticism or opposition. It is understandable that any deviation from the status quo in an organization may be met with resistance; particularly if the change entails a reduction of the autonomy of professionals or reallocation of authority among professionals. Nonetheless, this example highlights the notion that a shift from measuring inputs to measuring outcomes, along with the introduction of new and interdisciplinary approaches to the delivery of services within the public sector, can lead to improvements in public administration that are both possible and worthwhile in enhancing organizational accountability and performance.

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