

Anticoagulation Clinics in North America: Operational Insights

Ross T Tsuyuki, Tammy Bungard, Carla M Grant, and Margaret L Ackman

ABSTRACT

Background: Although anticoagulation management services have been established since the early 1970s, and reports have consistently confirmed their delivery of high-quality care, little is known about how existing services operate.

Objective: To describe the key operational characteristics of anticoagulation management services in North America.

Methods: A survey was sent by regular mail to a random sample of anticoagulation management services in the United States ($n = 250$) and to all Canadian clinics ($n = 15$). Demographic characteristics, processes of patient care, and quality assurance measures were assessed.

Results: Overall, 228 of the 265 clinics were eligible for inclusion and could be reached by mail; of these, 118 (52%) responded to the survey. The clinics were staffed by pharmacists (68% of the clinics [$n = 80$]), nurses (38% [$n = 45$]), clerical personnel (26% [$n = 31$]), physicians (19% [$n = 22$]), nurse practitioners (10% [$n = 12$]), and physician assistants (3% [$n = 4$]). Most of the clinics were operating at maximum capacity, with a median of 300 appointments per month (equally split between in-person and telephone appointments). Referrals originated primarily from physicians, and 47 (40%) of the 118 clinics accepted referrals only for specific indications. The majority of the clinics used algorithms to systematically assess and manage patients (87% [103/118]) and computer systems to document patient care (86% [101/118]). Warfarin dosing algorithms were used by 82% (84/103) of the clinics, and the same proportion (82% [97/118]) performed quality assurance checks. In the event of an adverse outcome, liability was reported to be shared among the referring physician and clinic staff for 48% (57/118) of respondents, whereas 37% (44/118) reported that clinic staff alone would be accountable.

Conclusions: To the authors' knowledge, this is the first survey describing the operational characteristics of anticoagulation management services. Clinic operations were generally consistent with those outlined in consensus guidelines. By providing insight into the daily operations of these services, this study allows recommendations of mechanisms to enhance clinic efficiency.

Key words: anticoagulation clinic, warfarin, pharmacy services, international normalized ratio, anticoagulants

RÉSUMÉ

Contexte : Bien que les services de gestion de l'anticoagulation existent depuis le début des années 1970 et que des rapports aient invariablement confirmé que ces cliniques dispensent des soins de haute qualité, nous en connaissons très peu sur le mode de fonctionnement de ces services.

Objectif : Décrire les principales caractéristiques du fonctionnement des services de gestion de l'anticoagulation en Amérique du Nord.

Méthodologie : Nous avons envoyé une enquête par courrier à un échantillon aléatoire de services de gestion de l'anticoagulation aux États-Unis ($n = 250$) et à toutes les cliniques d'anticoagulation du Canada ($n = 15$). L'enquête évaluait les caractéristiques démographiques, le processus de soins aux patients et les mesures d'assurance de la qualité.

Résultats : En général, 228 des 265 cliniques satisfaisaient aux critères de sélection de l'enquête et étaient joignables par courrier; sur ce nombre, 118 (52 %) ont répondu à l'enquête. L'effectif des cliniques se compose de pharmaciens (68 % des cliniques [$n = 80$]), de personnel infirmier (38 % [$n = 45$]), d'employés de bureau (26 % [$n = 31$]), de médecins (19 % [$n = 22$]), d'infirmières et d'infirmiers praticiens (10 % [$n = 12$]), et d'adjoints au médecin (3 % [$n = 4$]). La plupart des cliniques fonctionnent à capacité maximale dont la médiane se situe à 300 consultations par mois (parts égales de consultations en personne et par téléphone). Les patients sont principalement aiguillés à la clinique par des médecins, et 47 (40 %) des 118 cliniques n'acceptent que les requêtes concernant des indications précises. La plupart des cliniques utilisent des algorithmes pour systématiquement évaluer et gérer les patients (87 % [103/118]) et des systèmes informatiques pour consigner les soins dispensés aux patients (86 % [101/118]). Une proportion semblable de cliniques utilisent des algorithmes pour calculer la dose de warfarine (82 % [84/103]) et effectuent des contrôles de qualité (82 % [97/118]). En cas d'un résultat clinique indésirable, 48 % des sondés (57/118) ont déclaré que la responsabilité serait partagée entre le médecin traitant et le personnel de la clinique alors que 37 % des sondés (44/118) ont répondu que seul le personnel de la clinique serait responsable.

Conclusions : À la connaissance des auteurs, c'est la première fois qu'une enquête évalue les caractéristiques de fonctionnement des services de gestion de l'anticoagulation. Le fonctionnement des cliniques respecte généralement celui décrit sommairement

INTRODUCTION

Anticoagulation therapy is highly efficacious in the prevention and treatment of many disorders, such as deep vein thrombosis, pulmonary embolism, atrial fibrillation, and valvular disease or replacement.¹ Warfarin therapy is safest and most effective when maintained within a narrow therapeutic window, as indicated by the international normalized ratio (INR). Maintaining the warfarin dose within this narrow window is often challenging, as it is influenced by many factors, including diet, acute or chronic diseases, and concomitant drug therapies, and there is wide interindividual variability in the dose–response relationship.² In addition, there is a delicate balance between the thrombosis associated with inadequate anticoagulant effect and the bleeding associated with excessive anticoagulation.^{1,3} Accurate dosing and appropriate monitoring are therefore crucial for maximizing efficacy and minimizing toxic effects.

In the community setting, anticoagulation therapy has historically been managed by primary care physicians.⁴ Under this model, the patient's blood is drawn in a laboratory for determination of INR, and the results are forwarded to the physician's office. Decisions about dosage adjustments are made by the physician or office staff and are subsequently communicated to the patient.⁵ This process may fail if patients do not have the laboratory testing done, if laboratory results are not communicated to the physician's office, or if the physician's office is not able to contact patients to advise on medication adjustments.⁵ For routine medical care, analyses of patterns of practice have reported a median of 45% of patients within their respective therapeutic INR range.^{6,9} These results are clearly suboptimal in light of the known benefits of maintaining patients within their therapeutic range.

To optimize the effectiveness of warfarin, specialty services known as anticoagulation management services have been developed to provide a systematic, focused, and coordinated approach to delivering anticoagulation care.¹⁰ Compared with routine medical care, these clinics are able to maintain superior anticoagulation control (patients within the therapeutic range 59% to 85% of the time),¹¹⁻¹⁶ which results in an impressive reduction in the frequency of major hemorrhagic and thromboembolic events.^{9,11,12,15,17} By achieving these superior patient

dans les lignes directrices consensuelles. En nous aidant à mieux comprendre le fonctionnement quotidien de ces services, cette enquête nous permet d'émettre des recommandations de mécanismes visant à accroître l'efficacité des cliniques.

Mots-clés : clinique d'anticoagulation, warfarine, services de pharmacie, rapport international normalisé, anticoagulants

outcomes, anticoagulation management services have consistently demonstrated overall cost savings to health care systems relative to other models of anticoagulation care.¹⁸⁻²²

Consensus guidelines have been developed to define the appropriate environment, process, and procedures necessary for quality medical care and optimal health outcomes in anticoagulation clinics.¹⁰ Although anticoagulation management services have been described in the literature since the early 1970s and new clinics continue to be established, little is known about how existing services operate. Such knowledge could provide insight into optimizing the efficiency of these services. As such, the purpose of this study was to determine and describe the key operational characteristics of anticoagulation management services in North America.

METHODS

Anticoagulation management services in the United States (including Alaska and Hawaii) were identified through a list on the Anticoagulation Forum website (<http://www.acforum.org>). The list was obtained in January 2000, and 250 clinics were randomly selected using a computer program. Clinics in Mexico were also sought, but none were identified. To identify all of the anticoagulation management services in Canada, local experts in the field were contacted, as was the sole Canadian manufacturer of warfarin at the time. Ethics approval was received from the Health Research Ethics Board at the University of Alberta.

For this cross-sectional study, a postal survey was mailed 3 times (in January, March, and June 2000) to the 250 randomly selected clinics in the United States and to the 15 clinics in Canada. To be eligible for inclusion in the analysis, respondents had to have an ambulatory anticoagulation service (self-reported).

The survey covered 3 general areas and was based in part on consensus guidelines published by Ansell and others¹⁰: organization and management of the clinic, the process of patient care, and evaluation of patient outcomes. The survey questions on organization and management of the clinic encompassed personnel working in the clinic, hours of operation,



availability of an after-hours service, and operating capacity of the service. The largest component of the survey captured data pertaining to the process of patient care, including criteria for service referral (indication[s] for therapy, health care provider[s] referring patients for care), use of management algorithm(s) or a computer system, mechanism(s) of INR assessment and patient appointments, and transfer of information (to patients and physicians). Patient evaluation was assessed by collecting information pertaining to quality assurance measures used by the clinics.

The survey tool was pretested by pharmacists not affiliated with the research project for readability and by staff of other ambulatory clinics for appropriateness and clarity of the questions. An expert in the field of anticoagulation management services reviewed the instrument for content and clarity.

Analysis of the survey data was primarily descriptive. Unless otherwise specified, the data are reported as

medians with interquartile ranges (IQRs) because of the variability in responses.

RESULTS

Survey Response

Of the 265 surveys mailed, 118 were completed and returned, which yielded a crude response rate of 45% (Figure 1). However, 33 of the 250 US clinics were ineligible for inclusion (21 because they were not operating an anticoagulation clinic and 12 because they could not be reached by mail), and 4 of the 15 Canadian clinics were excluded because they were not operating an ambulatory clinic; the response rate was therefore 52% after exclusion of undeliverable surveys and ineligible clinics.

Clinic Organization and Management

The majority of the anticoagulation management clinics had one full-time equivalent (FTE) pharmacist (68%

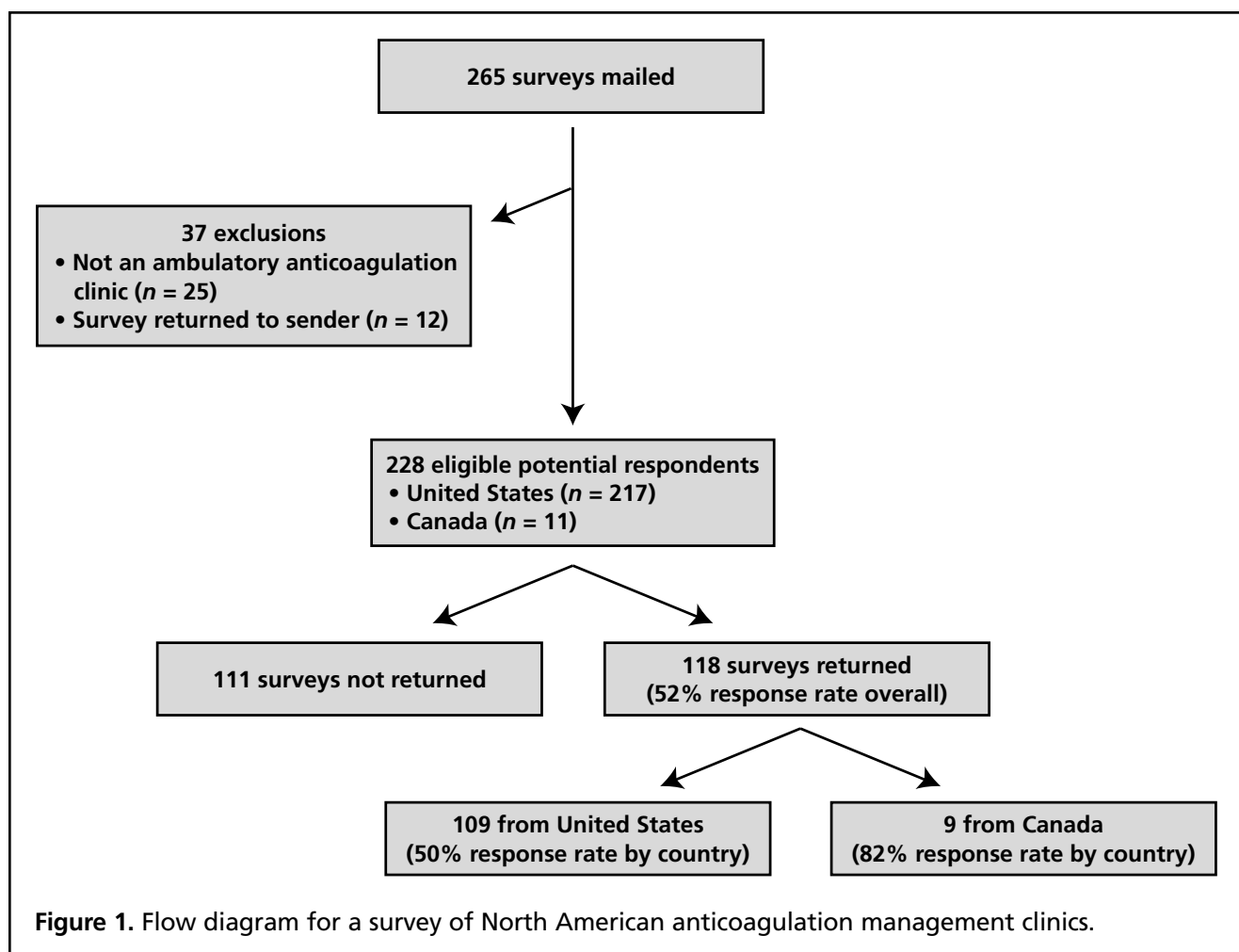


Table 1. Description of Operations of 118 Anticoagulation Management Services in Canada and the United States

Characteristic of Service	Median (IQR)	Mean ± SD
No. of hours per week	40 (19–40)	32 ± 15
No. of days per week	5 (4–5)	4 ± 1
No. of appointments per month	300 (160–600)	488 ± 536
INR determinations (% of clinics)*		
Venipuncture at laboratory	90 (14–100)	94 ± 41
Venipuncture at clinic	8 (5–40)	27 ± 32
Point-of-care technology used at clinic	90 (34–98)	67 ± 37
Point-of-care technology used in patient's home	2 (1–5)	3 ± 4

IQR = interquartile range, SD = standard deviation, INR = international normalized ratio.

*The median number of clinics that used each method (and the corresponding IQR) was determined, and these values were converted to percentages for reporting purposes.

[80/118]) and/or nurse (38% [45/118]) working within the clinic. Twenty-two (19%) of the clinics reported having physicians on staff, with the physicians working a median FTE of 0.3 (IQR 0.1–0.5); 12 clinics (10%) had nurse practitioners working a median of 0.8 FTE (IQR 0.5–1.0), and 4 clinics (3%) had physician assistants working a median of 0.5 FTE (IQR 0.3–5.0). Clerical support was available in 31 (26%) of the clinics, with a median of 0.7 FTE (IQR 0.5–1.0). Clinics reported operating a median of 5 days and 40 hours per week (Table 1). There was large variability in the number of appointments per month: median 300 (IQR 160–600). Sixty-three (53%) of the clinics reported operating at maximum capacity, and 35 (30%) were operating at 75% capacity. Seventy-three (62%) of the clinics had an after-hours on-call service operated by physicians (53% [39/73]), pharmacists 47% [34/73]), and registered nurses (12% [9/73]). In the event of an adverse patient outcome, liability was reported to be shared

among the referring physician and clinic staff for 48% (57/118) of respondents, whereas 37% (44/118) reported that clinic staff alone would be accountable.

Process of Patient Care

The vast majority of referrals to the anticoagulation management services were from physicians (Table 2), with nurses and pharmacists referring some patients. Most clinics (60% [71/118]) reported accepting referrals for anticoagulant therapy for any indication. A third of the clinics reported exclusion criteria for patients, the most common reasons being contraindications to therapy, pediatric patients, and noncompliance with previous therapy.

Most of the clinics (87% [103/118]) reported using a management algorithm for systematic assessment of patients following referral. More than 85% of respondents

Table 2. Characteristics of Referrals to 118 Anticoagulation Management Services in Canada and the United States

Characteristic of Referrals	No. (%) of Clinics	
Health care professional making referral*		
Physicians	62	(53)
Selected physicians	60	(51)
Working in hospital affiliated with clinic	61	(52)
Specialists	59	(50)
Involved with clinic management	38	(32)
Pharmacists	11	(9)
Nurses	19	(16)
Indications for which clinic provides service*		
Any indication	71	(60)
Venous thromboembolism	106	(90)
Atrial fibrillation	107	(91)
Valvular heart disease	107	(91)
Orthopedic conditions	72	(61)

*Choices were not mutually exclusive.



reported taking the following steps: verifying INR results; assessing for hemorrhage or thromboembolism; and assessing for changes in medications, underlying medical conditions, diet, and lifestyle. The clinics also reported verifying the patient's current dose of warfarin (96% [113/118]), maintaining complete medication profiles (95% [112/118]), and assessing compliance with therapy (94% [111/118]). Virtually all of the clinics reported providing written educational material to patients regarding their warfarin therapy (99% [117/118]). One-on-one teaching was employed by 93% (110/118) of the anticoagulation management services, and most clinics (80% [94/118]) reported providing a phone number that patients could call for answers to their questions. Audiovisual teaching aids (52% [61/118]), teaching classes (13% [15/118]) and computer-assisted learning (2% [2/118]) were less commonly used to educate patients.

A warfarin dosing algorithm was used by 82% (84/103) of the respondents; most of these algorithms outlined dosage adjustment (90% [76/84]) and the frequency of clinic follow-up (83% [70/84]). Clinics reporting the use of dosing algorithms most commonly had adapted their tools from the primary literature (48% [40/84]), and this had been done by the clinic staff or clinic managers. Validation of dosing tools was reported by 42% (37/89), with the majority of clinics basing validation on their quality assurance evaluations; however, 27% (24/89) had no validated dosing tools, and 31% (28/89) did not know if the tool had been validated.

Most clinics reported that patients went to a laboratory for venipuncture or that point-of-care technology was used in the clinic itself to obtain INRs (median 90% of clinics for each option) (Table 1). The CoaguChek and CoaguChek Plus (Roche Diagnostics, Indianapolis, Indiana) were used by 51% (31) and 26% (16) of the 61 clinics reporting use of point-of-care technology, respectively. INRs were reported to be the sole laboratory value monitored by 61% (71/117) of the clinics, whereas 39% (46/117) of the clinics reported also monitoring complete blood counts on a routine basis. One hundred and one (86%) of the 118 anticoagulation management services used a computer system to document the care of patients; of these, 61 (60%) used CoumaCare software (Wilmington, Delaware), with locally developed programs being the most common alternative.

Communication of results to patients was split evenly among clinic appointments (76% [90/118]) and telephone follow-up (79% [93/118]) (the responses to this question were not mutually exclusive). One-fifth of the clinics also reported communicating with patients through letters, written instructions in the clinic, and e-mail. Information

transfer to the patient's referring or family physician was reported by two-thirds of clinics. The frequency of this information transfer was variable: 44% (32/73) of clinics reported sending information to physicians after each visit, 16% (12/73) sent information only if there changes in therapy, and a minority reported transferring information only if problems arose. Almost all of the clinics (96% [113/118]) reported discharging patients from their care once the course of therapy was finished, but in many cases therapy was lifelong.

Quality Assurance

The majority of the clinics that responded to the survey (82% [97/118]) reported some form of quality assurance. Most of the clinics with a quality assurance program (88% [85/97]) reported assessing the proportions of INRs within the therapeutic range, as well as the rates of hemorrhagic (77% [75/97]) and thromboembolic (71% [69/97]) complications.

Canadian Anticoagulation Management Services

The 9 Canadian clinics that responded to the survey appeared similar in many respects to their US counterparts. One difference was the lack of use of physician assistants and nurse practitioners in Canada. Other differences between the 2 countries were in the use of computer systems for patient tracking (56% [5/9] in Canada, 88% [96/109] in the United States) and performance of quality assurance evaluations (67% [6/9] in Canada, 83% [91/109] in the United States).

DISCUSSION

By offering a systematic, coordinated approach to managing anticoagulant therapy, anticoagulation management services have long been accepted as a care model that improves anticoagulation control,¹¹⁻¹⁶ generates high satisfaction among patients and physicians,²³ and confers cost savings to health care systems.¹⁸⁻²² As such, these services have become increasingly common across North America, and in many jurisdictions have become the standard of care. However, little is known about their operations. To our knowledge, this is the first survey describing the operational characteristics of these services.

The results of this survey indicate that the typical anticoagulation management service is staffed by a full-time pharmacist or nurse, takes referrals from physicians for a variety of indications for anticoagulant therapy, and operates every business day. Patients' care is managed through the use of algorithms, and the patients



typically receive one-on-one education. For determination of INR, patients undergo venipuncture at laboratories or receive point-of-care assessments within the clinic. Follow-up with patients is evenly split between clinic appointments and telephone contact, and information is transferred to the referring physician on a periodic basis rather than after each visit. After-hours services are provided. Quality assurance measures are used to assess the adequacy of anticoagulant control and rates of hemorrhage and thrombosis. The typical clinic operates at or near maximum capacity, and patients are discharged only upon completion of therapy.

In general, it appears that anticoagulation management services are operating largely in accordance with consensus guidelines.¹⁰ In terms of organization and management, health care professionals with recognized degrees (primarily pharmacists and nurses) staff these programs, with physicians overseeing clinic operations. In terms of patient care, the clinics perform thorough assessments applicable to anticoagulant therapy for referred patients, have established protocols for initiation and maintenance of warfarin dosing and frequency of follow-up, and have a standardized process for delivering patient education. Further, most of the clinics reported using computer software to systematically track patients. Lastly, for the process of patient evaluation, quality assurance assessments are done by most clinics, with applicable measures of control of anticoagulation and rates of thromboses and hemorrhage being tracked.

Although anticoagulation management services improve patient care and outcomes, they are often overwhelmed by the demand for this service—they become victims of their own success. At the time of this survey, most of the clinics reported that they were operating at or near maximum capacity. By providing some insights into how the clinics operate, this survey has allowed us to suggest ways to improve efficiency. First, most of these services (60%) currently accept all referred patients for management, but their limited resources are arguably best used for patients who are either new to warfarin or have a history indicative of poor anticoagulation control (e.g., interacting medical conditions, other medications, prior thromboembolic or hemorrhagic events, or problems with medication adherence). Although one-third of clinics reported having clinical exclusion criteria, most of these criteria were based on contraindications to warfarin therapy rather than patient history or stability of the patient's condition with warfarin. Compounding this issue, only 4% of the clinics discharged patients before completion of therapy, which in many cases is lifelong. For patients receiving long-term therapy, once the anticoagulant therapy has been stabilized through services provided by the clinic, it may be reasonable to transfer

care to the primary care physician (if patient volume exceeds clinic resources), with the possibility of re-referral to the service should the need arise. Second, only 26% of the clinics reported using clerical support. Good technical support facilitates the efficient use of the pharmacist's or nurse's time to manage greater numbers of patients. Several tasks should be delegated to administrative support personnel, such as transferring information to referring physicians (which was done by two-thirds of clinics), entering information into computer software programs, scheduling appointments, and performing quality assurance assessments based on information in the database. Finally, in cases where INR testing is not performed within the clinic (as with point-of-care testing and private clinics determining INR via venipuncture), the use of telephone follow-up may offer a time-saving alternative to in-person visits (there is currently an even split between these 2 forms of follow-up).

This study had limitations with respect to the survey population. First, not all clinics operating in the United States are listed on the Anticoagulation Forum website, although this site offered the most comprehensive list of clinics available. Further, not all members of the Anticoagulation Forum operate anticoagulation clinics, which made it impossible for us to distinguish nonresponders that were operating a clinic from those not operating a clinic. This might have had the effect of lowering the effective response rate, the second limitation of the survey. Finally, the data from this survey were obtained a number of years ago; nonetheless, many of the issues relating to anticoagulation patient management are still relevant today.

In summary, this study is the first report of key operating characteristics of anticoagulation clinics in North America. Its results may provide some insights into ways to improve the operating efficiency of these important services.

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Ross T Tsuyuki, BSc(Pharm), PharmD, MSc, FCSHP, FACC, is with the Division of Cardiology, Faculty of Medicine and Dentistry, University of Alberta, Edmonton, Alberta.

Tammy Bungard, BSP, PharmD, is with the Division of Cardiology, Faculty of Medicine and Dentistry, University of Alberta, Edmonton, Alberta.

Carla M Grant, BSc(Pharm), is with Regional Pharmacy Services, Capital Health, Edmonton, Alberta.

Margaret L Ackman, BSc(Pharm), PharmD, is with Regional Pharmacy Services, Capital Health, Edmonton, Alberta.

Address correspondence to:

Dr Ross T Tsuyuki
Faculty of Medicine and Dentistry
University of Alberta
EPICORE Centre, 220 College Plaza
University of Alberta Campus
Edmonton AB
T6G 2C8

e-mail: ross.tsuyuki@ualberta.ca

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ON THE FRONT COVER

Castilleja angustifolia

The photograph on the front cover depicts *Castilleja angustifolia*, also known as Indian paintbrush. It was taken by Robin Ensom in May 2008 at Canyonlands National Park in Utah with a Panasonic DMC-TZ3 camera.



The sweet flowers of this plant are edible and were consumed by various American Indian tribes. Because of their high selenium content, the plants were also used for medicinal purposes. For example, the Chippewa used Indian paintbrush to treat rheumatism, and the Nevada Indian tribes used the

plant to treat venereal diseases and to enhance the immune system. Indian paintbrush is purported to have health benefits similar to those of garlic, provided only the flowers are consumed and only in moderation, but the plant is potentially toxic if consumed in large amounts. (Information source: Wikipedia, <http://en.wikipedia.org/wiki/Castilleja>)

CJHP would be pleased to consider photographs of medicinal plants taken by CSHP members for use on the cover of the Journal. If you would like to submit a photograph, please send an electronic copy (minimum resolution 300 dpi) to Sonya Heggart at sheggart@cshp.ca.

