

**“I know my value”**



*Achieving high quality anticoagulation  
management with specialised clinic care*

# Vitamin K antagonists and monitoring provide patients with highly effective anticoagulation

*The growing need for anticoagulation will require more efficient models of care*



## **Warfarin and monitoring are used to manage several diseases**

The vitamin K antagonist (VKA) warfarin is the most commonly used oral anticoagulant (OAC) in clinical practice.<sup>1</sup> It is frequently used to reduce the risk of stroke in patients with atrial fibrillation (AF) and also to treat or prevent venous thromboembolism (VTE).<sup>2</sup> In addition, patients who have received a mechanical heart valve (MHV) currently require lifelong treatment with warfarin.<sup>3</sup>

Warfarin is a highly effective oral anticoagulant, offering significant improvements over placebo or antiplatelet agents.<sup>4</sup> Regular monitoring of the International Normalized Ratio (INR) ensures therapeutic efficacy and reduces the risk of bleeding complications.<sup>5</sup> In addition to ensuring clinical effectiveness, monitoring also provides a means of assessing patient adherence,<sup>1</sup> general health and the opportunity to address patient questions regarding their anticoagulation treatment.

## **The demand for anticoagulation care is rising**

Millions of people worldwide are already taking OACs.<sup>6</sup> This number will continue to rise due to the population ageing and the growing prevalence of conditions which predispose to thromboembolic events.<sup>7-9</sup> In particular, AF is already being described as an epidemic. In 2010, AF was estimated to have affected around 5.2 million people in the US (projected to 12.1 million in 2030) and around 8.8 million in the EU (projected to 12.9 million in 2030).<sup>8,9</sup>

Until recently, many patients, particularly the elderly<sup>10</sup> and Asian patients,<sup>11</sup> have been undertreated with warfarin due to concerns about bleeding complications. However, there is now a growing awareness that, even in high-risk patients, the benefit of stroke reduction outweighs the risk of bleeding associated with warfarin therapy.<sup>12</sup>

The rising number of patients on OACs will automatically lead to an increased demand for anticoagulation care. In addition, as patients get older, they are more likely to be treated with multiple other drugs and to be affected by cognitive impairment and may become more forgetful.<sup>13</sup> Consequently, it has been suggested that elderly patients may require more frequent monitoring.<sup>14</sup>

To meet the rise in demand, healthcare providers will need to develop efficient models of anticoagulation care.

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# Choosing the right model of care for your patients

*Point-of-care testing models have simpler and more effective workflows than usual care*

Effective anticoagulant management is critical for achieving good clinical outcomes for warfarin patients and for making optimal use of the financial and human resources available within the local healthcare system. In addition, healthcare providers are increasingly aware of the need to develop management systems which offer improved convenience and flexibility for the patient.

The three main models of care that are currently used in clinical practice are (1) usual care, (2) alternative site testing (AST), and (3) patient self-monitoring.

## Usual care

- Many patients taking warfarin are monitored by a hospital physician or general practitioner (GP) in a traditional model referred to as usual care (Fig. 1)
- Typically patients attend appointments at their GP's surgery or local hospital. At each appointment a venous blood sample is drawn and sent to a centralised laboratory for INR testing<sup>15</sup>
- Once the result is available, the patient is contacted and advised of any warfarin dose adjustments<sup>15</sup>
- Studies that describe usual care have often reported that no specific standardised protocol of care is used by primary care physicians,<sup>16</sup> and in some instances no dosing algorithm is used; instead, individual physician knowledge and experience is utilised<sup>17</sup>
- In addition, GPs and hospital clinics may have little time or few resources available for educating patients on anticoagulation safety<sup>18,19</sup>

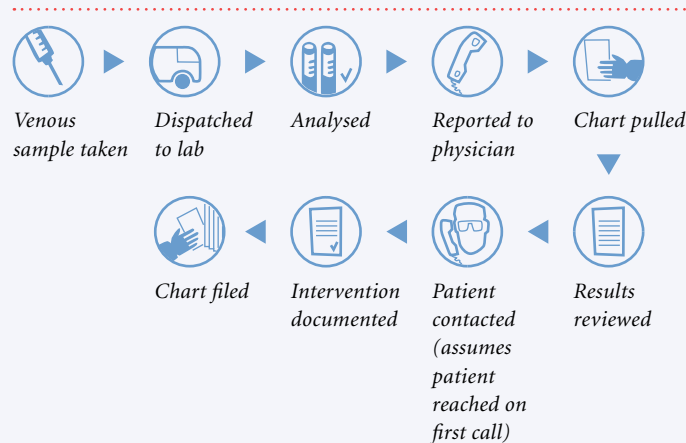


Fig. 1: Workflow in the usual care model

### Alternative site testing (AST)

- Increasing evidence shows that better outcomes can be achieved if patients are managed by a specialised anticoagulation management service<sup>2</sup>
- Specialised management can occur at sites separate from the patient's GP or hospital outpatient clinic and is therefore often called alternative site testing (AST) (Fig. 2)
- The most common of these alternative sites is the anticoagulation (AC) clinic
- The role of an AC clinic is to provide consistent, systematic and protocol-driven care<sup>20</sup> and recommendations have been published which recommend that this is achieved by using standardised protocols, dosing algorithms, extensive patient education and a systematic approach to patient tracking<sup>6</sup>
- In addition, AC clinics may perform near-patient testing point-of-care (POC) INR devices in order to streamline the clinic workflow<sup>15</sup>
- Many AC clinics are run by pharmacists or nurses<sup>21</sup> and the use of computerised decision support systems (CDSS) can reduce reliance on physician delivery of oral anticoagulant therapy<sup>2</sup>

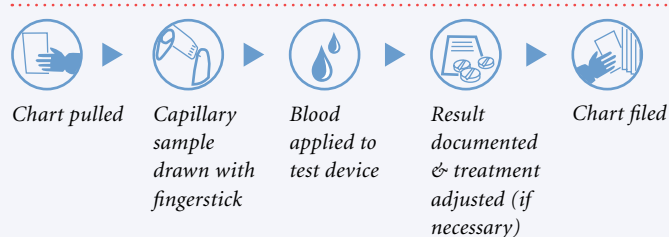


Fig. 2: Workflow in the AST model

### Patient self-monitoring

- Due to the availability of POC INR meters, testing can be easily transferred to the patient, thereby reducing the pressure on busy AC clinics
- In the patient self-testing (PST) model (Fig. 3), patients have their own meter and perform an INR test at a time convenient to them. They report the result to their health care professional and are provided with instructions on dose adjustment<sup>22</sup>
- Alternatively patients can also learn to adjust their own dose, in a model referred to as patient self-management (PSM)<sup>22</sup>

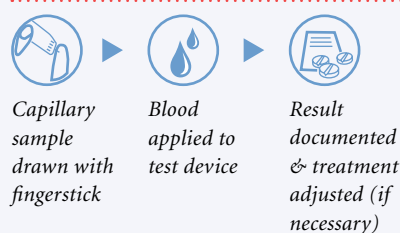


Fig. 3: Workflow in the patient self-monitoring model

# AST improves clinical outcomes

## *Increasing patients' safety and quality of life*



### **Staying longer in INR therapeutic range is the key to success**

Determination of the time in therapeutic range (TTR) is the most recognised way to measure the therapeutic effectiveness of warfarin management over time and has been shown to correlate strongly with clinical outcomes (Fig. 4).<sup>23,24</sup> Many studies have now established that the structured care found in AC clinics can improve TTR and produce better clinical outcomes than those which are achieved with usual care.<sup>15,21,25,26</sup>

- **AST increases the amount of time or the number of INR results that are within the therapeutic range.** This has been demonstrated in a number of settings in both developed and developing countries (Fig. 5)<sup>15,18,21</sup>
- **AST reduces the rate of complications.** A review of available studies in which care was managed by an anticoagulation management service indicated a 59% reduction in major hemorrhagic events and a 68% reduction in thrombotic events (Fig. 6)<sup>25</sup>
- **AST reduces the rate of hospitalisations.** Two separate studies found that usual care patients were 2.6 times<sup>21</sup> and 4.2<sup>26</sup> times more likely to be hospitalised for warfarin-related complications than AST patients

### **AST results in better clinical outcomes due to a combination of:**

- **Shorter time periods between INR tests.** In one study, AC clinic patients had significantly fewer INR tests drawn more than 6 weeks apart than the usual care group (3.7% vs 8.1%)<sup>26</sup>
- **Enhanced patient education.** The intensive education provided by AC clinics may improve warfarin adherence and alert patients to the potential of drug-drug and drug-food interactions<sup>2</sup>
- **Specialised AC clinic staff.** Staff in AC clinics will have received specialist training regarding warfarin therapy<sup>27</sup>
- **Provides real time results.** Dose adjustment is based on a current result rather than one which may be one to two days out of date<sup>15</sup>
- **Use of dosing algorithms or computerised decision support system (CDSS).** Several studies have demonstrated that CDSS can increase TTR and improve clinical outcomes.<sup>2</sup> It enables non-attending patients to be quickly identified and contacted,<sup>21</sup> and there is less chance that patients can be lost to follow-up<sup>2</sup>

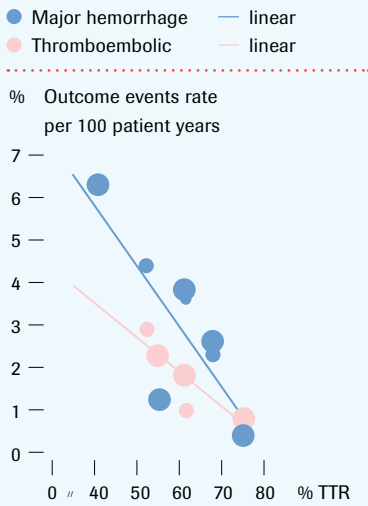


Fig. 4: TTR is directly linked to the rate of major hemorrhage and thromboembolic events.<sup>24</sup>

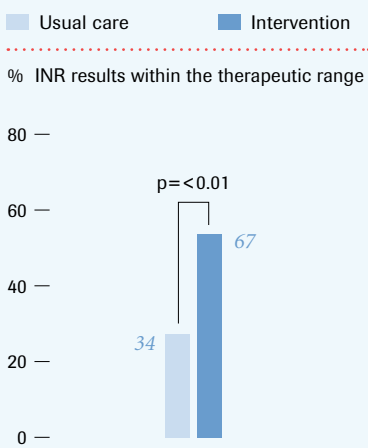


Fig. 5: A new approach to anticoagulation therapy, utilising decision support software, POC testing and workflow redesign (intervention group), increased the frequency of INR results within the therapeutic range.<sup>15</sup>

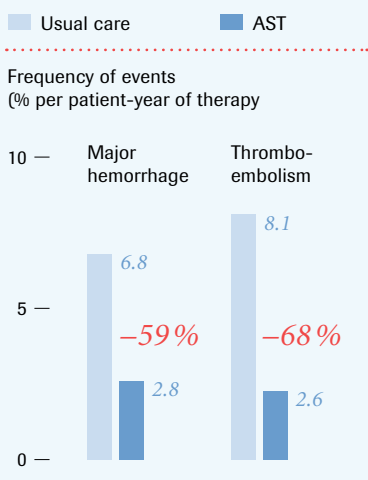


Fig. 6: AST reduces the rate of major hemorrhage and thromboembolic events.<sup>25</sup>



*Many studies have now established that the structured care found in AC clinics can improve TTR and produce better clinical outcomes than those which are achieved with usual care<sup>15,21,25,26</sup>*

# AST improves workflow efficiency

*Saving physicians time and reducing the number of consultations*



AC clinics which utilise point-of-care testing and CDSS can develop a streamlined approach to managing patient care, whereas the usual care model is generally quite time-consuming for both patient and health care professional.

- **Fewer consultations.** In AST, INR testing and dose adjustment can be achieved in a single visit. For usual care, two consultations are typically required<sup>15</sup>
- **Less retrieval of clinical records.** In AST, administrative staff only need to obtain a patient's clinical records once, whereas for usual care, clinical records are often obtained on at least two separate occasions<sup>15</sup>
- **Dose adjustment 'on the spot'.** In AST, the patient is usually given their dose adjustment recommendation before they leave their appointment. In the usual care model, the physician or physician's representative must contact the patient to provide them with dose-adjustment guidance. This can be particularly time-consuming if multiple attempts are required before the patient is reached<sup>15</sup>
- **Lower risk of errors.** With AST, near-patient testing reduces the risk of laboratory or communication errors. With usual care, blood samples can be lost during delivery to the laboratory or there may be communication errors which prevent the sample being analysed or the result being conveyed back to the physician. This may require the patient to re-attend for another blood draw<sup>15</sup>
- **More physician time available for other tasks.** In AST, routine visits can be handled by nurses or pharmacists, freeing up physician time for other work. With usual care, physicians monitor all patients regardless of the complexity of the case<sup>15</sup>



# AST is more cost-effective than usual care

## *Lowering costs and increasing financial revenue*

A number of studies have demonstrated that AC clinics are generally more cost-effective than usual care as they can reduce overall costs and in some cases generate revenue for the healthcare provider.

- **Lower staff costs.** AC clinics tend to have lower staffing costs as they are usually run by nurses or pharmacists, who cost less to employ than physicians.<sup>28</sup> In addition, administrative costs are also lower due to improved workflow efficiency<sup>15</sup>
- **Lower hospitalisation costs.** Reduced hospitalisation rates achieved with AC clinic care can lead to cost savings of approximately US dollars 1,000 per patient-year of therapy<sup>25</sup>
- **Increased revenue.** In many countries, warfarin monitoring by usual care does not generate revenue as physicians are not specifically reimbursed for providing this service, especially if they are only providing a telephone consultation.<sup>29,30</sup> In contrast, in some countries, specialised AC clinics can attract additional funding which can be a source of revenue for the healthcare provider (Fig. 7)<sup>15,31</sup>

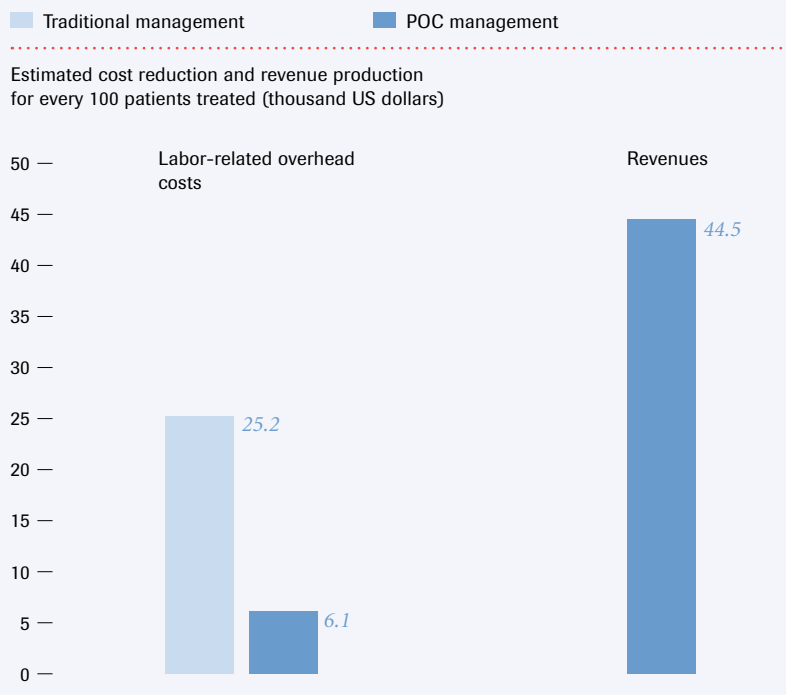


Fig. 7: The use of POC devices in AC clinics can generate revenues and reduce costs (based on Medicare minimum allowable charges and assuming an average of two visits per patient per month).<sup>15</sup>

# AST improves patient satisfaction

*Patients prefer to be cared for in an AC clinic than by usual care*

Overall, patient satisfaction is higher if patients are cared for by AC clinics compared with the usual care model.

- Patients prefer capillary sampling to venous sampling as it is perceived to be less painful<sup>32</sup>
- A number of studies comparing usual care with AST have assessed patient satisfaction and have concluded that patients prefer to be cared for in an AC clinic (Fig. 8)<sup>28,33,34</sup>
- Patients who returned to usual care after being in an AC clinic were less satisfied than patients who remained in an AC clinic<sup>33</sup>

*Overall, patient satisfaction is higher if patients are cared for by AC clinics compared with the usual care model<sup>28,32-34</sup>*

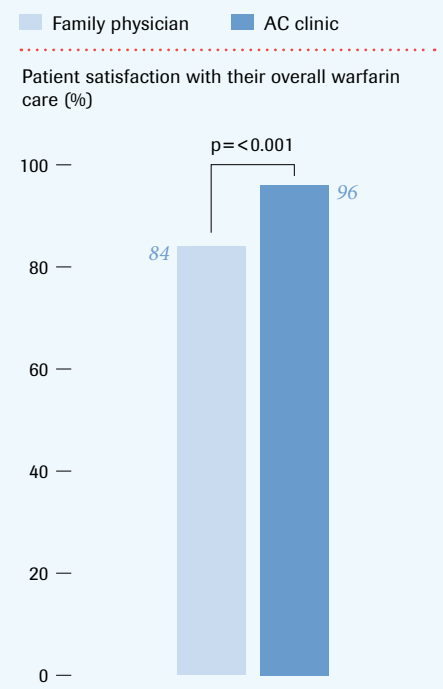


Fig. 8: Patient satisfaction is higher in patients who are cared for in an AC clinic<sup>34</sup>

# AST can help to meet the rising demand for anticoagulation care

## *An efficient and highly effective model of care*

To meet the rise in demand, healthcare providers will need to develop efficient models of anticoagulation care. Dedicated AC clinics offer improved workflow efficiency and can be more cost-effective than usual care.<sup>15,25,28</sup> In addition, the use of dosing algorithms or CDSS enables nurses and pharmacists to directly manage patients,<sup>2</sup> therefore reducing the burden on physicians. Consequently, AC clinics may prove to be a highly effective option as the number of patients requiring oral anticoagulation continues to increase.

### Take-home messages:

- **Worldwide, the prevalence of conditions with an indication for OACs is growing<sup>7,12</sup>**
- **To meet this rise in demand, healthcare providers need to develop efficient models of anticoagulation management**
- **Dedicated AC clinics offering structured and protocol-driven care can improve clinical outcomes and be more cost-effective than usual care models<sup>25</sup>**
- **AC clinics can be managed by specialised pharmacists or nurses, reducing the burden on physicians<sup>2</sup>**
- **Performing POC INR tests within an AC clinic saves time and is preferred by patients<sup>32</sup>**
- **For more information, please visit our website: [www.coaguchek.com](http://www.coaguchek.com)**



## References

- 1 Schulman, S. (2012). *Is the warfarin saga over?* J R Coll Physicians Edinb 42, 51-55.
- 2 Ryan, F., Byrne, S., & O'Shea, S. (2008). *Managing oral anticoagulation therapy: improving clinical outcomes. A review.* J Clin Pharm Ther 33, 581-590.
- 3 Eikelboom, J.W., & Hart, R.G. (2012). *Antithrombotic therapy for stroke prevention in atrial fibrillation and mechanical heart valves.* Am J Hematol 87, S100-S107.
- 4 Hart, R.G., Pearce, L.A., & Aguilar, M.I. (2007). *Meta-analysis: antithrombotic therapy to prevent stroke in patients who have nonvalvular atrial fibrillation.* Ann Intern Med 146, 857-867.
- 5 Levi, M., de Peuter, O.R., & Kamphuisen, P.W. (2009). *Management strategies for optimal control of anticoagulation in patients with atrial fibrillation.* Semin Thromb Hemost 35, 560-567.
- 6 Garcia, D.A., Witt, D.M., Hylek, E., Wittkowsky, A.K., Nutescu, E.A. et al. (2008). *Delivery of optimized anticoagulant therapy: consensus statement from the Anticoagulation Forum.* Ann Pharmacother 42, 979-988.
- 7 D'Arcy, J.L., Prendergast, B.D., Chambers, J.B., Ray, S.G., & Bridgewater, B. (2011). *Valvular heart disease: the next cardiac epidemic.* Heart 97, 91-93.
- 8 Colilla, S., Crow, A., Petkun, W., Singer, D.E., Simon, T. et al. (2013). *Estimates of Current and Future Incidence and Prevalence of Atrial Fibrillation in the U.S. Adult Population.* Am J Cardiol 112, 1142-1147.
- 9 Krijthe, B.P., Kunst, A., Benjamin, E.J., Lip, G.Y., Franco, O.H. et al. (2013). *Projections on the number of individuals with atrial fibrillation in the European Union, from 2000 to 2060.* Eur Heart J 34, 2746-2751.
- 10 Fustinoni, O. (2011). *The case for an elderly targeted stroke management.* Front Neurol 2, 1-6.
- 11 Ma, C. (2012). *Current antithrombotic treatment in East Asia: Some perspectives on anticoagulation and antiplatelet therapy.* Thromb Haemost 107, 1014-1018.
- 12 Levi, M., Hobbs, F.D., Jacobson, A.K., Pisters, R., Prisco, D. et al. (2009). *Improving antithrombotic management in patients with atrial fibrillation: current status and perspectives.* Semin Thromb Hemost 35, 527-542.
- 13 Costa, G.L., Ferreira, D.C., Valacio, R.A., & Vieira Moreira, Mda C. (2011). *Quality of management of oral anticoagulation as assessed by time in therapeutic INR range in elderly and younger patients with low mean years of formal education: a prospective cohort study.* Age Ageing 40, 375-381.
- 14 Ansell, J., Hirsh, J., Hylek, E., Jacobson, A., Crowther, M. et al. (2008). *Pharmacology and management of the vitamin K antagonists: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition).* Chest 133, 160S-198S.
- 15 Wurster, M., & Doran, T. (2006). *Anticoagulation management: a new approach.* Dis Manag 9, 201-209.
- 16 Nichol, M.B., Knight, T.K., Dow, T., Wygant, G., Borok, G. et al. (2008). *Quality of anticoagulation monitoring in nonvalvular atrial fibrillation patients: comparison of anticoagulation clinic versus usual care.* Ann Pharmacother 42, 62-70.
- 17 Young, S., Bishop, L., Twells, L., Dillon, C., Hawboldt, J. et al. (2011). *Comparison of pharmacist managed anticoagulation with usual medical care in a family medicine clinic.* BMC Fam Pract 12, 1-7.
- 18 Saoakaew, S., Sapoo, U., Nathisuwan, S., Chaiyakunapruk, N., & Permsuwan, U. (2012). *Anticoagulation control of pharmacist-managed collaborative care versus usual care in Thailand.* Int J Clin Pharm 34, 105-112.
- 19 Nasser, S., Mullan, J., & Bajorek, B. (2011). *Challenges of older patients' knowledge about warfarin therapy.* J Prim Care & Comm Health, 1-10.
- 20 Ebell, M.H. (2005). *A systematic approach to managing warfarin doses.* Fam Pract Manag 12, 77-83.
- 21 Rudd, K.M., & Dier, J.G. (2010). *Comparison of two different models of anticoagulation management services with usual medical care.* Pharmacotherapy 30, 330-338.
- 22 Bloomfield, H.E., Krause, A., Greer, N., Taylor, B.C., MacDonald, R. et al. (2011). *Meta-analysis: effect of patient self-testing and self-management of long-term anticoagulation on major clinical outcomes.* Ann Intern Med 154, 472-482.
- 23 Phillips, K.W., & Ansell, J. (2008). *Outpatient management of oral vitamin K antagonist therapy: defining and measuring high-quality management.* Exp Rev Cardiovasc Ther 6, 57-70.
- 24 Wan, Y., Heneghan, C., Perera, R., Roberts, N., Hollowell, J. et al. (2008). *Anticoagulation control and prediction of adverse events in patients with atrial fibrillation: a systematic review.* Circ Cardiovasc Qual Outcomes 1, 84-91.
- 25 Ansell, J.E. (2003). *Optimizing the efficacy and safety of oral anticoagulant therapy: high-quality dose management, anticoagulation clinics, and patient self-management.* Semin Vasc Med 3, 261-270.
- 26 Chamberlain, M.A., Sageser, N.A., & Ruiz, D. (2001). *Comparison of anticoagulation clinic patient outcomes with outcomes from traditional care in a family medicine clinic.* J Am Board Fam Pract 14, 16-21.
- 27 Witt, D.M. (2010). *Optimizing use of current anticoagulants.* Hematol Oncol Clin North Am 24, 717-726.
- 28 Chan, F.W., Wong, R.S., Lau, W.H., Chan, T.Y., Cheng, G. et al. (2006). *Management of Chinese patients on warfarin therapy in two models of anticoagulation service – a prospective randomized trial.* Br J Clin Pharmacol 62, 601-609.
- 29 Garton, L., & Crosby, J.F. (2011). *A retrospective assessment comparing pharmacist-managed anticoagulation clinic with physician management using international normalized ratio stability.* J Thromb Thrombolysis 32, 426-430.
- 30 Wittkowsky, A.K., Nutescu, E.A., Blackburn, J., Mullins, J., Hardman, J. et al. (2006). *Outcomes of oral anticoagulant therapy managed by telephone vs in-office visits in an anticoagulation clinic setting.* Chest 130, 1385-1389.
- 31 *Setting the standards in anticoagulation service delivery. Educational resource produced by Anticoagulation Europe, the National Centre for Anticoagulation Training (NCAT) and Roche Diagnostics in 2006.* Available at [http://www.roche.co.uk/fmfiles/re7208002/products\\_services/anticoagulationCare/Setting\\_the\\_Standards\\_in\\_Anticoagulation\\_Service\\_Delivery.pdf](http://www.roche.co.uk/fmfiles/re7208002/products_services/anticoagulationCare/Setting_the_Standards_in_Anticoagulation_Service_Delivery.pdf) (last accessed January 2014).
- 32 Woods, K., Douketis, J.D., Schnurr, T., Kinnon, K., Powers, P. et al. (2004). *Patient preferences for capillary vs. venous INR determination in an anticoagulation clinic: a randomized controlled trial.* Thromb Res 114, 161-165.
- 33 Bungard, T.J., Ritchie, B., Garg, S., & Tsuyuki, R.T. (2012). *Sustained impact of anticoagulant control achieved in an anticoagulation management service after transfer of management to the primary care physician.* Pharmacotherapy 32, 112-119.
- 34 Wilson, S.J., Wells, P.S., Kovacs, M.J., Lewis, G.M., Martin, J. et al. (2003). *Comparing the quality of oral anticoagulant management by anticoagulation clinics and by family physicians: a randomized controlled trial.* CMAJ 169, 293-298.

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