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Comments to Proposed Decision Memo for
Prothrombin Time (INR) Monitor for Home Anticoagulation Management
(CAG-00087R)

Thank you for the opportunity to comment on your proposed decision memo posted at https://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=209

I am providing five comments. Some are based on evidence that CMS has not heretofore considered.

1. Require that the Home INR monitoring training service (G0248) shall be face-to-face and documented as such.
2. Allow the treating physician to designate an alternative recipient of INR results.
3. Allow caregivers to perform tests for eligible beneficiaries in the home.
4. I propose a list of ICD-9-CM codes for conditions that support medical necessity.
5. I propose CMS change the descriptors of HCPCS II codes G0248 and G0249.

1. Require Face-to-Face Training (G0248) and Its Documentation:
Change NCA Requirement 3: The additions are underlined. The deletions are struck through.

The beneficiary or his/her caregiver *has undergone a~~n~~* face-to-face *educational program on anticoagulation management and demonstrated the correct use of the device (G0248) prior to receiving ongoing Home INR Monitoring services (G0249 and G0250) ; and*

Rationale:
Face-to-face training is the most reliable method to assure the beneficiary or caregiver has the knowledge, skills, cognition, and manual dexterity necessary to accurately and reliably obtain the blood sample and then perform the test. The scientific studies supporting both the NCA and original NCD either employed a face-to-face training method or did not clearly describe the type of training. It is reasonable to presume the face-to-face training method of the home-test studies substantially contributed to their findings of home-test accuracy and reliability. Accordingly, before allowing G0248 to be provided without face-to-face training, CMS should require scientific evidence to show it

is equally safe and effective. CMS should not presume that non-face-to-face training is safe and effective.

An unrecognized INR result error can happen when the patient obtains the blood sample improperly. Improper techniques include:

1. Aggressive finger/hand massage, and
2. Repeat puncture of the same finger to augment the blood sample.

A falsely low INR result can cause an anticoagulant medication overdose and subsequent hemorrhagic death. A falsely high INR result can cause an anticoagulant medication under dose and subsequent stroke.

The Medicare Part B Contractor, NHIC, California has issued a local coverage policy which supports my recommendation. NHIC states in its IDTF LCD that the training for new patients should be face-to-face, not exclusively by a DVD machine, telephone, or other device.[1]

Supporting Evidence:
The studies that support home testing are listed in the **Table 1** at the end of this letter. The type of patient training performed in each study is listed for your review. Some of the studies are for self-management as well as self-testing.

In 1997, when the FDA cleared PROTIME MICROCOAGULATION SYSTEM[2] K961835, the supporting study was based on the following method:

> *Patients who agreed to participate in the study received a 30-60 minute training session at the clinic which included explanation, demonstration, and practice performing the test procedure. The patient was required to demonstrate the ability to perform the assay prior to enrollment in the study.*

Although the type of training needed for COAGUCHEK XS SYSTEM[3] K062925 and INRATIO SELF-TEST® [4] K021923 is not specified in the FDA clearance documents, I believe this omission warrants reconsideration of the supporting scientific evidence with respect to training methods. I recommend CMS contact the FDA on this matter.

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[1] IDTF LCD: *In-person training is required, the RN or other staff cannot be replaced by a DVD machine, telephone, etc. NCD 190.11 applies to these services.*

[2] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/PMNSimpleSearch.cfm?db=PMN&id=K961835

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/PMNSimpleSearch.cfm?db=PMN&id=K062925

[4] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/PMNSimpleSearch.cfm?db=PMN&id=K021923

INRatio® made by HemoSense, Inc. has a training manual[5] which advises trainers to train patients to use a "hanging drop" for the test sample[6] and

> *…instruct trainees not to apply strong repetitive pressure i.e. not to milk the finger. Point out that this may cause inaccurate results.*[7]

2. Allow the treating physician to designate an alternative recipient of INR results.
The current descriptor of G0249 requires … *reporting of test results to physician….* I recommend CMS permit the treating physician to instruct the IDTF to report the result exclusively to the physician's designee.

Rationale:
Treating physicians commonly refer patients to anticoagulation clinics.[8] Some referring physicians instruct the IDTF to report the results exclusively to the clinic. Sometimes the report is made directly to its computer[9] instead of by fax or telephone. Based on the current code descriptor, the IDTF also must report the INR result to the referring physician, even when the treating physician requests the IDTF report the results exclusively to a physician designee. CMS's permission will allow IDTFs to avoid duplicate test reporting.

Supporting Evidence:
Of the ten studies cited in the NCA, three[10] used anticoagulation clinics to manage patients.

3. Allow Caregivers to Perform Tests for Eligible Beneficiaries in the Home
To effectuate this request, I recommend the following changes in the coverage requirements. The additions are underlined. The deletions are struck through.

> Add the underlined portion to Requirement 3: *The beneficiary* or his/her caregiver *has undergone an educational program on anticoagulation management and demonstrated the correct use of the device prior to its use in the home; and*
>
> Add the underlined portion to Requirement 4: *The beneficiary* or his/her caregiver *has undergone an educational program on anticoagulation management and demonstrated the correct use of the device prior to its use in the home; and*

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[5] HemoSense, Inc., 651 River Oaks Parkway, San Jose, CA 95134 USA (877) 436-6444 toll free, (408)719 1393 phone, (408)719-1184 fax
[6] Page 11 http://www.hemosense.com/support/productlit.shtml
[7] Page 12 http://www.hemosense.com/support/productlit.shtml
[8] A specialized clinic for anticoagulation management coordinated by other health care professionals such as pharmacists, nurse practitioners, registered nurses, and other physicians.
[9] Coumadin® Product Label: p26 http://www.fda.gov/medwatch/safety/2006/coumadin_PI_april2006.pdf *Time in therapeutic range is significantly greater (56%-93%) in patients managed by anticoagulation clinics, among self-testing and self-monitoring patients, and in patients managed with the help of computer programs. Self-testing patients had fewer bleeding events than patients in usual care.*
[10] **Gardiner** x2 and **Menedez-Jandula**

Change Requirement 5: ~~*Self*~~ Home-*testing with the device occurs no more frequently than once a week.*

Rationale:
The medical benefit of a home INR test will be the same when the caregiver or the beneficiary performs it.

Supporting Evidence:
The FDA has cleared a home INR test when performed by the patient or caregiver. The FDA clearances for the three machines on the market state:

Name and FDA Clearance Code	**Market Clearance Statement**
COAGUCHEK XS SYSTEM[11] K062925	*The system is intended for properly selected and suitably trained users or their caregivers….*
INRATIO SELF-TEST[12] K021923	*…for monitoring of oral anticoagulation therapy by trained patients or their caregivers….*
PROTIME MICROCOAGULATION SYSTEM[13] K961835	Patients and caregivers not mentioned.

4. ICD-9-CM codes
The following list of ICD-9-CM codes is proposed to describe the following covered conditions:

Presence of artificial heart value

ICD-9-CM code Number	**Descriptor**
V43.3	*Organ or tissue replaced by other means; Heart valve*

Chronic atrial fibrillation

ICD-9-CM code Number	**Descriptor**
427.31	*Atrial fibrillation*

11 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/PMNSimpleSearch.cfm?db=PMN&id=K062925
12 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/PMNSimpleSearch.cfm?db=PMN&id=K021923
13 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/PMNSimpleSearch.cfm?db=PMN&id=K961835

Deep venous thrombosis

ICD-9-CM code Number	Descriptor
451.11	*Phlebitis and thrombophlebitis; Of deep vessels of lower extremity; Femoral vein (deep) (superficial)*
451.19	*Phlebitis and thrombophlebitis; Of deep vessels of lower extremity; Other (Femoropopliteal vein, Popliteal vein, Tibial vein)*
451.2	*Phlebitis and thrombophlebitis; Of lower extremities, unspecified*
451.81	*Phlebitis and thrombophlebitis; Of other sites; Iliac vein*
453.40	*Venous embolism and thrombosis of unspecified deep vessels of proximal lower extremity*
453.41	*Venous embolism and thrombosis of deep vessels of proximal lower extremity*
453.42	*Venous embolism and thrombosis of deep vessels of distal lower extremity*
453.9	*Venous embolism and thrombosis of deep vessels of distal lower extremity; Of unspecified site*

Rationale:In my medical opinion, all of these diagnosis codes reflect the anticoagulation indications intended by the NCA. Frequently, the exact source of a recurrent pulmonary embolism is unknown but the physician strongly suspects it arises from a deep venous thrombosis and requires long term anticoagulation. When embolism occurs from a deep venous thrombosis, the 453 series codes should be reported. Both 451 and 453 conditions may warrant long term anticoagulation.

Contractors should only require the one ICD-9-CM code that describes the condition for which home testing is covered. A second code: V58.69: *Long-term (current) use of other medications, high risk medications* should not be required because the NCA states this requirement. A physician and non-physician practitioner reasonably can be expected to know that it is not reasonable and necessary to routinely perform an INR test when patient is not taking warfarin. The likelihood home INR testing will be ordered in the absence of warfarin therapy is so low, that, if a second ICD-9-CM code is required, most likely there will be more claim denial errors than proper denials.[14]

5. HCPCS Code Descriptor Changes:

If CMS agrees with my comments, I recommend the following changes to the HCPCS II codes for Home Prothrombin Time INR Monitoring.[15] The additions are underlined. The deletions are struck through.

[14] Personal Opinion of former CMD NHIC California
[15] HCPCS Book CMS Manual System (Publication 100-04)

G0248: *Demonstration, at initial use, of home INR monitoring for patient ~~with mechanical heart valve(s)~~ who meets Medicare coverage criteria, under the direction of a physician; includes: demonstration use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results and documentation of a patient* or caregiver's *ability to perform testing*. (requires face-to-face service)

G0249: *Provision of test materials and equipment for home INR monitoring to patient ~~with mechanical heart valve(s)~~ who meets Medicare coverage criteria; includes provision of materials for use in the home and reporting of test results* (e.g. by phone, fax, E-mail, computer to computer link) *to physician* or physician's designee*; per 4 tests*. (does not require face-to-face service)

G0250: *Physician review; interpretation and patient management of home INR testing for a patient ~~with mechanical heart valve(s)~~ who meets ~~other~~ coverage criteria; per 4 tests (does not require face-to-face service)*

Thank you for considering my comments.

Respectfully yours,

Gerald N. Rogan, MD.

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Table 1: Methods of Patient Training Reported in INR Home-test Studies

Author	Citation of method for training
White[17]	*…patients …who demonstrated an ability to use the monitor…*[18] *A member of the study team taught potential patients how to use the monitor, observing the patient determine at least one prothrombin time successfully.*[19]

[16] Gerald Rogan, M.D. is a consultant specializing in public payer programs, especially Medicare part B. He served as the carrier medical director for NHIC CA Part B Medicare from 1997-2003. Dr. Rogan holds BA and MD degrees from the University of Michigan. He became board certified in emergency medicine in 1980, renewed in 1993. He practiced emergency medicine and family practice for 23 years mostly in private practice in northern California providing a variety of inpatient, outpatient and home services.
[17] **White** RH, McCurdy SA, von Marensdorff H, Woodruff DE Jr, Leftgoff L. Home prothrombin time monitoring after the initiation of warfarin therapy: a randomized, prospective study. *Ann Intern Med* 1989; **111:** 730–37.
[18] Ibid: Summary, p 730

Sawicki [20]	*Patients were randomized … based on a structured treatment and teaching program ….[21] The* [patient training] *program consisted of 3 consecutive weekly teaching sessions up to 90 minutes…. The quality of the INR value self-monitoring was checked by the teaching nurse at the end of the first and at the beginning of the following two sessions.[22]*
Beyth [23]	*The intervention consisted of patient education about warfarin, training to increase patient participation, self-monitoring of prothrombin time, and guideline-based management of warfarin dosing.[24] Patients were initially assessed, educated, and taught to use the portable monitor while hospitalized; training lasted 30 minutes to 1 hour. Within 3 days of the discharge from the hospital, the lay educator or study investigator made a home visit to assess patient's use of the portable monitor and to check the prothrombin time.[25]*
Cromheecke [26]	*Instruction … on use of an automated device was given via video presentation and live demonstration. Patients were then given the opportunity to measure their own INR (at least once or as many times as they wished) in the presence of an instructor.[27]*
Körtke [28]	Training not specified. *The patients in Group B were trained in INR self-management 11 days after surgery.[29]*
Sidhu [30]	Training not specified. *We successfully trained 41 of 44 patients. Self-managed anticoagulation is … easily learned …it is suitable for approximately two thirds of patients…*
Fitzmaurice (2001) [31]	No information about type of training.
Fitzmaurice (2002) [32] (NCA)	*The intervention comprised two training sessions of one to two hours duration. Patients were allowed to undertake patient self management on successful completion of training.*

[19] Ibid: Patients and Methods, p 731
[20] **Sawicki** PT. A structured teaching and self-management program for patients receiving oral anticoagulation: a randomized controlled trial. *JAMA* 1999; **281:** 145–50.
[21] Ibid, summary, p 145
[22] Ibid, p 146
[23] **Beyth** RJ, Quinn L, Landefeld CS. A multicomponent intervention to prevent major bleeding complications in older patients receiving warfarin: a randomized, controlled trial. *Ann Intern Med* 2000; 133: 687–95.
[24] Ibid, Summary, p 687
[25] Ibid, Methods, p 689
[26]**Cromheecke** ME, Levi M, Colly LP, et al. Oral anticoagulation self-management and management by a specialist anticoagulation clinic: a randomised cross-over comparison. *Lancet* 2000; **356:** 97–102.
[27] Ibid, Methods, p 98
[28] **Körtke** H, Korfer R. International normalized ratio self-management after mechanical heart valve replacement: is an early start advantageous? *Ann Thorac Surg* 2001; **72:** 44–48.
[29] Ibid, Patients and Methods, p 842
[30] **Sidhu** P, O'Kane HO. Self-managed anticoagulation: results from a two-year prospective randomized trial with heart valve patients. *Ann Thorac Surg* 2001; **72:** 1523–27.
[31] **Fitzmaurice** DA, Machin SJ. Recommendations for patients undertaking self-management of oral anticoagulation. *BMJ* **2001**; **323:** 985–89.
[32] **Fitzmaurice** DA, Murray ET, Gee KM, Allan TF, Hobbs FDR. A randomised controlled trial of patient self management of oral anticoagulation treatment compared with primary care management. J Clin Pathol. **2002**;55:845-849.

Fitzmaurice (2005) [33] (NCA)	No information about type of training.
Gadisseur [34]	*… trained patients; … receive training …; … training program.*
Gardiner (2005) [35]	Training not specified. Success required *suitably trained patients.*
Gardiner (2004) [36] (NCA)	*We conclude that PST is a reliable alternative to hospital clinic attendance and is acceptable to the majority of suitably trained patients.*
Gardiner (2005 #2) [37] (NCA)	Training not specified
Khan [38]	*receive education*
Sunderji [39](NCA)	*Exclusion criteria were …inability to attend training sessions.*
Menéndez-Jándula B[40]	*The self-management group …received simple instructions*
Menéndez-Jándula [41](NCA)	No additional information
Völler (2001) [42]	No information
Völler (2005) [43] (NCA)	No information
Völler (2005) [44](NCA)	Reference not found

[33] **Fitzmaurice** DA, Murray ET, McCahon D, Holder R, Raftery JP, Hussain S, Sandhar H, Hobbs FD. Self management of oral anticoagulation: randomised trail. BMJ. **2005**:331(7514):1057.
[34] **Gadisseur** AP, Breukink-Engbers WG, van der Meer FJ, van den Besselaar AM, Sturk A, Rosendaal FR. Comparison of the quality of oral anticoagulant therapy through patient selfmanagement and management by specialized anticoagulation clinics in the Netherlands: a *Med* 2003; **163:** 2639–46.
[35] **Gardiner** C, Williams K, Mackie IJ, Machin SJ, Cohen H. Patient self-testing is a reliable and acceptable alternative to laboratory INR monitoring. *Br J Haematol* **2005**; **128:** 242–47.
[36] **Gardiner** C, Williams K, Mackie IJ, Machin SJ, Cohen H. Patient self-testing is a reliable and acceptable alternative to laboratory INR monitoring. *British Journal of Haematology*. **2004**;128:242-247
[37] **Gardiner** C, Williams K, Longair I, Mackie IJ, Machin SJ, Cohen H. A randomised control trial of patient self-management of oral anticoagulation compared with patient self-testing. *Br J Haematol*. **2005**;132(5):598-603
[38] **Khan** TI, Kamali F, Kesteven P, Avery P, Wynne H. The value of education and self-monitoring in the management of warfarin therapy in older patients with unstable control of anticoagulation. *Br J Haematol* 2004; **126:** 557–64.
[39] **Sunderji** R, Gin K, Shalansky K, et al. A randomized trial of patient self-managed versus physician-managed oral anticoagulation. *Can J Cardiol* 2004; **20:** 1117–23.
[40] **Menéndez-Jándula B**, Souto JC, Oliver A, et al. Comparing selfmanagement of oral anticoagulant therapy with clinic management: a randomized trial. *Ann Intern Med* 2005; **142:** 1–10.
[41] **Menéndez-Jándula** B, Souto JC, Oliver A, Montserrat I, Quintana M, Gich I, Bonfill X, Fontcuberta J. Oral Anticoagulation Monitoring Study Group. Prothrombin measurement using a patient self-testing system. *Am J Clin Pathol*. 2001;115:280-287
[42] **Völler** H, Dovifat C, Glatz J. Home management of anticoagulation. *Eur Heart J Suppl* 2001; **3** (suppl Q)**:** Q44–49.
[43] **Völler** H, Glatz J, Taborski U, Bernardo A, Dovifat C, Heidinger K. Self-management of oral anticoagulation in nonvalvular atrial fibrillation (SMAAF study). *Z Kardiol*. 2005;94(3):182-6
[44] **Völler** H, Dovifat C, Wegscheider K. Experience with INR self-management: patient selection and complication rates. *Z Kardiol.* 2005:94(12):801-7.

Ansell[45]	*The education and training of patients for self-monitoring are described…*
Ansell[46]	Training not specified
Watzke[47]	*Training in self-testing on the CoaguCheck® monitor was taught for two hours in groups of 5 to 10 patients by a lab technician who had prior experience in conventional testing and in testing with the monitor. …each patient performed a minimum of two tests on himself and was able to watch the others testing.*[48]
Hasenkam[49]	*Training in self analysis was undertaken by two dedicated nurses. After 3 weeks the patients were individually interviewed for dedicated teaching about medication and analysis technique. At an interview after 6 weeks the patient's ability to perform analysis was subject to final evaluation and a decision on continued project participation was made.*[50]
Hasenkam [51]	*…patients were trained in our department in INR self-testing immediately after the heart valve replacement.*[52]
Cosmi[53]	*The patients were instructed in the use of the portable PT monitor (Coagucheck, Roche Diagnostic, Germany) by physicians and nurses in each of the participating Centers. Three training sessions were conducted in each center. Patients were allowed to proceed with the study after the performance of the test had been judged satisfactory by the instructions in the last training session.*[54]

[45] **Ansell** J, Jacobson A, Levy J, Völler H, Hasenkam JM; International Self-Monitoring Association for Oral Anticoagulation.; Guidelines for implementation of patient self-testing and patient self-management of oral anticoagulation. International consensus guidelines prepared by International Self-Monitoring Association for Oral Anticoagulation.; *Int J Cardiol.* 2005 Mar 10;99(1):37-45.
[46] **Ansell**, J; Patel, N; OStrovsky, D; Nozzolillo, E; Peterson, A; Fish, L; Long Term Patient Self-management of Oral Anticoagulation.; *Arch Intern Med*, vol. 156 Nov 13, 1995
[47] **Waztke**, H.H.; Forberg, E; Svolba, G; Jiminez-Boj, E; Krinninger, B; A Prospective Controlled Trial Comparing Weekly Self-testing and Self-dosing with the Standard Management of Patietns on Stable Oral Anticoagulation; *Thromb Haemost* 2000:83:661-5
[48] Ibid, p 662
[49] **Hasenkam** JM, Kimose HH, Knudsen L, Grønnesby H, Halborg J, Christensen TD, Attermann J, Pilegaard HK.; Self management of oral anticoagulant therapy after heart valve replacement. *Eur J Cardiothorac Surg*. 1997 May;11(5):935-42.
[50] Ibid, Study protocol, p 937
[51] **Hasenkam** JM, Knudsen L, Kimose HH, Grønnesby H, Attermann J, Andersen NT, Pilegaard HK.; Practicability of patient self-testing of oral anticoagulant therapy by the international normalized ratio (INR) using a portable whole blood monitor. A pilot investigation.; *Thromb Res*. 1997 Jan 1;85(1):77-82.
[52] Ibid, page 78
[53] **Cosmi B**, Palareti G, Carpanedo M, Pengo V, Biasiolo A, Rampazzo P, Morstabilini G, Testa S.; Assessment of patient capability to self-adjust oral anticoagulant dose: a multicenter study on home use of portable prothrombin time monitor (COAGUCHECK).;*Haematologica.* 2000 Aug;85(8):826-31.
[54] Ibid, page 827

Anderson[55]	*Enrolled patients were instructed in the use of the portable monitor by the study nurse and were required to perform the test successfully under supervision before being allowed to proceed with the study.*[56]
Hirsh[57] *	Not relevant to training question
Laupacis[58] *	Not relevant to the training question
Samsa[59] *	This study describes how best to conduct studies to determine the value of INR self-testing. The differences in training can affect the study findings. Self-testing patients *often receive extensive training on operation of their home testing equipment.*[60] *An optimal study design would standardize the non-device-related components of patient education as much as possible.*[61] *Patients in trials were selected by interview as likely to be …particularly…competent.*[62]
Heidinger[63]	Patients were trained according to the standards of the Association of Self-Management of Anticoagulation. Patients undertaking self management must be trained by a competent healthcare professional and must remain in contact with a named clinician.[64] *In Germany, around 50 000 patients currently manage their own anticoagulation therapy, and there is a nationally approved, formalised training programme for patients.*[65] would be considered satisfactory. *If the external quality control procedure is unsatisfactory on more than one occasion, the patient's technique and device must be assessed by the training centre. If performance in the external quality control procedure is persistently poor, the patient should be withdrawn from the self-management programme.*[66]

[55] **Anderson DR**, Harrison L, Hirsh J.; Evaluation of a portable prothrombin time monitor for home use by patients who require long-term oral anticoagulant therapy.; *Arch Intern Med*. 1993 Jun 28;153(12):1441-7.
[56] Ibid, page 1442
[57] **Hirsh** JH, et al. Oral anticoagulants: mechanism of action, clinical effectiveness, and optimal therapeutic range. *Chest* 2001;119:8S-21S.
[58] **Laupacis** A, et al. Antithrombotic therapy in atrial fibrillation. *Chest* 1998;114:579S-589S.
[59] **Samsa** GP, and Matchar DB. Relationship between test frequency and outcomes of anticoagulation: a literature review and commentary with implications for the design of randomized trials of patient self-management. *Journal of Thrombosis and Thrombolysis* 2000;9:283-292.
[60] Ibid, p 284
[61] Ibid, p 284
[62] Ibid, p 289
[63] **Heidinger** KS, Bernardo A, Taborski U, Muller-Berghaus G. Clinical outcome of self-management of oral anticoagulation in patients with atrial fibrillation or deep vein thrombosis. Thrombosis Research. 2000;98:287-93.
[64] http://www.bmj.com/cgi/content/full/323/7319/985
[65] Recommendations for patients undertaking self management of oral anticoagulation; *BMJ* 2001;323:985-989 (27 October)
[66] Ibid.

Heneghan (2006)[67]	Extensive attended training *However, self-monitoring is not feasible for all patients, and requires identification and education of suitable candidates.*

* (Referenced in NCD: CAG-00087N)

[67] **C Heneghan**, P Alonso-Coello, J M Garcia-Alamino, R Perera, E Meats, P Glasziou *;* Self-monitoring of oral anticoagulation: a systematic review and meta-analysis; *Lancet* 2006; 367: 404–11, page 410.