

## Software support for 'doing the right thing right'

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Many patients with chronic or paroxysmal atrial fibrillation (AF), deep venous thrombosis and/or pulmonary embolism, who should be maintained on warfarin are not. Studies have reported that only 46% of people with AF over the age of 75 years with a history of stroke or transient ischemic attack (TIA) were on warfarin in primary care, and that less than half of people aged over 75 years with AF were discharged from the hospital on warfarin (1). The two reasons competent physicians give for avoiding anticoagulation in patients with evidence-based indications for long-term warfarin are, first, an exaggerated fear of an intracranial bleed (serious it is if one occurs, but the incidence is 0.1–0.3 %/year in properly controlled patients), and, secondly, the time consuming and manpower resource intense burden of caring for patients with this “narrow index”, and potentially dangerous, drug (2).

Centers for Medicare & Medicaid Services (CMS), in its position paper authorizing coverage of eligible CMS beneficiaries for home INR (point-of-care) testing, indicated that <35% of their beneficiaries who are on warfarin are managed in an anticoagulation monitoring and management service, with or without home testing. The others receive what is euphemistically characterized as “usual care”, meaning the individual physician prescribing warfarin for patients uses the “back of the envelope system” (3). The combination of home self-management and care under an anticoagulation monitoring and management service (AMMS) has been shown to reduce warfarin-related complications by 60–70% (4).

Elements of an AMMS include a registry of patients being managed, detailed education of patient and family (the latter very important because the average age of patients on warfarin for AF is 72 years), qualifications of personnel, physician supervision, written protocols for testing frequency, definition of the targeted therapeutic INR range, allowable dose adjustments by a registered nurse or pharmacist with follow-up repeat INR testing, tracking and contacting of patients overdue for their INR, and communications with physician, patient and family (5).

Most AMMS use a software system to track their patients on warfarin. Several such systems, each with their own advocates, are available to physicians in the US and elsewhere. They include

ANTHEMA, Anticoagulation Management Program, Clever Clog, CoagCare, CoagClinic, CoumaCARE, DAWN AC, DoseResponse, DrugCalc, Health System Organizer for Oral Anticoagulation Treatment, Intelligent Dosing System, PARMA, Rapid Anticoagulation Interpretation and Dosing. Comparisons of their features are available (6). Most provide routine statistical reports to users on the key “process”, or, “indirect outcome” measure, namely % time in therapeutic range (TIR). While studies of “usual care” generally show TIR of <50%, AMMS, especially when combined with home self-management, can reach the 65–75% range, levels shown to be associated with markedly reduced rates of complications.

DAWN AC has served a particularly large segment of the European anticoagulation community. In their report in this issue of *Thrombosis and Haemostasis* Poller et al. (7) included 2,631 patients from 13 centres randomly assigned to computer versus manual care and showed that at a group of experienced centres with a special interest in oral anticoagulation, the DAWN AC computer-dosage program proved as safe clinically as manual dosage by experienced medical staff. Thus, matching the performance of the comparison (“manual”) group was a difficult challenge, as it was a truly state-of-the-art collection of expert practitioners. The methodology is well presented and easy for the reader to follow.

The main findings were impressive: a) the TIR improved from an already high 63.4% (manual) to an even more enviable 66.8% (computer-assisted); b) clinical events of bleeding and thrombosis (the ideal true “outcome” measures) were almost identical.

Several unanswered questions remain: (i) Would the authors have found CHADS2 scores warranting treatment in all cases? (ii) How would DAWN AC perform without the backup of experienced physicians who “...provided the dosage on 32.9% of occasions...in only 5.7% because the computer failed to provide a dose”? The reasons for the physician-directed dose modifications are clearly identified and appear to have been very appropriate, but what if an AMMS wanted to use DAWN AC without such intense expert physician backup on every single INR-based dose determination? (iii) What were the costs of the computer-

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based versus manual system? In our Harvard Vanguard Medical Associates AMMS, we spend >\$1.2 million US dollars/year, not including the costs of lab tests and prescription medications, to manage some 3,200 patients, or close to \$400/patient/year. Fal-lon Clinic's experience with 3,400 Medicare risk patients on war-farin is similar. The authors note that a separate report on the cost-effectiveness of the DAWN AC computer program in re-lation to the above study is being prepared in collaboration with the assistance of a team of health economists. We can all look forward to seeing the results. (iv) We could also use cost-effec-tiveness studies of the two systems that include the costs of com- plications-related care. A number of studies have shown favor-

able results overall (8, 9). (v) While the overall TIR difference was 3.5%, only three of the centres (numbers for patient years: 139.4, 234.7 and 561.7, respectively, as shown in Figure 3), had a statistically significant favorable result. The other 10 did not. (vi) Will pre-warfarin genetic testing further improve the safety of warfarin prescribing for patients with chronic or paroxysmal AF? While the FDA has issued a "black box warning" advoca- ting such genetic testing, it is unclear whether this is warranted at this point in time, or is this a case of governmental "pre-mature ejaculation" (10, 11).

This study is a true "labor of love" by expert physicians from several countries. It adds greatly to our repertoire.

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