

ORIGINAL ARTICLE

External quality assessment for warfarin dosing using computerised decision support software

T P Oppenkowski, E T Murray, H Sandhar, D A Fitzmaurice

J Clin Pathol 2003;56:605-607

See end of article for authors' affiliations

Correspondence to:
Dr D A Fitzmaurice,
Department of Primary
Care and General Practice,
Medical School, University
of Birmingham B15 2TT,
UK;
d.a.fitzmaurice@bham.ac.ukAccepted for publication
27 March 2003**Aim:** To establish and evaluate an external quality assessment scheme for warfarin dosing for users of a computerised decision support system, BAP-PC.**Design:** Analysis of 12 months of clinical data from 10 primary care centres using BAP-PC within an oral anticoagulation clinic. Data were analysed for individual centres and compared with aggregated data for all practices. Individual feedback forms were provided to participating centres.**Results:** A total patient population of 367 (range, 17-65/centre) was analysed. On average, patients spent 69% of time in the therapeutic range (range, 60-76%). Patients were seen on average every 27 days (range, 24-30). The average point prevalence was 86% (range, 76-100%). In total, 33 adverse events were reported (0-13/practice). Serious adverse events ranged from 0 to 1 for each practice. This translates into a serious adverse event rate of 1.6/100 patient years.**Conclusions:** Practices were successful in maintaining good therapeutic international normalised ratio control, with centres achieving 60% or higher time in range. There are some doubts about the quality of data collection at a practice level because there were no reported events in half of the participating centres. The observed event rates do concur with previously reported data, however. Further cycles of the scheme are necessary to establish it as a useful research and benchmarking tool.

The number of patients receiving oral anticoagulant treatment (primarily warfarin in the UK) has increased exponentially over the past decade, because of the increased use of warfarin as a thromboprophylactic agent in non-rheumatic atrial fibrillation.¹⁻⁴ One important development that has arisen out of a need to facilitate the management of this increase has been the use of computerised decision support systems (CDSS) to assist with the dosing of warfarin within both primary and secondary care clinics.

Previous studies have shown that the use of a CDSS for determining the dose of warfarin can result in improved quality of therapeutic control when compared with manual dosing systems.⁵⁻⁸ In addition, the process of performing clinical audit is made easier through CDSS and may be more reliable because of it.

The Birmingham Anticoagulation Programme for Primary Care (BAP-PC) is a CDSS that has been used by primary care centres in the UK since 1998. The software incorporates a modification of the validated "Coventry equation" for translation of international normalised ratio (INR) results into warfarin doses.⁹⁻¹¹

"The relatively narrow therapeutic window for successful oral anticoagulation continues to make therapeutic management a difficult task"

Historically, although great efforts have been made to ensure that the therapeutic haemostatic deficit induced by warfarin is measured accurately,¹² the relatively narrow therapeutic window for successful oral anticoagulation continues to make therapeutic management a difficult task.¹³ The need for consistency and accuracy of measuring the induced deficit has led to the development of the INR, the international sensitivity index, and external quality assessment (EQA) schemes. EQA is an essential element in ensuring that the INR is measured consistently in different environments. Institutions such as the UK National External Quality Assessment Scheme for Blood Coagulation play a pivotal role in this process.

In contrast, no EQA scheme for warfarin dosing has been developed. Thus, although we may be confident that the measured INR is accurate, we cannot be sure whether the appropriate management decision has been taken by the responsible clinician. There has been little interest in assessing the quality of dosing decisions based on the derived INR. Therapeutic INR control has historically been poor; however, CDSS provides an opportunity for improvement. In parallel, it should be possible to undertake quality assessment procedures to ensure reliable performance.

We report the first data from a novel scheme designed to develop an EQA scheme for warfarin dosing for BAP-PC users. The primary function of BAP-PC is to convert patient derived INR into a warfarin dose.

METHOD

The software is installed on a practice computer running Windows 95 or later Windows upgrades. BAP-PC is installed independently from the clinical system. After each anticoagulation clinic, the software's backup facility is used to transfer data on to a floppy disk. Once a year, each practice participating in the EQA uses the software feature "Export data to Birmingham" to save data on to floppy disks and send to the department of primary care and general practice at Birmingham University. By using this function, all data are anonymised with only a unique patient number for identification by practice received. All data were analysed for each individual practice, in addition to being pooled into an aggregate of user data. All practices that had used BAP-PC for the defined study period were eligible to participate.

Data used for the EQA process were as follows:

- (1) The number of patients on warfarin who have had at least one consultation within the audit period.

Abbreviations: BAP-PC, Birmingham Anticoagulation Programme for Primary Care; CDSS, computerised decision support software; EQA, external quality assessment; INR, international normalised ratio

Table 1 Adverse events

	Mean	Range
Adverse events	3.3	0–13
Non-serious adverse events	2.9	0–12
Serious adverse events	0.4	0–1

Table 2 Haemorrhagic and thromboembolic adverse events

	Haemorrhagic adverse events	Thromboembolic adverse events
Adverse events	33	0
Non-serious adverse events	29	0
Serious adverse events	4	0

(2) The number of serious and non-serious adverse events during the audit period.

(3) The proportion of visits in therapeutic range. "Therapeutic range" refers to patient INRs within ± 0.5 units of the target INR established for a condition indicating warfarin.¹⁴

(4) Point prevalence, which considers how many active patients, (patients who are on warfarin and have had a consultation within the past three months of the end date of the set audit period) were in range at their last consultation. Patients who have not had a consultation within the past three months of the audit period are excluded from this.

(5) The proportion of time spent in therapeutic range, assuming a linear change between results.¹⁵

(6) Average review frequency; that is, the average period of time between warfarin clinics attended by patient(s).

(7) "Poorly controlled" patients; that is, those individuals who spent less than 60% time within the therapeutic range.

(8) The proportion of time the warfarin dose suggested by BAP-PC has been accepted by the health professional (general practitioner, nurse) running the anticoagulation clinic.

An essential part of the EQA process is the feedback to BAP-PC users. This involves providing users with a standard audit form listing details of individual audit outcomes. Furthermore, individual practice results are compared with the aggregate audit result of all 10 participating practices. An important element of each individual feedback is the identification of poorly controlled patients. Such patients, identified by their ID numbers, are pointed out to individual practices to facilitate improved control or referral into hospital care.

RESULTS

Ten practices were able to provide complete data sets for the period 1 January 2001 to 1 January 2002. These data comprised a patient population of 367 on warfarin treatment (representing 250 patient years). The practice sizes varied from 17 to 65 patients.

Adverse events were classified as serious or non-serious, and defined as any bleeding or thrombotic episodes occurring while on warfarin. Serious events were defined as those requiring medical intervention. The total number of adverse events was 33 (0–13/practice). There were four serious adverse events (0–1/practice), which translates into a serious events rate of 1.6/100 patient years (table 1).

All adverse events were haemorrhagic episodes (table 2), with serious adverse events comprising one each of: cerebral infarct, intracranial bleeding (died of cerebral bleeding),

Table 3 International normalised ratio control

	Mean (%)	Range (%)
Time in range	69	60–76
Point prevalence	86	76–100
Visits in range	58	53–70
Review frequency (days)	27	24–30

gastrointestinal bleeding (patient died later of a combination of septicaemia, infective endocarditis, and cerebrovascular accident), and epistaxis (patient died one month later of carcinoma of the bronchus).

On average, patients spent 69% of time in range, 58% of patient visits were in range, and patients were being seen every 27 days. The average point prevalence was 86%. Time in range varied from 60% to 76% between practices, visits in range between 53% and 70%, and point prevalence values ranged from 76% to 100% (table 3).

DISCUSSION

Participating practices were representative of service general practices and came from a wide socioeconomic background. All practices had received training through the university department in oral anticoagulation management before establishing their service. The therapeutic management data are consistent with previously published data from primary care, both within and without clinical trials.^{16–17}

However, there are doubts about the quality of data collection at practice level, because half of the practices reported no adverse events. Of course, this could mean that none had occurred, but it may be that they were not recorded. The rate of serious adverse events of 1.6/100 patient years is lower than some previously published data.^{18–19} Whereas Palareti *et al* stated a rate of major haemorrhagic events of 1.4,¹⁹ Cannegieter *et al* gave a rate of 2.5.²⁰ Our results may represent a degree of under-recording.

Further research needs to be undertaken into how individual practices define and distinguish between serious and non-serious adverse events. Standardisation of definitions of adverse events would facilitate more accuracy in reporting thromboembolic and haemorrhagic episodes, and thus enhance the quality of external assessment.²¹ Further cycles of the EQA scheme will be required to establish whether this process is useful to practices and also as a research tool.

"We feel that our study has demonstrated proof of principle and that further developments are necessary to ensure a useful resource in the same way that we now have a national scheme for external quality assessment of international normalised ratio measurement"

We are aiming to develop this scheme to include all practices using BAP-PC. We believe that the Birmingham EQA serves as an additional safeguard to ensure good practice in oral anticoagulation management. We would like to see similar data published from other software manufacturers, and would welcome the chance to combine data to provide a more comprehensive analysis. We feel that our study has demonstrated proof of principle and that further developments are necessary to ensure a useful resource in the same way that we now have a national scheme for EQA of INR measurement. This EQA may be useful as a benchmarking tool for practices in that their individual results are shown in comparison to the aggregate result of all practices using BAP-PC over the same time period. With the anticipated further devolution of anticoagulation services to primary care, the need for such benchmarking becomes more important. We will also need to deal

Take home messages

- On average, patients spent 69% of the time in the therapeutic range (range, 60–76%), 33 adverse events were reported (0–13/practice), and serious adverse events ranged from 0 to 1 for each practice (serious adverse event rate of 1.6/100 patient years)
- Thus, BAP-PC enabled practices to maintain good therapeutic international normalised ratio control
- There are some doubts about the quality of data collection at a practice level because there were no reported events in half of the participating centres, although the observed event rates do agree with previously reported data
- Further cycles of the scheme are necessary to establish it as a useful research and benchmarking tool

with the issue of how to provide quality assurance for dosing for those patients undertaking self management.

ACKNOWLEDGEMENTS

Thanks to Dr A Riaz who designed the BAP-PC software. DF is supported by an NHS Career Scientist Award. EM is supported by an MRC Health Services Research Fellowship.

REFERENCES

- 1 **Manotti C**, Moya M, Palareti G, *et al*. Effect of computer-aided management on the quality of treatment in anticoagulated patients: a prospective, randomised, multicentre trial of APROAT (Automated Program for Oral Anticoagulant Treatment). *Haematologica* 2001;**86**:1060–70.
- 2 **Baglin T**. Decentralised anticoagulant care. *Clin Lab Haematol* 1994;**16**:327–9.
- 3 **Rose P**. Audit of anticoagulant therapy. *J Clin Pathol* 1996;**49**:5.
- 4 **Young AJ**, Beswick KBJ. Decision support in the United Kingdom in general practice: past, present and future. In: Greenes RA, Peterson H, Protti D, eds. Proceedings of the 8th Congress on Medical Informatics. MEDINFO 95. Amsterdam: North-Holland 1995:1025–9.
- 5 **Ryan PJ**, Gilbert M, Rose PE. Computer control of anticoagulant dose for therapeutic management. *BMJ* 1989;**299**:1207–9.
- 6 **Kubie A**, James AH, Timms J, *et al*. Experience with a computer-assisted anticoagulant clinic. *Clin Lab Haematol* 1989;**11**:385–91.
- 7 **Fitzmaurice DA**, Hobbs FDR, Murray ET, *et al*. A randomised control trial comparing primary care oral anticoagulant management utilising computerised decision support (DSS) and near patient testing (NPT) with traditional management. *Family Pract* 1995;**12**:253–4.
- 8 **Fitzmaurice DA**, Hobbs FDR, Murray ET. Primary care anticoagulant clinic management using computerised decision support and near patient international normalised ratio (INR) testing: routine data from a practice nurse-led clinic. *Fam Pract* 1998;**15**:144–6.
- 9 **Riaz A**, Murray Ellen T, Hobbs FDR, *et al*. Validation of a software system for anticoagulant dosing in primary care. *Thrombus* 2001;**5**:1–3.
- 10 **Vadher BD**, Patterson DLH, Leaning MS. Validation of an algorithm for oral anticoagulant dosing and appointment scheduling. *Clin Lab Haematol* 1995;**7**:339–45.
- 11 **Poller L**, Wright D, Rowlands J. Prospective comparative study of computer programs used for management of warfarin. *J Clin Pathol* 1993;**46**:299–303.
- 12 **Haemostasis and Thrombosis Task Force for the British Committee for Standards in Haematology**. Guidelines on oral anticoagulation: third edition. *Br J Haematol* 1998;**101**:374–87.
- 13 **Fitzmaurice DA**, Hobbs FDR, Murray ET, *et al*. Evaluation of computerized decision support for oral anticoagulation management based in primary care. *Br J Gen Pract* 1996;**46**:533–5.
- 14 **Fitzmaurice DA**, Machin S. Recommendations for patients undertaking self-management of oral anticoagulation. *BMJ* 2001;**323**:985–98.
- 15 **Rosendaal FR**, Cannegieter SC, van der Meer FJM, *et al*. A method to determine the optimal intensity of oral anticoagulant therapy. *Thromb Haemost* 1993;**69**:236–9.
- 16 **Fitzmaurice DA**, Murray ET, Gee KM, *et al*. Does the Birmingham model of oral anticoagulation management in primary care work outside trial conditions? *Br J Gen Pract* 2001;**51**:828–9.
- 17 **Fitzmaurice DA**, Hobbs FDR, Murray ET, *et al*. Oral anticoagulation management in primary care with the use of computerized decision support and near-patient testing. Randomized, controlled trial. *Arch Intern Med* 2000;**160**:2343–8.
- 18 **Palareti G**, Leali N, Coccheri S, *et al*. Bleeding complications of oral anticoagulation treatment: an inception-cohort, prospective collaborative study (ISCOAT). *Lancet* 1996;**348**:423–8.
- 19 **Palareti G**, Manotti C, D'Angelo A, *et al*. Thrombotic events during anticoagulant treatment: results of the inception-cohort, prospective collaborative ISCOAT study. *Thromb Haemost* 1997;**78**:1438–43.
- 20 **Cannegieter SC**, Rosendaal FR, Wintzen AR, *et al*. Optimal oral anticoagulant therapy in patients with mechanical heart valves. *N Engl J Med* 1995;**33**:11–17.
- 21 **Fihn SD**, McDonnell M, Martin D, *et al*. Risk factors for complications of chronic anticoagulation. *Ann Intern Med* 1993;**118**:511–20.



External quality assessment for warfarin dosing using computerised decision support software

T P Oppenkowski, E T Murray, H Sandhar, et al.

J Clin Pathol 2003 56: 605-607

doi: 10.1136/jcp.56.8.605

Updated information and services can be found at:

<http://jcp.bmj.com/content/56/8/605.full.html>

These include:

References

This article cites 15 articles, 7 of which can be accessed free at:

<http://jcp.bmj.com/content/56/8/605.full.html#ref-list-1>

Email alerting service

Receive free email alerts when new articles cite this article. Sign up in the box at the top right corner of the online article.

Notes

To request permissions go to:

<http://group.bmj.com/group/rights-licensing/permissions>

To order reprints go to:

<http://journals.bmj.com/cgi/reprintform>

To subscribe to BMJ go to:

<http://group.bmj.com/subscribe/>