# **Refereed papers**

# Lessons from the implementation of a near patient anticoagulant monitoring service in primary care

Simon de Lusignan MSc MRCGP Senior Lecturer, Primary Care Informatics

Andrew Singleton BSc MBA MSc Non-clinical Scientist

Sally Wells RGN Research Nurse, Primary Care Informatics

Department of Community Health Sciences, St George's Hospital Medical School, London, UK

### ABSTRACT

**Objective** To evaluate the implementation of a primary care, nurse-led, near patient anticoagulant monitoring service.

**Design** Action research workshops, supported by questionnaires and clinical audit, to define the strengths and weaknesses of the service and the effectiveness of the computerised decision support system used to set the dosage of anticoagulant and time interval to the next appointment.

**Setting** 13 general practices that implemented anticoagulant monitoring in a primary care organisation in south east England.

**Participants** 18 practice nurses, 72% of whom had over 20 years' clinical experience; the university-based investigators and managers from the primary care organisation.

Main outcome measure The nurses felt that the patients preferred the practice-based service, finding it more personal and accessible. However, circumstances arose where the nurse's intuition had to override the software's advice. The nurses found it stressful when they were unclear whether their decision making represented acceptable variation or dangerous practice. An audit tool was developed to measure the extent to which there was variation from the software's recommendation, and patterns of variation emerged. Most evident was that nurses responded to uncertainty by practising cautiously, shortening the interval until the next visit and slightly reducing the recommended dose of warfarin.

**Conclusions** The group, by sharing their experiences through a structured series of workshops, developed an understanding of when it might be appropriate to vary from the decision support software's recommendations and how this could be audited. The technological solution modelled on hospital practice proved hard to implement in primary care.

**Keywords** (MeSH terms): anticoagulants, computerassisted, decision making, family practice, medical informatics, medical informatics applications, warfarin

## Introduction

Patients with atrial fibrillation are at increased risk of stroke. Although anticoagulation with warfarin reduces this risk considerably, it is not widely prescribed to this at-risk group of patients.<sup>1,2</sup> Warfarin is a potentially dangerous drug as it has a narrow therapeutic index: give too much and patients are at risk of haemorrhage,

give too little and it offers little protection from thrombosis. Warfarin is monitored using an international normalised ratio (INR) to measure the degree of anticoagulation.<sup>3</sup> Dosage prediction programmes for warfarin have been in existence for some time, with the first computer models based on hospital doctors' decisions.<sup>4,5</sup> More recently, a wider range of approaches have been used to develop more sophisticated computerised decision support systems (CDSS). Near patient testing allows monitoring to be provided outside the hospital setting. Traditionally patients had to travel to the local hospital for testing, where junior doctors adjusted their warfarin dose without the benefit of CDSS.<sup>6,7</sup> The combination of near patient testing and CDSS allows warfarin testing to take place in local clinics or in patients' homes, with the service provided by nurses or other non-medical staff. Where comparison has been made between nurses using computerised decision support and junior doctors using clinical judgement, the nurses achieved better control for patients with an INR target ratio of 2–3, and as good control as the doctors when target INR is 3–4.5.<sup>8</sup>

A primary care organisation (PCO) recognised the potential benefits of a practice-based anticoagulation service and implemented it across 13 practices, deciding that practice nurses would be the appropriate professional group to deliver the service. They put on a training course comprising the relevant biomedicine: how anticoagulants work, the patients who need it and for how long, interactions and safety issues. The practice nurses also received training on the near patient testing device (Coagucheck - Roche Diagnostics), the CDSS (Eider software) and in quality assurance.<sup>9-11</sup> They were advised that the dose generated by the CDSS was a suggestion, but there had to be good reason not to follow it. The nurses were also required to identify a general practitioner (GP) who would provide them with day-to-day support. Despite these careful preparations, the implementation did not go entirely smoothly and the nurses running the clinics found them stressful. Against this backdrop, the authors were commissioned by the PCO to evaluate the clinics and identify what the problems were. The action research adopted is described in this paper.

## Method

Action research is a problem-solving intervention, involving the researchers as well as the subjects of the study in actively looking for ways to overcome obstacles. Its approach is systematic, involving problem definition, reflection and learning, and the design of action interventions to overcome the barrier or barriers identified.<sup>12</sup> Action research was an appropriate research method as it would allow two of the research team to use their local knowledge and experience fully in the investigation. SW had been involved in near patient anticoagulant clinics for over five years in one practice, and had been mentor to many of the nurses offering this service; and S de L is a part-time GP in the locality.

We looked for relevant background information prior to establishing a timetable for the action

research. We searched Medline for information about atrial fibrillation and stroke, use of anticoagulants and near patient testing. We read PCO board minutes, the training course timetable and any documents relating to the implementation of the clinics available from the PCO or practices. We contacted PCO managers and lead clinicians involved and gave them the opportunity to submit any materials. So we could search these materials more effectively and group them into emergent themes, we imported them into qualitative research software (N'VIVO – QSR version 1.2).

Workshops, questionnaires and clinical audit were chosen as the principal elements of the research process. We designated the workshop as the primary source of information gathering. We decided to do this as we wanted the nurses to be the centre of the investigation as they were likely to have good oral communication skills. Questionnaires were used to confirm the findings of the workshops and, if appropriate, one or more clinical audits were carried out to check whether any issues about practice were supported by clinical data.

The workshops were a combination of plenary discussions and work in pairs or small groups. Field notes were taken of the discussions by one of the research team, any flipchart lists were retained and each nurse completed a workbook of their discussions which was handed in at the end of the session. Consensus established in the discussion reported back to all the nurses in questionnaire form with the results of the questionnaires used to verify findings.

Participants were invited to share their experiences openly and honestly. We emphasised confidentiality and anonymity within the group. Ground rules for feedback stressed the importance of valuing all contributions. Questions were designed to elicit both positive and negative features of running anticoagulant clinics.

We elected to timetable three workshops, and all the nurses involved in the clinic were invited to each of the workshops regardless of whether they had attended a previous session or not. The aim of the first was to identify the benefits the clinics had offered and lessons learned. The second would explore the principal barriers to implementing the clinics and ways to overcome them. The final workshop would hand over the learning from the evaluation and explore whether the group wished to go on meeting.

## Results

The 18 practice nurses who ran the clinics were very experienced. Nearly three-quarters of them had more than 20 years' nursing experience, and 67% had over 10 years' experience of working in primary care. Eighty-three percent had been running anticoagulant clinics for between six and 12 months. Most of the nurses saw more than ten patients per week, and had appointment times of between six and ten minutes.

All 18 nurses attended the first workshop. The field notes on the consensus discussions, the workbooks and flipcharts all indicated that the nurses had had very positive comments from patients about the practice-based clinics:

Patients really like attending the surgery. (Nurse H) The patient knows the results straight away. (Nurse F) Patients prefer the clinics – more convenient, less waiting time. (Nurse I)

However, there were a number of concerns about the equipment and the CDSS. All three small groups listed problems with inflexibility within the software in the real clinical situations in which the nurses found themselves. The study team noted that over a number of specific issues knowledge was being exchanged between participants, and problems for one nurse were solved by another (for example, how to deal with a patient who was taking different warfarin doses on alternate days).

A post-workshop questionnaire asked nurses to rate a number of statements from 1 (strongly disagree) to 5 (strongly agree). There was good agreement with statements about the benefits of general practice-based clinics, but negative themes emerged in the discussions and on the flipcharts about uncertainty with the software and about quality control procedures (see Table 1).

The second workshop was attended by 12 nurses. The nurses displayed anger and frustration with the software. They often experienced cognitive dissonance when the software was advising one thing and their clinical experience was suggesting that they should do another. In these circumstances they turned to the lead GP within their practice, who usually agreed with their clinical judgement. None were aware of any of their patients having had a major bleed as a result of over-treatment or thrombosis as a result of undertreatment. At that stage the clinics had treated 792 patients (0.71% of a locality population of 107 296 patients).

We devised an audit tool to measure the extent to which the nurses varied from the CDSS advice (see Figure 1). This entailed completing a simple audit form between workshops two and three. Treatment of 15 patients attending the clinic were recorded. Their reason for taking warfarin, age and sex were recorded, along with any variation in warfarin dose or interval to the next appointment. Eleven nurses completed the audit, providing a sample of 165 patient encounters.

Nurses were very cautious, hardly ever giving more warfarin than recommended, but showed much more flexibility in arranging follow-up dates than the CDSS recommended (see Figures 2 and 3). Nurses hardly ever recommended the patient take an increased dose of warfarin; this only took place in 5.5% (9/165) cases. The two doses that were  $\geq 3$  mg over that recommended were given to patients who were being started on warfarin. Thirty-four percent (56/165) of patients were given a lower dose than recommended by the CDSS. Twenty-one percent of patients (35/165) were given follow-up appointments further ahead than recommended by the CDSS, and 24% (40/165) sooner. Most of these were a week either side of that recommended. No association could be found between the INR target range and dose alteration.

Exceeding the dose recommended was generally done for difficult-to-control patients when their INR fell to well below their target range. Reduction in dose often reflected the nurses' intuition and cautious approach. The follow-up date was changed to fit in with patient holidays and other commitments. It was sometimes done to fit in with patient or nurse concerns.

Eight nurses attended the final workshop. This examined the results of the audit. The nurses reflected on the pattern of variation and how it represented their attempt to balance safety with lifestyle. For example, an elderly patient, where there may be doubts about

Positive themes		Negative themes	Negative themes		
Patient satisfaction	4.80	Perceived software problems	3.66		
Patients prefer primary care service	4.50	Uncertain about quality control	3.53		
Improved compliance	4.59				
Nurse satisfaction	3.91				

#### Table 1 Average Likert scores for post-workshop questionnaire statements

Scale 1–5: strongly disagree = 1, strongly agree = 5

Reason for variation (please state the reason when either the dose or the recall interval is not the same as that suggested by the decision support software) Only complete this when	Please add further comments overleaf or on another piece of paper if needed			
	Actual INK measured			$ \rightarrow  $
	Target range for INR			+
About the patient and their indication + target range				
Al	ે Diagnosis			+
No. weeks recall changed by: Only complete if giving a DIFFERENT RECALL from that recommended	5-6 More			$\parallel$
				+
	2		$\left  \right $	+
	1-2		$\left  \right $	+
Recall interval compared with that recommended by CDSS	Shorter than CDSS		$\left  \right $	+
	Same as CDSS			+
	ronger than CDSS		$\left  \right $	+
Dose changed by (amount in mg): Only complete if giving a DIFFERNT DOSE from that recommended by CDSS	3.00 or more			
	2.50			
	2.00			
	1.50			
	1.00			
	0.50			
Dose of warfarin issued compared with that recommended by CDSS	Lower than CDSS			
	Same as CDSS			
	Higher than CDSS			
	Patient ID			

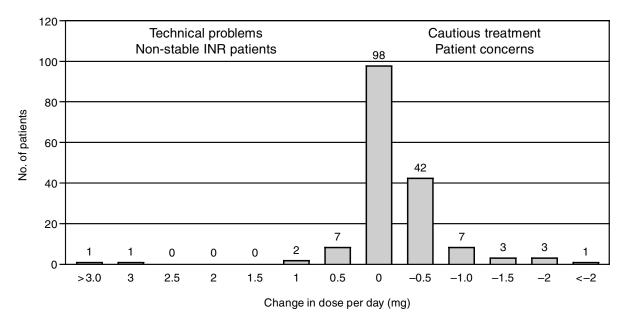


Figure 2 Variation in warfarin dose from the recommendation of the CDSS (n=165)

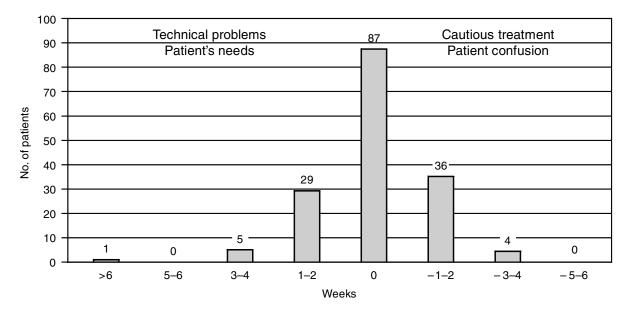


Figure 3 Variation in recall interval from the recommendation of the CDSS (n=165)

cognitive function, might be recalled more often. The workshop reinforced the appreciation of the nurses of the opportunity to discuss experiences in a sympathetic group, and share ideas of how to consult effectively and where the boundaries of acceptable variation from the CDSS guidance might lie. Their intention was to continue this group as a mechanism for long-term support, and within which to externalise the experience gained in practice.

## Discussion

The action research identified tension associated with overriding the CDSS recommendations as the greatest problem in implementing this system. This was entirely unpredicted. The nurses' training, whilst providing the necessary biomedical and technical knowledge, specified how INR monitoring is usually performed in the haematology clinic, rather than discussing how it could be incorporated into their everyday practice. The nurses' pragmatic response was to practise cautiously.

The study has implications for those looking to introduce CDSS into clinical practice. Although a technical process, the implementation was also a social process – nurses were taking responsibility for patients taking a medication with potentially serious adverse effects.<sup>3</sup> They were doing this within their individual general practices, with day-to-day support coming from a doctor within that practice team rather than from their peer group. A shortcoming of the implementation was the lack of a nursing group to provide mutual support, share knowledge and accelerate learning.<sup>13</sup>

The number of nurses involved in the study diminished towards the end, limiting its completeness. Of the original 18 nurses involved: four left their job; 12 out of the remaining 14 attended the second workshop and 11 of these completed the audit; two went on leave, and one was absent, leaving eight who attended the final workshop. No causal link could be found between those who left their posts and running the clinic, though this high rate of job turnover is unusual in practice nursing. Although there was variation from the CDSS recommendations, there were no reported cases of over- or under-dosing with warfarin during the period of the study. The variation from the dose suggested by the software was 35%, which is higher than the 25% found by Vadher et al when they studied nurses using CDSS.8 However, it is less than the 43% gap found when doctors' decisions were compared with that suggested by the CDSS.

Robinson *et al* suggest that 'cognitive dissonance' – occurring when the CDSS clashes with the intuition of the clinician – provides insight and a mechanism for learning in the consultation.<sup>14</sup> Our findings suggest that the educational benefit of CDSS in consultation is limited – and that the creation of a group, a community of practice, within which knowledge can be socialised and shared, was more effective.<sup>15,16</sup> Primary care organisations should consider using accredited anticoagulant training courses, which might have provided more opportunities for networking with other practitioners.<sup>17</sup>

The socio-technical literature provides further insights. Goorman and Berg point out the danger of modelling new technologies based on an idealised model of how work should be done rather than recognising that although real life often appears complex, healthcare work is usually pragmatic.<sup>18</sup> 'Practical rationality', as they would term the cautious response of the nurses, 'can only be overlooked at a high price (i.e. system failure)'.<sup>19</sup> Berg's alternative approach to implementation would have been to recognise that technological implementation involves transformation of organisations and individuals, and it always has unforeseen consequences.<sup>20</sup> Further research is needed to define where the boundary lies between acceptable variation from the CDSS recommendations and what represents dangerous practice. A greater understanding is needed of the value of providing groups for mutual support and for developing a shared body of knowledge about how to implement near patient monitoring. The cost-effectiveness of different ways of providing anticoagulant services needs to be compared. Nurse-run general practice clinics need to be compared from the per-spectives of case-mix as well as control, with patients self-monitoring at home, and hospital clinics.<sup>21</sup>

## Conclusions

Studying dosage of warfarin and interval to the next review appointment assisted by CDSS was expected to be a simple area of biomedicine: it was supposed that what traditionally took place in hospital clinics could be modelled, and using near patient testing devices and CDSS could be readily translated into the primary care setting. However, the nurses using CDSS experienced cognitive dissonance. In these circumstances, the nurses felt stressed and most often responded by being cautious – reducing the dose or recall interval – though variation occurred in both directions. The study demonstrates that technological solutions modelled on hospital practice may have unforeseen consequences and be hard to implement in primary care.

#### ACKNOWLEDGEMENTS

SW's time and the workshops used for this evaluation were funded by Roche Diagnostics, Lewes, East Sussex. The opinions expressed are those of the authors and not those of Roche, or the participating PCO.

#### REFERENCES

- 1 Devereaux PJ, Anderson DR, Gardner MJ *et al.* Differences between perspectives of physicians and patients on anticoagulation in patients with atrial fibrillation: observational study. *British Medical Journal* 2001;323:1218–22.
- 2 Go AS, Hylek EM, Chang Y *et al*. Anticoagulation therapy for stroke prevention in atrial fibrillation: how well do randomized trials translate into clinical practice? *Journal of the American Medical Association* 2003;290:2685–92.
- 3 Fitzmaurice DA and Murray ET. Oral Anticoagulation Management and Stroke Prevention. Newmarket: Hayward Medical Communications, 2002.
- 4 Carter BL, Taylor JW and Becker A. Evaluation of three dosage-prediction methods for initial in-hospital stabilization of warfarin therapy. *Clinical Pharmacology* 1987;6:37–45.

- 5 Wilson R and James AH. Computer-assisted management of warfarin treatment. *British Medical Journal Clinical Research* 1984;289:422–4.
- 6 Delaney BC, Hyde CJ, McManus RJ *et al.* Systematic review of near patient test evaluations in primary care. *British Medical Journal* 1999;319:824–7.
- 7 Fitzmaurice DA, Hobbs FD, Delaney BC, Wilson S and McManus R. Review of computerized decision support systems for oral anticoagulation management. *British Journal of Haematology* 1998;102:907–9.
- 8 Vadher BD, Patterson DL and Leaning M. Comparison of oral anticoagulant control by a nurse-practitioner using a computer decision-support system with that by clinicians. *Clinical and Laboratory Haematology* 1997;19:203–7.
- 9 General Haematology Task Force. Guidelines for near patient testing: haematology. *Clinical and Laboratory Haematology* 1995;17:301–10. www.bcshguidelines.com/ ebooks/ebook.asp
- 10 British Committee for Standards in Haematology. Guidelines on oral anticoagulation. British Journal of Haematology 1998;101:374–87.
- 11 UK NEQAS (National External Quality Assessment Schemes) for Blood Coagulation: www.ukneqas.org.uk/ Directory/HAEM/coagul.htm
- 12 Hart E and Bond M. *Action Research for Health and Social Care: a guide to practice.* Buckingham: Open University Press, 1999.
- 13 de Lusignan S, Wells S and Singleton A. Why general practitioners do not implement evidence: learning environments must be created that capitalise on teams' wealth of knowledge. *British Medical Journal* 2002;324:674.
- 14 Robinson P, Purves I and Wilson R. Learning support for the consultation: information support and decision support should be placed in an educational framework. *Medical Education* 2003;37:429–33.
- 15 Wegner E, McDermott R and Synden WM. Managing Organisational Knowledge Through Communities of Practice. Boston, MA: Harvard Business School Press, 2002.

- 16 Nonaka I and Takeuchi H. *The Knowledge-creating Company: how Japanese companies create the dynamics of innovation*. Oxford: Oxford University Press, 1995.
- 17 University of Birmingham, Royal College of Nursing. Three-day anticoagulant training course: medweb5. bham.ac.uk/files/pcgp/Courseinfosheet33D ay.pdf
- 18 Goorman E and Berg M. Modelling nursing activities: electronic patient records and their discontents. *Nursing* 2000;7:3–9.
- 19 Berg M, Aarts J and van der Lei J. ICT in health care: sociotechnical approaches. *Methods of Information in Medicine* 2003;42:297–301.
- 20 Berg M. Implementing information systems in healthcare organizations: myths and challenges. *International Journal of Medical Informatics* 2001;64:143–56.
- 21 McCahon D, Fitzmaurice DA, Murray ET et al. SMART: Self-Management of Anticoagulation, a Randomised Trial [ISRCTN19313375]. BMC Family Practice 2003;4:11.

#### CONFLICTS OF INTEREST

None.

#### ADDRESS FOR CORRESPONDENCE

Simon de Lusignan Senior Lecturer, Primary Care Informatics Department of Community Health Sciences St George's Hospital Medical School London SW17 0RE UK Tel: +44 (0)20 8725 5661 Fax: +44 (0)20 8767 7697 Email: slusigna@sghms.ac.uk

Accepted March 2004