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AN EVALUATION OF THE PATIENT EXPERIENCE OF A COMMUNITY BASED ANTICOAGULATION SERVICE IN BARNET

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July 2009

Contents

ACKNOWLEDGEMENTS	3
EXECUTIVE SUMMARY	4
BACKGROUND.....	6
CONTEXT OF THE STUDY.....	6
LITERATURE REVIEW	6
THE STUDY	9
AIMS.....	9
OBJECTIVES	9
RESEARCH QUESTIONS.....	9
METHOD.....	10
MANAGEMENT AND GOVERNANCE	10
STUDY DESIGN.....	10
SAMPLING.....	10
RECRUITMENT	10
ETHNOGRAPHIC OBSERVATION.....	10
INTERVIEWS, QUESTIONNAIRES AND CLINICAL DATA.....	11
DATA MANAGEMENT AND ANALYSIS	11
MAIN FINDINGS.....	12
DESCRIPTION OF SAMPLE.....	12
THE TYPE OF PATIENT WHO TAKES WARFARIN	12
LIFE ON WARFARIN	14
THE COMMUNITY BASED ANTICOAGULATION SERVICE	15
THE COAGUCHEK TECHNOLOGY	18
REFLECTIONS ON THE OLD SERVICE.....	19
SUGGESTIONS FOR THE FUTURE	21
DISCUSSION.....	23
SUMMARY OF KEY FINDINGS.....	23
STRENGTHS AND LIMITATIONS OF THE SAMPLE AND METHOD	23
RECOMMENDATIONS	24
APPENDIX: INSTRUMENTS USED	25
INTERVIEW SCHEDULE.....	25
HEALTH LITERACY INSTRUMENT	26
WARFARIN KNOWLEDGE AND ADHERENCE INSTRUMENT	27

Acknowledgements

We thank the patients who gave their time and shared their experiences, and the health professionals and others who supported this study.

Executive summary

BACKGROUND

1. This report describes an evaluation of the patient experience of a community based anticoagulation service based at the Torrington Speedwell Practice in Finchley. The study was commissioned by Barnet PCT to inform the commissioning of anticoagulation services. The empirical work was conducted between January and May 2009 by a BSc medical student (Ms Oyelakin) from University College London under the supervision of Prof Greenhalgh and Dr Boynton, who provided additional analytic input in preparing this report. Ethical approval was obtained from UCL Research Ethics Committee.

METHOD

2. The sampling frame was the anticoagulant clinic population at Torrington Speedwell. A total of 22 participants were recruited. The study design was mixed method, comprising semi-structured interviews with the patients and ethnographic observation of pharmacists seeing patients in the clinic. Data were analysed and synthesised with reference to the wider literature on efficacy and effectiveness of anticoagulation services and user-centred design.

MAIN FINDINGS

3. Most patients interviewed were elderly and suffered from multiple chronic illnesses which had a significant impact on their lives. They viewed warfarin therapy as contributing positively to their health and some said they would not be alive without it. They took their medication seriously and were almost 100% compliant with the recommended dosages. Patients in this sample had moderate to high health literacy and a good understanding of the benefits and risks of warfarin therapy. However, some patients' understanding of the possible effects of over- and under-treatment (i.e. 'out of range' results) were hazy.
4. Our ethnographic observations of the community based clinic revealed a popular service in a busy purpose built health centre. The clinic had a friendly and informal atmosphere while at the same time conveying a professional, efficient ethos.
5. The patients interviewed unanimously favoured the new anticoagulation service over the hospital-based service used previously. There were ten main reasons for this:
 - a. Convenience of setting (closer to home, easier to park)
 - b. Shorter waiting time (and if turn up early, often seen early)
 - c. Friendly staff with professional manner
 - d. Minimally invasive test (much less risk of bruising), and blood test less operator-dependent
 - e. Sample analysed in front of patient (hence, very low risk of samples getting lost or mixed up)

- f. Instant result
 - g. Clear, structured paper printout
 - h. Good explanation of result and what action to take (though some patients felt patronised by the 'simple' explanation)
 - i. Ad hoc advice available from pharmacist on other medication and general health issues
 - j. Less risk of hospital acquired infections (especially for immunocompromised patients)
6. Overall, the new service was perceived as 'modern' and 'efficient', and contrasted with the 'primitive' hospital clinic.
7. Few disadvantages were identified, though one participant noted how if the computer system behind CoaguChek fails this can cause problems for testing and possible treatment.
8. Patients were very keen that the service should continue, and some but not all felt it would be good to provide CoaguChek machines in GP surgeries and/or patients' homes (especially for the housebound). However, patients recognised that extending the service would raise additional operational issues.

RECOMMENDATIONS

9. On the basis of this evaluation, and bearing in mind that it was beyond our brief to assess costs or cost-effectiveness, we have no hesitation in recommending that the community based anticoagulation service at Torrington Speedwell continues.
10. The question of whether the CoaguChek service is further extended cannot be answered solely on the basis of the findings of this study, but we believe that pilot studies in different community and home settings may be worthwhile.

Background

Context of the study

At the time this study was commissioned in late 2008, a new community based anticoagulant service had been running at Torrington Speedwell practice in Finchley for 10 months. This service used a near patient testing technology, CoaguChek, which requires a fingerprick blood test and gives an immediate result (as opposed to the regular hospital-based anticoagulant service which requires a sample of whole blood and provides results to the patient 1-2 days later). Barnet PCT was considering whether to continue the community based service, and commissioned University College London (UCL) to undertake an evaluation. The fieldwork for the evaluation was done by a BSc medical student.

BSc students at UCL are required to undertake a research project leading to a 15,000 word dissertation. This study was undertaken partly as a pilot to see whether a 'win-win' situation could be found in which UCL students add value to the PCT's work while also being exposed to 'real' research topics. The goal of the BSc project was not to offer direct solutions for the challenges faced by services in Barnet but to (a) produce a piece of high-quality research and (b) capture the service user perspective in a way that the PCT could assimilate into its decision making cycle. This report was written by Prof Greenhalgh and Dr Boynton, drawing heavily on raw data and preliminary conclusions of the student BSc dissertation.

Literature review

The student undertook an extensive literature review of different aspects of anticoagulation services. Her full report can be supplied on request. Briefly, her findings include:

- Cardiovascular disease, including coronary heart disease and stroke, remain the leading cause of death and morbidity in the UK, accounting for 35% of premature deaths. Warfarin (an oral vitamin K antagonist) is the most commonly prescribed anticoagulant because of its well-established benefit in the prevention of stroke and thromboembolism. The commonest indication for warfarin therapy is atrial fibrillation but other conditions (e.g. valve replacement, hypercoagulation disorders) together account for a significant proportion of patients on warfarin.
- Warfarin has a relatively good safety profile but its effect on blood clotting requires regular monitoring because it has complex pharmacokinetics and pharmacodynamics. Food, other drugs and comorbidity can alter the free warfarin levels in the blood. Thus, managing patients on warfarin is labour intensive and requires skilled staff. Furthermore, such management depends on the patient's knowledge and health literacy.
- The very rare incidence of adverse events (especially bleeding from overcoagulation) in clinical trials may be an under-estimate of the risk of these events outside the research setting, since monitoring of patients is

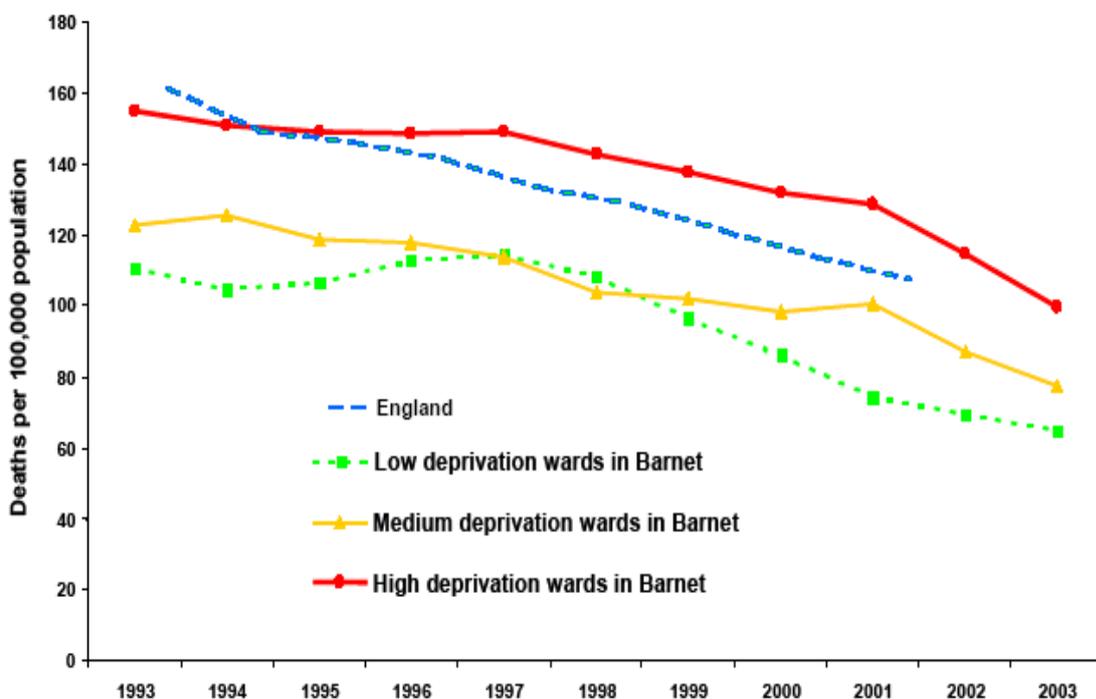
generally more intensive in research trials. Indeed, in a US audit published in 2008, anticoagulant was ranked first in the number of total mentions of 'deaths for drugs causing adverse effects in therapeutic use'. In the UK around 7-8 deaths a year are attributed to the side effects of warfarin. Worryingly, a recent meta-analysis showed that patients in atrial fibrillation spend only around half their time with their INR in the recommended range.

- Research shows that health professionals may fail to follow guidelines in prescribing warfarin because of perceptions about the risk of haemorrhage. Furthermore, miscommunication and personal preferences lead to both non-adherence and lack of knowledge of warfarin therapy by the patient. Thus, many patients whose cardiovascular risk profile would benefit from a therapeutic dose of warfarin are either not taking it at all or have suboptimal anticoagulation control
- In 2007 the National Patient Safety Agency published guidance to make anticoagulant therapy safer. This included ensuring that all patients are issued with a book containing information on warfarin use, an identity card for emergency, and a diary for recording their International Normalised Ratio (INR) results. The most recent INR should be within recommended limits and arrangements should be in place for monitoring and follow up.
- Most people with cardiovascular disease are in late middle age or elderly. Such illness is a major physical and social burden to the patient and family. Established cardiovascular disease is associated with negative emotions (depressive symptoms, anger and hostility, and anxiety) as well as chronic psychosocial stressors, particularly occupation or work-related stress and acute life stress. Social support may or may not be adequate and there may be conflict within the family. The need for the patient to attend for warfarin monitoring should be considered in this wider personal and social context.
- There is a well-established association between 'non compliance' with warfarin therapy and homelessness, poor housing, inadequate material resources, living alone, no other household member able to render care, and adverse health status. In other words, for complex but entirely understandable social reasons, the poor, the socially excluded, the sick and the lonely are less likely to gain maximum benefit from warfarin therapy. Services that are based locally (hence more accessible to the poor and socially excluded) may offer opportunities for reducing inequalities.
- New technologies offer two important benefits in warfarin monitoring. First, point-of-care monitoring devices (especially the CoaguChek device used in this study) makes a laboratory setting unnecessary and provides an immediate result. Second, such devices are programmed with computer based algorithms which have been shown to be significantly better than subjective judgement in determining an effective and safe dose of warfarin. Thus, the contemporary evidence-based management of a

patient on warfarin is to monitor the INR using a point-of-care device and use the internal functionality of the software to advise the patient how much warfarin to take until their next appointment.

- The CoaguChek device has comparable validity and reliability to laboratory testing, but some skill is needed to use the machine. One recent study showed that pharmacist-led anticoagulation management based in the community is more effective in achieving target INR and longer intervals between tests than GP-led management using the same software, perhaps because GPs follow the algorithm less closely.

Figure 1: Variation in mortality in low-deprivation and high-deprivation wards in Barnet



The study

Aims

To explore the patient experience of community based anticoagulation services in Barnet with a view to informing the provision and commissioning of services by the PCT.

Objectives

In addressing the above aim, we sought to

- Recruit a maximum variety sample of service users who had current or recent experience of the new anticoagulant service at Torrington Speedwell (and usually, recent past experience of attending hospital-based anticoagulant clinics at either Barnet General or Whittington hospital)
- Capture the patient experience and contextualise it in relation to their clinical and social background, using a range of methods including ethnographic observation, individual semi-structured interviews, and review of clinical records
- Analyse and synthesise the data to produce a succinct summary of key themes
- Make provisional recommendations for the PCT

Research questions

The following aspects of the patient experience were identified as being of particular interest to the PCT:

- Overall, how do patients perceive the new community based service – for example, is this experience positive and if not, why not?
- Overall, how do they perceive the *technology*?
- To what extent is the new service accessible, acceptable and equitable?
- What suggestions do users have for improving the service overall?
- Have any critical events occurred, and if so, what are these and what can we learn from them?

Method

Management and governance

UCL was the official sponsor of the research and provided indemnity. The study protocol was approved by UCL's Research Ethics Committee in December 2008. Plans for data management and confidentiality measures were approved by UCL's Data Protection Officer in November 2008. Students followed UCL guidance for community based research and were closely supervised at all times by academic staff. Ethical issues emerging in the fieldwork were passed to supervisors who advised on an appropriate course of action.

Study design

The design was mixed-method study on a target of 20 patients, comprising

- Ethnographic observation of the anticoagulant clinic
- Qualitative (semi-structured) interview
- Brief standardised health literacy test (REALM)
- Brief standardised test of warfarin knowledge and adherence (Tange)

Sampling

We sought, ideally, a maximum variety sample representing as wide a range as possible in relation to age, socio-economic status, ethnicity, medical condition, presence of comorbidity, health literacy, and presence of absence or complications. In reality the sample was 'convenience' in that all patients on particular clinic lists were approached and asked if they would give an interview when they next attended. The only exclusion criterion was inability to communicate in English *and* absence of interpreter (lay or professional).

Recruitment

In accordance with UCL's ethical guidelines for student research, potential participants were not approached by the student directly but (as far as possible) by a known and trusted professional – in this case the pharmacist organising the clinic. Posters were put up inviting patients to volunteer for the study, but in practice almost all participants were recruited by personal contact. All potential participants were offered an information sheet but most chose not to read the detail. All were required to give written consent. They were told that their responses would be treated in strict confidence and that their participation would not affect their care in any way. They were not paid for the interviews but were assured that their feedback would be used to improve local services.

Ethnographic observation

The student sat in on anticoagulant clinics over a four-day period at Torrington Speedwell and made detailed ethnographic field notes on these sessions. She

observed three different pharmacists. She typed up the field notes immediately afterwards and these were used as qualitative data.

Interviews, questionnaires and clinical data

Interviews were held at Torrington Speedwell in a room adjacent to the anticoagulant clinic. Participants were given the choice of whether their interview would be recorded. In those who declined (one out of the sample of 22), contemporaneous notes were taken instead and typed up immediately after the interview. All other interviews were audiotaped and transcribed in full. The interview schedule is given in the appendix. All participants were offered an opportunity to check the transcript of their interview for accuracy; two did this.

The health literacy questionnaire used was the 7-item REALM instrument, reproduced in the appendix.

Warfarin adherence and knowledge was measured using the instrument developed by Tange et al, reproduced in the appendix.

Clinical data on the patient's condition were collected only to the extent that these were volunteered in the semi-structured interview; patients' medical records were not accessed. The patient was not clinically examined.

Data management and analysis

Interviews were transcribed by a professional transcription agency and anonymised before storing. The qualitative data were analysed using thematic content analysis by the constant comparative method. This is a standard qualitative approach which essentially involves grouping data into broad themes and comparing new data on each theme with existing data on the same theme, thus highlighting both commonalities in responses and also 'disconfirming' data (when someone feels differently from the majority, for example). The student used a simple 'framework' approach for the interview analysis (i.e. inserting key findings into an Excel spreadsheet in which each interviewee is a new row on the spreadsheet, and the columns represent different themes in the data). When interpreting her empirical data she drew on insights from the literature.

Main findings

Description of sample

Overall the sample comprised 22 patients with the following characteristics:

- 14 males, 8 females
- Ethnic origin: White British 12, White other (southern/eastern Europe) 10
- Age range 54-90 (median 79)
- Reason for anticoagulation atrial fibrillation 14, valve replacement 5, hypercoagulability 1, not stated 1

22 participants agreed to be interviewed for the research.

The overall health literacy score ranged from 2 to 7 out of 7 (median 7) and the warfarin knowledge score ranged from .05 to 1 out of 1 (median .07 for men and .09 for women). This suggests that our study did not access patients with low health literacy, cognitive deficits or major problems with understanding. However, our sample was in an unselected group of patients; many had had only minimal education and had worked in low-skill occupations (i.e. it was not an especially 'middle class' sample). It may be that having a long term condition and being seen regularly for monitoring leads to an increase in health knowledge and health literacy.

Note that pseudonyms have been used in all quotes and unusual medical conditions replaced with fictional alternatives to protect confidentiality.

The type of patient who takes warfarin

Many patients in our sample were relatively old and chronically sick; some (but by no means all) had difficult social circumstances. They tended to face these with stoicism. In the following quotes some medical details have been fictionalised and the initials given correspond to pseudonyms not real names.

“Well, I’ve had several hospitalisations; I’ve had 17 operations in the last 13 years, knee replacement, cancer, heart problems of course, two cardioversion, two angioplasties, [laughter] costing the NHS a fortune” (Mr A, age 91)

“Until I was 63, I had no need of hospitals, doctors, nurses or anything. Since then I suppose I’ve been looked after by hundreds” (Mr D, age 69)

“I’ve got a problem with the bowel, problem with the bladder, I have high blood pressure, asthma ... I have a heart problem. I’ve got atrial fibrillation ... I had a surgery last year, nine months ago, for biopsy because I had been diagnosed with prostate cancer... I also I have, um, polymyalgia, I’ve got a problem with my eyesight ... there’s a shadow on my lung. And also I’m deaf in my right ear.” (Mr G, age 54)

In the context of what were often multiple medical problems with social implications, as well as increasing frailty, warfarin management was just one more problem in a long list:

'My illness has only been this giddiness as far as I'm aware. This blood pressure, like, it's been like it for years. But I don't class that as an illness. All this business [warfarin]. But the giddiness is what I worry about now. The car driving. I could lose my licence in April.'
(Mr P, age 81)

Many such patients felt that they were, in a sense, living on borrowed time. Some came from families where members had died young of cardiovascular disease. Others had had dramatic near-miss events. They were openly grateful for the modern pharmaceuticals which were (in their eyes) keeping them alive:

'Thank you for all the help you're giving me. Anything that keeps me alive for a bit longer, I'm very, very privileged. My maternal grandmother died just after her 72nd birthday. My mother died a week after her 72nd birthday. So when I was getting to the age of 72, I thought, 'Right this is my last year.' And I went for it. I'm now 77 and every year is a bonus.'
(Mrs N, age 77)

'Well I didn't know anything about it [illness], I had never been ill before until I collapsed. And they sent me to Barnet. They sent me to [...] Hospital, and that's when they told me the aortic valve had got to be replaced. Been on Warfarin ever since, not worked since. I get bored a lot. What can I do? I can't get insurance, I can't get a job. That's basically it.'
(Mr R, age 65)

'I just, I guess by the time you're 80, you should be dead, you know, and so if this is living, I guess I have to put up with it. But it's no inconvenience to me.'
(Mr M, age 82).

'The only thing I could wish for is that I could get off of it and they could get my AF right. But they can't get my AF right, so I should be here probably for the rest of my days, coming to see them. And, you know, if they could get my AF right, that would be my ambition. But they've tried, as I've told, at the [...] Hospital, and they failed. They tried hard, but they couldn't do it. And I think I'm stuck with it now. But the service I've got, I'm very happy.'
(Mr J, age 79)

Many patients, whilst elderly and relatively sick, were still very active. Some were carers or looked after grandchildren, others were still in employment. Warfarin management had to be fitted into what were, for some, very busy lives:

'But I do quite a bit of charity work. At the moment, during the year, during Lent, we do charity and bring and buys and things like that. Over the last week I have

done seven baskets of flowers, if I'd known, I should have brought a photograph to show you them.'
(Miss T, age 80)

Life on warfarin

Whilst patients new to warfarin therapy found it highly inconvenient and frustrating to attend a clinic once a week or fortnight, those who had been on the drug for years seemed to have accommodated to the idea.

'It's [warfarin] part of the furniture. It's part of the wallpaper of my life.'
(Mr L, age 83)

Indeed, those who had been on the drug a long time were extremely reluctant to stop it even for one or two doses:

'That's what's worrying me, this last few days when I've been told to stop it because I'm having surgery tomorrow and I think, I'll either get a stroke or not, you know, because if the warfarin is stopped, I mean there's, you know, another risk isn't there?'
(Mrs N, age 77)

Patients saw the warfarin as a lifeline and compliance with medication was very high. Every patient in this study scored 100% on the 'adherence' sub-scale in the questionnaire on warfarin knowledge and adherence. In the ethnographic observation of the clinic, most out of range results were caused by factors other than non-compliance – such as antibiotic treatment, recent alcohol intake, and planned reduction for a dental extraction, though one patient had accidentally missed a dose.

Most patients also scored very highly on the 'knowledge' scale of the questionnaire. However, significant numbers of participants had limited knowledge about the implications of over and under anticoagulation when INR results were outside the recommended range.

Some patients had developed sophisticated rituals to remember to take their warfarin:

'I get them [warfarin] ready every night before I go to bed. I get my tablets for the following day, I've got a little box. And it's sectioned up. And my warfarin tablets are always in the evening after I've eaten my dinner.' (Mrs N, age 77)

Taking warfarin was such an important aspect of people's lives that family members often took on the role of 'reminder':

'But I am, I am very good taking them [warfarin]. And well, if you knew my husband, you'd know why! He's so keen on me taking the tablets, so he always says, 'Have you taken your Warfarin?' So I'm pretty good with them.'
(Mrs W, age 58)

Patients on warfarin were uneasy when the interval between blood tests was reduced as this indicated instability in their condition:

'Now it's three weeks. So it's getting better. Might go up to six weeks again, what I was once before.'
(Mr B, age 84)

"I wouldn't mind if the appointment was in the next 2 years"
(comment made by patient being observed in ethnographic study of clinic)

Because anticoagulation clinics are ubiquitous and all patients carry a warfarin book (i.e. a paper record of their blood tests, results and dosages), moving around the country was seen as problematic:

'I tell you what has been good, I go down to Devon in the summer, and I've gone into the local hospital, and they've done it for me. So it's very flexible.'
(Mr P, age 81)

Many patients had been on warfarin for years and had an intuitive feeling for what their INR would be before the test result came back. One patient observed in the clinic saw the blood flow freely when his finger was pricked and said "it's thin" – meaning, he predicted (rightly), that his INR would be higher than the recommended range. Some patients felt they knew instinctively how often they should be called back for tests.

'I do have a little bit of a go sometimes because I mean I've been on it 17 years, and they're trying to tell me how to use it. And I will say, 'I know all about the tablets, well the numbers and all this. But it's like the other week, I was supposed to be between 3 and 4. And it was 4.5. So she said to me, 'I'm going to do, cut out one tablet on the Saturday, one on a Sunday, I want you to come back in a month.' And I said, 'No, I'll come back in two weeks because I think a month is too long,' because it was getting a bit erratic, you know. And I think a month was too long. So she agreed with me in the end. Now she's done it again that I come back in a month.'
(Mr R, age 65)

Despite often being an authority on their own body in relation to warfarin pharmacodynamics, most patients were happy to accept a traditional sick role in which their doctor made the decisions:

"The only drugs I know are what I take and recommended by my GP."
(Mr B, age 72)

The community based anticoagulation service

Our ethnographic observations of the community based clinic revealed a popular service in a busy purpose built health centre. Many but not all patients were registered with one of the GP practices operating from the ground floor of the same

centre. Patients appeared to feel welcome and well oriented in the health centre despite the fast pace of work and multiple different clinics and services going on under one roof. The anticoagulant clinic was on the first floor in a relatively quiet part of the building and had a separate reception desk. The clinic had a friendly and informal atmosphere while at the same time conveying a professional, efficient ethos.

Patients were unanimous in perceiving the new service to be an improvement on the old hospital based service. They liked the local convenience, the friendliness, the accessibility of staff, and the short waiting times (typically 5-10 minutes). They also liked the less invasive nature of the test, the immediacy of the result and the fact that their sample was being analysed before their eyes (so specimens could not get mixed up).

'I sat down, washed my hands, sat down, a tiny pin prick was used to extricate a tiny blob of blood from my finger tip, which I didn't feel. The machine gave out a reading; the reading was discussed with me and explained why it was necessarily to slightly adjust my Warfarin. A new appointment was recommended and made. And that took five minutes.' (Mr S, age 82)

'I live around the corner and my doctor is here as well' (Mr R, age 65)

'I always get seen, I come here much earlier than I should do and I always seem to get served early.' (Mr M, age 83)

Patients liked the format of the printout from the CoaguChek machine, which they found to be clearly structured and easy to follow:

'They do it there [pointing to pink form] and show you when the next appointment is. So you've got everything – that is what it [INR] is today. And that's the dose they want me to have, that's the next appointment.' (Mr R, age 65)

This structured form was used by the pharmacist to explain to the patient what dose to take and when they needed to return. One or two patients found the explanations unnecessary and patronising:

'They go through [pink form containing summary of consultation] and they go point by point as if I were demented. Well I'm not demented. I can see why they do it. But it's, you know, okay? But they've got to do it. And I think the risk of asking someone to assess whether their patient is capable of remembering, is probably too high.' (Mr L, age 83)

'it's like, you know, with in school, with the backward children...The only thing she's not doing [is] 'Repeat what I said'. That's what we tell children!' (Mrs P, age 80)

A significant benefit of the test being done by a pharmacist appeared to be that patients could ask about their other medication while waiting for the INR test result. Indeed, pharmacists were seen as authorities on other aspects of care and access to them was a definite perceived benefit of the new service:

'I've been very, very pleased with the service, the quality of care, and any small queries I've had, I've either rung the hospital or spoken to the lady who does the test, and there's always been plenty of information and help with whatever I've needed. So I think it's first class.' (Ms M, age 75)

Our ethnographic observations showed that the pharmacists frequently offered health advice that was not related to the warfarin therapy. For example, one pharmacist observed a patient's fingernails and suspected that he may have a fungal infection. She advised him to visit his GP about it. Another patient reported that the pharmacist provided travel advice based on his current INR result.

'She took my blood, she told it's not good day for me to fly because I was scheduled to fly to Spain next week, but she recommended to not to, because my INR was a bit too low.' (Mr G, age 54)

The pharmacists were not, however, seen by most patients as substitutes for the doctor or nurse. Indeed, one patient felt it was now less easy to get a medical opinion:

'The lady I met this morning in there, she, she seems to know what she's doing. But I wouldn't say they're [pharmacists] cleverer than a nurse, because I don't think they've got the experience. They're okay with what they're doing now, because they know what they're doing, but asking, you know, some people, like questions, when you get down to the last details, if you've got really serious problems, I wouldn't think that they could explain that to you. A nurse, if she doesn't know, she will call on a doctor straightaway. So you're getting, you're getting two instead of one, if you know what I mean. She can pass you to somebody else. I don't know if they can do that here, I'm not sure, I don't know.' (Mr Y, age 79).

Others simply did not know what level of competence to assign to the pharmacist, as the following comment from a retired nurse shows:

'How qualified is a pharmacist?' (Mrs J, age 79)

Whilst not entirely sure of the pharmacists' area of competence, many patients commented on the high level of professionalism shown by this group:

'Obviously better qualified [than nurses] to start with ... They're very conscientious, that's one thing that I admire most about them, the fact that they,

they're quite in control of everything that they are doing. They are focused on what they are doing which is not always the case at Barnet. And they get on with the business. It's very reassuring, yes it is ... The girls are quite firm about what they want you to do, and I'm quite clear. And so, altogether, it's a very reassuring experience.' (Mr A, age 91)

One patient described how the pharmacist had faxed blood test results from the CoaguChek clinic across to a hospital clinic in time for her appointment there.

The CoaguChek technology

The CoaguChek technology in the new clinic was seen as modern, efficient and convenient. It was contrasted negatively with the 'old-fashioned' use of traditional needles and test tubes in the hospital service:

'I also felt that the taking of the blood was in a sense, if I may, but not sound too clever, but a little bit primitive.' (Mr A, age 91)

Some patients were yet to be convinced that the new technology was as accurate as the old technology, but they had confidence in the figures produced and believed they were 'accurate enough'.

'I presume that they're getting an accurate reading. I'm not worried about it, because as long as it's between 2 and 3, whether it's 0.1 difference, I can't see that it's going to make a lot of difference.' (Mrs N, age 77)

'I've never given it a lot of thought. It appears to work because my INR is, seems to be right. I have no idea whether the results that it gives are correct or not. I mean I don't know how they are calibrated or how they are checked. No one has told that. But I mean if somebody said, 'Well the machines are very carefully checked once a week,' or something, well fine. But it doesn't bother me. I take the pills. I'm on a high dosage which I get annoyed when several of my best friends are 3 or 4 mg a day and I'm on 8. But it must be because my blood is so strong. But the machine, well it does its job, or appears to. I mean I don't give it much thought at all.' (Mr D, age 69)

Interestingly, the computerised algorithm used by the CoaguChek machine sometimes recommended longer intervals than the patients had been used to with the old service, and this sometimes caused anxiety.

'I think they leave you too long sometimes.' (Mr R, age 65)

Whilst the old technology was seen as 'primitive', the new technology (like any highly sophisticated computer system) came with risks of rare but catastrophic failure:

'I think it's a good service. As long as they keep punctuality and as long as computers have back up, because computers do go wrong ... And so you have the back up, you have to have back up. Otherwise when you have no back up, what do you do when you come in and the computer doesn't work? You do it by hand, and then it takes a long time, and then you have a schedule, you have in an hour, say a dozen people. Suddenly you have to squeeze that dozen people in to that hour, and you can't do it. So you have to have some sort of back up. Not, if the computer goes wrong and right you can't do it, you must have something that you put it to one side and you continue with another computer or whatever.'

(Mr H, age 81, interviewed on the day the computer system was down.)

Reflections on the old service

The almost exclusively positive reports of the new service contrasted with patients' views on the old hospital-based service, which by comparison was seen as inefficient, unwelcoming, and not to be trusted.

'Well that, you see, that 5cc of blood was wasted. You only need a drop, but then they took 5cc. And it took a long time. First you had to wait in a queue every day, you know, you had an appointment at 10.30, and if you were seen at 11 o'clock, it was good, very good. I thought that system was wasteful. You know, it's wasteful in human resources and wasteful in time and wasteful in patients' time and subject to mistakes because every time you put a sample, it was put in a bag, and that bag, you know, could get lost in the post. Sometimes I had the book back two days, three days, sometimes a week. You know.'

(Mr H, age 81)

The unpredictability of waiting times at the hospital clinic was seen as a major disadvantage by most patients, especially those in a carer role.

'The only blemish in my life is that my wife has Alzheimer's sadly and she is in a care home...Sometimes that delay in the phlebotomy clinic, haematology clinic [old anticoagulant service], meant that I miss her meal and that is even more important than my health [silence]. So it concerned me.' *(Mr S, age 82)*

Patients contrasted the knowledgability and approachability of the pharmacist in the community service with the traditional division of labour in the old hospital based clinic, where the phlebotomist had no real clinical knowledge:

'They [hospital phlebotomists] never tell you nothing because there was nobody there to tell you because, you know, you'd been waiting probably an hour or two anyway. And by the time you gave the blood, there was nobody around, only the lady behind the desk who you handed your book to. Only she can't explain very much to you. She probably doesn't know. I often said to them up in Barnet, you know, why does your blood level come up and it goes down? She didn't know, 'I don't know myself,' she said. And that was the lady that was taking the blood. So she didn't know.'

(Mr Y, age 79)

Some phlebotomists in the old service were clearly more skilled than others at getting the blood out of the patient:

'The other matter, sticking the needle into the vein, sometimes when they are not experienced enough, the nurse [phlebotomist], she would poke the needle and then look for the vein, and that was a bit unnerving, the blood was swimming on both sides. That happened to me twice. But it was funny because people noticed, who is going there, and there are cubicles, 1, 2, 3, 4. And they first look which cubicle she's in. And there was some man said, 'Go to cubicle 3.' And he said, 'Oh I have to go to toilet.' And he left somebody else to go because that was the nurse who couldn't find the vein! So it wasn't only me. It was the other people as well.'
(Mrs P, age 80)

With the new finger prick service, the size of the prick was tiny compared to a traditional blood test, and the heavy bruising associated with damaged veins (a significant issue for patients on anticoagulants) became a thing of the past.

Another disadvantage of the hospital service perceived by some patients was the risk of hospital-acquired infections (which was significant in the immunosuppressed):

'Well they changed to an appointment system. So I thought it would be better, but it was still a 20 minute wait. Again, the nurses were fantastic. You sat – what worried me, because I have a poor immune system still, was that we were in a very small room, and if people were coughing, I'd tend to put a scarf across my mouth, because I must not pick up infections, because when I do, well when I picked up a serious infection last year, I ended up in the emergency and I was in Barnet again. And off the warfarin. So that was the last time I sat in that. And I thought, 'Thank God I won't have to do this any more,' ... sitting in that enclosed atmosphere.'
(Mr D, age 69)

Some, however, had been positive about the old service – particularly, it would seem, the early risers. Whereas the community clinic was open 8.45 to 3.30, the old clinic had opened much earlier.

'It was very good. I used to go up early. It was very good. I used to get the results back by post either the following day or two days later. It was very good, yes. It was possibly getting a bit crowded, but I used to go early so it didn't bother me at all.'
(Mrs M, age 61)

'It worked. Erm, I mean it was quite convenient for me because I live quite close to Finchley Memorial Hospital and I liked the system of being able to get an appointment at 7.30 a.m. in the morning, so that it didn't interrupt the day. And so, no, I mean it worked. And then you got the book back through the post.'
(Mrs L, age 69)

'They were pretty good. I used to go there, book the appointment and that's it, no problem. I never had a problem whatsoever really honestly.'

(Mr G, age 54)

The above comments should be interpreted in the light of the fact that the three patients who made them all said they preferred the new service.

Suggestions for the future

Patients' most pressing concern was that the current service at Torrington Speedwell should not be withdrawn.

'I was hoping that this [evaluation] wasn't a prelude to them closing the service down!'

(Mr A, age 91)

The convenience of the technology led some patients to suggest that it should be installed in more locations:

'A compromise might be the availability of coaguCheck machines for self tests at surgeries (as with BP monitors).'

(Mr L, age 83, respondent validation response via email)

Others tentatively suggested that CoaguChek might be used for home monitoring, especially by housebound patients.

'... It's good as it is, very good. So will they have it, you know, in our houses in a few years' time? The machine? It would make our life much easier. Yes. It means not having to come here.'

(Mrs M, age 61)

'The only query I might, could add on this is that erm, if there was any way of treating myself at home, and then if there was any sign of a change, then I would have to get in touch with somebody to tell them what the situation was. That would certainly make it easier, but then I would need a machine at home. And I don't know how expensive they are. It would certainly save me coming in every few weeks or whatever the latest timing is. I don't know whether the National Health would then consider the patient himself treats himself inasmuch as takes the blood reading, checks what the result of that is, would be possible I would have thought. Am I right? So that there must be situations where people can't get to the service. You know, at the moment I can, but there could well be a situation arising in a few years' time, when I can't. And then that means arranging for some sort of transport, and the cost makes it difficult for everybody all the way round. As I say, if it would be possible then for a patient to treat themselves, I don't know. You would be able to tell me whether that was possible.'

(Mr G, age 85)

This last patient rightly acknowledges that the machine will not make him independent in self management. He captures the uncertainties associated with

giving frail patients responsibility for using the machine and interpreting the test result. Even with an inbuilt algorithm, some human judgements are involved. Mr G does not know how home based monitoring would play out for such patients – and neither do we.

Whilst some patients saw home based machines and self monitoring as the future, others focused on developing and expanding the community based service. One patient shrewdly anticipated a substantial increase in burden of need for warfarin monitoring, and suggested that if this occurred, a purpose-built ‘warfarin suite’ might be justified:

‘... Doctors are putting more and more old people – old people aren’t dying, so the number of people on warfarin treatment must be expanding at quite an alarming rate. So, erm, they have had to develop clinics that can cope with the volume ... But this clinic wouldn’t be able to cope with the number, I imagine, that normally comes. So that’s got to be planned for. Erm, eventually, although will the NHS be able to afford it, you need purpose built clinics erm, with pleasant welcoming suites. Erm, you go in, you come out. As long as they can make sure that the waiting time doesn’t increase, I would want to develop – you see, here you’ve had to go into a strange clinic and they have had to give up a particular room for a particular time each week. That room may not have been necessarily designed – it’s a sort of general purpose. But I would like to see there’s more a place, a place which is more devoted to that sort of thing, if you’ve got a higher volume. There’s no point until you have a higher volume. But if they take everyone off the hospital arm blood test, then your volume would increase a great deal. I don’t know how you would do it, whether hospital grounds could build something in the ground which would be the warfarin clinic, fine, but that’s what eventually they will have to do, because doctors are going to continue to put more and more people – the volume is going to increase as I have said’. (Mr D, age 69).

Discussion

Summary of key findings

Overall, this evaluation of the patient experience of the new community based anticoagulation service was very positive. Most patients interviewed were elderly and suffered from multiple chronic illnesses which had a significant impact on their lives. They viewed warfarin therapy as contributing positively to their health and some said they would not be alive without it. They took their medication seriously and were almost 100% compliant with the recommended dosages. Patients in this sample had moderate to high health literacy and a good understanding of the benefits and risks of warfarin therapy. However, some patients' understanding of the possible effects of over- and under-treatment were hazy.

Our ethnographic observations of the community based clinic revealed a popular service in a busy purpose built health centre. The clinic had a friendly and informal atmosphere while at the same time conveying a professional, efficient ethos.

The patients interviewed unanimously favoured the new anticoagulation service over the hospital-based service used previously. There were ten main reasons for this:

- a. Convenience of setting (closer to home, easier to park)
- b. Shorter waiting time and if turn up early, often seen early)
- c. Friendly staff with professional manner
- d. Minimally invasive test (much less risk of bruising), and blood test less operator-dependent
- e. Sample analysed in front of patient (hence, very low risk of samples getting lost or mixed up)
- f. Instant result
- g. Clear, structured paper printout
- h. Good explanation of result and what action to take (though some patients felt patronised by the 'simple' explanation)
- i. Ad hoc advice available from pharmacist on other medication and general health issues
- j. Less risk of hospital acquired infections (especially for immunocompromised patients)

Overall, the new service perceived as 'modern' and 'efficient', and contrasted with 'primitive' hospital clinic

Patients were very keen that the service should continue, and some but not all felt it would be good to provide CoaguChek machines in GP surgeries and/or patients' homes (especially for the housebound). However, patients recognised that extending the service would raise additional operational issues.

Strengths and limitations of the sample and method

Our sample of 22 participants was relatively large for a qualitative study and represented a fair demographic spectrum, though the absence of Black or Asian

patients was a significant weakness of the study. Because of the wide socio-economic and ethnic diversity of the Barnet population, and the different needs and expectations of different users, this sample was probably insufficient to capture the full range of patient experience.

Medical students have the advantage of being (in the words of one of our students) in a 'liminal zone' – that is, they are part-professional and part-lay. This allows them potentially to bridge the medical world and the patient's lifeworld. However, using medical students also had potential disadvantages: they lacked credibility with some NHS staff who were reluctant to allow them access to patients, and they were seen as part of the 'system' by patients so disclosure of major misgivings about the service would have been less likely than with (say) an independent researcher.

The emphasis on in-depth qualitative interviews had the advantage of providing a 'rich picture' of the patient experience in particular cases, but the findings are not *statistically* representative of the overall experience of Barnet patients. There is always a trade-off between depth (of insight) and breadth (representativeness) when considering a study design in health services research. Findings from this study could now be taken forward in larger surveys to gain a quantitative picture of the issue. In particular, a recently produced questionnaire instrument on satisfaction with anticoagulation services could be given to a larger sample of patients to supplement the findings of this study.

Recommendations

On the basis of this evaluation, and bearing in mind that it was beyond our brief to assess costs or cost-effectiveness, we have no hesitation in recommending that the community based anticoagulation service at Torrington Speedwell continues. The question of whether the CoaguChek service is further extended cannot be answered solely on the basis of the findings of this study, but we believe that pilot studies in different community and home settings may be worthwhile.

Appendix: Instruments used

Interview schedule

- Please tell me about yourself (Hint: Living situation – alone, as a couple?
Employment status; Education Level)
- Please tell me about your illness and why you are on warfarin
- Please tell me what you think of the old anticoagulant service
- Please describe the last time you went to that clinic?
- Please tell me what your expectation of the new service was
- Are your expectations being met?
- Please tell me what you think of the new service
- Please describe the last time you went to that clinic?
- Please tell me what you think about the anticoagulation clinic run by a pharmacist rather than a nurse?
- Please tell me what you think about the machine used for your INR test?
- If you were going to redesign the service, what will it be?
- Is there anything else you will like to tell me about the new anticoagulation service?

Health literacy instrument

The health literacy instrument used was the Rapid Estimate of Adult Literacy in Medicine—Short Form (REALM-SF)

Instruction: Starting at the top of the list, please read each word aloud to me. If you don't recognize a word, you can say 'pass' and move on to the next word. Your results will be kept strictly confidential and will not be included in your official medical records.

If the participant takes more than 5 seconds on a word, say "pass" and point to the next word. Hold this scoring sheet so that it is not visible to the participant.

Word on list	Scoring key		
Fat	Not scored		
Flu	Not scored		
1. Behaviour	1 Correct	2 Mispronounced	3 Not attempted
2. Exercise	1 Correct	2 Mispronounced	3 Not attempted
3. Menopause	1 Correct	2 Mispronounced	3 Not attempted
4. Rectal	1 Correct	2 Mispronounced	3 Not attempted
5. Antibiotics	1 Correct	2 Mispronounced	3 Not attempted
6. Anaemia	1 Correct	2 Mispronounced	3 Not attempted
7. Jaundice	1 Correct	2 Mispronounced	3 Not attempted

REALM-SF Scoring

Total Correct (0-7)	Grade Level
0	≤ 3rd grade
1-3	4th - 6th grade
4-6	7th - 8th grade
7	≥ 9th grade

Reference for REALM: Arozullah A.M, Yarnold P.R, Bennett C.L, Soltysik M.S, Wolf M.S, Ferreira R.M, Lee S.D, Costello S, Shakir A, Denwood C, Bryant F.B, Davis T. (2007). Development and validation of a short-form, rapid estimate of adult literacy in medicine. Medical Care. 45(11):1026-1033.

Warfarin knowledge and adherence instrument

The questionnaire below has been developed to test patients' knowledge of warfarin therapy^a and adherence to medical advice^b

1. ^aWhat is the (a) colour and (b) strength of your warfarin tablet(s)?
2. ^aDo you know the indication for your warfarin therapy?
3. ^aDo you know what warfarin does to your body?
4. ^bDo you take your warfarin tablet regularly (say, in the past 1 week)?
5. ^aWhat will you do if you missed a dose?
6. ^aDo you know what may happen with under-anticoagulation?
7. ^aDo you know what may happen with over-anticoagulation?
8. ^aDo you know what drugs or foods may interact with warfarin?
9. ^bWhen you visit a doctor or a dentist, will you always tell them of your warfarin therapy?

Reference for Warfarin Knowledge and Adherence Instrument: Tang E, Lai C, Lee K, Wong R, Cheng G and Chan Y (2003) Relationship Between Patients' Warfarin Knowledge and Anticoagulation Control. *Annals of Pharmacology*. 37 (1): 34-39.