Improving the safety and efficacy of warfarin therapy in a metropolitan private hospital: A multidisciplinary practice improvement project

ABSTRACT

Background: Warfarin is a very complex, high risk therapy and one that carries the potential for severe adverse events. The aim of this project was to improve warfarin management through the application of the best available evidence. The project was undertaken in a 250 bed acute care metropolitan private hospital. Interventions: A suite of evidence-based interventions were used including audit and feedback, patient and provider education, and decision support aides. Measures: This project used the ongoing collection of warfarin process and outcome clinical indicator data to measure improvement. Results**:** Compliance with loading protocol increased by 12% (42% to 54%); patient education prior to discharge increased by 54% (31% to 85%); INR's > 5 decreased by 2.6% (3.7% to 1.1%); and abnormal bleeds fell by 1.2% (1.2% to 0%). Conclusion: This multifaceted bundle of interventions was successful in influencing clinician behaviour and improving compliance with evidence-based warfarin guidelines.

KEYWORDS

Nursing, warfarin, quality and safety, practice improvement, knowledge transfer, multidisciplinary collaboration, statistical process control charts.

BACKGROUND

Warfarin therapy is widely prescribed for the prevention and treatment of venous and arterial thrombosis and embolism (Hirsh *et al* 2008; Institute for Clinical Systems Improvement [ICSI] 2006; Gallus *et al* 2000). In our organisation we have seen the number of inpatients on warfarin significantly increase over the last 10 years. This is in part due to strong evidence of its benefit in patients with atrial fibrillation (Hirsh *et al* 2008; ICSI 2006; Gallus *et al* 2000). This has lead to warfarin now being one of the top 20 most prescribed drugs in Australia, with over 2 million prescriptions issued each year (Department of Health and Ageing 2008).

Although effective, warfarin therapy is very complex to manage. The average daily dose required can differ dramatically from person to person varying from 0.5mg/day

to 15mg/day (Gallus *et al* 2000). This wide gap in individual responses to dosage requirements can be due to a number of factors including age, weight, cardiac or liver impairment, diet, or drug interactions (ICSI 2006). In order to manage warfarin safely it must be closely monitored and titrated to avoid under or over-dosage and although it has well-proven efficacy as an anticoagulant it does come with considerable risks. Indeed, it is potentially a very hazardous drug with reports suggesting major bleeding in approximately 1-2% of people and intracranial bleeding in 0.1-0.5% (Gallus *et al* 2000).

This combination of a potentially dangerous drug with a complex therapeutic regimen considerably increases the likelihood of adverse events. In a systematic review of the literature Runciman *et al* (2003) identified that between 2-4% of all hospital admissions in Australia are related to adverse drug events and that anticoagulant medication, such as warfarin, is the second most common drug class implicated (second only to chemotherapy agents). Warfarin is also in the top five most cited medications in NSW Public Hospitals incident reports (The Clinical Excellence Commission [CEC] 2006).

The impetus for this project started in 2007 when the organisation was invited by the NSW Therapeutic Advisory Group (TAG) and the NSW Clinical Excellence Commission (CEC) to trial their new Medication Safety Self Assessment for Antithrombotic Therapy (MSSA-AT). This tool was initially developed in the United States by the Institute of Safe Medication Practices and had recently been adapted for the Australian context by NSW TAG and the CEC (CEC 2007a). The self-assessment required a multidisciplinary team to rate the organisation's compliance with best practice initiatives, discussing each initiative until a consensus was reached on the level of organisational implementation (from not implemented to fully implemented). On completion of the self assessment our overall score was calculated at only 44% (of the maximum possible score). From the MSSA-AT results it was clear that warfarin management was the priority antithrombotic therapy for further investigation.

AIM

The primary project aim was to improve the safety and efficacy of warfarin therapy through the application of the best available evidence on warfarin management. A

number of secondary objectives were set in order to achieve this aim. These included; the comprehensive audit of current warfarin therapy management practices against evidence-based best practice; benchmarking of these results with comparable organisations; identification and prioritisation of areas for practice improvement and; the sustaining of implemented practice change.

METHOD

It was decided that the project would use a very pragmatic yet systematic approach in order to achieve effective and enduring change. Consequently, the project employed a practice improvement methodology. This methodology was first used to monitor and improve processes in the manufacturing industry but has subsequently been adopted by many other industries including the health care sector (Wilson & Harrison 2002). It is a process that recognises clinicians are best able to improve practice systematically through trial and error based on practical experience of what works and what doesn't. This approach acknowledges that clinical practice is an inherently messy terrain.

Using the practice improvement methodology, the project followed a sequence of steps starting with the identification and diagnosis of the problem; measuring the size and scope of the problem; identifying the most appropriate interventions for our particular context; implementation of the interventions and finally, a re-measurement of the baseline indicators to ascertain if the interventions had been effective (NSW Health 2003). This sequence is represented graphically in Figure 1. The Shewart-Nolan Practice Improvement Model.

[Insert Figure 1 about here]

Ethical issues:

This is an evidence implementation project and like other such projects it is considered to be of low or negligible ethical risk (Hutton, Eccles & Grimshaw 2008). However, an ethics self assessment checklist for quality improvement projects was completed, as required by organisational policy and this confirmed that there were no identifiable ethical issues that would require full ethics review.

Setting:

The project ran over a twelve month period in a 250 bed acute care private hospital in metropolitan Australia. The hospital has over 20,000 separations annually and caters for all surgical and medical specialties excluding maternal and paediatric care. The case mix is 70% surgical and 30% medical and 45% of the patient population is over 65 years of age. Given that warfarin is a complex therapy, requiring coordinated interdisciplinary care, the target population for the project interventions included all nursing, pharmacy and medical staff.

Measures:

A number of process and outcome indicators were used as project measures. The measurement of process indicators is based on the premise that when a process is evidence-based it can be assumed that an improvement in compliance with the process will result in a subsequent improvement in patient outcomes (CEC 2007b). The warfarin process indicators from the Quality Use of Medicines in Australian Hospitals indicator set (CEC 2007b) were selected and include:

1. Percentage of patients with an international normalized ratio (INR) above 4 whose dosage has been adjusted or reviewed prior to the next warfarin dose;
2. Percentage of patients with atrial fibrillation who are discharged on warfarin;
3. Percentage of patients discharged on warfarin who receive written information regarding warfarin management prior to discharge;
4. Percentage of patients prescribed hospital initiated warfarin whose loading doses are consistent with hospital approved protocol.

Warfarin specific outcome indicators from the Australian Council of Healthcare Standards (ACHS 2007) clinical indicator set were also selected. The four outcome indicators relevant to warfarin therapy from this set are:

1. Percentage of patients receiving warfarin who experience abnormal bleeding;
2. Percentage of patients receiving warfarin who experience a cerebral haemorrhage;
3. Percentage of patients receiving warfarin with an INR greater than 5;
4. Percentage of patients receiving warfarin who die as a result of an adverse event.

Planning the intervention:

The project was made feasible by the appointment of a part-time project facilitator (first author) whose position was funded through a multidisciplinary research grant. The facilitator was a Clinical Nurse Specialist (CNS) who was supported and mentored by a senior nursing academic (second author) also employed by the hospital.

A multidisciplinary team of doctors, pharmacists, managers and academics as well as a consumer representative was formed to address the problem. The inclusion of a consumer representative was particularly important. It provided a patient perspective which significantly helped in shaping the way the project was conceived and implemented, enhancing the project's chance of success. Bringing together the multidisciplinary team ensured 'buy in' from each of the professional groupings and enabled a shared vision and goal to be articulated and confirmed by all. This was pivotal to the project's realisation and established a much higher degree of confidence in the likelihood of its success than would otherwise have been the case.

The team then set out to identify and diagnose the potential barriers to the provision of evidence-based warfarin therapy in our organisation. This involved collection of baseline audit data and the conducting of structured brainstorming sessions with medical, nursing and pharmacy clinical staff. The focus of these sessions was to identify the barriers to safe and effective warfarin therapy for inpatients. The results were then organised and collated by the project team into a cause and effect diagram, otherwise known as a fishbone diagram (see figure 2). This information was then used to help identify specific project interventions that would overcome our identified barriers.

[Insert Figure 2 about here]

Project Interventions:

After review of the diagnostic data (baseline audit results and brainstorming sessions) the project team identified three specific aims for the project, namely:

1. Increase the percentage of patients who receive warfarin education prior to discharge to 100%;

2. Increase the percentage of patients whose loading dose is consistent with approved protocol by 10% and;
3. Maintain adverse outcomes below the ACHS benchmark level.

In order to achieve these aims the team developed a set of multifaceted interventions specifically targeted at improving clinician compliance with best practice in these areas. The implementation science literature was used to inform the selection of these interventions. Implementation research is the scientific study of interventions to promote the systematic uptake of clinical research findings into routine clinical practice (Schünemann *et al* 2004) and a number of beneficial interventions have previously been studied including educational outreach, reminders, educational meetings, audit and feedback, and the provision of educational materials (Grimshaw *et al* 2004; Schünemann *et al* 2004; Grol, Eccles & Wensing 2005; Ostini *et al* 2009). The strategies selected for this project are listed and discussed below:

Decision support tools:
Two decision support tools were trialled and implemented to assist clinicians in making informed, evidence-based choices regarding their patients' warfarin management.

The first decision support tool -for medical staff- was an evidence-based nomogram to aide in the selection of loading doses for patients commencing on warfarin therapy. These nomograms have been shown to decrease the incidence of bleeding associated with warfarin commencement whilst achieving therapeutic levels in a comparable time to that seen with unaided physician prescribing (ICSI 2006). It was decided that the uptake of the nomogram by medical staff would be maximised if it was placed on the reverse of the current warfarin chart, effectively putting it directly in the hands of every warfarin prescriber. Bereznicki and colleagues (2007) note that this strategy is especially useful in increasing prescriber compliance with dosing guidelines.
The second tool was directed at nursing staff and came in the form of an evidence-based electronic clinical pathway for patients on warfarin. The hospital is fortunate to have a sophisticated electronic patient records system which includes electronic clinical pathways. The project team worked with the information technology department to develop a new evidence-based electronic clinical pathway for patients

commencing on warfarin. This pathway consisted of a checklist of interventions and reminders for clinical staff. The interventions and reminders are automatically triggered as the patient passes predetermined clinical milestones. For example, the reminder to send an INR each morning is automatically cancelled when the patient has achieved therapeutic levels for more than two consecutive days. This simple yet effective intervention is supported by the literature which demonstrates that the use of checklists and reminders in clinical pathways significantly improves compliance with evidence-based guidelines (Wolff, Taylor & McCabe 2004).

Education initiatives:

Education initiatives were divided into patient and staff-specific initiatives. A review of our patient education processes was undertaken by the project facilitator in consultation with clinicians and following this a number of changes were initiated.

The highest priority for clinicians was the reintroduction of the 'warfarin booklet'. The patient education booklet supplied by the pharmaceutical manufacturer had recently been discontinued and replaced with two loose-leaf sheets of paper. Although the information provided on these sheets was similar, patients and staff felt that the loose-leaf sheets were easily misplaced or damaged. As well, these sheets did not contain a place to record the patient's INR results, whereas the booklet did. A major challenge and subsequent achievement of the project was the petitioning of the pharmaceutical manufacturer and successful reinstatement of the previous warfarin education booklet. Staff also expressed the need for the warfarin booklet to be available in languages other than English; accordingly it was translated into the most common languages of our patient population. A warfarin patient education DVD was also purchased as an optional education tool.

A warfarin patient education checklist was developed to assist staff in providing and assessing warfarin education. The checklist was a double sided form. On one side was a set of warfarin patient education learning objectives (adapted from the Liverpool Hospital Safer Systems Saves Lives project 2006). Having these objectives helped standardise patient education sessions and prevent the omission of important information. The list of objectives enabled staff to record and track patients' warfarin education accurately thus making it possible to stagger the process of information-

giving over the course of a patient's admission. Having the objectives in the patient notes also reminded other staff to reinforce the information at every opportunity.

On the other side of this form was a tool to assist clinicians to asses their patients' warfarin knowledge as well as their self confidence in their ability to manage the therapy on discharge. Although it has not been unequivocally established in the research that these two factors directly influence patient outcomes, the literature suggests that an association between them can nevertheless be inferred (Newal, Morgan & Johnston 2005). The form also has an area for the documentation of a 'medicines discharge plan'. This plan contains information on patient follow-up. Follow-up options differed between patients based on their knowledge, self confidence and ability to achieve their learning objectives. Patients could be followed-up by phone or through our extended care home visiting program.

In relation to staff education, the project team agreed with research findings that didactic lectures have little impact on changing clinician behaviour (Grimshaw *et al* 2004; Schünemann *et al* 2004). It was therefore decided that the staff education initiative would comprise a self-paced online information package. This type of approach is described as 'just in time' education, where learners can access information as it is needed and when it is relevant (Hunt, Sproat & Kitzmiller 2004). This approach was less resource-intensive then traditional ward in-services and was also sustainable beyond the life of the project.

Audit and feedback:

Process and outcome indicators were monitored throughout the course of the project through monthly chart audits. This served two important functions: Firstly, it provided a measure of the impact of the various project interventions, and secondly, it enabled regular feedback to the various clinicians, providing an ongoing motivation to change. Audit and feedback is one of the most effective strategy for producing behavioural change in clinicians both on its own and when used, as in this project, as part of a multifaceted approach (National Health & Medical Research Council [NHMRC] 2000;Grimshaw *et al* 2004; Schünemann *et al* 2004; Tooher *et al* 2005).

Opinion leaders:

Opinion leaders have been well demonstrated to have an influence on the clinical practice of their peers (NHMRC 2000; Grimshaw *et al* 2004; Schünemann *et al* 2004; Tooher *et al* 2005). Practice improvement initiatives require championing by key stakeholders. In our project it was important to secure the support and input from senior physicians, nurses, educators and managers. Consequently, key opinion leaders were recruited onto the project team. These included an influential vascular physician, the nurse unit managers and educators of the vascular and cardiac wards, and the director of nursing.

Data Collection and Analysis:

The baseline and ongoing collection of process and outcome clinical indicator data was collated in monthly retrospective chart audits of all patients identified as being on warfarin therapy. Inpatients currently on warfarin therapy were identified from a number of sources including pathology, pharmacy and patient health history records. The audits were conducted by an experienced registered nurse following audit guidelines setout by the CEC and ACHS.

The audit results were displayed in Statistical Process Control (SPC) charts. There are a number of different types of SPC charts but all are based on observing the variability of data in relation to the mean. In SPC charts a central line is plotted on the graph representing the mean and then upper and lower control limits (UCL & LCL) are plotted at three standard deviations from that mean (Benneyan, Lloyd & Plesk 2003). Theoretically, 99.74% of all data should fall within these control limits and thus, these boundaries are used to help define the threshold for special cause variation and statistical significance (Portney & Watkins 2009). A number of other criteria for defining special cause variation are also common and include: Any one point that falls outside the 3 standard deviation control limits; 2 out of the last 3 points falling outside the 2 standard deviation limit; 4 out of the last 5 points falling outside the 1 standard deviation limit; 8 or more consecutive points all above or all below the mean, also called a ‘run’; and 6 or more consecutive points moving up or down across the mean, also called a ‘trend’ (Portney & Watkins 2009; National Health Services Scotland ND).

RESULTS

Baseline:

The baseline audit of process indicators showed that there was 100% compliance with reviewing patients with INRs >4 prior to their next dose. It also showed that 94% of all patients with AF were being discharged on warfarin. In light of these good results the project team decided to concentrate on the two indicators with the poorer compliance rates, namely, the percentage of patients who receive written information prior to discharge, at 31%, and the percentage of patients whose initial dose is consistent with approved protocol, at 42%.

At the time of the baseline audit none of the ACHS adverse warfarin outcomes were identified. There were no bleeds, cerebral haemorrhages, deaths, or INRs >5 in the month audited. However, the project team acknowledged that these events are rare and therefore not easily detected in a single audit. Consequentially, it was decided to maintain the ongoing monitoring of these indicators over the course of the project.

Process indicators:

Prescriber compliance with the hospital-approved loading protocol increased over the course of the project by 12% from 42% to 54%. These results are not statistically significant but they do suggest that our multifaceted interventions were, at least in part, effective (note the absence of any special cause rule violations in figure 3). This 12% improvement is greater than the project target which was set at 10%. This conservative target was chosen based on the extensive literature which describes the difficulty in modifying doctors' prescribing practices (Dartnell 2001; Ostini *et al* 2009).

[Insert Figure 3 about here]

The number of patients receiving education prior to discharge increased dramatically over the course of the project from 31% to 85% an increase of 55%. This was a statistically significant improvement as seen by the two special case rule violations evident in figure 4. Although a significant improvement it does fall a little short of the ACHS benchmark, of 88%, and our own project target, of 100%.

[Insert Figure 4 about here]

Outcomes indicators:

The percentage of patients with an INR > 5 decreased over the course of the project falling from 3.7% to 1.1%. This was below the ACHS level which was 3.5%. This is an important clinical improvement given patients are much more likely to suffer a serious adverse event if levels are not contained within the recommended range between 2 to 3 (Gallus *et al* 2000). The percentage of patients who experienced abnormal bleeding fell from 1.2% to 0% over the course of the project, again staying below the ACHS benchmark level which was 1.4%. The percentage of patients who experienced a cerebral haemorrhage and the percentage of patients who die as a result of an adverse reaction to warfarin remained unchanged throughout the course of the project at 0%. This was equal to or better than the ACHS reported figures of 0.12% and 0% respectively.

[Insert Figure 5 about here]

An unexpected result identified on analysis of the SPC charts was the dramatic decline in all measures during the December audit. The percentage of patients receiving written information prior to discharge decreased in that month, returning to almost baseline levels of 39%. A significant decline was also seen in the percentage of patients whose loading dose was consistent with approved protocol (note the LCL violation in figure 4). This indicator fell to 20% which was 25% below the initial baseline level. In this same month there was also a significant spike (note the UCL rule violation in figure 5) in the number of INRs >5, increasing from 4% to 14% of all cases.

The decline in these process indicators may reflect operational changes common in most private hospitals during the holiday season. Routinely during this period there are ward closures and extensive levels of staff leave (annual and recreational) or are relocated outside their 'home' unit and this can potentially result in patients being cared for by nursing and medical staff who are unfamiliar with warfarin therapy management procedures. The increase in INR outcome indicator may also be influenced by the holiday season. At this time of year many patients experience

significant changes to their normal routine including changes to their diet and their alcohol consumption which can lead to fluctuations in INR levels (Hirsh *et al* 2008; ICSI 2006; Gallus *et al* 2000).

DISCUSSION

Prior to this project, the lack of a coordinated multidisciplinary approach to warfarin therapy had proven the major obstacle to achieving safe and effective practice in our organisation. Increasingly, nurses are taking on the role of clinical leaders, modifying and transforming policy and practice within the multidisciplinary environment (Davidson, Elliot, Daly 2006).The clear success of this project is directly attributable to the depth and breadth of the multidisciplinary collaboration which was achieved from nursing leadership. The project was facilitated and led by a CNS working within a model of interdisciplinary team leadership. This approach focuses on the joint success of the team rather than any single individual's performance (McCallin 2003). Because nurses are many and their skills varied, they are very well placed to work across the multidisciplinary team.

The increasing emphasis on the consumer and consumer participation has been said to have helped empower nurses to take the lead in clinical practice issues (Davidson *et al* 2006). This project had a strong consumer focused approach and from the outset the project team agreed to adhere to a Quality Use of Medicines (QUM) philosophy. One of QUM's guiding principles is the primacy of the consumer (Department of Health & Ageing 2002). Consumers bring a different perspective to a project providing a constant reminder that the true aim of any quality project, with knowledge transfer as its core goal, is ultimately to improve patient outcomes. The inclusion of a consumer representative was so successful that it has since been adopted into subsequent hospital quality projects.

This project was also one of the first in Australia to use the MSSA-AT which had only recently been contextualised for our healthcare sector by NSW TAG and the CEC. This tool was useful to the project in a number of ways. Firstly, it required a multidisciplinary group to gather and discuss anticoagulation management and this in itself was seen as a benefit. Secondly, this group then rated our organisation against the best practice initiatives in the MSSA-AT. The results of the self assessment

provided us with a baseline measure of our current anticoagulation practices and also enabled us to anonymously benchmark ourselves with hospitals of comparable demographics.

It has long been known that the best science often fails to influence clinical practice (Lenfant 2003; Green & Seifert 2005; Duffy 2005; Ginexi & Hilton 2006; Sussman et al 2006; Lang et al 2007). This so-called 'evidence-practice' gap has received significant attention in academic debate (Ousey 2000; Segaric & Hall 2005; Rooks 2006; Walker 2008). As many commentators now well understand, the process of transferring the results of empirical research into clinical practice is fraught with complexity (see Graham et al 2007; Gerrish & Mawson 2005; Doran & Sidani 2007; Lang et al 2007). The key to enduring and positive cultural change is embedding changed attitudes, values and behaviours into everyday organisational life. A major component of this is 'hard wiring' these changes into institutional policy, procedure and practice.

We believe this was achieved in this project in a number of ways: First, two protocols (a warfarin commencement and warfarin reversal protocol) were developed and endorsed by the organisation. The protocols were then posted on the clinical website and incorporated into hospital policy and procedure structures and processes. Second, the new warfarin clinical pathway was successfully integrated into existing processes and now sits within the organisation's computerised clinical pathway system available for all clinicians to use as part of their everyday practice. Third, the use of an online self-paced education module also provided project sustainability, enabling ongoing staff education on warfarin therapy well beyond the life of the project. Finally, in an effort to maintain improvements, the warfarin process and outcomes indicators have been delegated to the Pharmacy Department for ongoing monitoring and are now included in routine hospital reporting.

One particular challenge of auditing the records of patients on warfarin therapy is the identification of these patients. Warfarin therapy is not limited to one patient group, neither is there a specific medical coding allocated to their record. In this project the identification of these patients required the collation of information from a number of different sources. The hospital pharmacy system could report on patients who had

been dispensed warfarin but this did not cover those patients who had brought in their own medication; the electronic patient medical record database could report on patients who were on warfarin prior to admission but this did not capture patients who had just commenced treatment. As well, the pathology system could report patients who had had an INR taken but not all patients may have required an INR. Using all three data sources, however, it was possible to identify the majority of cases.

CONCLUSION

This multidisciplinary project used clinical indicator data and a practice improvement methodology to transfer knowledge of best practice warfarin therapy. The multidisciplinary team achieved some significant progress in warfarin management and patient outcomes including a 12% improvement in compliance with warfarin initiation guidelines; a 48% improvement in patients receiving warfarin education prior to discharge and; an incidence of adverse events maintained well below the Australian Council on Healthcare Standards benchmark. The project has not only improved patient outcomes but has also helped increase the interest and acceptance of nurse-led, multidisciplinary, evidence-based quality improvement initiatives within the organisation.

Postscript:

This project was entered into and received two nationally competitive awards, namely, the ACHS Quality Improvement Award for 2008 and the Australian Private Hospitals/Baxter Award 2008 for Clinical Excellence (quality of care and patient outcomes).

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Figure 1: The Shewart-Nolan Practice Improvement Model.

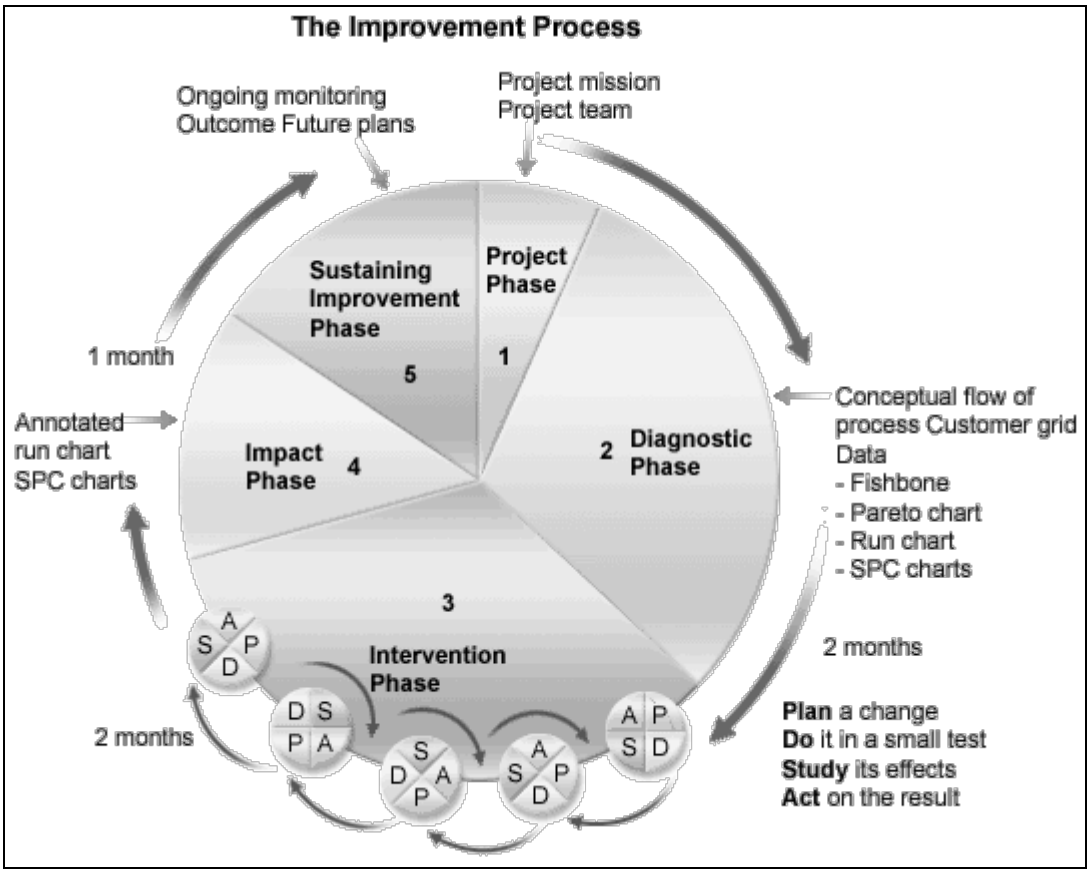

Figure 2: Fishbone Diagram: Barriers to evidence-based warfarin management.

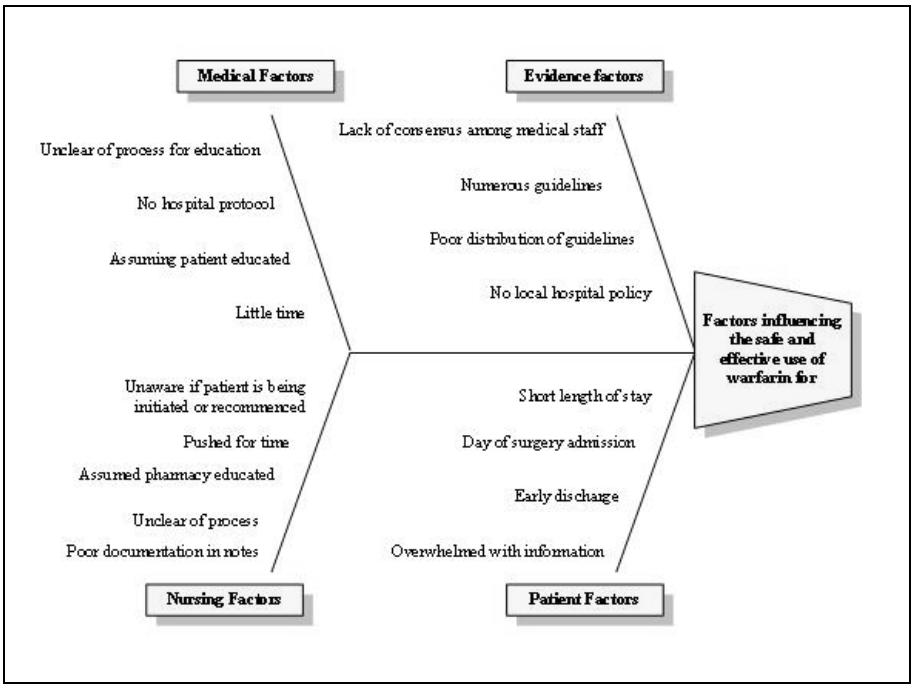

Figure 3: Process Indicator**:** Percentage of patients prescribed hospital initiated warfarin whose loading doses are consistent with approved protocol.

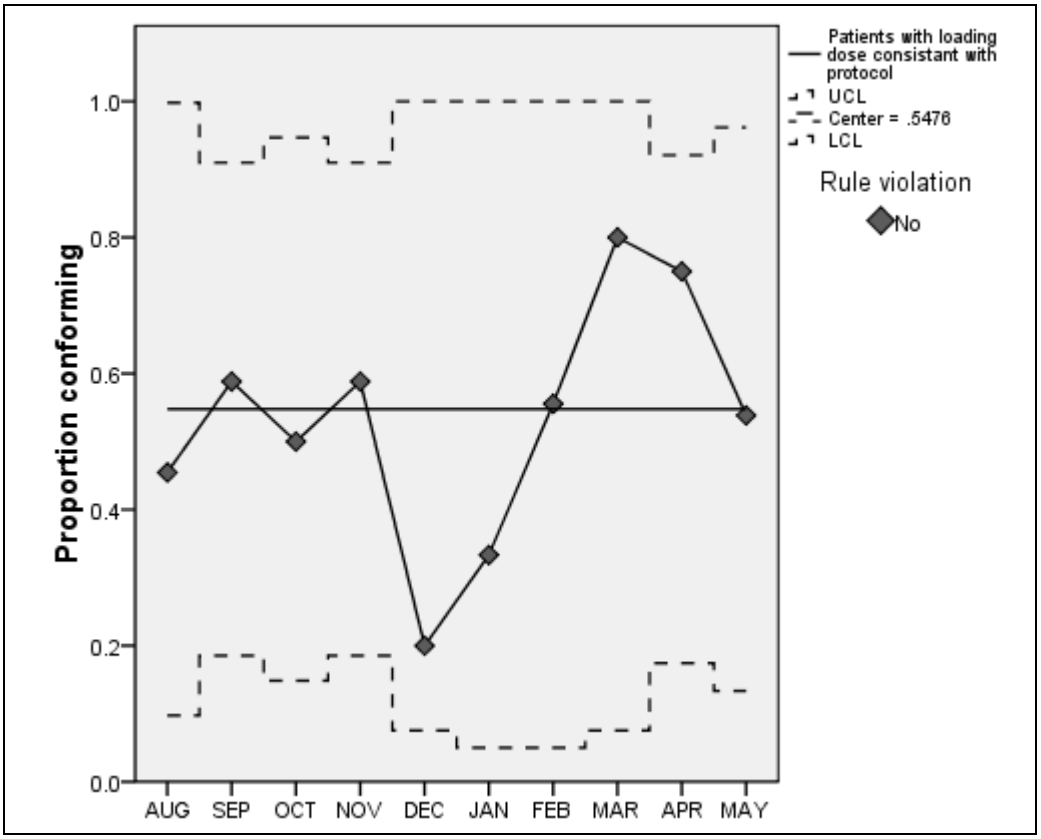

Figure 4: Process Indicator: Percentage of patients discharged on warfarin that receives written information regarding warfarin management prior to discharge.

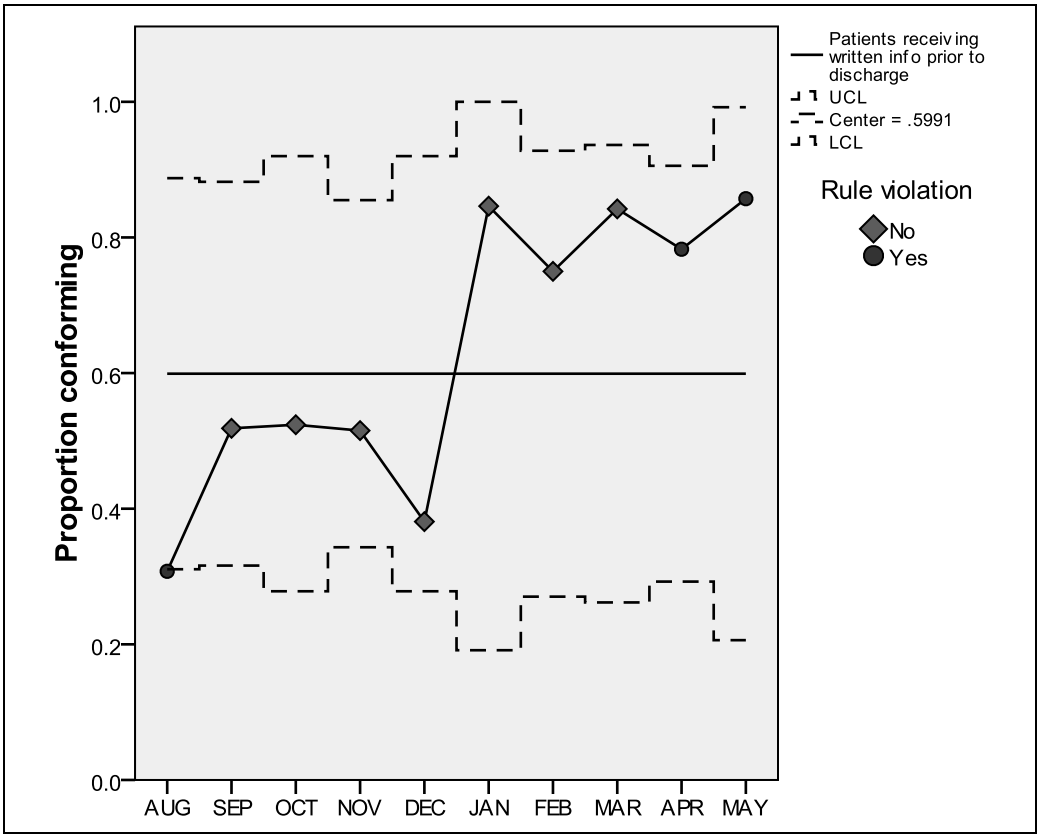

Figure 5: Outcome Indicator**:** Percentage of patients receiving warfarin with an international normalized ratio (INR) >5.