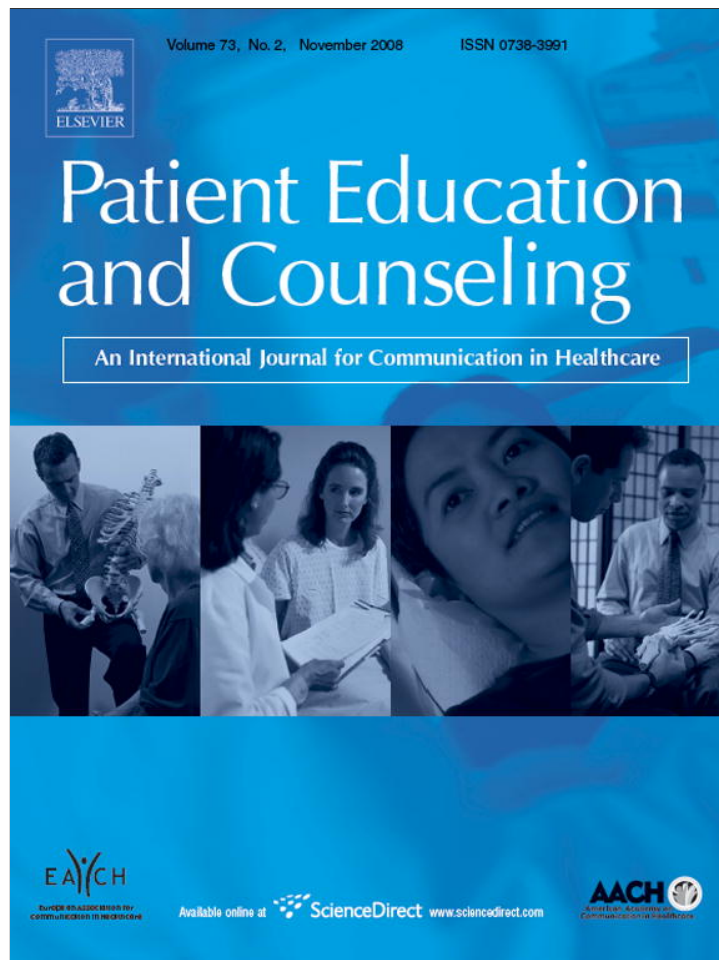


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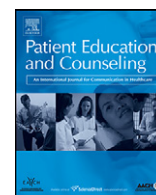
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Optimising anticoagulant education in the paediatric setting using a validated model of education[☆]

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ABSTRACT

Objective: Providing education to patients requiring anticoagulant therapy may be associated with improved outcomes. This study investigated the knowledge outcomes of a validated educational intervention.

Methods: Parents of children with congenital heart disease requiring warfarin therapy took part in an educational intervention. Warfarin knowledge was assessed prior to commencing the program, immediately following its completion and 6 months following completion.

Results: Parents demonstrated a statistically significant improvement in their warfarin knowledge immediately following completion of the program ($p < 0.0001$), with this improvement being sustained over time.

Conclusion: Current approaches to educating parents of children requiring warfarin therapy are likely suboptimal. Using a validated model of education may be associated with improved knowledge outcomes for patients.

Practice implications: Consideration to the processes used in delivering patient education may result in improved patient knowledge outcomes.

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1. Introduction

Warfarin (CoumadinTM or MarevanTM) is the most widely prescribed anticoagulant in the world and is prescribed for the treatment or prevention of thrombotic complications [1]. The management of warfarin is complicated by its narrow therapeutic window which necessitates regular blood monitoring to ensure safety and efficacy of therapy.

The level of knowledge the patient and family have regarding warfarin therapy is indirectly proportional to their risk of complications, primarily major bleeding [2,3]. As major bleeding is the

most serious side effect of warfarin therapy, education programs that inform families of techniques to reduce that risk are of significant importance.

Numerous papers have been published with respect to the provision of warfarin education to adult patients [3–11]. Unfortunately, these papers did not routinely assess whether their interventions were associated with the primary aim of patient education, that is, an improvement in patient understanding. No papers to date have been published addressing warfarin education in the paediatric setting.

A nurse-coordinated Anticoagulation Clinic was established at the Royal Children's Hospital (RCH) (Melbourne, Australia) in April 1999. All patients requiring warfarin management at this institution must be referred to the Anticoagulation Clinic. At the time of commencing this study, 86 children were receiving warfarin management. As RCH is the major cardiac referral centre for south-eastern Australia, the majority of patients managed by the Anticoagulation Clinic had an underlying cardiac anomaly.

The anticoagulation service routinely provides warfarin education to patients and their families. In the past, families were provided with information regarding their child's indication for warfarin

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Abbreviations: RCH, Royal Children's Hospital; PRECEDE, Predisposing Reinforcing and Enabling Causes in Educational Diagnosis and Evaluation; INR, International Normalised Ratio.

therapy, warfarin tablet presentation and dosing, warfarin's mechanism of action, monitoring requirements, possible confounders to stable therapy and potential warfarin-related adverse events. A purpose-designed handout reiterating key principles of warfarin therapy in children was provided to families. This education was not based upon any established model or published template for warfarin education. Parental understanding of warfarin therapy following implementation of this education strategy was previously assessed and found to be suboptimal [12]. Only 26% of parents knew why their child was receiving warfarin. Parental understanding of the timing of warfarin's effect and the impact of dietary changes upon control of anticoagulation was particularly poor.

We hypothesised that a coordinated education strategy, using a validated model of education, would likely produce improved knowledge outcomes for the parents of children requiring warfarin therapy. As well as determining whether such an intervention produced an immediate improvement in parental understanding of warfarin therapy, we aimed to determine if any such improvement could be sustained over time. A structured plan outlining the objectives and strategies that would facilitate achievement of desired outcomes was developed [13–15]. For the purpose of this study, the Predisposing, Reinforcing and Enabling Causes in Education Diagnosis and Evaluation (PRECEDE) model of health education was employed [14]. The PRECEDE model had previously been used to develop a successful education intervention for adult patients receiving warfarin therapy [7]. This model enables the development of a rigorously designed and structured educational intervention [14].

2. Methods

Data obtained from a previous assessment of parental understanding of warfarin therapy at the RCH was used to determine knowledge deficits and key learning needs [12]. The PRECEDE educational model provided the framework for this educational intervention. The program incorporated oral presentation, group discussion and the provision of written material. Fig. 1 summarises the education program.

All families of children requiring warfarin therapy at the RCH who had English language proficiency ($n = 86$) were invited to participate in this education and training program, which also incorporated a pilot study of home monitoring of warfarin therapy. English proficiency was assessed during clinical interaction with families. Due to resource constraints, a maximum of 15 families could be entered onto the home International Normalised Ratio (INR) monitoring program. This study was approved by the RCH Ethics in Human Research Committee.

Parents who provided written informed consent to participate in the education and training program were required to attend two group learning sessions and two individual sessions scheduled over a four-week period. A *Warfarin Education Manual* was developed to provide written material that mirrored the content of the lecture and group discussions.

Knowledge was assessed at three time points: baseline, at program completion and at 6 months post program completion. A questionnaire was developed to facilitate assessment of parental understanding using a combination of multiple choice, short answer and true/false questions (Appendix A). This questionnaire was reviewed by non-clinical personnel within the RCH Division of Laboratory Services to determine its suitability for the target population based upon an estimated reading competency level of 12 years of age. The University of Melbourne Statistical Unit reviewed the questionnaire for face validity. Each question on the 12-point questionnaire had a numerical value assigned reflecting a perfect answer. These values combined to form a perfect score of

40 points. Data was analysed descriptively using percentages and means (plus standard deviations, confidence intervals and/or ranges). The results of knowledge assessment at the different time points were analysed using paired *t*-tests. A *p* value of less than 0.05 was considered to be statistically significant. Data generated was analysed using a statistical software package, STATA, release 8.1 (Stata corporation, College Station, TX).

3. Results

Fourteen families with children who were established on warfarin therapy provided written informed consent to participate in this program which commenced in March 2003 and concluded in October 2003. One parent only from each family completed all the study requirements (10 mothers; 4 fathers). This parent was self-chosen as the person designated to perform the home INR tests. The academic background of participating parents ranged from parents with a high school certificate to post-graduate university qualifications. The mean age of children was 14.6 years (range 6.6–23 years). All patients had an underlying cardiac anomaly and required warfarin for primary thromboprophylaxis. At each of the three assessment points, all parents demonstrated a sound understanding of their child's primary medical condition (question 2).

Table 1 summarises the results of the questionnaire that was used to determine the level of parental understanding specific to warfarin therapy in children. Parental understanding significantly improved in all areas following completion of the education program, with this improved knowledge being maintained 6 months later.

A maximum score of 40 was achievable on the questionnaire. Two-sample *t*-test identified a significant difference between the baseline mean score on the knowledge assessment questionnaire (22.0; 95% CI 20.3–23.7) and the second assessment conducted at the completion of the education program (33.1; 95% CI 31.4–34.7) ($p < 0.0001$). A similar significant difference was found between the baseline score and that achieved on the third assessment, 6 months after program completion (32.4; 95% CI 30.3–34.6) ($p < 0.0001$). There was no statistical difference between scores achieved on the second and third assessments.

4. Discussion and conclusion

4.1. Discussion

The provision of education to patients requiring oral anticoagulant therapy has reportedly been associated with significant benefits, including improved compliance, reduced frequency of adverse events and improved stability of therapy [2,3,16–20]. Invariably, studies reporting such outcomes have assumed the benefits reflected improved knowledge outcomes following education. Whether these reported improvements in clinical outcomes are reflective of an improvement in patient understanding or a response to feeling supported remains unclear as discrete knowledge outcomes were not assessed. Our study aimed to discover the level of understanding parents of children requiring warfarin therapy obtained following a novel educational intervention based upon an established model of education [14]. This study is the first published report of an intervention aimed at optimising warfarin education within a paediatric setting.

The medical literature pertaining to anticoagulant management reports that providing warfarin education to patients and families is associated with improved outcomes. Warfarin's likelihood for having numerous interactions would suggest patient education is of vital importance [21]. However, the literature to date has largely

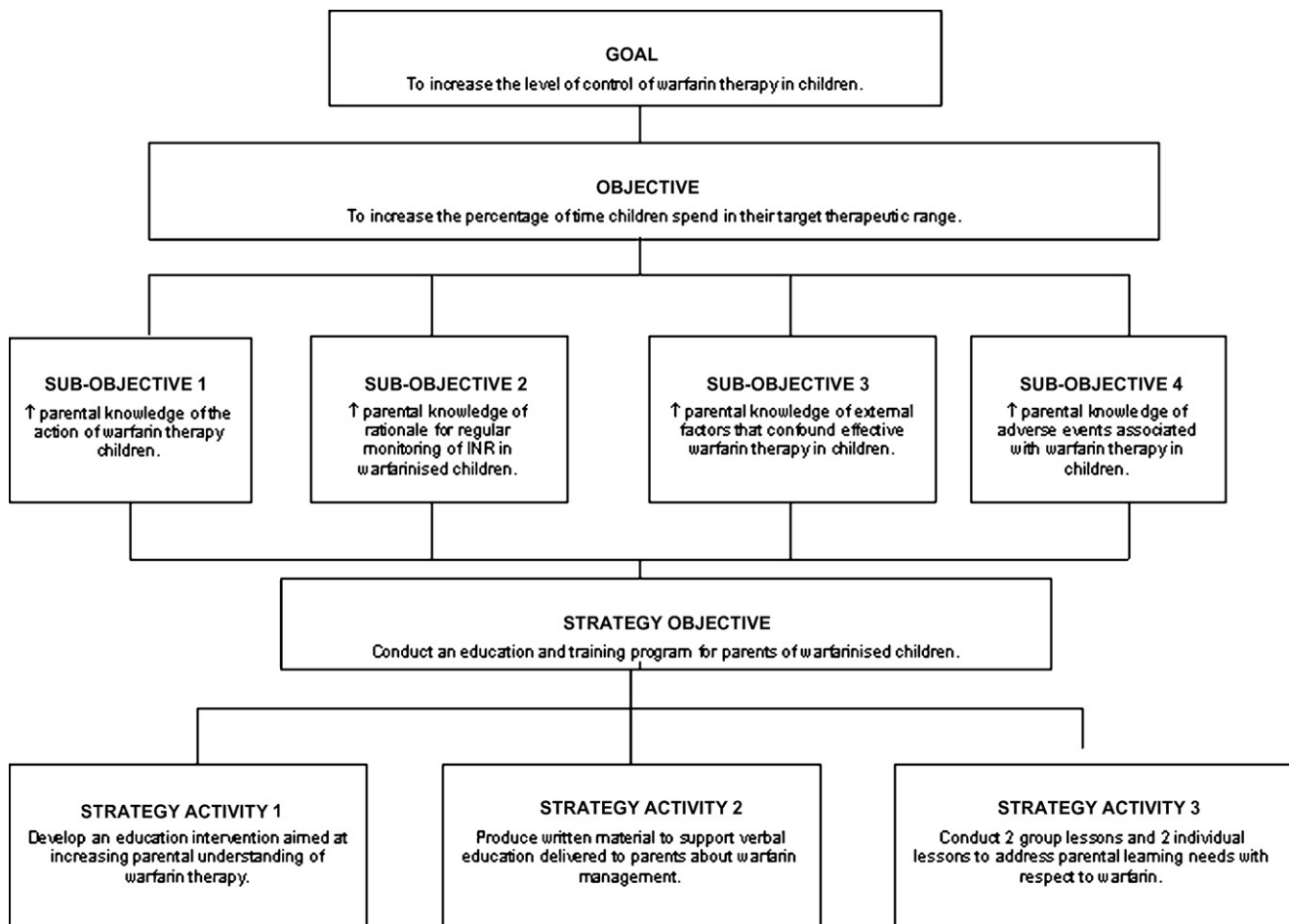


Fig. 1. Education plan for teaching parents about warfarin therapy in children.

overlooked the one key outcome of patient education, that being an improvement in patient understanding. If educational strategies currently employed are not successfully teaching patients about their therapy, consideration must be given to the processes by which that education is being delivered. It has been suggested that improved knowledge outcomes in patients can be achieved by using validated models of education to guide the delivery of interventions aimed at increasing patient understanding [13].

The novel educational intervention for parents of children requiring warfarin therapy was implemented over a 7-month period, with 14 families with a child established on warfarin therapy participating. Participation in this program was limited due to resource constraints imposed by the concomitant home INR monitoring study. All child participants in this study had an underlying cardiac anomaly, which is consistent with the most common indication for anticoagulation therapy in a paediatric

Table 1
Summary of parental understanding following participation in the novel education program

Question number (format)	Question	Baseline assessment	Second assessment (program completed)	Third assessment (6 months after program completion)
Percentage (%) correct				
1. Short answer	Understood indication for warfarin	28	93	86
3. Short answer	Knew timing of warfarin's effect	50	100	86
4. Short answer	Knew name of test used to measure warfarin	86	100	100
5. Short answer	Understood warfarin's mechanism of action	17	80	76
7. Multi-choice	Knew regular exercise did not interfere with warfarin stability	71	100	100
8. True/false	Knew Vitamin K reverses warfarin's anticoagulant effect	93	100	100
11. Short answer	Knew the estimated annual risk of major bleeding associated with warfarin therapy	43	100	100
12. Short answer	Knew their child's target therapeutic INR range	100	100	100
Number				
6. and 9. Multi-choice	Number of factors known to affect warfarin therapy	2.6	6.8	5.9
10. Short answer	Number of known warfarin therapy complications (excluding bleeding)	0.6	3.8	3.5

*Question 2 measured parental understanding of underlying illness

population [22–24]. The age-range of child participants in this study was skewed towards an older age compared to the total population of children receiving warfarin management at this institution [24]. This difference was attributed to the demands of the home INR monitoring study which may have discouraged parents of younger children from participating.

The key outcome of this intervention was parental knowledge. The PRECEDE model of health education formed the basis for the parent education program. All parents who participated in this program demonstrated a statistically significant improvement in their understanding of warfarin therapy in children compared to baseline levels, with this improved understanding being retained 6 months after completion of the program. This same model of health education has been used to guide the development of a warfarin education program for adults on one occasion [7]. Although methods of statistical analysis differed between the current study and that previously reported, both confirm improved and sustained patient/parental understanding following implementation of an education program based upon the PRECEDE model. Use of the PRECEDE model of education provided valuable structure to the educational program and facilitated process evaluation of the intervention.

4.2. Conclusion

The hypothesis that a coordinated education strategy using a validated model of education would achieve improved knowledge outcomes for parents of children receiving warfarin therapy is supported. This concept has never previously been reported in the area of paediatric anticoagulant management, and indeed, has been referred to rarely in the adult literature. As such, it is difficult to compare the outcomes of this educational intervention to anything in the published literature that has a similar patient demographic. Future studies need to address whether increased patient understanding, rather than the mere attendance at an education session, is truly associated with an improvement in secondary outcome measures such as frequency of adverse events, stability of therapy and quality of life.

The number of participants in this educational intervention was small, however the magnitude of change in parental understanding of warfarin therapy in children was highly significant. The outcomes of this novel education program may be limited by the concurrent participation of parents in a pilot study of home INR monitoring. Parents who have no desire to be involved in the monitoring of their child's anticoagulant therapy may not be as motivated as this cohort of parents, and may therefore not have achieved similar levels of knowledge improvement.

4.3. Practice implications

Consideration must be given to the best method of reinforcing key principles of warfarin management that may increase the stability of warfarin therapy over time. The implementation of the PRECEDE-based education program produced improved knowledge outcomes that were sustained at a time of reassessment, 6 months after the program's implementation. It is unlikely that such a level of parental understanding will be maintained over a longer period of time if some form of reinforcement is not provided. The medical and nursing literature has not adequately assessed this issue in relation to any educational intervention targeting medication knowledge.

Consideration should be given to the processes by which patients are educated about medications such as anticoagulants. This study was undertaken as existing processes for educating parents about their children's anticoagulant therapy were found to

be suboptimal. Providing parents with warfarin education based upon a validated education model was associated with a statistically significant improvement in parental understanding of warfarin therapy that was sustained over time.

Acknowledgement

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Appendix A. Knowledge assessment questionnaire

1. Why is your child taking warfarin?
2. Does your child have an underlying medical condition? (circle) Yes/No. If yes, specify:
3. If your child takes a dose of warfarin today, when will that dose affect the result of their monitoring test?
4. What is the name of the test used to measure warfarin?
5. In your own words, explain how warfarin works.
6. What factors make managing warfarin in children and teenagers more difficult than managing warfarin in adult patients? (list as many as you know of)
7. Which of the following does NOT interfere with stable warfarin therapy?
 - a. Over the counter herbal preparations.
 - b. Regular exercise.
 - c. Changing brands of warfarin.
 - d. Sporadic alcohol intake.
 - e. Halving or quartering warfarin tablets.
 - f. Occasional omitted doses.
8. Vitamin K can be used to reverse the blood thinning effect of warfarin. True/False.
9. Which of the medicines on the list below do you think CAN be given to a child receiving warfarin without concern for its effect?
 - paracetamol
 - naprosyn
 - phenergan
 - aspirin
 - dimatapp
 - garlic tablets
 - horseradish tablets
 - Vitamin C
 - St John's Wort
 - Gingko jojoba
 - Antibiotics
10. Write down any warfarin-related side effects that you know of, besides bleeding.
11. In any given 12-month period, what is the estimated risk of a person taking warfarin having a major bleeding event? (____% per year).
12. Do you know the "target range" of your warfarin therapy?
 - Yes or No
 - If yes, what is it?

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