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Short communication

A patient-centered approach to the development and pilot of a warfarin pharmacogenomics patient education tool for health professionals

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Abstract

Objective: To describe an exploratory project to develop and pilot a novel patient educational tool that explains the concept of pharmacogenomics and its impact on warfarin dosing that can be utilized by health professionals providing patient counseling.
Methods: A pharmacogenomics educational tool prototype was developed by an interdisciplinary team. During the pilot of the tool, focus group methodology was used to elicit input from patients based on their perspectives and experiences with warfarin. Focus group sessions were audio recorded and transcribed, and the data were analyzed through consensus coding in NVivo.
Results: The focus group participants were generally unfamiliar with the concept of pharmacogenomics but were receptive to the information. They thought the patient education tool was informative and would provide the most benefit to patients newly initiated on warfarin therapy.
Conclusions: Preliminary results from this exploratory project suggest that implementation and further feasibility testing of this pharmacogenomics patient education tool should be performed in a population of newly initiated patients taking warfarin.

Keywords: Pharmacogenomics; Patient education; Warfarin; Individualized medicine

Introduction

Warfarin is an oral anticoagulant medication commonly used for the treatment or prevention of thromboembolic disorders. Management of patients on warfarin can be challenging due to the need for long-term therapy and frequent laboratory monitoring to maintain a therapeutic international normalized ratio (INR). Significant patient counseling efforts are expended and health care resources utilized to educate patients and their families about warfarin medication compliance, drug–food interactions, drug interactions, and laboratory follow-up. As part of the Joint Commission National Patient Safety Goals for hospitals, such education is initiated in the inpatient setting.[1,2] Well-informed patients taking warfarin

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demonstrate enhanced medication adherence, which may result in increased efficacy of the drug and enhanced patient safety.[3,4]

Patients often have unpredictable responses to medications including warfarin. Patients' warfarin doses frequently require multiple adjustments to reach their individual target INR range. It can be a time-consuming and frustrating process to identify an appropriate warfarin dose for a patient. For example, a warfarin dose for one individual may result in a high INR, which leads to an increased risk of bleeding events, but for another individual, the same warfarin dose results in a low INR, which may lead to a thrombotic event. Adverse drug events due to warfarin are a leading cause for emergency room visits and hospital admissions in older adults.[5] Genetic variants are now known to be a major factor in determining the inter-individual variation in the response to warfarin.[6–8]

The "era of the genome" commenced with the sequencing of the human genome in 2003. This genetic revolution created the field of pharmacogenomics, the study of the relationship between an individual's genetics and its effect on drug therapy.[9] Warfarin has a narrow therapeutic index, which has been shown to have wide patient variability in the anticoagulant dose needed to achieve target therapeutic goals. A patient's response to warfarin has been shown to be impacted by genetic variants in the hepatic enzyme cytochrome P450 2C9 (CYP2C9) and the vitamin K–epoxide reductase complex enzyme (VKORC1), among other factors.[10,11] The importance of CYP2C9 is due to its primary drug metabolism role for the active drug enantiomer S-warfarin, while VKORC1 is the enzyme that catalyzes the rate-limiting step of vitamin K recycling in the vitamin K-associated blood coagulation pathway.[12] In 2010, the Federal Drug Administration (FDA) updated warfarin labeling to include dose-initiation recommendations for patients with known genetic variations of the *CYP2C9* or *VKORC1* genes.

Currently, integration of genetics into warfarin dosing and patient education is a novel and unfamiliar practice for most pharmacists and other health professionals. Lack of confidence, lack of genetic education in training programs, and need for continuing education for practicing clinicians are obstacles in implementing warfarin pharmacogenomics in the clinical setting and in patient counseling interactions.[13–17] Recent direct-to-consumer genomic testing has put genetic information directly into the hands of consumers, which they may take to their health care providers and increasingly expect genetic results to inform clinical decision-making.[18] There is an emerging need for patient education to be developed to encourage open discussions about drug–gene interactions between patients and health professionals.

Treatment decision aids incorporating illustrations have been shown to increase patient involvement and improve knowledge retention of complex health issues.[19–23] Decision aids benefit from incorporation of simple language to increase knowledge and comprehension by writing for the average reader, organizing the information to serve patients' needs, using short sentences and sections, using active voice, and using "you" and other pronouns that speak to the patient.[24] A systematic approach to development of treatment decision aids may include user-centered observations, multi-disciplinary synthesis, and iterative development.[20,22,25,26] Importantly, incorporating elements of adult learning theory into the development and pilot process of new patient education tools aids delivery of information that adult patients need to know, in the capacity that they can learn, and at the time they need to know it.[27]

This article describes the preliminary results obtained from the development and pilot of a patient education tool for warfarin pharmacogenomics using a patient focus group approach.

Materials and methods

The interdisciplinary research team, including pharmacists, physicians, a bioethicist, research assistants, and an illustration and design specialist, developed content, established goals, constructed a timeline, and established data collection methods for the project. The prototype was developed in collaboration with an illustration and design specialist through four iterations before piloting the pictograph prototype in focus groups of patients taking warfarin.

Prototype development was based on previous models used for developing health treatment decision aids and creating health communication using pictures.[19–23,25,26] To increase patient comprehension and knowledge retention on the complex topic of pharmacogenomics, the research team incorporated plain-language elements and adult learning theory.[24,27]

The final prototype format was one page in layout and included ten panels. Each panel included text as well as an accompanying illustration that pictorially represented the written information. We selected a ten-panel format to allow sufficient space for written text and the illustrations to enhance communication of a complex educational topic. The colors of the panels were blue, green, black, and white, which the interdisciplinary team selected due to their complementary nature and ease of reading. The information was presented in a question-and-answer format to explain how genetic variants may impact warfarin dosing. The prototype used in the pilot is shown in Figure 1.

Based on professional experience in prescribing, counseling, and providing warfarin patient education, the research team decided that the prototype would focus solely on warfarin as it relates to genetics as adjunct to currently used warfarin patient education resources at our institution. In addition, the research team felt a brief introduction on warfarin (what it is, why it is prescribed, and how it works) was appropriate to include. The prototype introduced warfarin, the concept of genetics, and the impact of genetic variance on warfarin dosing.