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# GeneScription: An Information Management System for Enabling Pharmacogenomics and Drug Safety Assurance

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# Emerging Landscape of Clinical Genotyping & Personalized Medicine

## Enabling Factors...

Human Genome (Sequence) is Complete

Genotyping Technologies are Available

Confirmed Links between Allelic Variations and Clinical Outcomes is Growing

## Hindrances to Implementation...

Consumers have Valid Reservations regarding the Use of Their DNA

Limited knowledge about the Utility of Genomics in Healthcare Professional Practices

Cost-Benefit for Disease Prediction is Uncertain

# Personalized Medicine vs. DNA-based Disease Prediction

- Personalized Medicine: Using a patient's genomic information (as well as other physiological parameters) to improve the safety and efficacy of pharmacological therapy, which is distinct from genomic screening for markers of disease predisposition/diagnostics.
- Implementation of Genomics in Healthcare: Initially, People will be more willing to provide DNA samples that provide better outcomes in pharmacotherapy, while more resistant to provide DNA samples for the identification of disease predisposition, and an understanding of these differences is key to enabling therapeutic decision support in clinical genotyping (AKA Pharmacogenomics).

# Cost of Adverse Drug Reactions (ADR) to Healthcare

- More than 750,000 patients die or sustain serious injury every year in U.S. hospitals from ADRs
- ADRs cost the U.S. Healthcare system over \$1.5 billion per year
- An exact rate of ADRs is difficult to calculate but has been estimated at 5% of all hospital admissions
- It is estimated that 50% of serious, atypical responders to the anticoagulant drug Warfarin are due to Single Nucleotide Polymorphisms (SNPs) in the patient's genome

# Adverse Drug Reactions (ADR), Genomics and Inadvertent Overdosing

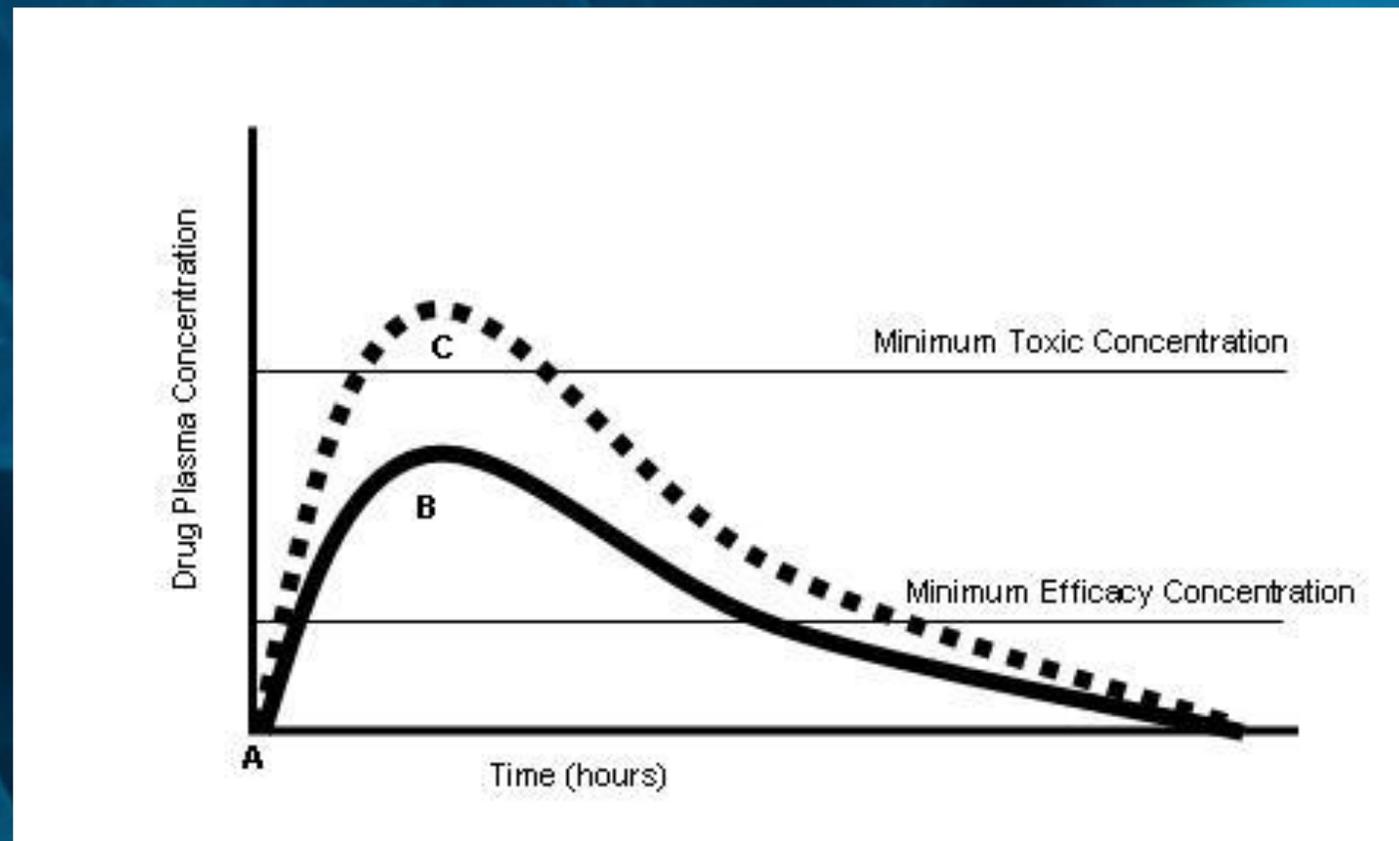
Drugs are 'dosed' based on an average of human parameters (volume of distribution, metabolic clearance rate)

In most cases, drugs are removed from the body through oxidative metabolism in the liver

The genes that encode the oxidative enzymes (AKA P450s) can harbor SNPs that cause an individual to metabolize a drug at a lower rate

In this case, the normal dose can reach plasma levels that exceed the minimum toxic concentration (inadvertent overdosing)

The 'side effects' vary from very mild to very serious symptoms



# GeneScript System

- Developed as a decisions support system for the clinic, with emphasis on professional training in personalized medicine in the healthcare community
- Designed primarily as a drug dispensing support system for the pharmacist. GeneScript contains all FDA approved drugs/doses, and all clinically-relevant SNPs
- GeneScript can be used as;
  1. A teaching tool w/ a mock patient population
  2. A clinical decision support system
  3. A patient counseling system

# GeneScription Accolades

- Desktop version created w/ input from pharmacists and pharmacy students
- Web version available free for educational purposes at [www.genescription.com](http://www.genescription.com)
- Core component of the pharmacy curriculum at Ohio Northern University, used by over 400 students (to date)
- Central component of continuing education program in pharmacogenomics for pharmacists

# GeneScription

## Patient

### Patient Selection

Patient Name:

#### Patient Info:

Patient ID	Gender	Date of Birth	Weight
75	Male	05/10/1976	87

#### Genetic Profile:

Allele Name	Predicted Protein	Effect In vivo	Effect In vitro
CYP2C9*3A	CYP2C9.3	Decreased	Decreased
CYP2C9*3B	CYP2C9.3	Decreased	Decreased

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### Drug Selection

Drug Name:

Generic Name	Trade Name	Form	Delivery	Dose Options
WARFARIN	ATHROMBIN	ORAL	IMMEDIATE RELEASE	25MG
WARFARIN	ATHROMBIN	ORAL	IMMEDIATE RELEASE	5MG
WARFARIN	ATHROMBIN	ORAL	IMMEDIATE RELEASE	10MG
WARFARIN	ATHROMBIN-K	ORAL	IMMEDIATE RELEASE	2MG
WARFARIN	ATHROMBIN-K	ORAL	IMMEDIATE RELEASE	25MG
WARFARIN	ATHROMBIN-K	ORAL	IMMEDIATE RELEASE	10MG
WARFARIN	ATHROMBIN-K	ORAL	IMMEDIATE RELEASE	5MG
WARFARIN	COUMADIN	INJECTION	IMMEDIATE RELEASE	4MG
WARFARIN	COUMADIN	INJECTION	IMMEDIATE RELEASE	75MG/VIAL
WARFARIN	COUMADIN	INJECTION	IMMEDIATE RELEASE	7.5MG

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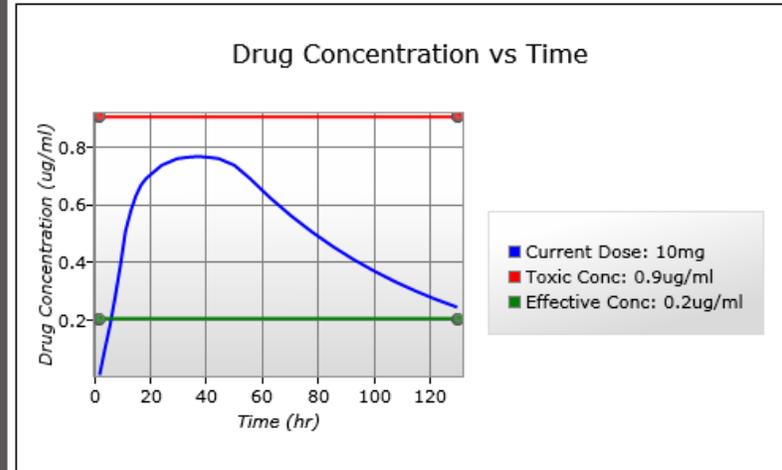
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### Dosage Selection

#### Pharmacokinetic Data:

Clearance	Half Life	Peak Time	Vol Dist	Bioavailability
0.045	37	2	0.14	0.93

#### Visualization:



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