

**Utah Patient Safety Steering Committee  
Adverse Drug Effects User Group**

**Failure Mode Effects Analysis on High Risk Drugs  
Anticoagulant Agents for Inpatient Use**

**January 2005**

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**Executive Summary**

***Background***

The Adverse Drug Effects (ADE) User Group was established to develop ways to identify events and ultimately reduce harm from the use of medications. Adverse Drug Events is one of patient safety issues specifically addressed in the Utah Department of Health Patient Safety Regulations. All institutions must have a program to identify events and use the information to prevent future events. Ideally, a part of these programs should be to systematically assess the potential for harm in the system and identify ways to prevent problems. High risk drugs are those agents that pose greater risk than most drugs. They typically have a narrow therapeutic index and have a high potential to cause harm. Consistently, the top three categories of high harm drugs are anticoagulants, opioids, and insulin. This is true both nationally and locally.

The Adverse Drug Effects (ADE) Users Group selected anticoagulants as a project to help prevent harm from high risk medications. The Utah Department of Health conducted a random population sample from 41 acute care hospitals in Utah. In 2001, anticoagulants were the second most common cause of inpatient adverse drug events, after narcotics. However, of the ADEs identified with anticoagulants, 55% resulted in harm to the patient, more than any other category. Based on data from participants in the Users Group, 33-55% of inpatients may be on an anticoagulant on any given day. The anticoagulants included in this analysis were the commonly used unfractionated heparin, low molecular weight heparins, warfarin, argatroban, and fondaparinux. It did not include thrombolytics or GPIIb/IIIa inhibitors which can pose even greater risk.

Failure Mode Effects Analysis (FMEA) is a technique to proactively assess risk and identify ways to prevent harm. The technique first involves flowcharting the process. For each step in the process failure modes are identified and potential causes for these failures. The effects of a failure are then assessed. The User Group used the Institute for Health Care Improvement (IHI) model for further assessing the risk. Each failure cause is assigned a score from 1-10 (1 being least risk situation; 10 most risk situation) for the likelihood of occurrence, likelihood of detection and the potential severity. The scores for each category are multiplied to achieve a risk priority index (RPI).

This project used FMEA as a way to identify potential problems in how we use anticoagulants. When a system failure with these medications occurs, patients who receive too much or too little medication can have significant adverse events including bleeding or thrombosis, with a potentially fatal result. High-level flow charting revealed that medication systems for using these drugs are very complex. There are many opportunities for failure in the system. The scoring was assigned by the Users Group using the methodology outlined by the Institutes for Healthcare Improvement (IHI). Potential problems in the process were identified. Each potential problem was scored from 1 to 10 for likelihood of it occurring (1=not likely, 10=very likely), severity when it occurred (1=not severe, 10=could cause death), and ability to detect the problem in the process (1=easily detected, 10=not likely to ever be detected). These three scores were multiplied to achieve a Risk Priority Number (RPN). The RPN helped to prioritize those issues most problematic.

### ***Key Findings***

Several learning opportunities occurred by applying this process. These will be divided into the high vulnerabilities areas of our systems and the key actions to prevent failure.

### ***High Vulnerabilities***

The Users Group specifically evaluated those steps in the process that had high scores (9 or 10) on the individual scoring of likelihood of occurrence, likelihood of detection, and severity, as well as the overall RPN (greater than 300). The following parts of the process scored high and represent a part of the system organizations should specifically address and identify ways to reduce harm in their system.

- Checking for contraindications to anticoagulants
- Checking for drug and food interactions.
- Double checking preparation in the pharmacy
- Drug available from floorstock.
- Nursing override of anticoagulant medication orders and administering prior to a pharmacist's check of the order.
- Failure to monitor patient and check for signs of bleeding and thrombotic disease progression.
- Failure to educate patients and their caregivers about their underlying disease state, how to use their medication, and what to do in the event of an adverse drug reaction.
- Duration of therapy not clearly established when patient starts receiving these medications.
- Follow-up appointments not established for patient.
- Follow-up with primary care provider does not occur.
- Patient unable to attend followup appointment.
- Patients do not get prescriptions filled or have gaps in their therapy.

## ***Actions to Reduce Occurrence of Failure***

Several consistent themes emerged from the process as ways to prevent failure in the system. These are summarized below.

- Establish and follow guidelines and protocols for the indications, dosing, and monitoring of anticoagulant therapy. Developing and following standard practices and following can reduce the risk of failure in many parts of the process. A bibliography of current literature guidelines and examples from several hospitals are included in the appendices. The appendices also include web resources available on this topic, many including current guidelines and methods to implement them.
- Consider anticoagulants other than heparin when appropriate. Heparin presents more opportunities for medication errors because of its availability in many different concentrations, various modes of preparation, and that it may be used by several different routes of administration.
- Assign clear accountabilities for monitoring such as checking the laboratory values and adjusting the dose as necessary.
- Develop alerting systems to notify clinicians of abnormal laboratory values.
- Use standard concentrations for parenteral anticoagulants.
- Consider the use of “smart” pumps or other safety checks to prevent infusion related medication errors.
- Develop a standard process for educating patients and their caregivers on the underlying disease, how to take their medication and what to do in the event of an adverse event.
- Assign clear accountabilities for patient education.
- Establish a standard process with clear accountabilities for the continuity of patient care after discharge including set follow-up appointment, establish who will provide ongoing care for anticoagulant therapy, communicate with primary care giver, and address barriers to obtaining prescriptions and getting to followup appointments.
- Double check therapy at transfer of care situations.

## ***Summary***

This process was useful to highlight many potential problems with using high-risk drugs and anticoagulants in particular. This project provides a process framework for any organization to evaluate their system. On one level, organizations can use the general learning that occurred as part of this project and apply it to their organization. The data in this project represent the observations of the participants of the Users Group. Organizations may also want to use a similar process to evaluate their own systems. They may find that other steps in their process may pose more significant risk for their specific organization than was identified more globally in this overall process. When an organization implements strategies to prevent harm, the scores can be reanalyzed with new RPNs calculated. The updated RPNs help to show the impact of a given methodology. All organizations should take this opportunity to evaluate potential problems in their system and address ways to prevent harm with anticoagulant medications.