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# Medication Safety – Pharma Industry Considerations Part 3 – High-Alert Medications

By **Brandon T. Reif, David J. An, Varanya Chiayaperm, and Paul L. Pluta** **Jan 24, 2022 8:00 am EST**


## ABSTRACT

This discussion provides fundamental information regarding medication safety and high-alert drugs. High-alert medications comprise a small and well-defined subset of critical therapeutic agents. Pharma industry designs product formulations, labeling, packaging, supporting information, and other product-related elements – all of which may potentially impact patient safety within the medication process. Errors with high-alert drugs are of special concern; these errors may cause significant and even fatal effects in patients. Example high-alert medication errors are described. Therapeutic categories of high-alert medications in various healthcare settings are identified. Pharma industry has great impact on total medication process; three general areas of pharma industry major impact are identified. Increased attention to medication safety by pharma industry personnel should help to reduce medication errors with high-alert and other drug products.

This discussion continues previous content in*Medication Safety – Pharma Industry Considerations - Part 1, Problem Overview (1)* and *Part 2, Drug Names (2).*

## INTRODUCTION

Medication safety is a significant concern in healthcare practice. Recent estimates suggest alarming numbers of medication errors in the US and global (millions of errors annually), numerous patient deaths (thousands), and significant costs associated with treatment ($ billions) (3,4).

High-alert medications (HAM) are a small but important subset of pharma products. HAM products include a range of pharmacologic agents with a variety of significant therapeutic indications. Several HAMs are indicated for critical emergency situations. HAM medication errors are of special concern in medication safety; HAM products may cause significant and even fatal effects on patients when medication errors occur. Multiple FDA guidance documents provide general approaches addressing medication safety in pharma product guidelines, but do not identify specific considerations for HAM. Healthcare practitioners often implement additional precautionary measures (Figure 1) for HAM products in their practice settings beyond what is generally provided in pharma commercial products.

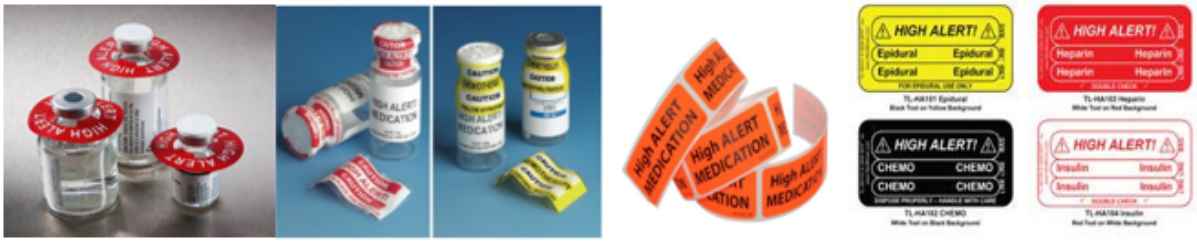


***Figure 1. High-Alert Drug Neckbands, Shrink Film Overseals, and Auxiliary Labels***

## Discussion Objectives

This discussion provides basic information related to medication safety aspects of HAM dosage forms. HAM pharmacologic categories including example drugs are described. Pharma industry has great impact on medication safety in pharma products through product appearance, labeling, packaging, information, and related elements. If pharma industry personnel became more aware of problems and the consequences of errors in healthcare practice, approaches to minimize errors might be proactively incorporated into design aspects of pharma products.

Discussion topics addressed include the following:

- HAM overview. HAM definition, drug mechanisms, representative errors, and possible consequences
- HAM categories and example drug products
- Pharma impact on HAM processes.

**Drug Names.** Confusion with drug names is a fundamental cause of medication errors. FDA has recognized the criticality of this problem and has issued several recent guidance documents specifically addressing safety considerations in the naming of pharmaceutical products (5-7). Global regulatory agencies have been equally responsive (8-11). Drug name problems have been previously discussed in this series (2).

## HIGH ALERT MEDICATION OVERVIEW

The Institute for Safe Medication Practices (ISMP) defines high-alert medications as “drugs that bear a heightened risk of causing significant patient harm when they are used in error.” (12) While the incidence of mistakes with HAM products may or may not be high, the consequences of these errors are clearly more devastating to patients. Medication errors with HAM category drugs have the potential to cause serious harm and even death.

### HAM Mechanisms and Medication Error Examples

The pharmacologic mechanisms and toxic effects of HAM drugs are many and varied depending on the specific drug. Tables below identify more than 20 individual HAM drug categories, all of which have potential for significant physiological effects caused by overdose situations. Representative examples demonstrate these effects and their causes. Other considerations such as patient age, general health, drug response (opioid naive vs. opioid tolerant), co-morbidities, and other factors complicate patient responses.Notable below are the severity of toxic effects and the rapidity of physiological response.

- **Digoxin.** Digoxin is a highly potent narrow therapeutic index (NTI) drug. A typical digoxin daily dose for adults is 0.125 mg. When an NTI drug dose is inadvertently changed by a small amount, significant pharmacologic effects may occur. An example: An elderly patient was prescribed *0.0625 mg* digoxin. **The dosage was transcribed multiple times due to patient transfer between several healthcare facilities; ultimately *0.625 mg* digoxin was administered – a 10x overdose (13)**. Another example: A hospitalized pediatric patient was prescribed *0.7 mg* digoxin -- a high *adult* dosage; the patient should have been administered *0.07 mg* digoxin (14). Both of the above events resulted in patient death. **These examples demonstrate no verification of drug/dose by a second person**.

- **Warfarin**. Excess antithrombotic/anticoagulant dosages cause toxic effects including spontaneous hemorrhage. For example, a warfarin patient was treated for a skin infection at a local urgent care center; Bactrim® (trimethoprim/sulfamethoxazole) antibiotic was prescribed. Several days after beginning Bactrim therapy, the patient was hospitalized for gastric bleeding. Antibiotics including Bactrim are known to interfere with warfarin metabolism effectively causing warfarin overdose.**This event demonstrates multiple communication failures -- the patient did not communicate that he was taking warfarin and healthcare practitioners did not ask about the patient’s medication history (15). Anticoagulant drugs are known to interact with many drugs, nutritional supplements, and foods.**

- **Morphine and Hydromorphone (Dilaudid®) dosage.**Morphine and hydromorphone are analgesic opioids. Hydromorphone is significantly more potent than morphine, for example:
    - Oral hydromorphone is 4x more potent than oral morphine; 7.5 mg oral hydromorphone = 30 mg oral morphine
    - Parenteral hydromorphone is 7x more potent than parenteral morphine; 1.5 mg IV hydromorphone = 10 mg IV morphine
    - Parenteral hydromorphone is 20x more potent than oral morphine; 1.5 mg IV hydromorphone = 30 mg oral morphine.

      **Drug changes, conversions from IV to oral, and simple name confusion (morphine, meperidine, hydromorphone, codeine, hydrocodone, and so on) all contribute to opioid medication errors**. An example: Patient with a chest injury was prescribed 10 mg IM morphine for pain but was erroneously administered 10 mg. hydromorphone. Both morphine and hydromorphone were stored together in the hospital narcotic drawer.**No drug/dose verification by a second person occurred.** The hydromorphone dose was equivalent to 60-70 mg morphine; the patient died (16).

- **Epinephrine.**Epinephrine is a highly potent drug (microgram dosage) often used in emergency situations. **Epinephrine may be administered by multiple routes (IV, IM, SC, others) depending on clinical indications.**
    - **Cardiac (IV).** A typical cardiac dosage is epinephrine 0.5 mg IV; dosage of 5 mL of 0.1 mg/mL solution is administered. Erroneous dosage using 5 mL of 1 mg/mL solution provides 10x epinephrine overdose and toxic cardiac and hypertensive effects.
    - **Respiratory (IM/SC).** Epinephrine doses for allergy, anaphylaxis, and asthma are administered IM or SC. A typical IM dose of 0.3 mg is provided as 0.3 mL of 1 mg/mL solution.**Erroneous IV administration instead of IM/SC causes cardiac effects**.
    - **Topical.**Vasoconstrictor properties of epinephrine are utilized to minimize bleeding and enhance topical anesthesia in minor surgical and dental procedures. Topical epinephrine 1:100,000 was ordered for topical use, but epinephrine 1:1,000 solution was administered – 100x overdose causing patient death (17).**Product solution labeling was omitted.**
- **Vecuronium.**A patient was prescribed Versed® (midazolam) for anxiety prior to an MRI. Vecuronium, a neuromuscular relaxant, was erroneously administered. An electronic dispensing device issued vecuronium when “ve” was entered into the system; the incorrect drug was not noticed by hospital personnel and mistakenly administered to the patient – ultimately causing death. **This event demonstrates the potential for medication errors involving electronic systems, unrestricted drug access, and no drug/dose verification by a second person (18).**

- **Potassium Chloride Injection.** Potassium chloride is available in vials containing 20, 40, and 60 mEq KCl for dilution in an IV fluid. Medication errors in which KCl injection was directly administered without being diluted caused patient death. Magnesium Sulfate 50% Injection, Potassium Phosphates Injection, and hypertonic (>0.9%) saline are other commercial electrolyte products that must be diluted before administration. **Products requiring dilution before administration to patients have potential for medication errors (19).**

- **Baclofen**. A pediatric patient was prescribed tryptophan for sedation. Baclofen (a skeletal muscle relaxant) was erroneously administered. The tryptophan 500 mg dosage applied to baclofen represents a 40x overdose; the child died. **This event demonstrates drug name confusion involving a HAM category drug and no verification of drug/dose before administration.** LASA errors – written, spoken, transcribed, etc. -- have potential for significant medication error (18).

- **Norepinephrine (Levophed®).** Norepinephrine is commercially available as a 1 mg/mL solution in a 4 mL container. This product is diluted in 1000 mL IV liquid for patient administration over several hours. A nurse injected undiluted drug into a patient – a 1000x overdose – causing patient death. **This event demonstrated unrestricted access to a highly potent drug requiring dilution prior to administration, and no drug/dose verification by a second person (18).**

- **General Causes of Medication Errors.** Like all drugs, HAM is subject to Look-Alike/Sound Alike (LASA) name confusion (e.g., Norvasc® vs. Navane®) (1,2,18), calculation errors especially with low (microgram) dosages calculations, leading and trailing zero omissions, missing decimal points, and other general misunderstandings; these causes of medication errors are also applicable to HAM.

## HAM CATEGORIES AND EXAMPLE PRODUCTS

ISMP has created lists of the most commonly seen classes and categories of HAM drugs in the acute care, community/ambulatory, and long-term care settings. These lists were compiled through error reports submitted to the ISMP National Medication Errors Reporting Program (ISMP MERP), reports of harmful errors in the literature, studies that identify the drugs most often involved in harmful errors, and input from practitioners and safety experts. The clinical staff at ISMP and members of the ISMP advisory board also reviewed HAM lists.

These lists are intended to determine which medicines require special safeguards to reduce the risk of errors such as strategies to standardize the prescribing, storage, preparation, and administration of these products; improving information about these drugs; limiting physical access, using auxiliary labels, employing clinical decision support and automated alerts, and using redundancies such as automated or independent double-checks when necessary.

## HAM in Acute Care Settings (20)

HAM categories in acute care settings are primarily IV drugs reflecting drug use in hospitals and other acute care facilities. The following list was updated in 2018.

| | CLASSES / CATEGORIES OF MEDICATIONS |
|---|---|
| 1 | Adrenergic agonists, IV (e.g.,**EPINEPH**rine, phenylephrine, norepinephrine) |
| 2 | Adrenergic antagonists, IV (e.g., propranolol, metoprolol, labetalol) |
| 3 | Anesthetic agents, general, inhaled and IV (e.g., propofol, ketamine) |
| 4 | Antiarrhythmics, IV (e.g., lidocaine, amiodarone) |
| 5 | Antithrombotic agents, including:<br>• Anticoagulants (e.g., warfarin, low molecular weight heparin, unfractionated heparin)<br>• Direct oral anticoagulants and factor Xa inhibitors (e.g., dabigatran, rivaroxaban, apixaban, edoxaban, bet<br>• Direct thrombin inhibitors (e.g., argatroban, bivalirudin, dabigatran)<br>• Glycoprotein IIb/IIIa inhibitors (e.g., eptifibatide)<br>• Thrombolytics (e.g., alteplase, reteplase, tenecteplace) |
| 6 | Cardioplegic solutions |
| 7 | Chemotherapeutic agents, parenteral and oral |
| 8 | Dextrose, hypertonic, 20% or greater |
| 9 | Dialysis solutions, peritoneal and hemodialysis |
| 10 | Epidural or intrathecal medications |
| 11 | Ionotropic medications, IV (e.g., digoxin, milrinone) |
| 12 | Insulin, subcutaneous and IV |
| 13 | Liposomal forms of drugs (e.g., liposomal amphotericin B) and conventional counterparts (e.g., amphotericin B d |
| 14 | Moderate sedation agents IV (e.g., dexmedetomidine, midazolam,**LOR**azepam) |
| 15 | Moderate and minimal sedation agents, oral, for children (e.g., chloral hydrate, midazolam, ketamine [using the p |

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|---|---|
| 16 | Opioids, including<br>• IV<br>• Oral (including liquid concentrates, immediate- and sustained-release formulations)<br>• Transdermal |
| 17 | Neuromuscular blocking agents (e.g., succinylcholine, rocuronium, vecuronium) |
| 18 | Parenteral nutrition preparations |
| 19 | Sodium chloride for injection, hypertonic, greater than 0.9% concentration |
| 20 | Sterile water for injection, inhalation, and irrigation (excluding pour bottles) in containers of 100 mL or more |
| 21 | Sulfonylurea hypoglycemics, oral (e.g., chlorpro**PAMIDE**, glimepiride, gly**BURIDE,** glipi**ZIDE, TOLBUT**amide) |

***Table 1. ISMP List of High-Alert Medications in Acute Care Settings***

Specific medications identified include:

- **EPINEPH**rine, IM, subcutaneous
- Epoprostenol (e.g., Flolan); IV
- Insulin U-500 (special emphasis*)
- Magnesium sulfate injection
- Methotrexate, oral, nononcologic use
- Nitroprusside solution for injection
- Opium tincture
- Oxytocin IV
- Potassium chloride for injection concentrate
- Potassium phosphates injection
- Promethazine injection
- Vasopressin IV and intraosseous

*All forms of insulin, subcutaneous and IV, are considered a class of high-alert medications. Insulin U-500 has been singled out for special emphasis to bring attention to the need for distinct strategies to prevent the types of errors that occur with this concentrated form of insulin.

## HAM in Community / Ambulatory Care Settings (21)

HAM categories in community / ambulatory setting include commonly used oral drugs. Ambulatory care sites with long-term care facilities, long-term acute care facilities, dialysis facilities, ambulatory surgery centers, and pharmacies providing services to them should also review other ISMP listings (Acute Care Table 2 and Long-Term Care Table 4).

The following list was originally developed in 2008 and has been updated in 2021.

| | **CLASSES / CATEGORIES OF MEDICATIONS** |
|---|---|
| **1** | Antithrombotic agents, oral and parenteral, including:<br>• Anticoagulants (e.g., warfarin, low molecular weight heparin, unfractionated heparin<br>• Direct oral anticoagulants and factor Xa inhibitors (e.g., dabigatran, rivaroxaban, apixaban, edoxaban)<br>• Direct thrombin inhibitors (e.g., dabigatran) |

| | |
|---|---|
| **2** | Chemotherapeutic agents<br>• Oral and parenteral chemotherapy (e.g., capecitabine, cyclophosphamide)<br>• Oral targeted therapy and immunotherapy (e.g., Palbociclib, (**IBRANCE**), imatinib (**GLEEVEC**), bolsutinib (**BO**<br>• Excludes hormonal therapy |
| **3** | Immunosuppressive agents, oral and parenteral (e.g., aza**THIO**prine, cyclo**SPORINE**, tacrolimus) |
| **4** | Insulins, all formulations, and strengths (e.g., U-100, U-200, U-300, U-500) |
| **5** | Medications contraindicated during pregnancy (e.g., bosentan,**ISO**tretinoin) |
| **6** | Moderate and minimal sedation agents, oral, for children (e.g., chloral hydrate, midazolam, ketamine (using the |
| **7** | Opioids, all routes of administration (e.g., oral, sublingual, parenteral, transdermal), including liquid concentrate formulations, and combination products with another drug |
| **8** | Pediatric liquid medications that require measurement |
| **9** | Sulfonylurea hypoglycemics, oral (e.g., chlorpro**PAMIDE**, glimepiride, gly**BURIDE**, glipi**ZIDE**,**TOLBUT**amide, |

***Table 2. ISMP List of High-alert Medications in Community/Ambulatory Healthcare***

Specific medications identified include:

- car**BAM**azepine
- **EPINEPH**rine, IM subcutaneous
- Insulin U-500 (special emphasis) *
- Lamo**TRI**gine
- Methotrexate, oral and parenteral, nononcologic use (special emphasis) *
- Phenytoin
- Valproic acid

*All oral and parenteralchemotherapy, and all insulins are considered high-alert medications. These specific medications have been singled out for special emphasis to bring attention to the need for distinct strategies to prevent the types of errors that occur with these medications.

## HAM in Long-Term Care (LTC) Settings (22)

HAM categories in LTC reflect an elderly patient population. Long-term acute care (LTAC) and LTC sites with subacute units where a variety of IV medications are administered should also review other ISMP listings (Acute Care Settings Table 2). The following list was originally developed in 2016 and has been updated in 2021.

Healthcare professionals should also utilize other resources such as the Beers Criteria and STOPP and START Criteria to evaluate medications given to the elderly (23,24); these evaluations differ from HAM considerations.

| | **CLASSES / CATEGORIES OF MEDICATIONS** |
|---|---|
| 1 | Anti-Parkinson’s drugs, including carbidopa, levodopa, and combination products that contain at least one of thes |

| | |
|---|---|
| 2 | Antithrombotic agents, parenteral and oral, including<br>• Anticoagulants (e.g., warfarin, low molecular weight heparin, unfractionated heparin)<br>• Direct oral anticoagulants (e.g., dabigatran, rivaroxaban, apixaban, edoxaban, betrixaban)<br>• Direct thrombin inhibitor (e.g., dabigatran) |
| 3 | Chemotherapeutic agents<br>• Oral and parenteral chemotherapy (e.g., capecitabine, cyclophosphamide)<br>• Oral targeted therapy and immunotherapy (e.g.,<br>• Excludes hormonal therapy |
| 4 | GABA analogs (e.g., gabapentin, pregabalin) use to treat neuropathic pain |
| 5 | Immunosuppressants, oral and parenteral (e.g., aza**THIO**prine, cyclo**SPORIN**), cyclophosphamide, tacrolimus, a<br>), adalimumab (**HUMIRA**), |
| 6 | Insulins, all formulations, and strengths (e.g., U-100, U-200, U-300, U-500) |
| 7 | Opioids, all routes of administration (e.g., oral, sublingual, parenteral, transdermal), including liquid concentrates<br>release formulations, and combination products with another drug |
| 8 | Parenteral nutrition preparations |
| 9 | Sulfonylurea hypoglycemics, oral (e.g., chlorpro**PAMIDE**, glimepiride, gly**BURIDE**, glipizide**, TOLBUT**amide) |

***Table 3. ISMP List of High-alert Medications in Long-Term Care (LTC) Settings***

Specific medications listed by ISMP include:

- Concentrated morphine solution (20 mg/mL), oral (special emphasis) *
- Digoxin, parenteral and oral
- **EPINEPH**rine, IM subcutaneous
- Insulin U-500 (special emphasis) *
- Iron dextran, parenteral
- Methotrexate, oral and parenteral, nononcologic use (special emphasis) *
- Phenytoin
- Sacubitril and valsartan (**ENTRESTO**)

*All routes of opioids, all parenteral and oral chemotherapy, and all subcutaneous and IV insulin are considered high-alert medications. These specific medications have been singled out for special emphasis to bring attention to the need for distinct strategies to prevent the types of errors that occur with these medications.

## PHARMA INDUSTRY IMPACT ON HAM PROCESSES

Pharma industry has great impact on the medication use process and on medication safety. Pharma should build safety into drug products throughout the entire product lifecycle – essentially the same as in an industry quality risk management (QRM) or CAPA program; FDA encourages “Safety by Design” (25). FDA has also instituted the Safe Use Initiative to create and facilitate public and private collaborations within healthcare community toward reducing medication errors; completed and current Safe Use program projects are listed on the FDA website (26).

Pharma emphasis addressing medication safety should be on the product user, use environment, and how the user interacts with the product and related components. The product-user interface should be forefront – this is where many medication errors occur. Actual product use in daily reality is significantly different than controlled pharma industry clinical study conditions. If pharma personnel involved in product-related design activities become aware of medication errors, measures to minimize errors may be integrated in pharma product characteristics.

Three general areas of pharma involvement in the medication use process are identified.

## Product / Label / Package Design

Pharma design activities include product formulation, dosage strength, naming, labeling, packaging, coloration, and related appearance considerations – the actual physical components of a pharma product. These activities are the responsibility of pharma industry and directly impact essentially all aspects of the medication process, i.e., correct selection of the intended product by healthcare professionals, caretakers, and patients is facilitated by product/label/package design and appearance.

**Guidelines.** FDA has published numerous guidance document addressing various aspects of medication safety related to pharma products and associated delivery devices (25,27,28,29). The cited references provide general considerations; more than 100 references addressing pharma products, labeling, packaging, drug information, and related non-clinical topics are available on the FDA website. These are comprehensive guidelines addressing product, labeling, packaging, human factors in use, and associated details.

**Pharma Considerations.** The pharma goal for products should be to design product-related elements that enable safe and correct use and minimizes elements which could cause hazards. Pharma product designers must understand how product will be used, who handles the product, sequence of use, environments of use, and related considerations, i.e., a comprehensive understanding of the complete medication process. QRM to identify potential problems with medication use is recommended. Further comments on this topic are planned for future discussion in this series.

## Healthcare Setting Operations

Healthcare setting issues involve drug use management and personnel activities such as policies, procedures, and daily practices in healthcare facilities. Communication of medication orders, electronic systems; drug storage, inventory, distribution, and access; environmental factors, and staff competency are addressed in these considerations. These are mostly" behind-the-scenes" activities that potentially contribute to medication errors; healthcare setting considerations are the daily operations in the facility.

**Resources.** Several comprehensive resources addressing healthcare setting operations warrant mention.

- ISMP. Medication Safety Self-Assessment for High Alert Medications (30). This document provides a self-assessment tool of multiple setting operations topics for eleven categories of HAM products.
- ISMP. Targeted Medication Safety Best Practices (31) is an ongoing listing of policies and procedures addressing medication safety issues. Best practices are added, updated, or archived, as necessary. Sixteen practices are currently addressed.
- ISMP. Top Medication Errors and Hazard for 2021 (32) is also available from ISMP. These include COVID-19 and other medication errors in product names, labels, packaging, and dilutions.
- American Society of Health-System Pharmacists. ASHP has published Guidelines for Preventing Medication Errors in Hospitals (33). This guideline identifies eleven stages in hospital operations and discusses associated safety considerations in each stage.

**Pharma Considerations.** Pharma industry can greatly impact the medication process in healthcare setting. For example, supplying HAM products with attached auxiliary labels (Figure 1 above) or other notable labeling would improve recognition of HAM products. Other possible supportive activities might include barcode labeling, electronic system improvements, continuing education on problem topics such as dosage calculations, and other setting-related initiatives. Additional comments on these topics are planned for future discussion in this series.

## Product information

Drug information developed by industry is used by healthcare professionals and by patients. Product information includes the Prescribing Information (PI), aka the product package insert (34). Patient labeling including Medication Guides, Instructions for Use, and Patient Information, aka Patient Package Inserts. The PI is used primarily by healthcare professions and is the basis for the respective patient documents. The PI format was changed in 2001 ("Physician Labeling Rule" or PLR format); products approved before 2001 may still utilize the original (non-PLR) format.

**Guidelines and Other Resources**. The FDA website contains numerous resources addressing drug labeling and product information (35,36). The FDA website enables access to all current drug product medication guides. Recommended formats and content for all documents are published. Document outlines contain comprehensive content requirements applicable to all pharma products; content specific to HAM is not identified. These are complete and lengthy documents.

**ISMP High-Alert Medication Learning Guides for Consumers (37).**ISMP has published concise learning guides (two pages) on specific high-alert drugs that are available on the ISMP website. These documents are clearly focused on medication safety; for example, the first lines of the ISMP Eliquis® (apixaban) learning guide states the following:

***Take extra care! Eliquis is a high-alert medication.***

***This means that Eliquis has been proven to be safe and effective, but serious harm,***

***such as severe bleeding or a stroke, can occur if is not taken exactly as directed.***

Following sections of the guide include Top 10 List of Safety Tips for Eliquis, Symptoms for which to seek immediate medical treatment (bleeding, blood clot, stroke, allergy), and product facts listing concise drug information. Sixteen ISMP Learning Guides are currently available on the ISMP website; some are also available in Spanish.

**Pharma Considerations.**Pharma industry can greatly impact product information aspects of the medication use process. The general outline of the package inserts and patient package insert / consumer guide / patient instructions for use are fundamental to product information. Enhancements to HAM product information clearly stating the serious consequences of medication errors, missed doses, food interactions, and other risks in therapy could be emphasized. Creative presentations of drug information to potentially increase impact on patients is recommended (Figure 2). Electronic texts, QR codes, videos, virtual user groups, and other communication methods should also be considered to improve user adherence and minimize errors. Additional comments on this topic are planned for future discussion in this series.


***Figure 2. Warfarin-Food Interactions***

## SUMMARY AND FINAL THOUGHTS

This discussion has briefly described fundamental HAM concepts relevant to medication safety. HAM are drugs that bear a heightened risk of causing significant patient harm when they are used in error. While the incidence of mistakes with HAM may not be high, the consequences of these errors are significant and may even be fatal. The mechanisms of HAM pharmacologic activity depend on the properties of each drug. Some HAMS are drugs with narrow therapeutic indexes; others are so designated due to other physiologic effects and other causes for medication problems. Example HAM medication errors are described; notable in these errors are the severity of effects and the rapidity of response, especially with parenteral dosages.

ISMP has created lists of the most commonly seen classes and categories of HAM drugs in the acute care, community/ambulatory, and long-term care settings. These listings are intended to determine which drugs require special safeguards to reduce the risk of errors.

Pharma industry can help to minimize the occurrence of HAM errors in three general areas of activities. Product, label, package, and required product information must be designed and developed with considerations for medication safety. Pharma industry can provide helpful tools and information for healthcare practice settings to help minimize medication errors. For example, auxiliary labeling, training videos, and other supportive content that addresses medication errors may be supplied. Product information for patients and healthcare practitioners

must emphasize the dangers of high-alert drugs. Product information includes other drugs that may interact with high-alert drugs, foods to avoid, and associated information relevant to medication safety. Creative presentation of Information to encourage patient adherence and reinforce drug safety and electronic communication methods, are recommended.

Pharma product guidelines are published by FDA and other regulatory agencies. The guidelines, however, do not specifically include HAM considerations. If pharma personnel can learn and understand HAM considerations, proactive practices can help to minimize HAM errors as well as influence safety considerations on all pharma products.

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