Potential Medication Concerns and Errors with Generics

Roaa Al-Gain, PharmD Candidate
Purdue University
Jan 2013
Learning Objectives

• Define generic drugs and their features compared to brand drugs

• Highlight the impact of generic substitution on adherence and improving patient safety outcomes

• Describe potential medication errors with generic drugs
## Brands vs. Generics

### Brand Drug
- **Innovative new drug**
- **May be called:**
  - Innovator
  - Original
  - Reference
  - Pioneer

### Generic Drug
- Drug that is chemically and therapeutically identical to a previously approved brand-drug
Generic drugs are **IDENTICAL** to brand-drugs in:

- Active ingredients
- Strength
- Dosage
- Quality
- Safety
- Therapeutic performance
- Indications
But they are not TWINS!

Generic drugs

• Have different appearance

• Have different new trade name

• Have different composition from referenced drug **BUT** only within the excipients

  • Excipients are non-active ingredients added to drug product
  • Examples: bulking agents, coloring agents, flavoring agents,...
  • Changing the excipient may modify the final product **BUT NOT** the entire pharmacological effect or performance
If they are identical, why do brand drugs and generic drugs look different?

Trademark laws in the US do not allow generic drugs to look exactly like the brand drugs available on the market.
How generics come to market?

• Every brand-name drug has an exclusive marketing period “patent”

• When the brand-name drug's patent protection expires, generic versions of the drug can be manufactured and seek approved for sale

• The generic version like the brand-name drug must meet the same quality and safety standards

• All generic drugs must be reviewed and approved by FDA
How do they compare?

http://www.offshorrx.com/why_generic_drugs.php
Great Deal at Less Price!

- Generic drug manufactures do not design or develop a drug from the scratch, therefore, their cost is much less.
- On average generic drugs will cost 50 to 70% less than their brand counterparts.
- Allowing other companies to produce and sell the exact same drug, increase competition and drive less drug cost.
- In the US, about 8 out of 10 prescriptions are filled with a generic drug.
Generic Substitution Rules

- May substitute generic for brand unless prescriber prohibits
- Generic substitution is regulated by State laws & regulations for generic substitution
- Patients may request brand or generic drug
- Pharmacists may be required to substitute generics for Medicaid patients
Generic Substitution Concerns: Narrow Therapeutic Index Drugs (NTI)

Definition

• Drugs with fine line between a dosage that is beneficial and one that is toxic

Examples

• Antiarrythmic (e.g. digoxin, procainamide)
• Antiepileptics (e.g. carbamazepine, ethosuximide, phenytoin)
• Levothyroxine Sodium
• Lithium
• Theophylline
• Transplant immunosuppressant medications (cyclosporine, mychophenolate mofetil, tacrolimus)
• Warfarin
How to approach NTI generic drug substitution?

• Do not do multiple substitutions

• Be consistent use either the generic or the brand

• Do not switch from generic to generic

• If the substitution is made, make sure the patient is monitored closely to avoid subtherapeutic or supratherapeutic
Generic medications are just as safe and effective as their brand-name equivalents but can be associated with unique medication errors.
Potential Errors

• **Physicians**
  • Using brand name only to list drugs in medication profile may lead to duplication of therapy

• **Pharmacists**
  • Changing products multiple times within a short period could confuse caregivers or patient, so pharmacy managers should weigh the benefits and risks of making such changes
  • Lack of counseling the patient about the change may reduce the adherence and lead to omission errors
Potential Errors

• Look-alike
• Sound-alike
• Different strength
• Multiple generics
• Combination product.....duplicate therapy
• Different dosage form.....omission risk and decrease adherence
• Unsafe labeling
• Different reconstitution, administration, stability, storage conditions
Dangerous Names

Warfarin by Generic Name

From the September 25, 2008 issue

In our August 14th issue, we mentioned the potential for confusion between a branded warfarin product, JANTOVEN, JANUVIA (sitaGLIptin), and JANUMET (sitaGLIptin and metFORMIN). Just as dangerous, if not more so, is that some health professionals and patients may not recognize that Jantoven is a brand of warfarin, and patients could easily end up taking two warfarin products together. A case was reported to us last week in which the patient took warfarin prescribed and dispensed under both names, which resulted in an INR of 9.7! On a discharge medication reconciliation form, warfarin was identified as a medication the patient had been receiving at home and continued while the patient was hospitalized. The physician checked “continue home warfarin” and wrote a new prescription based on the inpatient warfarin order. The community pharmacy dispensed Jantoven, but didn’t discuss the nature of the drug with the patient and didn’t ask any questions that might have determined if the patient already had warfarin at home. It’s unfortunate that manufacturers feel they must brand long-established products such as warfarin (COUMADIN), a high-alert medication, since it only adds to the potential for dangerous confusion. When branded generics are dispensed to patients, it is important that the generic name be listed on the prescription container label, along with the brand name, as necessary, whether Jantoven or Coumadin. Presently, many community pharmacies simply list the brand name for branded products, but that might not help the patient identify duplicate medications. This error was also caused by a failure with discharge counseling, which should be an integral component of discharge reconciliation, no matter which health professional provides the service.
When generics looks different...Errors happen

- Risk of errors increased when switching patient to generic drugs that looks different than brand drugs used for long time
- Risk of error increased with multiple purchasing from different manufacturers
- Risk of error increased in patients with complex medication regimens, limited health literacy, or polypharmacy
- Patient adherence may be compromised due to confusion about:
  - Different drug appearance
  - Different dosage form (e.g. tablet vs soft gel capsule)
  - Different name or similar name to other medication
Why generics should look-like the brand?

**ORAL SOLID MEDICATION APPEARANCE SHOULD PLAY A GREATER ROLE IN MEDICATION ERROR PREVENTION**

*From the July 28, 2011 issue*

Generic products are widely dispensed in US hospitals and ambulatory pharmacies as a cost-effective substitute for brand-name medications. According to the Generic Pharmaceutical Association, generic medications are dispensed for 69% of all ambulatory prescription medications but account for only 16% of the total costs of all dispensed prescription drugs. (1) While generic medications have been approved by the US Food and Drug Administration (FDA) as bioequivalent to their associated brand-name medications, oral generic medications often look substantially different than their brand-name counterparts and other generic versions of the same medications. Thus, consumers can receive different looking tablets or capsules every time they refill their prescription if generic products are dispensed. For example, **PROZAC** (FLUoxetine) has ten different generic bioequivalent products, but each is different in appearance. (2) Generic manufacturers design their product’s appearance, making no effort to ensure it looks like other generics or the brand-name product, primarily to avoid litigation with brand-name manufacturers that claim intellectual rights to the appearance of their products. (3)

**Risks when generics don’t look like the brand**

Patients and many healthcare practitioners have learned to rely on the color, size, and shape of oral solid medications as one—but hopefully not the only—way to ensure the right medication has been dispensed, taken, or administered. When a generic drug is different in appearance from the brand product or other generic products, patients and healthcare practitioners can become confused. Historically, medication appearance was considered a passive control
Be aware about Inconsistent Label Information!

• A study found that inconsistencies among the safety information of generic drug labels.
• About two-thirds of the generics drugs studied did not have identical labeling as the brand drugs.
• The discrepancies occurred in the warning sections and adverse reactions.
• Up to 9% of the review labels showed differences of more than 10 side effects which could be a potential safety issue if the patient or prescriber missed this information

Be an Educated Consumer

• Keep list of all medications you are using
• Write down the generic name and the brand name
• Compare the label of generics and brand names, just to be sure the dosage is the same
• If you fill new prescription with GENERIC version instead of BRAND, check the main ingredients on each product they should be identical
Be an Educated Consumer

• If you want to buy generic OTC drug or change the formulation of your medication (e.g. tablet to syrup):
  • check the composition
  • make sure it is not in combination with other drug
  • has the same strength
• Ask your pharmacist to help you!