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For more information call 877.228.8278 and our customer service representatives can assist you.

Note: Independent tests were performed by Northview Laboratories, Inc.
Genes: Does One Size Fit All?

Amy Fox, PharmD Candidate, Ohio Northern University

What is Genetic Testing?

One of the newest technologies being looked at for medical purposes is genetic testing. A big push for genetic testing is to help personalize medications for patients. In general, medications are currently prescribed based on the “average” patient. This means that a medication should work the same for one patient just as it does another. It can be thought of as a “one size fits all” method. Prescribing centered on genetic testing is aiming to individualize drug therapy based on patient specific genes. One of the most significant highlights of genetic testing is looking at cytochrome P450 (CYP) enzyme metabolites. Many drugs are metabolized by CYP enzymes from the liver. Differences in genetic make-up can effect how CYP enzyme work, and not everyone will metabolize the drugs the same way. Because of this, it may not be appropriate to use a “one size fits all” method, but rather a more personalized approach.

Genetic Testing for Antipsychotic Drug Therapy

Genetic testing is now being looked at for antipsychotic drug therapy. Antipsychotic drug side effects can be serious and are usually present when too high of a dose is given. Side effects may include extrapyramidal symptoms, a prolonged QT interval, dyslipidemia, postural hypotension, sedation, seizures, sexual dysfunction, diabetes, and/or weight gain. Currently, antipsychotic drug regimens are done by trial and error. To start an antipsychotic medication, many prescribers use the motto of “start low and go slow.” This means starting at a low dose and titrating up to effect or until side effects are seen. Medications are used based off of the “average” patient. Genetic testing helps to determine if the patient will need a lower than normal dose to avoid side effects of the drug, or they may need a higher dose to achieve therapeutic success if his or her metabolism of the drug is faster. This can help get to the correct dose faster by giving the prescriber an idea of where to start dosing, which in turn is of clinical benefit to the patient.

What’s the Importance?

Most antipsychotics are metabolized by the CYP2D6 enzyme. Some of these include aripiprazole, haloperidol, and risperidone. Based on genetics, different alleles account for differences in CYP enzymes. There are four different categories one can fit into in regards to CYP2D6: poor metabolizers, intermediate metabolizers, extensive metabolizers, and ultrarapid metabolizers. Poor metabolizers are those with little or no CYP2D6 function. This means it takes poor metabolizers longer to metabolize a drug, which will increase the drug’s half-life. By increasing the half-life, the drug will remain in the body longer and this could lead to a greater chance for the side effects mentioned before. Intermediate metabolizers have some CYP2D6 functioning, but are not considered “normal.” Extensive metabolizers are classified as normal functioning of CYP2D6. This is the category where most individuals fall. Ultrarapid metabolizers have an increased functioning of the CYP2D6 enzyme. This means the drug will be metabolized faster than normal, which shortens the half-life of the drug. It also may lead to a failure in therapeutic success due to under-treatment. Genetic testing helps identify the patients that may need a dosage reduction to avoid side effects such as poor metabolizers. On the other hand, it helps identify ultrarapid metabolizers that may need an increased dosing frequency to achieve the goal of treatment.

What does the Future Hold?

Although this sounds very convincing, some studies have been showing conflicting data. Genes may have a part in personalizing antipsychotic medication for individuals, but there seems to be other factors that also have an influence. Many antipsychotics are metabolized by more than one CYP enzyme, which may account for inconclusive data results. Also, the receptors that the drugs bind to could have genetic variation and be considered a factor. Overall, genes are not a “one size fits all,” and medication prescribing may become more personalized with genetic testing in the future.

PREVENTING INFECTION FROM THE MISUSE OF VIALS

Thousands of patients have been adversely affected by the misuse of single-dose/single-use and multiple-dose vials. The misuse of these vials has caused harm to individual patients through occurrences and outbreaks of bloodborne pathogens and associated infections, including hepatitis B and C virus, meningitis, and epidural abscesses. Adverse events caused by this misuse have occurred in both inpatient and outpatient settings, according to the Centers for Disease Control and Prevention (CDC).

The misuse of vials primarily involves the reuse of single-dose vials, which are intended to be used once for a single patient. Single-dose vials typically lack preservatives; therefore, using these vials more than once carries substantial risks for bacterial contamination, growth and infection.

Since 2001, at least 49 outbreaks have occurred due to the mishandling of injectable medical products, according to the CDC. Twenty-one of these outbreaks involved transmission of hepatitis B or C; the other 28 were outbreaks of bacterial infections, primarily invasive bloodstream infections. While many of these outbreaks occurred in inpatient settings, a high percentage occurred in pain management clinics, where injections often are administered into the spine and other sterile spaces using preservative-free medications, and in cancer clinics, which typically provide chemotherapy or other infusion services to patients who may be immuno-compromised. In addition, more than 150,000 patients required notification during this time frame to undergo bloodborne pathogen testing after their potential exposure to unsafe injections.

The CDC is aware of at least 19 bloodborne or bacterial infection outbreaks since 2007 associated with the misuse of single-dose/single-use vials. Seven involved bloodborne pathogen infections, and 12 were bacterial infections. All of these outbreaks occurred in the outpatient setting, with eight occurring in pain remediation clinics. According to CDC officials, these examples likely underestimate the harm resulting from the misuse of single-dose/single-use vials. Due to the difficulty of tracing the misuse of vials to infections, the adverse impact of misusing a vial is typically not seen immediately. Adverse events related to unsafe injection practices and lapses in infection control practices are underreported, and it remains a challenge to measure the true frequency of such occurrences.

Recommended processes and procedures

Single-dose/single-use vials

- Use a single-dose/single-use vial for a single patient during the course of a single procedure. Discard the vial after this single use; used vials should never be returned to stock on clinical units, drug carts, anesthesia carts, etc. The One & Only Campaign from the CDC and Safe Injection Practices Coalition emphasizes ONE needle, ONE syringe, ONLY ONE time. See campaign resources, including video at: http://www.cdc.gov/injectonsafety/1anonlly.html

- If a single-dose/single-use vial must be entered more than once during a single procedure for a single patient to achieve safe and accurate titration of dosage, use a new needle and new syringe for each entry. Note: USP 797 states that single-dose/single-use vials must be used within one hour, with any remaining contents discarded.

- Do not combine or pool leftover contents of single-dose/single-use vials. Do not store used single-dose/single-use vials for later use, no matter what the size of the vial.

Multiple-dose vials

- Only vials clearly labeled by the manufacturer for multiple dose use can be used more than once.

- Limit the use of a multiple-dose vial to only a single patient, whenever possible, to reduce the risk of contamination.

- When multiple-dose vials are used more than once, use a new needle and new syringe for each entry. Do not leave needles or other objects in vial entry diaphragms between uses, as this may contaminate the vial’s contents.

- Disinfect the vial’s rubber septum before piercing by wiping (and using friction) with a sterile 70 percent isopropyl alcohol, ethyl/ethyl alcohol, isophorone, or other approved antiseptic swab. Allow the septum to dry before inserting a needle or other device into the vial.

- Once a multiple-dose vial is punctured, it should be assigned a "beyond-use" date. The beyond-use date for an opened or entered (e.g., needle-punctured) multiple-dose container with antimicrobial preservatives is 28 days, unless otherwise specified by the manufacturer.

- Store multiple-dose vials outside the immediate patient treatment area; observe the manufacturer’s storage recommendations.

What is the Future Hold?

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