Pharmacy Benefit News

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Specialty Spotlight

Is Precision Medicine Linked to a Perfect DNA Model?

"Precision medicine is more complicated than portrayed by politicians and even some top health officials. "There is a paradigm shift in the treatment of cancer as we move to precision medicine," says Lincoln Nadauld, MD, of Intermountain Healthcare, a large system of hospitals and clinics based in Utah. "But that doesn't mean the outcomes are going to be perfect in every case." Many academic medical centers are studying precision medicine and hoping to make it standard in cancer care. But as a tumor grows, it accumulates so many genetic changes that it is not always clear which one is the "driver mutation" fueling its uncontrolled growth. As a result, it might not be clear which drug to use. Oncologists can also be stymied because they are shooting at a moving target. Even if they correctly identify one driver mutation, another can emerge weeks or months later, making the previous drug regimen ineffective at fighting the tumor. "The promise of precision medicine in cancer is that you'll be able to find an actual driver mutation and match a drug to it," says Nadauld. "The problem is that it's never quite as easy as we'd like it to be."

Source: *Boston Globe (08/30/15) Begley, Sharon*

Commentary:

Genomics and the hope for individualized, precision, medicine is all the rage. But we must temper our enthusiasm with the understanding that a wealth of new information may not be useful, or more importantly, may provide noise that leads us to wrong conclusions or prevents us from finding the true information. The value of information obtained from DNA testing is probably impossible to accurately characterize; however, having a wealth of information does not necessarily bring clarity. Statistical testing will most certainly be used to identify associations and determine which information is probably useful. Yet, our statistical testing tools have been well studied in small sets of data, but less so in very large data sets. The threat of "big data" is that we find associations that have no value, are not causations, or provide no real meaning. Honesty, application of the scientific method, transparency of methods, and rigorous evaluation of results remain the cornerstones of any evaluation.

New Treatments for Cholesterol – Expense Is The Only Discussion

With the approval on August 27, 2015 of the second in a powerful—and very expensive—new class of cholesterol lowering drugs, doctors are facing an increased dilemma on whether people who need to lower their cholesterol but cannot tolerate statins should be prescribed new drugs that cost more than $14,000 a year. Stephen Kopecky, MD, who directs a program at the Mayo Clinic for statin-intolerant patients, says he is aware that middle-age and older adults who typically need statins may blame the drugs for aches, pains, and memory losses that have other causes. He thinks some statin intolerance is real despite what clinical trials have shown. However, in the vast majority of cases, there is no objective test to tell real from imagined statin intolerance.

"The looming bill for the new drugs," says Peter Neumann, a health economist at Tufts Medical Center in Boston, "raises questions about how much we are willing to pay for effective innovation in the face of uncertainty about long-term effects." Doctors with patients who maintain they are intolerant to statins say they are confronted with a clash between the art and the science of medicine. Peter Libby, MD, a doctor and researcher at Brigham and Women's Hospital in Boston, says that in his role as a physician, "the patient is always right." But, he adds, "as a scientist, I find randomized, large-scale, double-blind studies more persuasive than anecdote."

Source:*New York Times (08/30/15) Kolata, Gina*

Commentary:

Cost and value are constantly discussed in the media. The newest medications, often called large molecule or specialty medications, are certainly expensive. While this discussion is incredibly important and deserves scrutiny, it is also important that we don't miss an important issue. What is the target population at risk and what is the value to that population? Cardiology medications have the capability to be even more important and impactful than the recent discussions of the cost of Hep C medications, because there are more patients. If the health care system is to have helpful debates, then we must know what treatments are the most impactful on populations at risk. This issue must be discussed first, and then let's talk about cost.

Nationwide E-prescribing of Controlled Substances

"On August 28, 2015, Vermont became the final state to allow e-prescribing for all controlled substances, including opioid analgesics such as oxycodone, hydrocodone, and morphine. Surescripts spokesperson Kelly Jeffers says the challenge now is to educate clinicians about the opportunity they have to e-prescribe controlled substances, and what is required on their part. For starters, they must have their e-prescribing software upgraded to meet standards set by The DEA. This means contacting their software vendor. Many vendors will perform the upgrade at no cost, although others charge for it, according to Jeffers. So far, only 4% of e-prescribers have had their software tweaked to handle controlled substances. The number of e-prescriptions for controlled substances is snowballing, according to Surescripts. The company, created by the pharmacy industry, routed 4 million of them in just the first half of 2015."

Source: *Medscape (08/31/15) Lowes, Robert*

Commentary:

Controlled substances were the last bastion of paper and traditional controls on prescriptions. With the increase in controlled, especially opiate, prescriptions, federal and state authorities have implemented electronic libraries of controlled substance prescriptions for review by prescribers, pharmacists, law enforcement professionals, and the DEA. The last step was nationwide electronic prescriptions, i.e., e-Rx, to digitally enter these prescriptions into the electronic libraries. Perhaps controls applied at the time of the eRx will help to dissuade fraud; however, competent prescribing of these medications using the evidence available is the most crucial element. For example, non-cancer prescribing of opiates for chronic pain management is not supported by the literature. Therapy without evidence leads to higher variance in outcomes, and misadventures that lead to fraud, drug-induced disease, severe side effects and drug dependence.

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For more information:
Carol Stern, CEO
(888) 701-5438
carol.stern@propharmaconsultants.com

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P.O. Box 280130
Northridge, CA 91328-0130
Phone No. 888.701.5438 | www.propharmaconsultants.com