

Pharmacy Benefit News

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Specialty Spotlight

Population Health vs. Precision Medicine

A great deal of focus has been placed on precision medicine, the approach to disease therapy and prevention based on genetic composition. In an article in the New England Journal of Medicine, Ronald Bayer, PhD, and Sandro Galea, MD, expressed that the attention on precision medicine is taking away from the concept of population health and the movement to improve the health care system as a whole. Bayer explains by comparing the two different perspectives, "For example, the question we want to ask about tobacco is 'why do some people smoke for a lifetime and never get cancer or emphysema?' My question is why 'do so many people who smoke get sick?' The answer from a public health point of view is to severely regulate tobacco consumption, not to figure out the genomic bases for figuring out lung cancer or heart disease."

Source: <http://healthleadersmedia.com/page-2/QUA-319912/Precision-Medicine-a-Threat-to-Population-Health>

Commentary:

The concept of translating a person's genetic makeup into individualized therapy may seem like an effective approach to medicine, but how much of an impact could it really have within the health care system overall? Even with a plethora of new developments, precision medicine may only benefit a relatively small fraction of patients, especially when much of the population is without basic health care. Furthermore, with much discussion about the high costs of newly approved specialty drugs, how does anyone expect to afford the individualized therapies that precision medicine is working to provide? The hope is that one day everyone will benefit from the understandings of the human genome; however, it will take an abundance of time and resources, as well as a health care system that is affordable and accessible to all.

[Find out more](#)

Evaluating Another FDA Approval: Repatha

The FDA has recently approved evolocumab (Repatha), a PCSK9 inhibitor, indicated for adults with heterozygous familial hypercholesterolemia, homozygous familial hypercholesterolemia, or clinical atherosclerotic cardiovascular disease requiring additional LDL cholesterol lowering. The new injectable works by blocking the actions of PCSK9, a protein that reduces the number of receptors with the ability to remove LDL cholesterol from the blood. With more available receptors, more LDL can be removed, resulting in a decrease in LDL cholesterol levels and possibly a decrease in cardiovascular events. John Jenkins, MD, Director of the Office of New Drugs, Center for Drug Evaluation and Research reports, "Cardiovascular disease is a serious threat to the health of Americans, and the FDA is committed to facilitating the development and approval of effective and safe drugs to address this important public health problem."

Source: <http://www.fda.gov/NewsEvents/Newsroom/>

Commentary:

Heart disease is the leading cause of death in the United States, and the FDA often moves quickly to approve innovative therapies that may reduce this incidence. However, just because a drug has the FDA's stamp of approval does not mean it will have a significant impact in the real world. The trials evaluating the safety and efficacy of evolocumab, while finding that the drug may successfully lower LDL cholesterol, provided no evidence that this surrogate outcome will actually lead to fewer heart attacks and strokes. The studies were also relatively short, the longest being 52-weeks, leaving the long-term effect of the drug unknown. Due to these limitations, the FDA has indicated this drug only for a certain population, including those who have been unsuccessful in lowering LDL cholesterol levels with statin therapy. Further investigation will need to be done to determine whether or not evolocumab has the ability to achieve clinical outcomes and reduce morbidity and mortality from cardiovascular causes.

Omega-3 and Cognitive Health - The Fishy Reality

There is some data to suggest that a diet rich in omega-3 fatty acids may benefit the cognitive health of older adults; however, evidence by the National Institutes of Health (NIH) indicates otherwise. A clinical trial following more than 3,500 individuals over 5 years found that supplementation with omega-3 fatty acids had no effect in slowing cognitive decline when compared to placebo. The participants were an average age of 72 years, were randomized to receive long-chain polyunsaturated fatty acids (LCPUFAs), specifically 350 mg DHA/650 mg EPA, and/or lutein/zeaxanthin or placebo, and were given cognitive function tests at baseline and every 2 years throughout the duration of the 5-year study. Data analysis showed no statistically significant difference in cognitive test scores between those who received omega-3 and those who did not.

Source: Chew EY, Clemons TE, Agron E, et al. Effect of omega-3 fatty acids, lutein/zeaxanthin, or other nutrient supplementation on cognitive function. *JAMA*; 2015;314(8):791-801.

Commentary:

Omega-3 fatty acids, commonly known as fish oil, have been associated with several possible health benefits. Most of these claims are lacking strong evidence. Contrary to the labeling of several different omega-3 products that are sold over-the-counter, this latest study shows that the brain and cognitive health benefits advertised may not be true. Further research may need to be conducted; however, it is likely that the cognitive benefit of fish oil may be little to none.

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