

# Pharmacy Benefit News

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## A Ding to Vitamin D Use

By Kelly Young

Edited by David G. Fairchild, MD, MPH, and Lorenzo Di Francesco, MD, FACP, FHM

"The U.S. Preventive Services Task Force (USPSTF) is recommending against vitamin D supplementation to prevent falls in community-dwelling adults aged 65 and older (grade D recommendation). The draft statement is a change from its 2012 recommendation in favor of supplementation."

"In a new analysis, the group found evidence that vitamin D supplementation did not reduce fall risk in patients who were not vitamin D deficient."

"The USPSTF continues to recommend exercise to reduce the risk for falls in community-dwelling elders (grade B), and multifactorial interventions may be offered to high-risk seniors (grade C)."

"In a separate draft recommendation statement, the task force maintained its 2013 position on vitamin D and calcium supplementation to prevent fractures in men and premenopausal women. There is still not enough evidence to recommend for or against the practice (grade I)."

"The group again recommends against postmenopausal women taking 400 IU or less of vitamin D and 1000 mg or less of calcium daily because there's no effect on fracture prevention (grade D). There was less certainty about higher doses (grade I)."

[USPSTF draft recommendations on fall prevention in seniors](#) (Free)

[USPSTF draft recommendations on vitamin D, calcium supplementation for fracture prevention.](#) (Free)

[USPSTF grade definitions](#) (Free)

Background: [Physician's First Watch coverage of 2012 USPSTF recommendations on fall prevention](#) (Free)

### Commentary:

It is common for Vitamin D levels to be drawn with standard labs. The goal is to minimize the impact of low Vitamin D levels on the patient. However, as the new USPSTF guidelines indicate, the impact on elderly falls is not an issue. Dosing is not an issue. Therefore, it remains to be seen if the impact on other clinical problems is validated or disproved.

Since low Vitamin D levels were identified to be associated with rickets and anemia, and Vitamin C levels were associated with scurvy, there has been a trend to associate low vitamin levels with other clinical problems. Yet, maybe we are stretching the argument. Low levels of specific vitamins may be a contributor to pronounced clinical problems, but less of an independent factor in issues with multiple causes such as falls.

Multifactorial problems require multifactorial treatments. More research should help to differentiate single causation from multiple causation.

## FORECASTING & PREDICTIONS – NOT MATHEMATICAL VOODOO!

How do you get current and predicted trends at your fingertips? Forecasting and Predictions are not mathematical voodoo. They are the frequent request of Pro Pharma clients. Clients also request how to manage trend to their prearranged target. For example, keep trend at national averages, OR keep trend 1-3% below national averages, OR what is the trend for Specialty Rx versus traditional medications?

The answer to clients is frequently trend predictions predicated on supportable, and measurable, methodologies! Trend models are supported, among other things, by cost accounting, unit cost and utilization increases, provider performance metrics, medication category impact, new entrant impact, age/gender movements, and projections for future growth. All of these analyses are aggregated and provided in Pro Pharma/ProData Analytics cloud-based solutions. So, how is trend predicted, and then managed?

Calculations: First, what is the trend that is associated with predictions? Trend calculations based on PMPM (per-member-per-month) are commonly composed of the ingredient cost, utilization, and new entrant components. Each of these PMPM components are calculated monthly and summed. The result is compared to prior period trends. Second, what are the drivers that contribute to each element of trend? Drawing from cost accounting of every dollar spent on medications and the period-over-period price increases, two elements of trend are readily available. New entrants and price trend analyses contribute the third element. Summing the results of these elements and comparing to prior periods is the trend prediction.

Trend Management: Aside from the actuarial models that Pro Pharma/ProData Analytics supports, the next problem is to manage trend throughout the year in order to reach targets. Analytics at your fingertips can help with monthly calculations and trends to identify components that require interventions. How do you manage Trend? Linking all elements of trend to their respective driver reports provides:

1. Medications incurring the largest price increases for formulary management
2. Financials for utilization trend leads to therapeutic category expansion/new PA targets/formulary planning
3. Provider performance for Comparative Price Sheets and Comprehensive Medication Reviews
4. Age/gender movement period-to-period impact the denominator of PMPM
5. Financials for new entrants provides a budget impact.

Results: The results are trends, and the elements necessary to manage the trend to your target. The result -- lower paid PMPM, lower budget PMPM, and lower trend.

[Learn More](#)

### Does Genotyping Reduce Adverse Effects from Warfarin?

By Amy Orciari Herman

Edited by David G. Fairchild, MD, MPH, and Lorenzo Di Francesco, MD, FACP, FHM

"Genotype-guided dosing of warfarin in older adults undergoing elective hip or knee arthroplasty helps prevent adverse events, according to a *JAMA* study."

"Roughly 1600 adults aged 65 and older were randomized to either genotype-guided or clinically guided warfarin for 11 days, beginning the night before or the night of arthroplasty. In both groups, clinical variables were used to guide dosing; in the genotype group, dosing also took into account four polymorphisms associated with warfarin metabolism, warfarin sensitivity, and vitamin K metabolism."

"The primary outcome — a composite of major bleeding, INR of 4 or greater, or death within 30 days, and venous thromboembolism within 60 days — occurred in 11% of the genotype-guided group versus 15% of the clinically guided group. The benefit was largely

### Control Drug Prices – The Industry Says No!

"Despite calls for controlling expensive drug costs coming from all sides of the political spectrum, any momentum to address the issue has been lost amid rancorous debates over replacing the Affordable Care Act and stalled by roadblocks erected via industry pushback." According to the Drug Pricing Lab, a Memorial Sloan Kettering Cancer Center program that has catalogued ideas for reducing prices, there are multiple proposals presented to Congress over the last two years. These proposals include:

1. Importation from other developed countries, where regulations keep prices down
2. Allowing government to negotiate the price of Medicare-covered drugs
3. Speeding approval of cheaper generics
4. Requiring notification before raising drug prices
5. Restricting consumer drug ads.



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treatment.

[JAMA article](#) (Free abstract)

[JAMA editorial](#) (Subscription required)

[Background: NEJM Journal Watch Cardiology 2013 coverage showing no benefit from genotype-guided warfarin dosing](#) (Free)

#### Commentary:

The advent of companion diagnostics to accompany drug prescribing is a new method to get the maximum benefit from the drug with reduced risk. This is a major improvement in many therapies, especially cancer chemotherapy, where genotyping indicates if the medication will be effective or not. It is also an additional piece of information to be used with blood levels of medications, radiographic studies, clinical dosing guidelines, and data on populations at risk to tailor therapy.

In the above study, the difference between genotyping and other methods may not be cost-effective. An editorialist concludes, "Genotype-guided warfarin dosing probably has some clinical utility but it might be simpler and less expensive to implement wider use of clinical dosing algorithms to reduce the harms of anticoagulation." [Note: Please Like Craig Stern Share ["DNA to Diagnosis to Treatment... A Dependent Paradigm"](#) if you wish to read more on this topic.]

Research and Manufacturers of America (PhRMA) increased member dues by one-half last year to prepare for battle. The pharmaceutical and health products industries spent \$145 million on lobbying for the first half of 2017, according to data from the Center for Responsive Politics. Drug makers say that high prices reflect heavy investment in innovation and drug development, and reject the notion that the industry wields too much influence in Washington." PhRMA responded..."So we will continue to be engaged with the administration to advance solutions that improve the marketplace and make it more responsive to the needs of patients."

*Kaiser Health News (09/25/17) Hancock, Jay*

#### Commentary:

The major concern is that lower prices will lead to lower profits that will lead to reduced innovation. Whether this is true or not, a major input to new innovation is government sponsored and funded research that provides innovative new therapies. Manufacturers pick up the development, distribution and marketing rights for these innovative therapies. Further, innovation is no longer solely a US driven proposition. China, India, Israel, Brazil, South Africa, and several countries in Europe are just some of the leaders in researching new innovative therapies and improvements on current therapies. Hence, the argument is more complex than just paying more to get more. This argument needs to be addressed from all vantage points to ensure that expensive drugs do not necessarily mean unaffordable drugs.

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## **CONTACT US**

P.O. Box 280130  
Northridge, CA 91328-0130  
(888) 701 - 5438  
[info@propharmaconsultants.com](mailto:info@propharmaconsultants.com)  
[info@prodataanalytics.net](mailto:info@prodataanalytics.net)

**[WWW.PROPHARMACONSULTANTS.COM](http://WWW.PROPHARMACONSULTANTS.COM)**  
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P.O. Box 280130  
Northridge, CA 91328-0130  
(888) 701-5438 | [www.propharmaconsultants.com](http://www.propharmaconsultants.com)

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