Pharmacy Benefit News

Issue # 298 | March 9th, 2017

Stay in Touch!

How Do You Identify a Potential Adverse Drug Reaction?

Drug-induced adverse reactions are common yet the correlation between the symptms and the drug are often overlooked. The following is a standard set of questions commonly used to determine the probability of an adverse drug reaction acting as the cause of observed signs and symptoms. Naranjo scores of 9 or 10 indicate that an event was "definitely" an ADR; scores of 5-8 rate the likelihood as "probable"; scores of 1-4 are "possible"; and scores of less than 1 are "doubtful."

We are publishing this algorithm in an effort to inform providers and patients of the need to consider adverse drug reactions when evaluating the reason for newly observed signs and symptoms.

The Naranjo Algorithm

Question	Yes	No	Do Not Know	Score
1. Are there previous conclusive reports on this reaction?	+1	0	0	
2. Did the adverse event appear after the suspected drug was administered?	+2	-1	0	
3. Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0	
4. Did the adverse reaction reappear when the drug was readministered?	+2	-1	0	
5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0	
6. Did the reaction reappear when a placebo was given?	-1	+1	0	
7. Was the drug detected in the blood (or other fluids) in concentrations known to be toxic?	+1	0	0	
8. Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?	+1	0	0	
9. Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0	
10. Was the adverse event confirmed by any objective evidence?	+1	0	0	

Source:
Naranjo CA, Busto U, Sellers EM, et al. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther. 1981;30:239-245. Reprinted with permission.
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Analytics at Work: A Real World Example

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Over The Bridge

Problem:
There is a general problem with relating Formulary Medications to their Therapeutic Categories. Health Plans and PBMs have traditionally used First Databank or Medi-Span to code therapeutic categories such as diabetes, hypertension, or cancer. Often a Health Plan cannot access the coding that a PBM or Formulary Vendor is using. Medicare has introduced the RxNorm System that does not require purchase of a Vendor's database and it is necessary for compliance with Medicare. Plans are also considering using RxNorm for general use.

Action: As a result of the above situation, a client requested bridge files for NDCs for drugs to the RxCUI Therapeutic Categories. This would allow the client to control the database, make changes, and ensure compliance of benefits with the Formulary Therapeutic Categories. ProData Analytics and Pro Pharma worked together to produce a table and to provide and maintain updates for changes in their NDCs.

Outcome: The result is that the Client now has complete control of their Formulary, Therapeutic Coding, Benefit Exclusions, etc. This bridge file allows for compliance with Medicare, Medicaid, and private insurance. They have saved time, resources, and redeployed staff to other urgent organizational issues.

Learn More

Two Chronic Health Conditions Drive 25% of Treatments

One in four Americans received treatment for at least two chronic health conditions such as diabetes and hypertension in 2012. Collectively, chronic care treatment accounted for 57 percent of all health care expenditures that year. (Source: Agency for Healthcare Research and Quality, Medical Expenditure Panel Survey Statistical.

Source: Health Expenditures For Adults by Number of Treated Chronic Conditions, Race/Ethnicity, and Age, 2012.

Commentary: Specialty medications to treat significant diseases like Hepatitis C, Multiple Sclerosis, Cancer, and Cystic Fibrosis have captured headlines due to their huge costs. Yet, diabetes and hypertension collectively are drivers of care for the general population. It is imperative that health care professionals and patients do not allow their attention to be diverted from common problems that drive health care resources. The entire population is subject to these chronic diseases especially due to the rise of obesity and sedentary lifestyles.

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Off Label Uses of Drugs is a Big Problem

The practice of using a medication for something other than its primary purpose is a common one. Off-label prescriptions can be powerful weapons in the fight against certain cancers and other difficult-to-treat conditions. Researchers at Stanford University are trying to remedy that gap in clinical understanding by detailing a new method of scraping Electronic Health Records (EHR) data for valuable information on off-label usages.

As a benchmark, a study from 2006 indicates that while 21% of all prescriptions are for drugs intended for off-label use, fewer than 30% of these decisions are supported by peer-reviewed data. While there is great potential for many pharmaceuticals to be used in beneficial new ways the original developers couldn't even imagine, there is also a risk of harm to patients who may not react as a provider could hope. Drug companies may invest in off-label tracking systems to see exactly how their products are used and how to spot patterns that may encourage new discoveries.

"Just as detection of abnormal spending is now a routine feature of credit card services, someday off-label use detection could be a routine part of health-care systems," says Nigam Shah, MBBS, PhD, lead author of the study. The combination of electronic

health records and molecular evidence can make a stronger argument for agencies to fund clinical trials.

Source: https://ehrintelligence.com/news/ehr-notes-data-analytics-help-track-off-label-drug-use/

Commentary:
This study focused on the use of Electronic Health Records (EHRs) as a source of rationale for medication usage. However, the larger issue is the use of medications for non-FDA approved

for medications require that the medication is used for FDA approved indications. The insurer concern is that effectiveness and safety are well established for labeled indications.

For off-label use both effectiveness and safety are question marks. Insurers may use “common practice in the community” as an alternative method for approving off-label uses of medications. This method usually requires at least three double-blinded placebo controlled studies on the medication usage in individuals similar to the patient; however, this criteria is usually hard to document.

This would be a significant improvement over current methods of evaluating and approving therapy, if manufacturers are going to use EHR and potentially social media to identify off-label usage and match it with effectiveness and safety data.

Pro Pharma is a Multi-Service Consulting Firm specializing in solutions for managing Pharmacy Benefits for Self-Insured Employers, Unions, Third Party Administrators, Managed Care Organizations, Physician Groups, Health Insurers/Workers' Compensation Insurers, and Integrated Health Networks.

Consulting Services Include Claims Management/Oversight and Management of Benefits, most specifically Client-Specific MAC List Development and Maintenance as follows:

- Medicaid Compliance and/or CMS FUL Compliance
- Flexible Pricing Determinants
- Lowest Cost
- Average of Lowest 3 Costs
- Average of all Generics
- Median of all Generics
- Flexible Price Sources, including, CMS, MediSpan, First Data Bank, Redbook
- Flexible Therapeutic Categories (Customizable)
- Flexible Generic Availability
- Immediate availability
- Predetermined time gap from end of patent
- Minimum number of Generic Manufacturers
- Decision allowance for generic, all store brands, re-packagers, multisource, and/or branded generics
- Flexible Code Basis, including GCN, GPI, and NDC

Pro Pharma's capabilities are focused on Data Analytics and based upon Demographic modeling of Integrated Medical and Pharmacy Data Sets. Our experience sets us apart and positions us as a valued Consultant for those clients interested in "Thinking Outside of the Box" to implement solutions to Benefit Management which are both Quality-Based and Cost-Conscious.

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