



Personalized Health Solutions, LLC

The future is
Personalized Medicine



The Role of PGx Testing in Home Health

Gulf Coast Senior Alliance

June 21, 2018



About Personalized Health Solutions

Personalized Health Solutions, LLC connects healthcare providers with state-of-the-art diagnostic laboratories performing Pharmacogenomics (PGx) testing, Toxicology and Wellness screens, and Molecular Testing.

Testing supplements the clinical examination and provides advantages to traditional “trial and error” prescribing by predicting an individual's response to a medication. Testing can reduce risk of adverse events and gets the patient on the correct therapy sooner.

Our mission is to bring health solutions to providers and their patients which personalize medicine, improve patient adherence, reduce cost and achieve better outcomes



About Personalized Health Solutions

Advantages that Personalized Medicine may offer healthcare providers and patients:

- Eliminate or reduce ‘trial and error’ prescribing of medication
- Understand individual drug response to determine the right drug and the right dose
- More precise health treatment plans resulting in greater likelihood of desired outcomes
- Reduce negative side effects
- Identify genetic variants that affect drug metabolism
- Control or reduce healthcare costs





Personalized Health Solutions Services

- **Pharmacogenomic (PGx) Testing**
- **DVT Solutions**
- **Molecular Testing - Respiratory Pathogen Panels**
- **Toxicology Screens**
- **Wellness Screens**

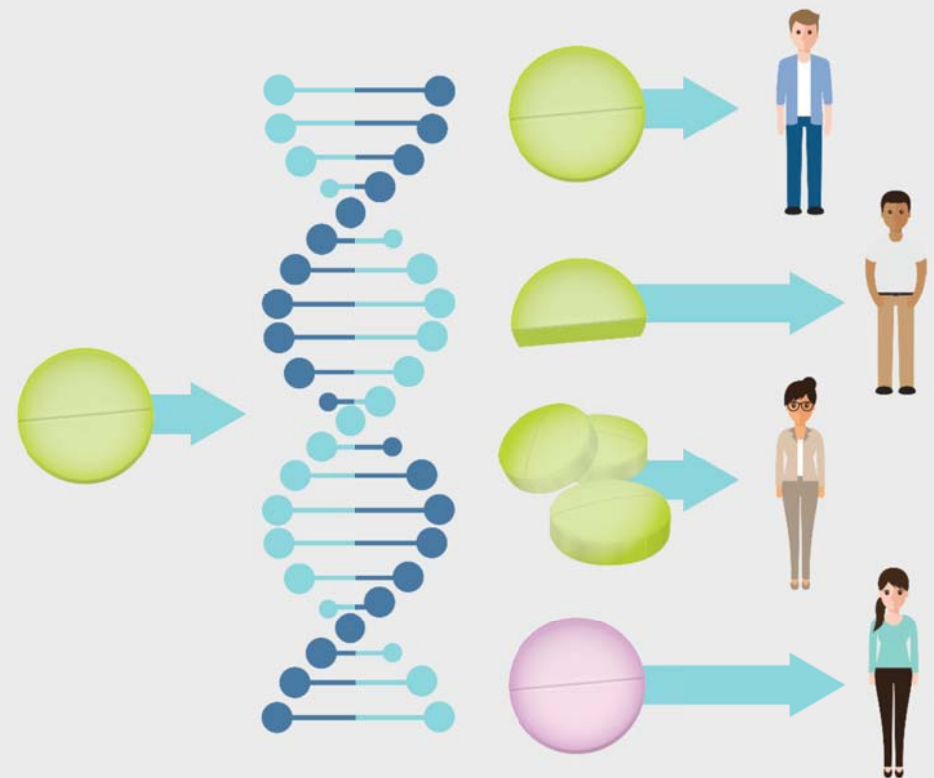




Pharmacogenomic (PGx) Testing

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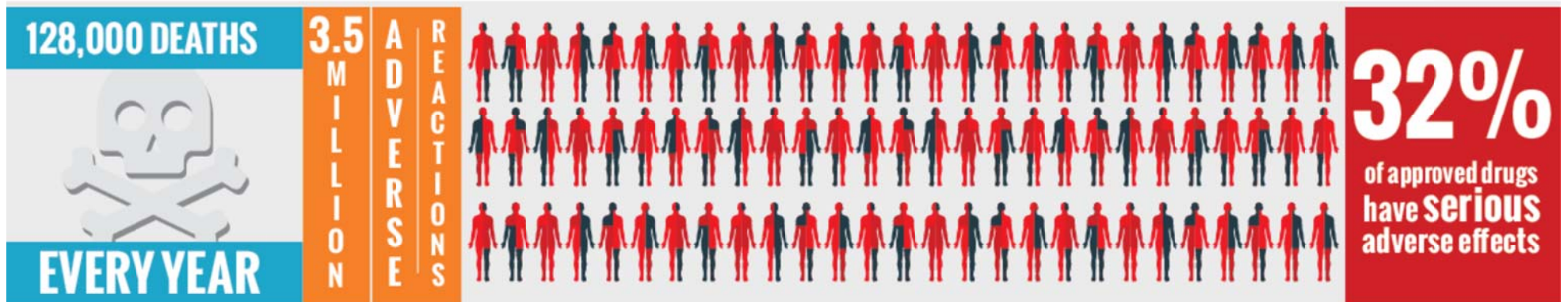
- Blend of Pharmacology (study of drugs) and Genetics (study of genes)
- Drugs metabolize differently based on an individual's inherited genetic variants
- Genetic variants may significantly affect patient's ability to break down and absorb many commonly prescribed medications.
- Testing helps physicians select effective, safe medications and doses that are tailored to an individual's specific genetic makeup
- PGx testing avoids reduced efficacy of medication or increased risk of adverse drug events.





PGx Testing; Adverse Drug Events

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An Adverse Drug Event (ADE) is an illness or injury resulting from the administration of a drug. An ADE could be because of an interaction with another drug, improper dosing, or because of a genetic variant in the way that an individual metabolizes a particular medication.

Incidence of Adverse Drug Events (ADEs)

- 128,000 deaths in the US are directly attributable to ADEs, ranking as one of the top five causes of fatalities in the US each year.
- ADEs are responsible for over 3.5 million outpatient visits each year, and more than 700,000 ER visits.
- One third of all new drugs approved between 2001 and 2010 had major safety issues after being made publicly available; as reported in JAMA, Yale researchers discovered 71 of 222 drugs were withdrawn, required a black box warning, or warranted a safety warning about risks.



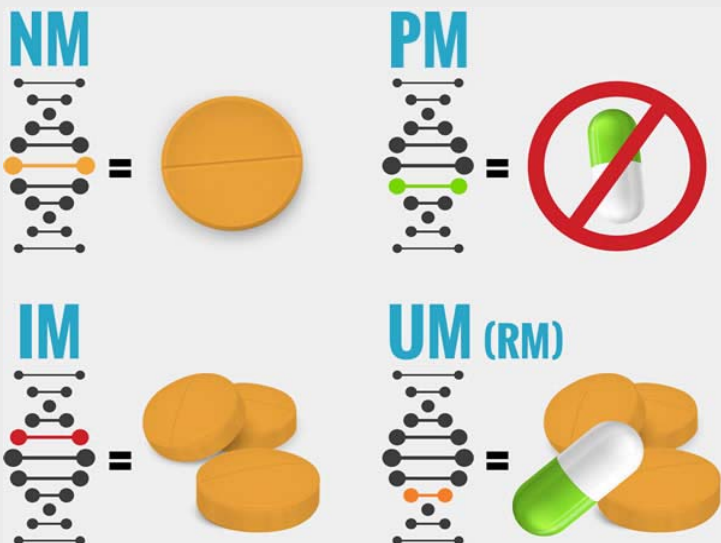
PGx Testing; Drug Metabolism

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Testing for genetic variants can help determine the safest medications and doses by identifying a patient's phenotype. The metabolic phenotype is a classification of how a given enzyme will metabolize or break down ingested drugs.

More than 75% of individuals have a variant on a specific gene that can affect metabolism of commonly prescribed medications.

Testing reveals the following Phenotypes:



Metabolizer Phenotype	Description	Effect
Poor Metabolizer (PM)	Patients with little to no functional metabolic activity.	Enzymes break down Standard drugs very slowly, creating risk of toxicity because drug is slow to be eliminated.
Intermediate Metabolizer (IM)	Patients with reduced metabolic activity.	At approved doses, enzymes will be slightly slower in breaking down Standard drugs, requiring a slightly lower dose to
Normal Metabolizer (NM)	Patients with normal metabolic activity.	Produces desired outcome as expected when dosed according to FDA approved labels.
Rapid or Ultrarapid Metabolizer (RM)	Patients with substantially increased metabolic	Enzymes break down and eliminate drugs very quickly, often reducing the effectiveness of the drug. Standard doses



PGx Testing; Dosing Recommendations

- Over 75% of individuals have genetic variations that affect how drugs are metabolized.
- Most of the diseases for which patients seek physician advice are treated by medications that are metabolized by a gene within the Cytochrome P450.
- Drugs used for diabetes, heart disease, hypertension, depression, anxiety, GERD, and chronic pain are metabolized by frequently studied genes CYP2D9, CYP2C19, and CYP2D6.
- PGx testing, as a component of medication therapy management, can reduce risk by predicting drug response and alerting prescribers to potential for toxicity or drug-drug interactions.

Gene	Percentage of Persons with Genetic Variant	Drugs Metabolized
CYP2C9	53% to 88%	Glipizide, Losartan, Phenytoin, Warfarin
CYP2C19	56% to 86%	Citalopram, Diazepam, Omeprazole
CYP2D6	52%	25% of All Drugs, Opioids, Anti-psychotics, Beta Blockers, NSAIDs, SSRIs



Utilization of Home Health Services

Home Health Agencies provided services to 3.5 million Medicare beneficiaries in 2013 at a cost of \$18 Billion.

- *Medicare Payment Advisory Commission, March 2015*

Patients receiving Home Health Services:

- Are often Elderly
- Take Multiple Medications
- Experience Poor Compliance



Top Diagnoses for Home Health Episodes in Alabama (2012 Data)

Diagnosis	Number of Claims	Percentage of Total
Orthopedic Aftercare	11348	7.44
Diabetes Mellitus	11168	7.32
Heart Failure	10335	6.77
Essential Hypertension	8237	5.4
Other and Unspecified Aftercare	7557	4.95
Care Involving Use of Rehabilitation Procedures	7278	4.77
Chronic Ulcer of Skin	6822	4.47
Chronic Bronchitis	6258	4.1
Other Deficiency Anemias	6049	3.97
Late Effects of Cerebrovascular Disease	5090	3.34

- Avalere analysis of the “100% Medicare Standard Analytic Files, 2012”



Medication Management

Medication related problems potentially interfere with optimal care outcomes.

“...as reductions in preventable hospital readmissions become a more important goal for health care quality improvement and payment policy...the challenge of ensuring good medication management that supports patient medication adherence among newly discharged patients becomes increasingly significant.”

- NEHI/Anthem Foundation



Hospital Readmissions

Congestive Heart Failure most common

Greater number of medications - increased likelihood of readmission

26% of readmissions are medication related:

Patient Nonadherence 23.8%

Untreated Condition for which Medication is Indicated 13.3%

Dose Too High 10.5%

Dose Too Low 10.5%

Preventable and Medication Related Readmissions Higher in Rural Areas (30%) than in Urban Areas (17%)



Patient Adherence

Does drug taking behavior correspond with agreed recommendations?

One third to one half of all patients do not take medications as directed.

– New England Journal of Medicine, 2005

Cost of poor adherence \$300 Billion dollars

- NEHI 2011



Patient Adherence Considerations

Confidence in Safety, Efficacy

Patient Engagement

Side Effects

Perception that medication is unnecessary

Low health literacy

Cost/Insurance Coverage



Potentially Inappropriate Medications (PIM)

Seniors at increased risk of side effects

Prone to medication side effects

Decline more rapid in patients with comorbidities
(Diabetes, Hypertension)

Beers list – American Geriatrics Society list of drugs
to avoid

“Less is More’ approach is often the best way to
improve health outcomes in older adults.”

- *Dedhiya et al, Journal of American Geriatric Pharmacotherapy*



Polypharmacy

Polypharmacy strongly related to hospital readmissions.

- *Journal of Medical Economics, 2016*

37.1% men and 36% women over 75 used at least 5 RX medications

Most common are HCTZ, atorvastatin, levothyroxine, Lisinopril, metoprolol, simvastatin, atenolol, amlodipine, metformin, furosemide

- *Rossi et al, American Journal of Geriatric Pharmacotherapy 2017*



Outcomes in Polypharmic Home Health Patients

Unity Health of Searcy, AR Study of Home Health patients aged 50 years and up

Pharmacy performed chart reviews for randomly selected patients

Reviewed for drug-drug, drug-gene, and drug, drug-gene interactions

Drug-drug and drug-gene related problems rise with polypharmacy.

35% of seniors experience ADEs, 50% preventable

10-17% of hospitalizations of older patients directly related to Adverse Drug Events

Patients aged 60 years and older account for 51% of ADE related deaths.



Outcomes in Polypharmic Home Health Patients (continued)

Patients in the tested group received a physician order for PGx testing

Patients followed for sixty days following hospital discharge

Outcomes included:

- Time to first re-hospitalization

- Time to first ED visit

- Number of falls during study

- Deaths

- Oasis scores at 30 and 60 days

 - Overall status, pain, confusion, anxiety, disruptive behavior, assistance with ADL, depression

***PGx profiling reduced hospitalizations by 39%
and ED visits by 71%***



Why PGx matters to Home Health

Value Based Payments

CMS Purchasing Pilot

Increases based on Outcomes rising from 3% in 2018 to 8% in 2022

Medicare Advantage – CMS May 2018 Final Rule gives MA payors broad discretion on services which improve outcomes

Acquisitions (i.e. Humana's acquisition of Kindred, Anthem's purchase of Aspire)



Implementing PGx for your Patients

Testing must be ordered by supervising physician or PA

Specimen submission includes

- two buccal swabs

- list of patient medications and supplements

- medical necessity documentation

Results available in three to five days

Contact Personalized Health Solutions at 251-706-2777