GTMRx Institute™

Get the medications right

www.gtmr.org

Pharmacogenomics: Lowering costs, improving outcomes through personalized medicine

August 7, 2019 | 1 p.m. Eastern

GTMRx Learning Network Webinar

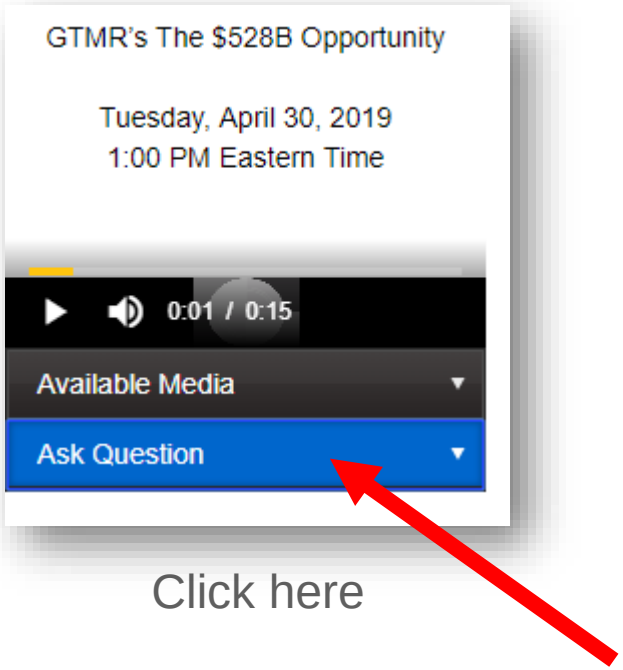
Agenda

- Welcome and Introductions
- Learning Objectives
- Presenters:
  - **Steven Goldberg, MD, MBA**, Board Member, GTMRx Institute
  - **Jane Cheshire Gilbert, CPA, CPAE,** Teachers' Retirement System of Kentucky
- Question and Answer Session

Audience Notes

- There is no call-in number for today's event.
- Audio is by streaming only. Please use your computer speakers, or you may prefer to use headphones.
- There is a troubleshooting guide in the tab to the left of your screen.
- Please refresh your screen if slides don't appear to advance.

Submit questions at any time

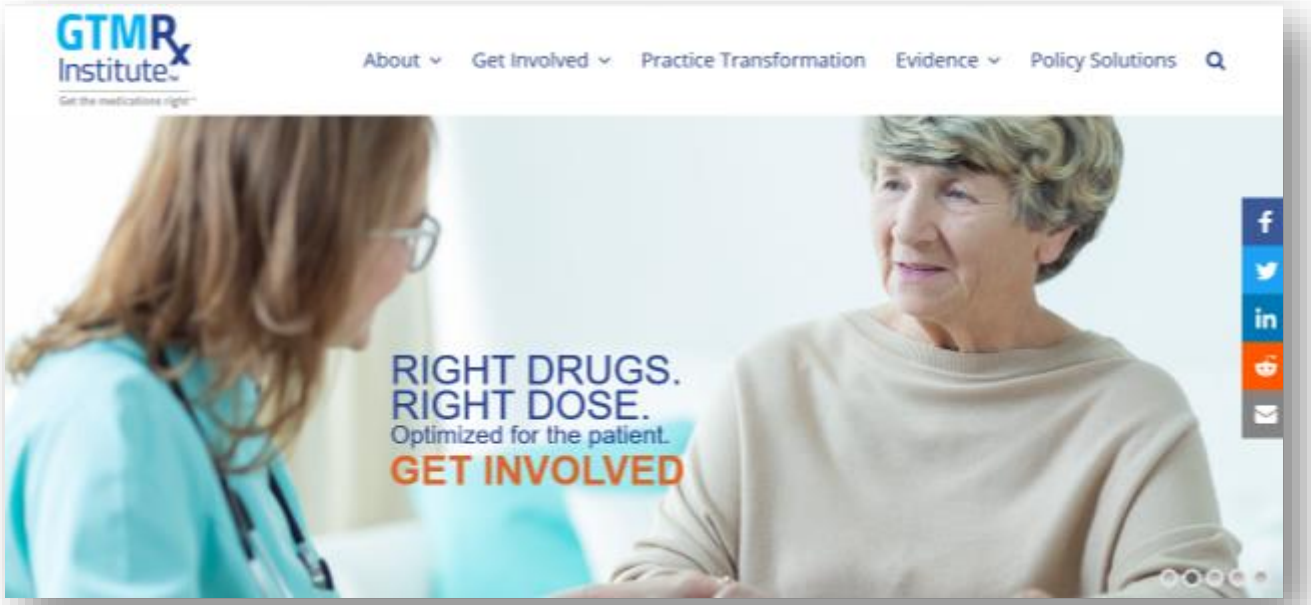


How to submit a question

To submit a question, click on Ask Question to display the Ask Question box. Type your question in the Ask Question box and submit. We will answer as many questions as time permits.

Audience Notes

- A recording of today's session will be posted within one week to our website, www.gtmr.org



Learning Objectives

After the webinar, participants will be able to:

- Define pharmacogenomics and its application to reduce adverse drug events and support better outcomes for patients.
- Describe salient elements of a program using pharmacogenomics and personalized medicine, with patient counseling and guidance from clinical pharmacists, to enhance treatment outcomes and lower costs; and
- Summarize three strategies employers can apply to benefit design to lower costs and improve outcomes through personalized medicine.

Our Presenters

STEVEN GOLDBERG, MD, MBACEO
Vice President, Medical Affairs, Population Health, Chief Health Officer, Health And Wellness, Quest Diagnostics; and Board Member, GTMRx Institute

JANE CHESHIRE GILBERT, CPA
Director Of Retiree Health Care for the Teachers' Retirement System of the State of Kentucky

Quick view of GTMRx Institute

A national platform creating a forum for more rapid practice and policy change to save lives and revolutionize the way care is delivered in order to optimize medication use.

Goal: To educate, inform and change the market so research and innovation moves to the practice level, payment models and policy align, and buyers receive value.

Vision: Enhance life by ensuring appropriate and personalized use of medication and gene therapies.

Mission: Bring critical stakeholders together, bound by the urgent need to optimize outcomes and reduce costs by *getting the medications right*.

Focus Areas

- **Practice Transformation**
- **Evidence & Innovation**
- **Payment & Policy Solutions**

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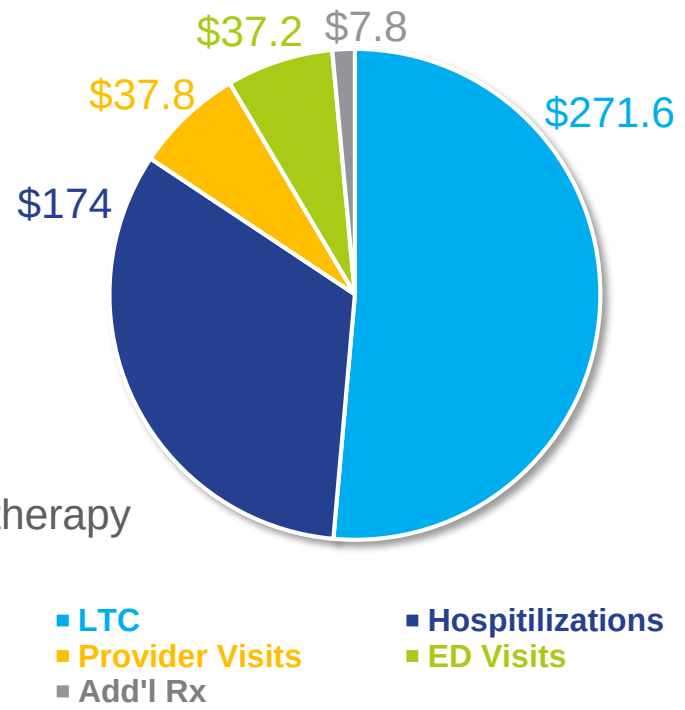
The $528 billion opportunity

- Medications are involved in **80%** of all treatments & impact every aspect of a patient's life.
- Nearly **30%** of adults in the U.S. take **5+** medications.
- **10,000** prescription medications available on the market today.
- Only **13%** of PCPs consult with a pharmacist before prescribing new prescriptions.
- **49 seconds** spent between physicians and patients talking about new medication during a **15-minute** office visit.
- **$528.4B in 2016** cost of non-optimized medication therapy
  - $174 billion **hospitalization** costs
  - $271.6 billion **long-term care** admissions
  - $37.2 billion **emergency department** visits
  - $37.8 billion additional **provider visits**
  - $7.8 billion **additional prescriptions**

The costs of using non-optimized medications



Founding and funding board members

Katherine Capps
Co-founder, Exec Director

Terry McInnis, MD, MPH, FACOEM
President & Co-founder

Paul Grundy, MD, MPH, FACOEM, FACPM

Brig. Gen. Allison Hickey (Ret.)

Deborah M. Gage

medecision

Ira Klein, MD, MBA, FACP

J&J

Steve Goldberg, MD, MBA

Quest Diagnostics

C. Edwin Webb, Pharm.D., MPH, FCCP

accp

Paul W. Abramowitz, Pharm.D., Sc.D. (Hon), FASHP

ashp

Health System, Payor or Foundation

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Workgroups

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VISION: To enhance life by ensuring appropriate and personalized use of medication and gene therapies.

MISSION: We bring critical stakeholders together, bound by the urgent need to optimize outcomes and reduce costs by ***getting the medications right.***

Focus of Working Groups

Practice Transformation (Skills, Tools & Knowledge)	Evidence & Innovation (Research-Based Best Practices)	Policy Solutions (Evidence-Based, Effective Solutions)
HIT Analytics (& AI) enablement		**Precision medicine enablement via advanced diagnostics**

Operational Activities & Outputs from Working Groups

▪ Accessing clinical data to support CMM ▪ Collaborative practice agreements ▪ Developing value-based business agreements ▪ CMM team-based care R&F ▪ Physician engagement and activation ▪ Patient engagement tools ▪ Barriers and enablers ▪ Expanding access to health IT solutions that liberate clinical data exchange for CMM practice	▪ Quality metrics (process, satisfaction, outcomes) ▪ Value metrics (cost and quality) ▪ Effective integration into delivery models and across settings ▪ Program and process guidance ▪ Building consumer demand ▪ Building physician demand ▪ Identification of expert practices ▪ Evidence for advocacy ▪ Building purchaser demand	▪ Enabling policy for CMM program reimbursement ▪ Overcoming policy & payment barriers to appropriate medication use ▪ Enabling benefit design / guide for employers ▪ Enabling policy for risk-based contracting (product & appropriate use)/ guide for practices & plans ▪ Recognition of emerging outcomes-based and population-based research (CBO scoring) ▪ Enabling policy & payment for gene therapies

Join a dynamic team of health care leaders!

Executive Members

VA | U.S. Department of Veterans Affairs

LabCorp

California Chronic Care Coalition in San Diego County

A sample of our 390+ GTMRx Institute member organizations

(inclusion does not constitute an endorsement of any program, product or organization)

American Association of Colleges of Pharmacy AACP

Discover • Learn • Care: Improve Health

MBGH

Midwest Business Group on Health

The Source for Leading Health Benefits Professionals

tria HEALTH

Washington State University

envision genomics

Brigham Health

BWH Brigham and Women's Hospital

Mid-America Coalition on Health Care

AIMM Alliance for Integrated Medication Management

AAFP American Academy of Family Physicians

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10 Steps to CMM:

#1

Identify patients that have not achieved clinical goals of therapy.

#2

Understand the patient's personal medication experience, history, preferences, & beliefs.

#3

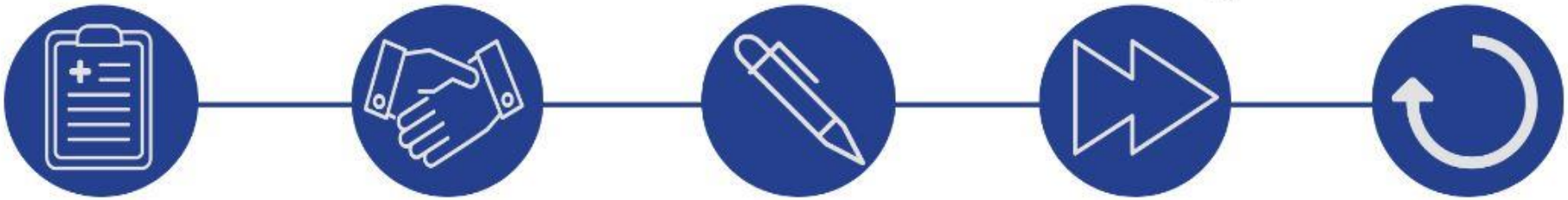
Identify actual use patterns of all medications including OTCs, bioactive supplements & prescribed medications.

#4

Assess each medication for appropriateness, effectiveness, safety (including drug interactions) & adherence, focusing on achievement of the clinical goals for each therapy.

#5

Identify all drug-therapy problems.



#6

Develop a care plan addressing recommended steps including therapeutic changes needed to achieve optimal outcomes.

#7

Ensure patient agrees with & understands care plan which is communicated to the prescriber or provider for content & support.

#8

Document all steps & current clinical status vs. goals of therapy.

#9

Follow-up evaluations are critical to determine effects of changes, reassess actual outcomes & recommend further therapeutic changes to achieve desired clinical goals & outcomes.

#10

CMM is a reiterative process! Care is coordinated with other team members & personalized goals of therapy are understood by all team members.

McInnis, Terry, et al., editors. *The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes*. 2nd ed., Patient-Centered Primary Care Collaborative, PCPCC Medication Management Task Force collaborative document.

What is Pharmacogenetics/Pharmacogenomics (PGx)?

The right medication for the right patient at the right dose

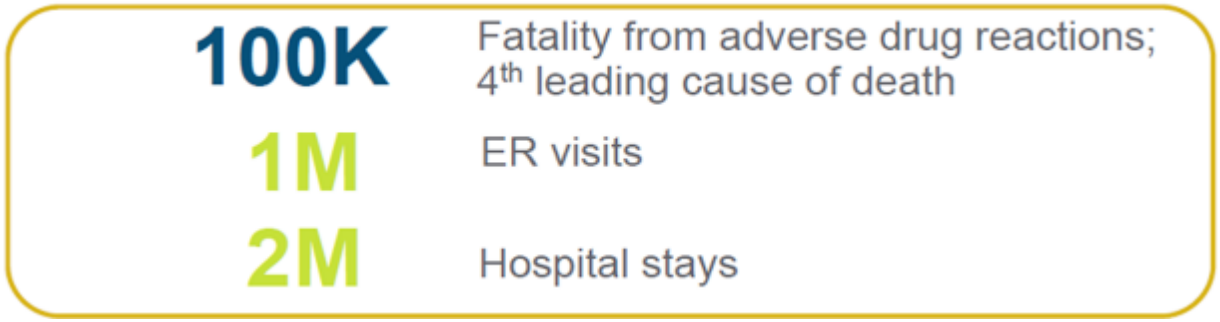
Pharmacogenomics (PGx) is the study of how an individual's genetic makeup affects their response to medication.

Evidence shows that an individual's genetic makeup is an important major factor in this differential outcome.

Pharmacogenomics (PGx) utilizes patient-specific genomic markers to assist the clinician in the selection of medications with the highest likelihood of success while minimizing the risk of toxicity.

1. Kalow W, Tang BK, Endrenyi L. Hypothesis: comparisons of inter- and intra-individual variations can substitute for twin studies in drug research. Pharmacogenetics. 1998;8:283–289.[PubMed]

Why Pharmacogenomics?



The Centers for Disease Control and Prevention estimate that Adverse Drug Events (ADEs) cost the United States about $3.5 billion annually. Anything that reduces that figure even by a few percentage points would have a significant impact on healthcare expenses in the US.

In outpatient settings, ADEs account for over 3.5 million physician office visits.

- Health.gov: https://health.gov/hcg/ade.asp
- FDA: https://www/.fda/gov/drugs/developmentapprovalprocss/developmnetresources/drugsinterationcslabeling/ucm110632.htm
- Society for Human Resource Management: https://www.shrm.org/resourcesandtools/hr-topics/benefits/pages/2017-drug-plan-cost-strategies..aspx

What does Pharmacogenomics mean to the physician?

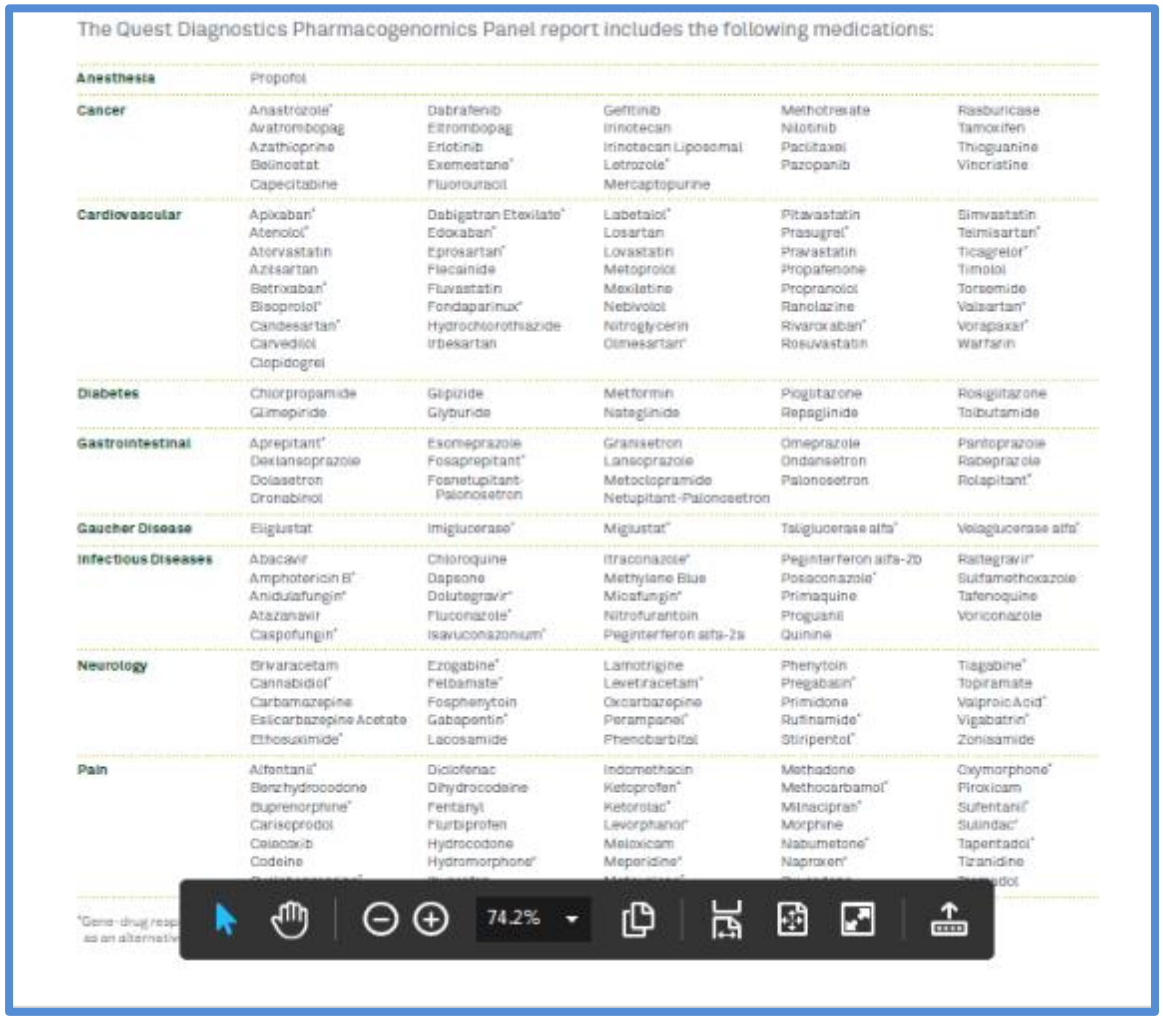
From the perspective of the physician, pharmacogenomics testing has at least three benefits

- Saves money on ineffective medications
- Prevents avoidable unpleasant or possibly fatal side effects related to some medications
- Improves the efficacy of the physician's comprehensive treatment plans, which leads to improved quality of life

Research suggests in inpatient settings ADE's are among the largest contributor to hospital-related complications.

Panel Report includes information on 288 medications

189 of these drugs have direct gene-drug information and 99 are listed as alternatives.



The Quest Diagnostics Pharmacogenomics Panel report includes the following medications:

Anesthesia	Propofol				
Cancer	Anastrozole*	Dabrafenib	Gefitinib	Methotrexate	Rasburicase
	Avatrombopag	Eltrombopag	Irinotecan	Nilotinib	Tamoxifen
	Azathioprine	Eriotinib	Irinotecan Liposomal	Paclitaxel	Thioguanine
	Belinostat	Exemestane*	Lotrozole*	Pazopanib	Vincristine
	Capecitabine	Fluorouracil	Mercaptopurine		
Cardiovascular	Apixaban*	Dabigatran Etexilate*	Labetalol*	Pitavastatin	Simvastatin
	Atenolol*	Edoxaban*	Losartan	Prasugrel*	Telmisartan*
	Atorvastatin	Eprosartan*	Lovastatin	Pravastatin	Ticagrelor*
	Azilsartan	Flecainide	Metoprolol	Propafenone	Timolol
	Betrixaban*	Fluvastatin	Mexiletine	Propranolol	Torsemide
	Bisoprolol*	Fondaparinux*	Nebivolol	Ranolazine	Valsartan*
	Candesartan*	Hydrochlorothiazide	Nitroglycerin	Rivaroxaban*	Vorapaxar*
	Carvedilol	Irbesartan	Olmesartan*	Rosuvastatin	Warfarin
	Clopidogrel				
Diabetes	Chlorpropamide	Glipizide	Metformin	Pioglitazone	Rosiglitazone
	Glimepiride	Glyburide	Nateglinide	Repaglinide	Tolbutamide
Gastrointestinal	Aprepitant*	Esomeprazole	Granisetron	Omeprazole	Pantoprazole
	Dexlansoprazole	Fosaprepitant*	Lansoprazole	Ondansetron	Rabeprazole
	Dolasetron	Fosnetupitant-Palonosetron	Metoclopramide	Palonosetron	Rolapitant*
	Dronabinol		Netupitant-Palonosetron		
Gaucher Disease	Eliglustat	Imiglucerase*	Miglustat*	Taliglucerase alfa*	Velaglucerase alfa*
Infectious Diseases	Abacavir	Chloroquine	Itraconazole*	Peginterferon alfa-2b	Raltegravir*
	Amphotericin B*	Dapsone	Methylene Blue	Posaconazole*	Sulfamethoxazole
	Anidulafungin*	Dolutegravir*	Micafungin*	Primaquine	Tafenoquine
	Atazanavir	Fluconazole*	Nitrofurantoin	Proguanil	Voriconazole
	Caspofungin*	Isavuconazonium*	Peginterferon alfa-2a	Quinine	
Neurology	Brivaracetam	Ezogabine*	Lamotrigine	Phenytoin	Tiagabine*
	Cannabidiol*	Felbamate*	Levetiracetam*	Pregabalin*	Topiramate
	Carbamazepine	Fosphenytoin	Oxcarbazepine	Primidone	Valproic Acid*
	Eslicarbazepine Acetate	Gabapentin*	Perampanel*	Rufinamide*	Vigabatrin*
	Ethosuximide*	Lacosamide	Phenobarbital	Stiripentol*	Zonisamide
Pain	Alfentanil*	Diclofenac	Indomethacin	Methadone	Oxymorphone*
	Benzhydrocodone	Dihydrocodeine	Ketoprofen*	Methocarbamol*	Piroxicam
	Buprenorphine*	Fentanyl	Ketorolac*	Milnacipran*	Sufentanil*
	Carisoprodol	Flurbiprofen	Levorphanol*	Morphine	Sulindac*
	Celecoxib	Hydrocodone	Meloxicam	Nabumetone*	Tapentadol*
	Codeine	Hydromorphone*	Meperidine*	Naproxen*	Tizanidine

74.2%

Gene List

Several genes are responsible for differences in drug metabolism and response. The most common are the Cytochrome P450 (CYP) genes. These genes code for the enzymes that are responsible for the metabolism of more than 70 percent of prescription drugs.

• ABCB1	• CYP2D6	• HLA-B*58:01
• ABCG2	• CYP3A4	• HTR2A
• ADRA2A	• CYP3A5	• HTR2C
• ALDH2	• CYP4F2	• IFNL3
• ANKK1	• DBH	• MTHFR
• BDNF	• DPYD	• NUDT15
• C11orf65	• DRD2	• OPRM1
• CEP72	• F5	• SLC47A2
• COMT	• G6PD	• SLC6A4
• CYP1A2	• GRIK1	• SLCO1B1
• CYP2B6	• GRIK4	• TPMT
• CYP2C19	• GRIN2B	• UGT1A1
• CYP2C8	• HLA-A*31:01	• UGT2B15
• CYP2C9	• HLA-B*15:02	• VKORC1
	• HLA-B*57:01	• 12q15

Source: Pharmacogenomics: Increasing the safety and effectiveness of drug therapy. American Medical Association. 2011 https://www.crediblemeds.org/files/3913/6973/9557/pgx-brochure2011.pdf

PGx Report – medication guidance section

Quest Diagnostics

Report Status: Final

TEST, JOHNP

Patient Information	Specimen Information	Client Information
TEST, JOHNP **DOB: 08/05/1991 AGE: 27** Gender: M Patient ID: ER99T533	Specimen: 40359110 Collected: 09/26/2018 / 13:32 PDT Received: 10/09/2018 / 08:34 PDT Reported: 10/09/2018 / 11:24 PDT	Client #: 1 DR.TEST

Medication Guidance

✕ **Warfarin** Coumadin	**Less than normal Sensitivity to Warfarin**	**CYP2C9; VKORC1**	**Actionable**
	Initiation Therapy: a dose increase may be required. Consider using the following warfarin dose range as provided in the FDA-approved label: 5-7 mg/day.OR consider using a personalized dose calculated by a pharmacogenetic algorithm. The estimated time to reach steady state is 4-5 days.		
⚠ **Acamprosate** Campral	**Favorable Response to Acamprosate**	**GRIN2B**	**Informative**
	The glutamate receptor, ionotropic, N-methyl D-aspartate 2B (GRIN2B) encodes the subunit N-methyl D-aspartate receptor subtype 2B of the glutamate receptor complex. These receptors are the predominant excitatory neurotransmitter receptors in the brain. The patient is heterozygous for A allele of GRIN2B variant rs2058878. Preliminary studies indicate that this genotype may associated with a favorable response to acamprosate treatment for alcoholism. Presence of the minor A allele was associated with lower risk of early relapse and longer abstinence during the first 3 months of acamprosate treatment. Replication of these results in a larger cohort is still needed to validate these findings.		
⚠ **Allopurinol** Zyloprim, Lopurin, Aloprim	**Normal Response to Allopurinol**	**ABCG2**	**Informative**
	The patient carries two copies of rs2231142 C allele. Unless other genetic risk factors are present, this genotype result indicates a normal response to allopurinol. Follow label-recommended standard dosage and administration. This genotype result cannot be used to identify patients at risk for severe cutaneous adverse reactions.		
⚠ **Amoxapine** Amoxapine	**Possible Sensitivity to Amoxapine**	**CYP2D6:Poor metabolizer**	**Informative**
	Like other tricyclic and tetracyclic antidepressants, amoxapine is metabolized by CYP2D6. However, the overall contribution of this enzyme in the metabolism of this drug is not well documented.Decreased CYP2D6 activity may result in higher amoxapine concentrations potentially leading to higher adverse events. There are no established dosing adjustments for patients with decreased CYP2D6 function, therapy must be initiated cautiously and adjusted according to the patient's response.		

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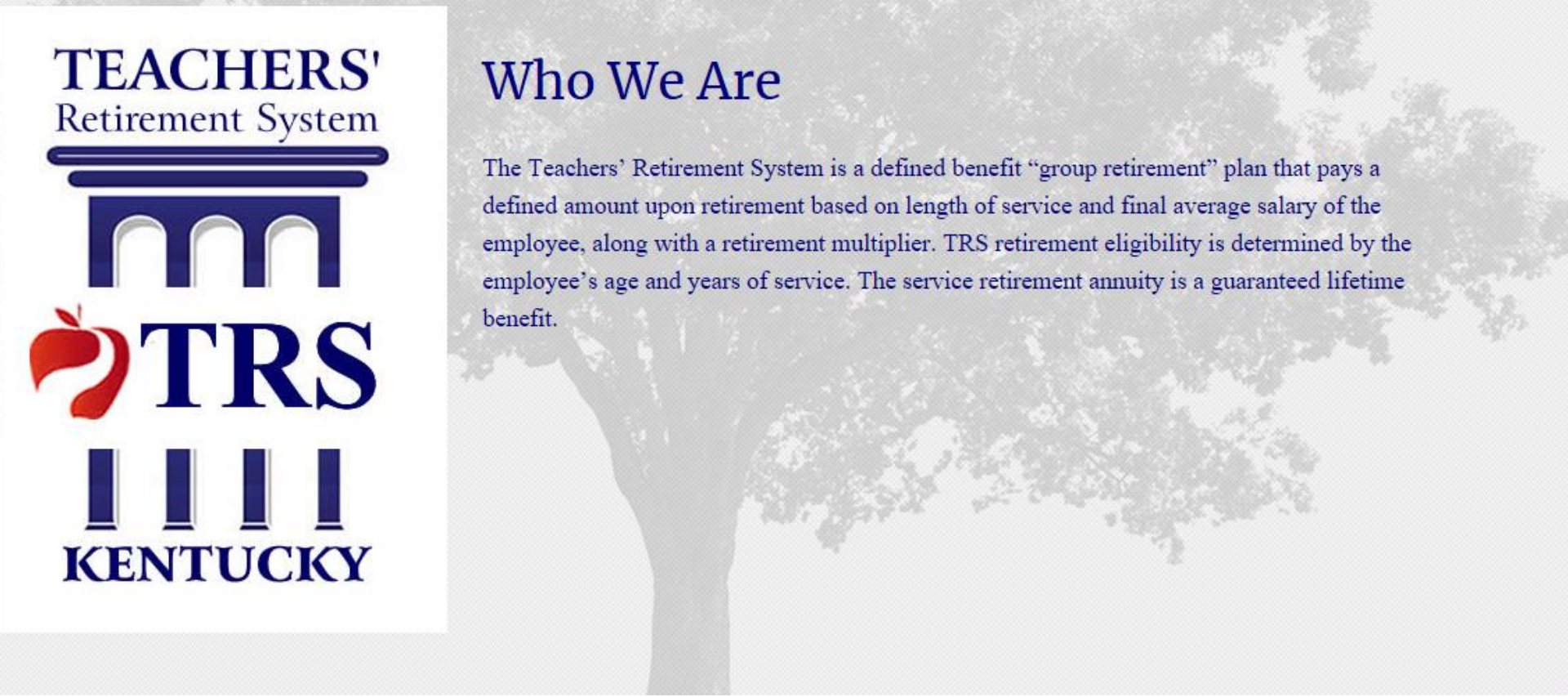
Our Presenter

JANE CHESHIRE GILBERT, CPA
Director Of Retiree Health Care for the Teachers' Retirement System of the State of Kentucky

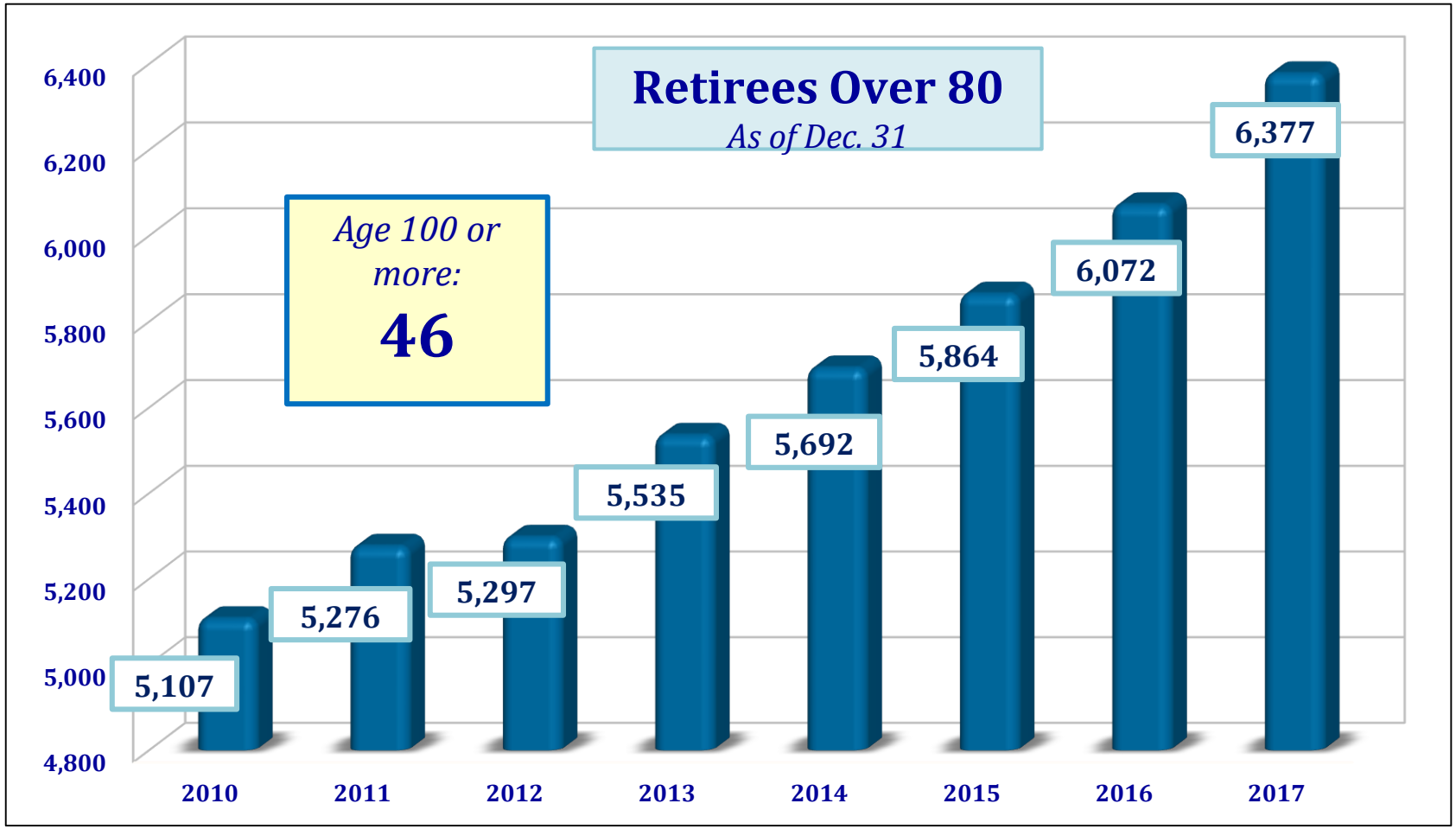
Who we are



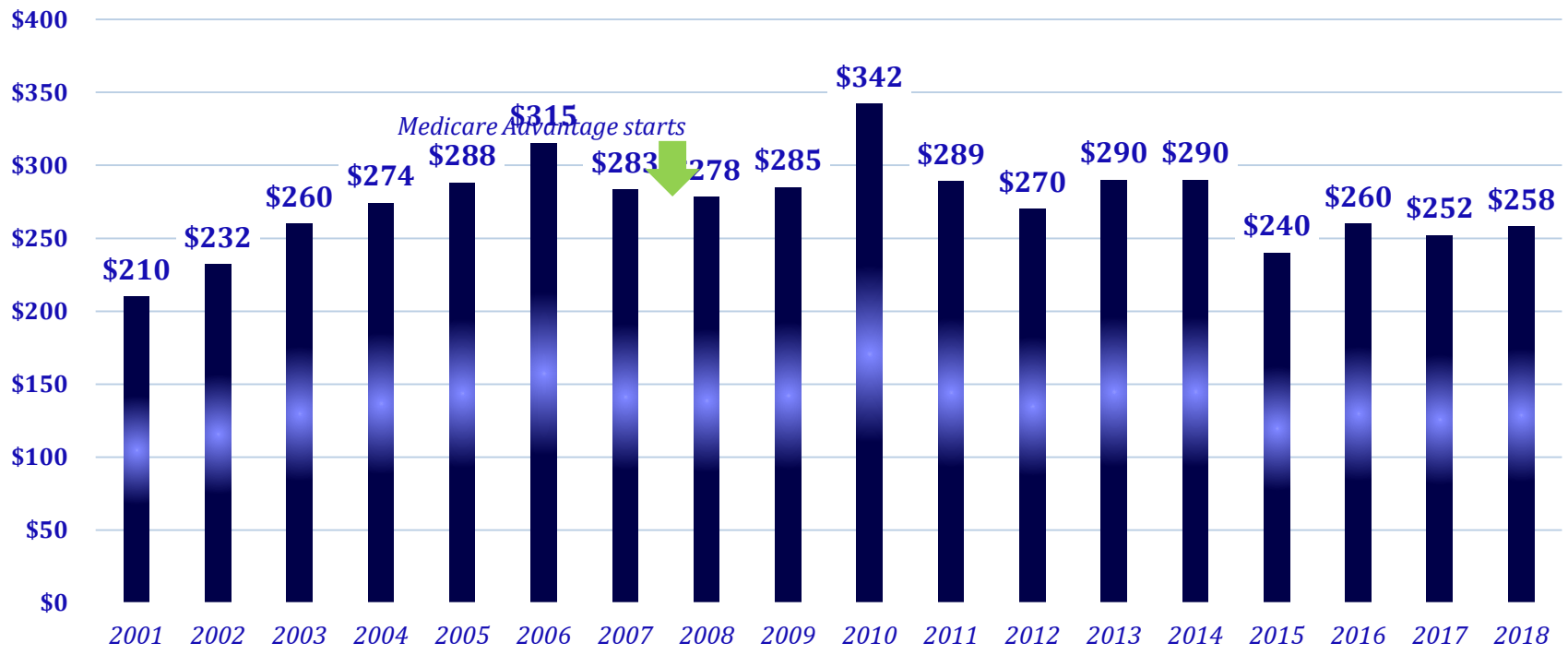
TRS Population

Member Recipients	
Females	72%
Males	28%

Longevity for TRS Retirees



TRS MEHP Premiums



Still Bending the Trend

Now, in 12th year, still saving $30 per person per month compared to Medicare supplement/complement projected medical costs for 2007, which equates to $12.2 million annually on Medicare Advantage alone (not including Medicare Part D).

What TRS Data Shows

- **84% of TRS retirees are on medications that are influenced by genetics**

- **23,000-plus TRS retirees may need to stop or change at least one medication**

What the data means – safety and savings

Taking medications that don't work for you is costly to your health and to your TRS insurance fund.

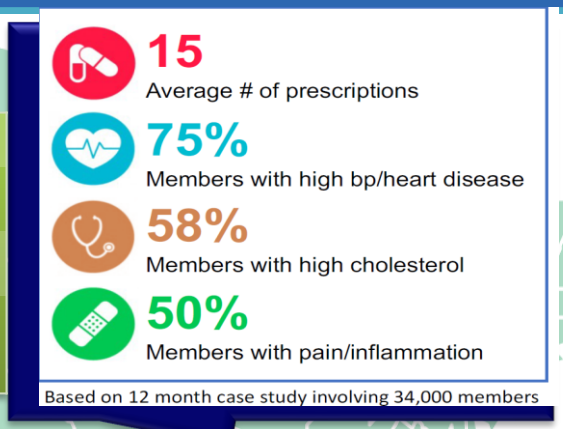
- 10% of members should stop prescription immediately
  - – Savings of $1.7M
- 57% of members are taking the wrong dosage
  - – Savings of $10M
- 33% of members have a better alternative available
  - – Savings of $10M

Using de-identified claims information, CLS provided the pension fund with an in-depth analysis of the potential return on investment with the program.

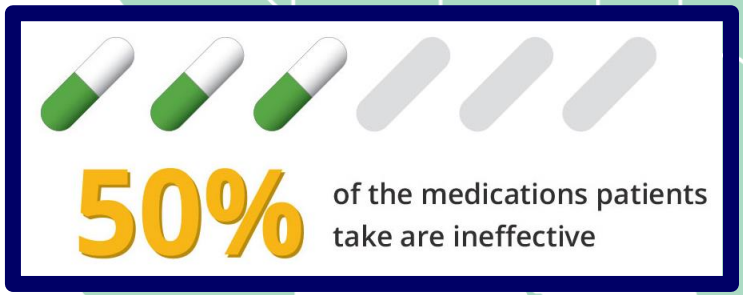
MEHP – What We Know

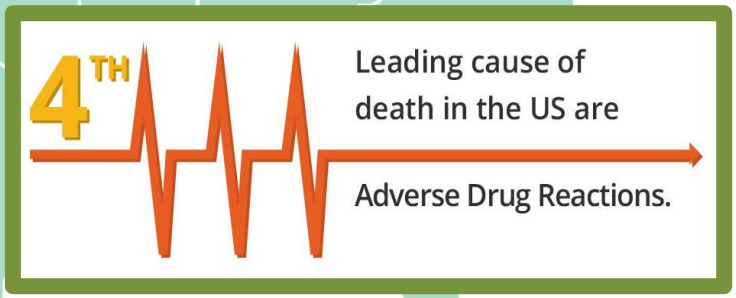
From TRS data

74	Average age of enrollees
6,000+	Retired teachers 80 and older
35,000	MEHP retirees aged 65 to 107
$105 million	Annual spending



Nationally, not just 65 and over





Source: Coriell Life Sciences

Solution: TRS Personalized Medicine Partnership

You

Your Doctor

Your Pharmacist

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E-PGx Program Components

Enterprise PGx is a turn-key program that combines genetic testing with expert pharmacy review to provide what physicians really need – credible and immediately actionable treatment guidance.

Population Analytics

"Will this program provide benefit for our members?"

Member Engagement

Fully-coordinated education and enrollment

Genetic Testing

Cost-effective DNA testing by CLIA-licensed laboratories

Pharmacy MTM Review

Clear, actionable recommendations via Medication Action Plan (MAP)

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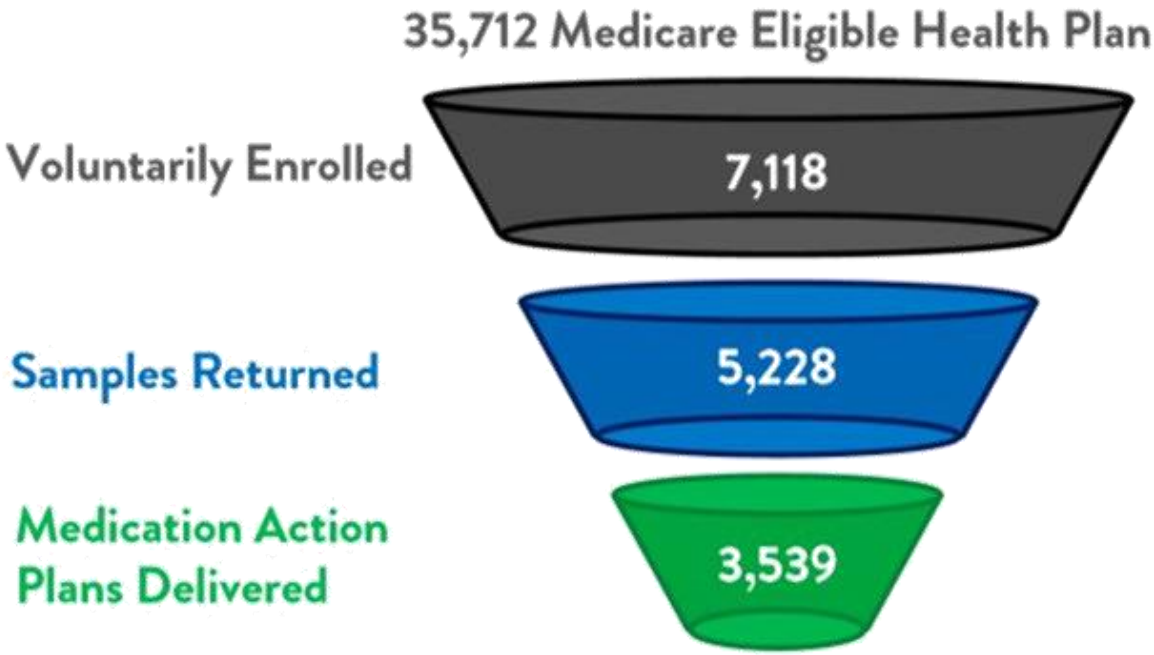
Metrics of Success

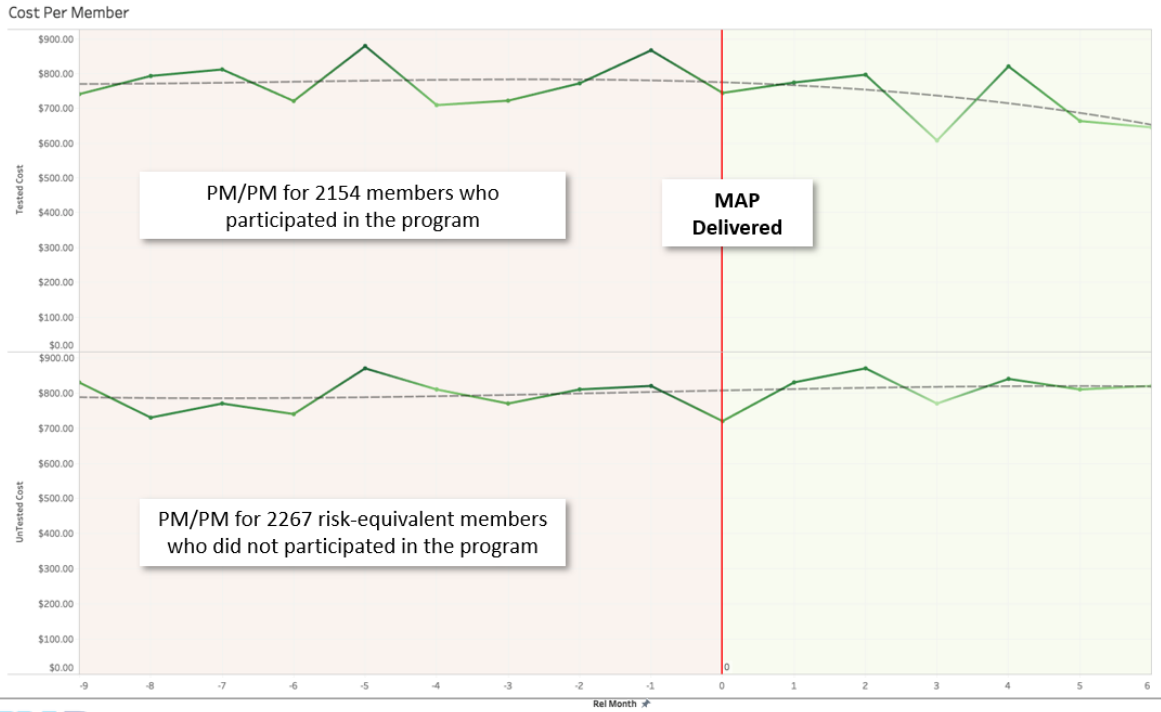


Medications	
Reviewed	4,118
Removed	577
Added	441

Metrics of Success

- ✓ 64% resulted in medication change recommendation
- ✓ 94% of recommendations accepted by prescribers

COST REDUCTION



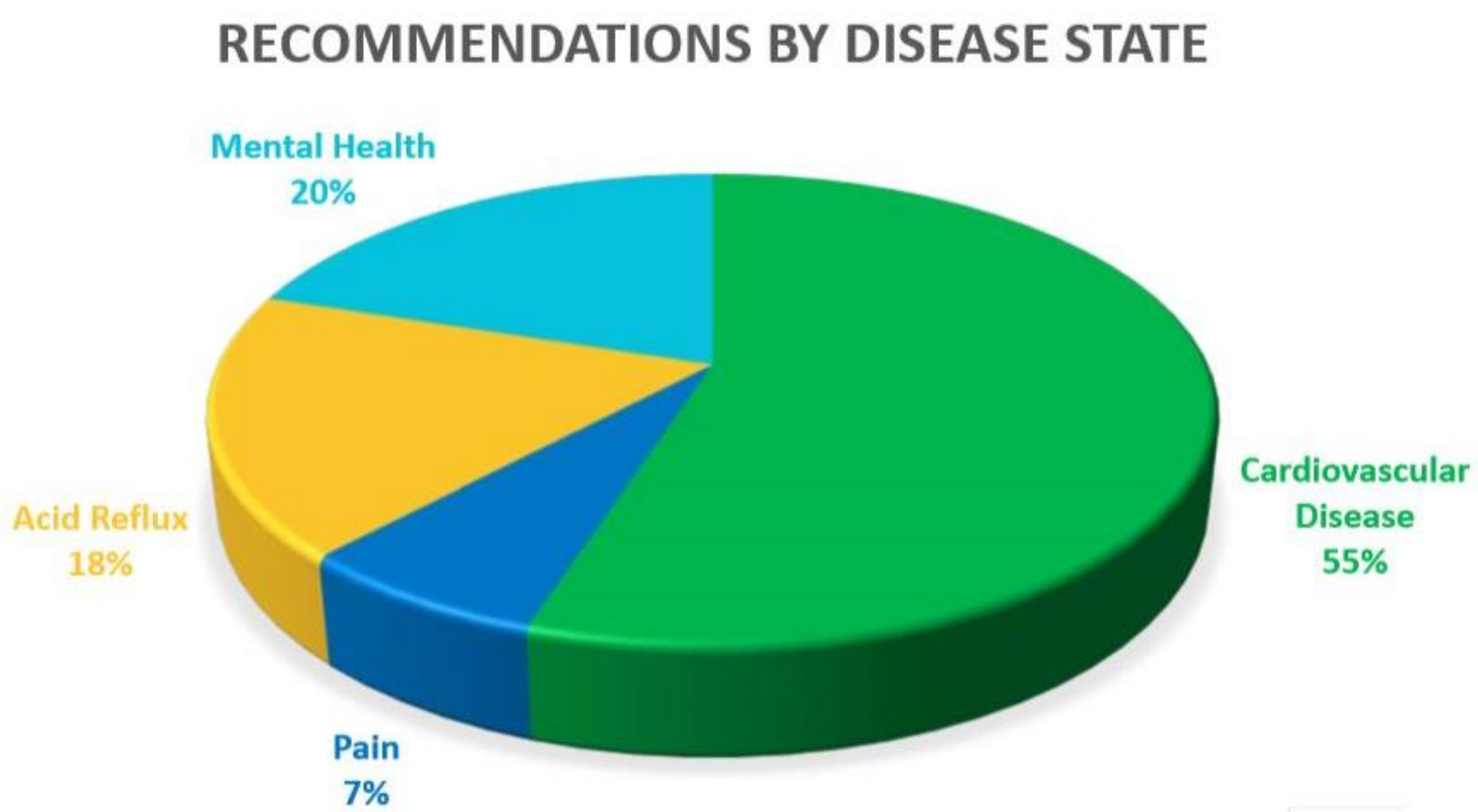
17%

Reduction in cost-to-plan spending after 6 months

2.5%

Increase in control group

Metrics of Success



MA3: Cost of Getting it Wrong

MA3

- Medication Adherence
- Medication Appropriateness
- Medication Adversity

Components of MA3 Cost

Clinic outpatient visits	**0.64%**
Specialty office visits	0.82%
Employee work days missed	0.95%
Laboratory services	0.09%
Urgent care services	0.48%
Emergency room visits	2.99%
Hospital admissions	67.18%
Home health visits	23.31%
Durable medical goods	1.55%

Medication Adherence

- Limited patient engagement in treatment decisions
- Cost
- Low perceived need/efficacy
- Concern about side effects
- Forgetfulness
- Lack of social support
- Impaired cognition
- Unclear or misunderstood medication instructions
- Low health literacy
- Complete drug regimen/high pill burden

Medication Appropriateness

- Is there an indication for the drug?
- Is the medication effective for the condition?
- Is the dosage correct?
- Are the directions correct?
- Are the directions practical?
- Are there clinically significant drug-drug interactions?
- Are the clinically significant drug-disease interactions?
- Is there unnecessary duplication with other drugs?
- Is the duration of therapy acceptable?
- Is this drug the least expensive alternative?

Medication Adversity

- Dose-related
- Non-dose-related
- Dose-related and time-related
- Time-related
- Withdrawal
- Failure of therapy

PGX-Empowered MTM

- ↓Adverse drug events
- ↑Patient satisfaction
- ↑Overall patient health
- ↑Quality of life
- ↑Use of generic medications
- ↓ Cost of medications
- ↓ Number of outpatient visits
- ↓ Cost of outpatient visits
- ↓ Number of lab tests
- ↓ Emergency department visits
- ↓ Number of hospitalizations
- ↓ Cost of hospitalization

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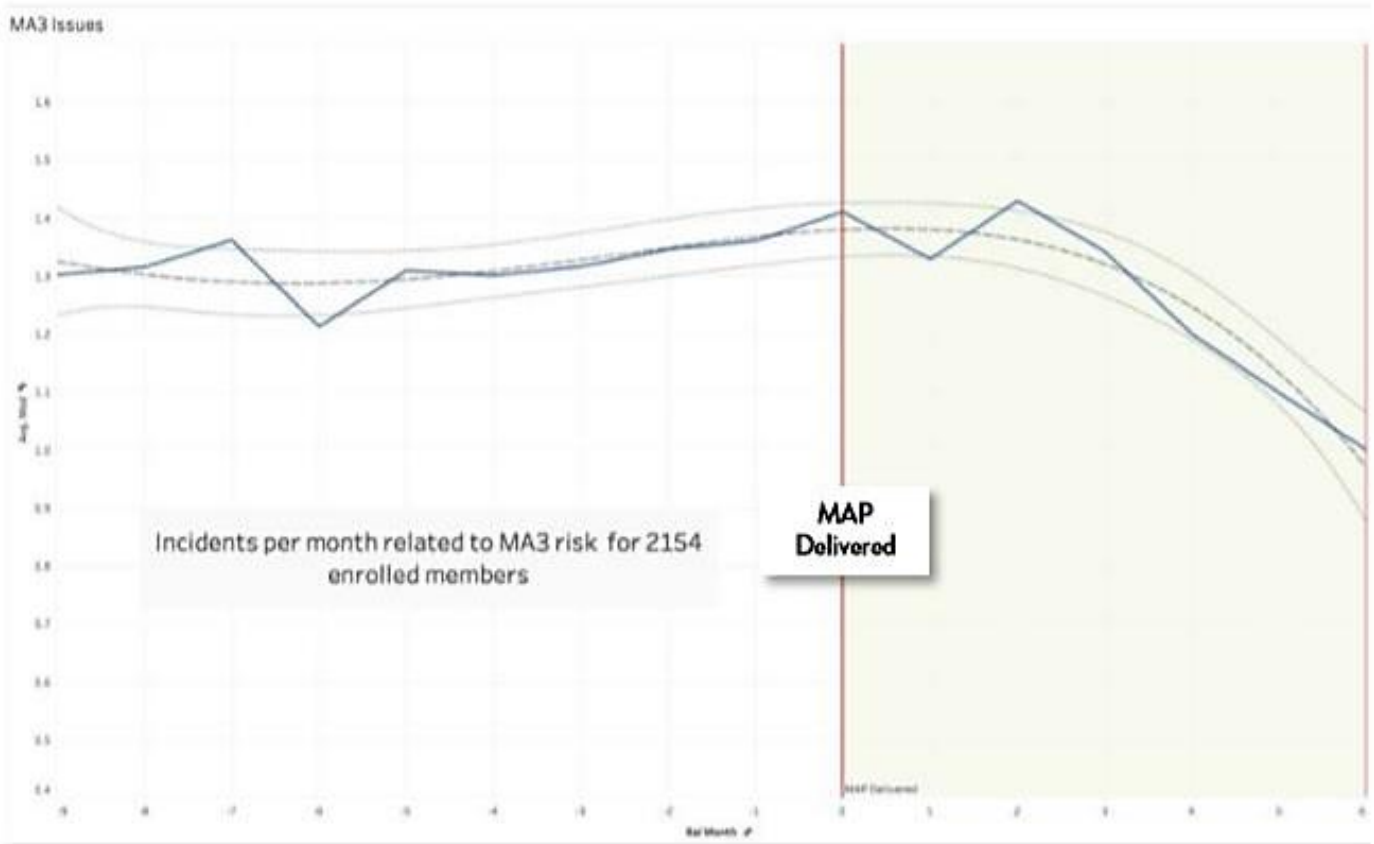
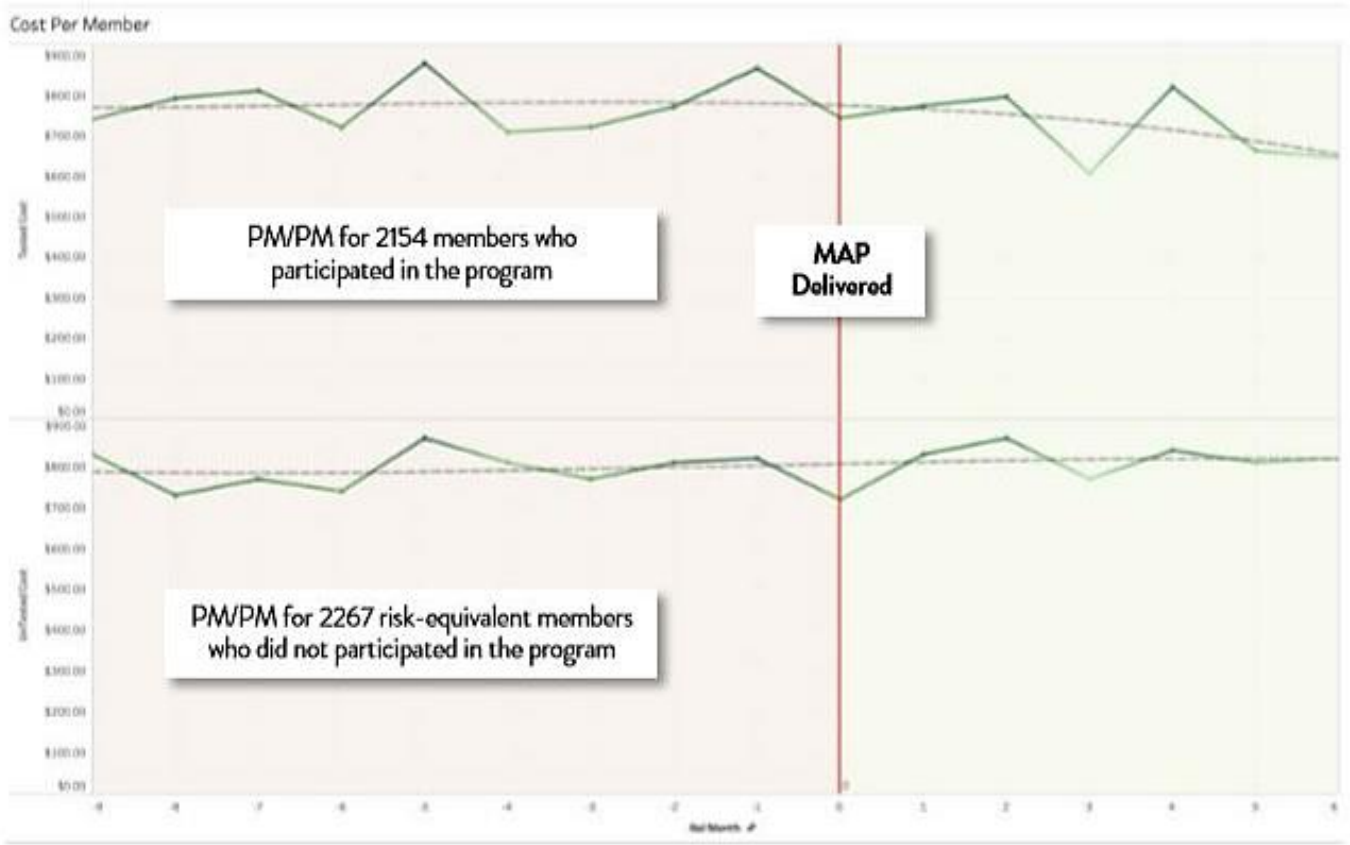
Risk Reduction



28 %

Reduction in MA3 related risk incidents

Cost Reduction



17%

Reduction in cost-to-plan spending after 6 months

2.5

Increase in control group

Invite and Enroll Members

Key Messages:

- ✓ We are making smarter use of healthcare dollars with a new personalized medicine program.
- ✓ We have engaged partners to work with your doctor.
- ✓ This new benefit will test your DNA to make sure your medications will be safe and effective for you.
- ✓ The analysis and test results will only be used by pharmacists and your doctor. Your information will not be shared with us.

Data Collection Kits

Kits returned in same box, processed by lab within 2 weeks

DNA Collection kits sent to members' homes upon enrollment

Know Your Rx Coalition *Pharm-Assist* Offering

MONDAY-FRIDAY 8AM –6 PM ET

KYRx@uky.edu www.KYRx.org

- Contact retirees with lower cost prescription alternatives
- Contact Prescribers and Pharmacies on retirees' behalf
- Guide retirees to lowest cost medication options ($4 generic lists, copay cards, etc.)
- Contact Express Scripts or CVS on retirees' behalf as needed
- Provide medication information and prescription coverage information specific to retirees' plan
- TRS joined drug purchasing coalition in January 2012
- Coalition makes thousands of outbound proactive calls due to tiering and formulary changes
- Since joining the coalition, the TRS generic fill rate has increased from 73% to 88%

Know Your Rx Coalition

855-218-5979

Clinical Director

Lucy Wells

Dedicated Clinical Pharmacists

Travis Albrecht
Marissa Boelhauf
Lea Goggin
Amy Griesser
Matt McMahan
Stacy Poskin
April Prather
Allison Russell
Patricia Walker
Zach Wilkerson

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DNA Testing is Not Sufficient

- Need to bring together rigorously-vetted genetic guidance with dozens of other factors of patient-specific prescribing risk.
- Healthcare providers should be empowered with answers rather than research materials.
- Real-time modeling should allow pharmacists and doctors to se the results of medication changes before they experiment with them on their patients.

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Get the medications right™

Access to Results of Pharmacogenomic Testing Information

- **A pharmacogenomic process model must include future access to gene/drug information. The client is purchasing not only the testing and results but the platform to store pharmacogenomic results for access by providers.**
- **Currently there is no direct access to results through electronic medical records (EMR).**
- **EMRs are not currently formatted to handle pharmacogenomic results.**
- **Results can be provided direct to the consumer/member. This may, however, cause confusion over how and when to use the results.**
- **TRS members utilize Know Your Rx Coalition, which provides provider and member access and ongoing interpretation of results.**

Current Solution is Embed Results in EMR

- **Must identify prevalent provider populations, hospitals and doctors.**
- **Embed results into hospital EMR on a case-by-case basis, assuming active medical record exists for the member.**
- **Know Your Rx can work with physician to embed results into physician-directed EMR**
- **Member/consumer can access information through a model similar to Know Your Rx**

There must be an active process to make pharmacogenomic results information available to providers

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Member Impact

- TRS member presented to the ER with Myocardial Infarction.
- Member previously had Pharmacogenomic gene panel test with results delivered by Know Your Rx Coalition Pharmacist.
- Member had hospital stay with surgery for stint implant.
- Upon Discharge member was prescribed an anticoagulant.
- Prior to picking up the drug the member contacted Know Your Rx to review the gene panel test results.
- The Pharmacist that reviewed the results identified an interaction with the specific drug prescribed which lead to a change in prescribed drug.

Question & Answer Session

STEVEN GOLDBERG, MD, MBACEO
Vice President, Medical Affairs, Population Health, Chief Health Officer, Health And Wellness, Quest Diagnostics; and Board Member, GTMRx Institute

JANE CHESHIRE GILBERT, CPA
Director Of Retiree Health Care for the Teachers' Retirement System of the State of Kentucky

Thank you!

- Please fill out the survey after today's session
- A recording of today's webinar and slides will be available in one week at www.gtmr.org
- Follow and like us! **gtmrxinstitute**