Welcome!

5th Annual CAP Center Symposium

Please enjoy the symposium from wherever you feel comfortable.

Agenda & Plan for the Day

Virtual Participants:

- After each speaker, you will be placed in a virtual room with 6-8 participants. Please have your list of round table questions pulled up or available.
- Continuing education information will be presented after each round table discussion.
- If you have questions during the presentations, please enter these into the chat and we will monitor these throughout the day. If there is not time to answer questions after the presentation, CAP Center will follow up with all the registered attendees with answers to the questions.
- If you would like follow up after the symposium, please contact Lisa.Nagel@ndsu.edu.

WELCOME

WEECOME	
Dr. Elizabeth Skoy, PharmD, FAPhA Professor, Director of CAP Center	12:00 PM
Dean Teresa Connor, PhD, PT, MBS Dean and Professor of College of Health and Human Services	
PHARMACOGENOMICS	12:15 PM
Dr. Natasha Petry, PharmD, MPH, BCACP Associate Professor of Practice, Clinical Pharmacist	12.13 PM
NORTH DAKOTA MEDICAID	
Dr. LeNeika Roehrich, PharmD, BCGP Clinical Pharmacist	1:00 PM
COLLABORATIVE PRACTICE IMPLEMENTATION Dr. Carly Smithers, PharmD Pharmacy Manager	1:45 PM
HEALTHY AGING	
Dr. Ryan McGrath, PhD Associate Professor, Director Healthy Aging North Dakota Dr. Jayme Steig, PharmD, CPHQ Assistant Professor of Practice, Clinical Pharmacist	2:35 PM
COMMUNITY HEALTH WORKERS	
Tiffany Knauf, MA Health Systems and Pharmacy Coordinator, Health Promotion and Chronic Disease Prevention Unit NACDD North Dakota Chronic Disease Director	3:20 PM
All presentations will be followed by round table discussions.	
CLOSING REMARKS	4:00 PM
SOCIAL	
Optional social to connect with each other. 4:15	5-5:00 PM



Exciting News from the School of Pharmacy!

NDSU / DSU PRE-PHARMACY PROGRAM

STARTING FALL 2026!



Traditional Pathway	Early Assurance Pathway (EAP)
3-year undergraduate track Pay DSU tuition and attend classes at DSU	2-year undergraduate track Pay DSU tuition for DSU courses & NDSU differential tuition for 3 Hyflex NDSU courses

- Kickstart your pharmacy career closer to home
- Curriculum designed to prepare you for pharmacy school
- Multi-campus support

FUTURE EXPLORATIONS:

- NDSU PharmD Professional Program training in Dickinson:
 - Mix of Hyflex courses and inperson learning experiences
 - Occasional infrequent required travel to Fargo
 - Scholarship Opportunities



Integrating Pharmacogenomics into Pharmacy Practice: Foundations, Applications, and Future Directions for Optimized Patient Care

Presented by: Natasha Petry, PharmD, MPH, BCACP Associate Professor of Practice, North Dakota State University Clinical Pharmacogenomics Pharmacist, Sanford Health



Disclosures

 Natasha Petry reports they have no relevant financial relationships with ineligible companies to disclose.

Objectives

- 1.Describe the foundational principles of pharmacogenomics and its clinical relevance in contemporary pharmacy practice.
- Apply the patient-care process to a patient case study optimizing drug therapy utilizing pharmacogenomic testing.
- 3. Identify emerging trends in pharmacogenomics to enhance patient care.
- 4. Describe actionable steps pharmacists and pharmacy technicians can take to incorporate pharmacogenomics into their pharmacy practice.

The Foundational Principles

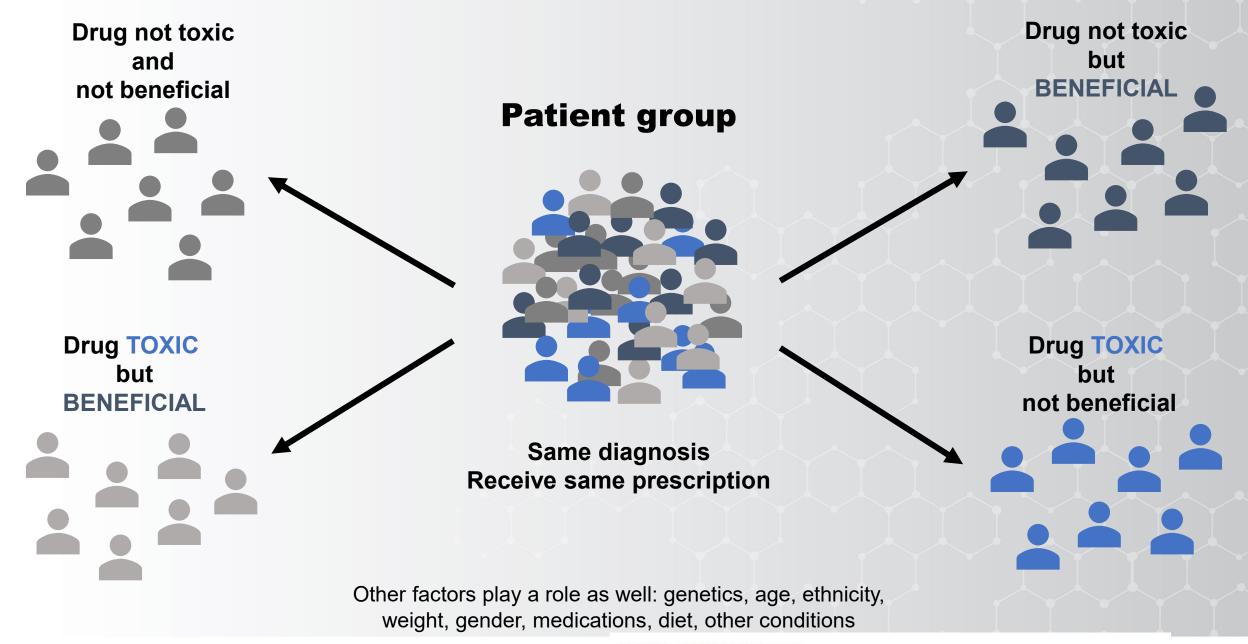
- Pharmacogenomics (PGx) is the study of the impact that genetic polymorphisms have on medication response
- Genetic polymorphisms may influence medication effectiveness and risk for toxicity
- The goals of PGx are to optimize medication efficacy and limit toxicity based on an individual's genetics
- The most common gene variations associated with medication response are single nucleotide polymorphisms (SNPs)
- Pharmacists play a key role in advancing PGx in clinical practice based on a patient's genetic profile

Genotypes to Phenotypes

- The human genome contains ~ 20,000 protein-coding genes intertwined in the DNA double-helix comprised of purines (adenine and guanine) and pyrimidines (cytosine and thymidine)
- According to the central dogma of biology, DNA from genes is transcribed to RNA which is then translated into specific proteins by ribosomes
- The resulting protein is the outward expression of the genotype and is termed as the phenotype, which is the observable trait(s) of an individual
- Genes have a substantial amount of interindividual variety
 - Due to the presence of these variations, the term allele is used to denote a specific version of a gene
 - An individual inherits two alleles for each gene, one from each parent

Overview of PGx

- PGx combines the fields of pharmacology and genetics to search for impactful genetic variations that lead to interindividual differences with respect to medication response
 - <u>Pharmacogenetics:</u> variations in a single gene that affects a medication response
 - <u>Pharmacogenomics:</u> the entire spectrum of genes that interact to determine medication efficacy and safety
- PGx is now more commonly used to guide clinical decision making as multiple proteins are often involved in determining the ultimate response to most medications
- The goals of clinical PGx are to optimize medication therapy and limit toxicity based on an individual's genetic profile
 - Optimizing make look like choosing the right medication and dose to achieve therapeutic outcomes and/or minimize toxicity



Pharmacogenomics (PGx)

- Two main areas:
- Differences in metabolism of medication (increased side effects or decreased efficacy)
- Patient's susceptibility to certain adverse effects of medications (Ex: abacavir and HLA-B*57:01)

Personalized medication selection

Improve efficacy

Reduce trial and error

Prevent or decrease side effects and toxicity

The Best Treatment



Patient A may see best results with **2 tablets** of a medication.



Another person, Patient B may only need **1 tablet** for their treatment.



A third person, Patient C will only need **one-half of a tablet** of this same medication.



A different person, Patient D, may need to take **a different drug** to see the same benefits as the previous 3 patients.

Definitions

- Genotype: type of variant present at a given location (i.e., a locus) in the genome
 - Variant: change in DNA sequence
 - Single Nucleotide Polymorphism (SNP): genomic variant at a single base position in the DNA.
- Phenotype: observable trait

- Gene: basic unit of inheritance that mostly codes for proteins
- Allele: one of two or more versions of DNA sequence

Benefits of PGx

Drug safety/toxicity avoidance

- Aid drug selection to avoid adverse reactions
- Aid dose selection to avoid toxicity

Increased efficacy

- Aid dose selection for maximum efficacy
- Identify patients who should be responsive to a given drug

Patient self-advocacy

Embedded in EMR

Medication Safety

Reassurance

Lifelong information

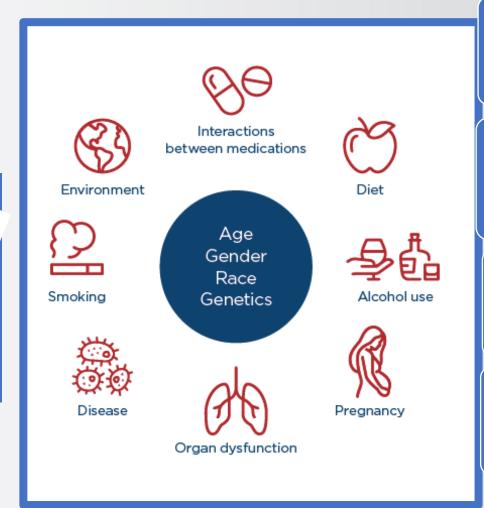
Prescription and OTC medication



Limitations of PGx

Not all medications!

Only one piece of the puzzle



Cost

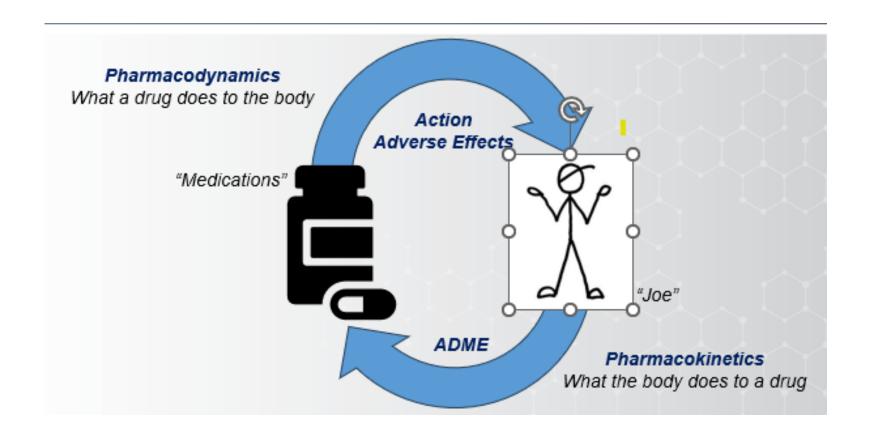
Limited insurance coverage

Limited or no genetic information for some medications

Lab approach to testing / return of results / variants tested

Race/ethnicity

PharmacoKinetics / PharmacoDynamics



PHARMACOKINETICS

How a drug moves through your body and gets metabolized or "absorbed" by the body's systems

Absorption: How will the medication enter the body?

Distribution: Where will the medication go? (Transporters)

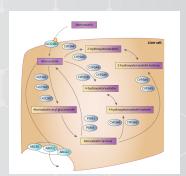
Metabolism: How is the medication broken down? (Liver)

Excretion: How does the medication leave?

Metabolism (Liver)



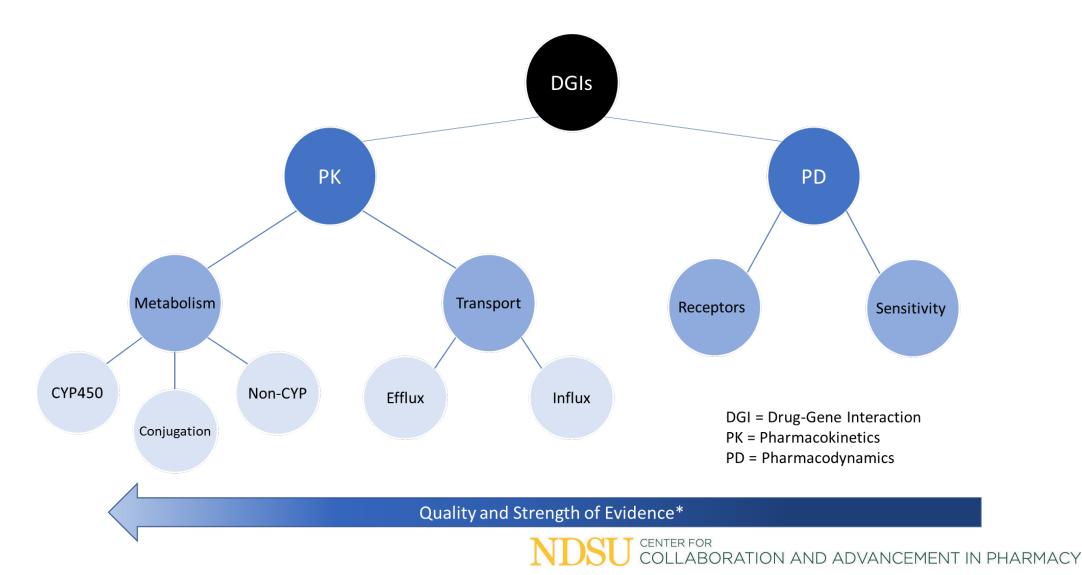
- Cytochrome P450s CYP2D6, CYP2C19, et al
- TMPT/DPYD UGT1A1
- G6PD



Distribution (Transporters)

- SLCO1B1
- ABCB1

PGx... not just metabolizing enzymes



Active Drugs

Absorbed through the GI tract



• Distributed in the blood



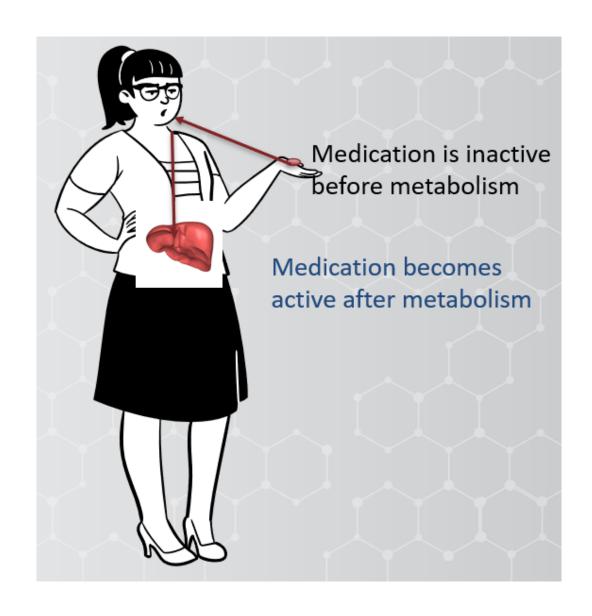
Broken down by liver enzymes CYP

Excreted by the kidneys



Prodrugs

- Require biological activation
 - Improve drug delivery or specificity
 - Improve bioavailability
 - Decrease toxicity
 - Cytochrome P450 enzymes
 - Genetic variants in CYP enzymes
 - Ex. Codeine > Morphine



Active Drug vs. Prodrug

Drug A is an active drug and therefore pharmacologic effects take place quickly, then broken down to less active we're

metabolites Metabolized to less active metabolites



I'm exerting my pharmacologic properties!

Drug B is a prodrug and therefore requires activation to its

active form Metabolized to an active drug



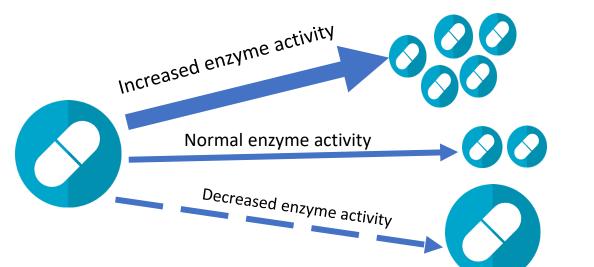
I'll work after a little transformation I'm exerting my pharmacologic properties!

not very active

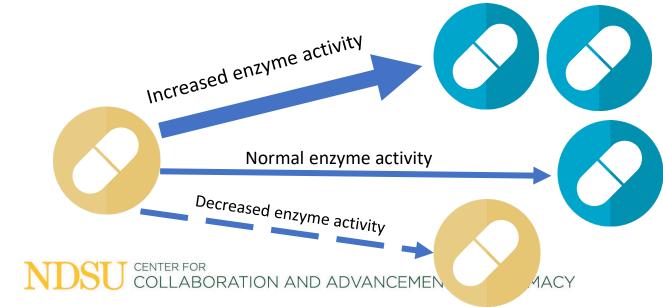


Active Drug vs. Prodrug

- Active Drug
 - Increased enzyme activity leads to
 - increased metabolism
 - decreased serum concentrations
 - may decrease efficacy
 - Decreased enzyme activity leads to
 - decreased metabolism to less active metabolites
 - may increase risk of side effects



- Prodrug
 - Increased enzyme activity leads to
 - increased conversion to active drug
 - may increase risk for side effects
 - Decreased enzyme activity leads to
 - decreased conversion to active drug
 - may decrease efficacy

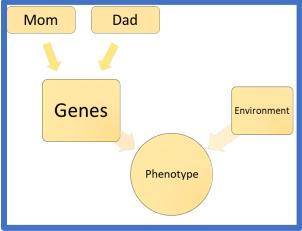


GENOTYPE-PHENOTYPE ASSOCIATION

- Different versions of a gene (alleles) can change gene function
- Pairs of alleles make up a distinct genotype
- For genes affecting drug therapy, the genes are highly predictive of the phenotype

Five Standard Genotype Assignments:

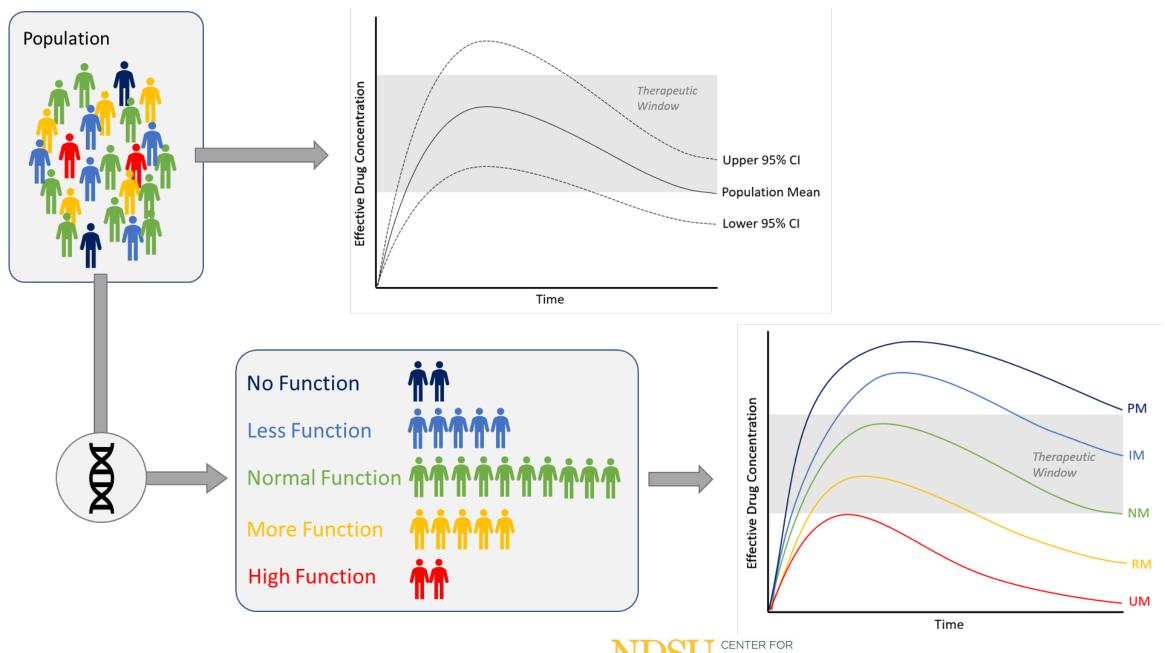
Metabolizer Phenotype	Allele 1	Allele 2
Ultrarapid (UM)	↑ function	↑ function
Rapid (RM)	\uparrow	Normal
Normal (NM)	Normal	Normal
Intermediate (IM)	Normal or ↓	\downarrow
Poor (PM)	↓ or 0	↓ or 0





Phenotypes (drug metabolizing enzymes)

Term	Functional definition	Genetic definition
Ultrarapid metabolizer	Increased enzyme activity compared to rapid metabolizers	2 increased function alleles, or more than 2 normal function alleles
Rapid metabolizer	Increased enzyme activity compared to normal metabolizers but less than ultrarapid metabolizers	Combinations of normal function and increased function alleles
Normal metabolizer	Fully functional enzyme activity	Combinations of normal function and decreased function alleles
Intermediate metabolizer	Decreased enzyme activity (activity between normal and poor metabolizer)	Combinations of normal function, decreased function, and/or no function alleles
Poor metabolizer	Little to no enzyme activity	Combination of no function alleles and/or decreased function alleles



Metabolism Implications

Citalopram (Active Drug)



Phenotype: Ultra-rapid Metabolizer

- Increased metabolism when compared to normal metabolizers
- Lower plasma concentrations will increase probability of pharmacotherapy failure (lack of efficacy)



Phenotype: Poor Metabolizer

- Greatly reduced metabolism when compared to normal metabolizers
- Higher plasma concentrations may increase the probability of side effects

Clopidogrel (ProDrug)



Phenotype: Ultra-rapid Metabolizer

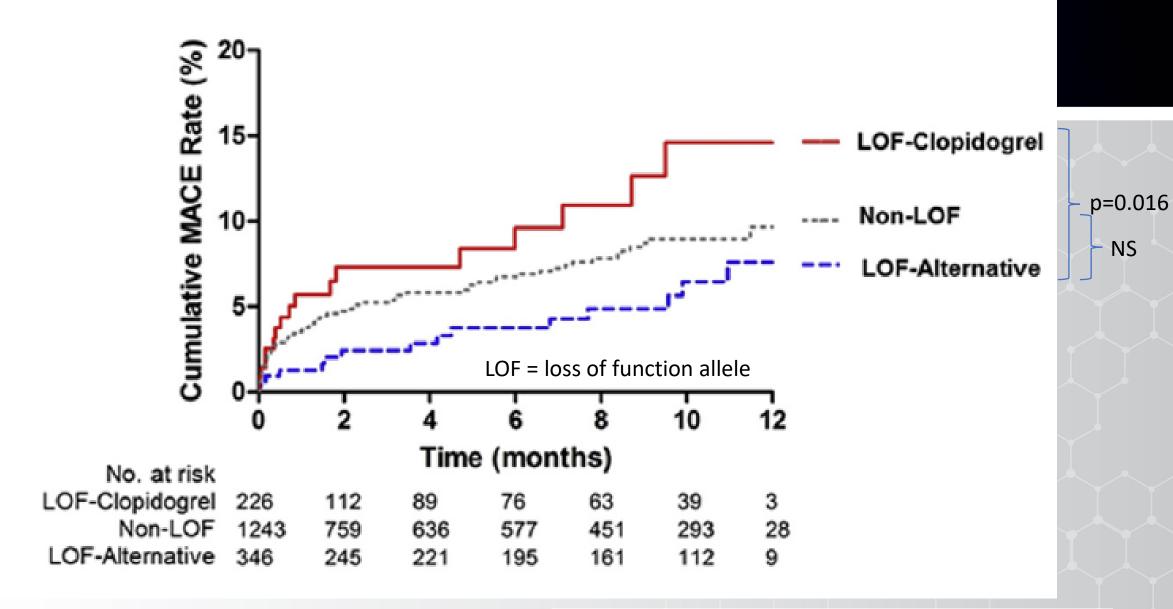
- Increased platelet inhibition
- Decreased residual platelet aggregation
- (in theory potential for increased side effects of increased bleeding)



Phenotype: Poor Metabolizer

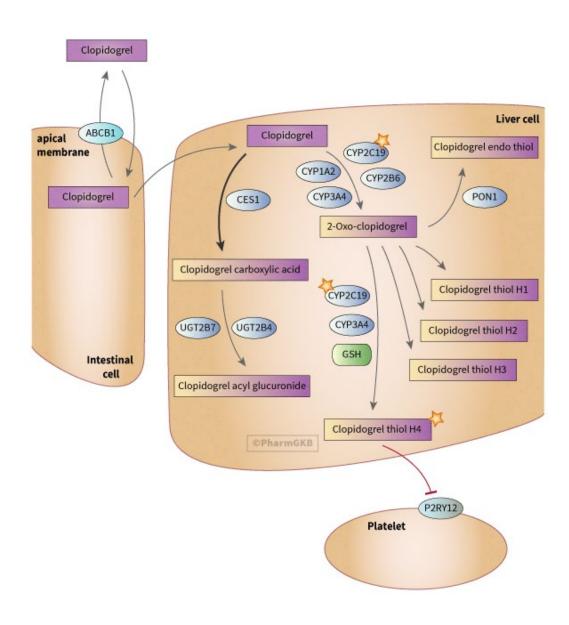
- Significantly reduced platelet inhibition
- Increased residual platelet aggregation
- Increased risk for adverse cardiovascular events due to lack of efficacy





NS

Representation of genes involved in metabolism of clopidogrel.



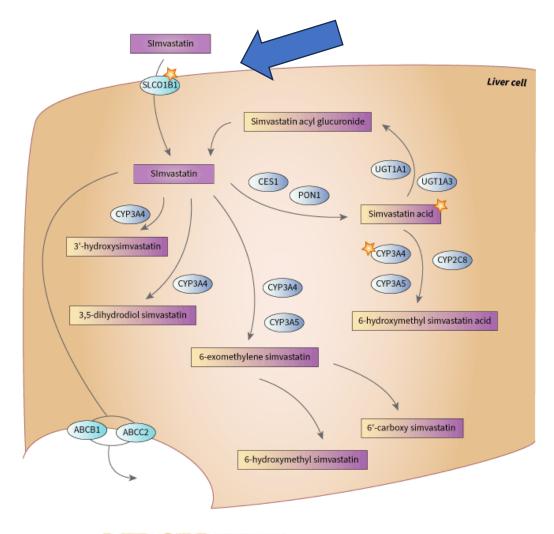
Drug-Transporter Genes of Interest

- Several transporters on the cell surface have genetic polymorphisms that have clinical PGx implications
- The <code>SLCO1B1</code> gene encodes for OAT polypeptide B1, which mediates the uptake of β -hydroxy- β -methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitors (i.e., statins) into the liver
- The ABCB1 gene encodes for the p-glycoprotein (P-gp) transporter, which typically functions to expel both drugs and xenobiotics from the cytoplasm of the cell
- Variations typically result in reduced function, increased bioavailability of drugs/xenobiotics, and increased risk for adverse effects

Transporter

Summary

Representation of the candidate genes involved in transport and metabolism of simvastatin.



Immune-Related Genes of Interest

- The human leukocyte antigen (HLA) genes encode for proteins that recognize "self" from "non-self" and play a key role in the function of the immune system
 - o They are among the most polymorphic genes in the human genome
- The presence of certain HLA alleles has been linked to serious, potentially life-threatening adverse skin reactions including Stevens-Johnson Syndrome, toxic epidermal necrosis, and/or hypersensitivity reactions
- HLA genes of interest and the medications associated with them include:
 - *HLA-B*57:01*: abacavir
 - ∘ *HLA-B*58:01*: allopurinol
 - o <u>HLA-B*15:02</u>: carbamazepine, oxcarbazepine, phenytoin, and lamotrigine

Resources





- ClinPGx
 - https://www.clinpgx.org/
- FDA
 - https://www.fda.gov/medical-devices/precision-medicine/table-pharmacogenetic-associations

PGx testing approaches

Pre-emptive

- Screening
- Test results available in chart at time of prescribing
- Usually panels

Reactive

- Targeted approach to therapy
 - Anticipation of beginning certain therapies
 - clopidogrel
 - Explain previous reactions
 - Medication failure
 - Adverse reactions
- Can be single gene or panel

CPIC guidelines

Guidelines	Drugs	Genes
CFTR and Ivacaftor	ivacaftor	CFTR
CYP2B6 and efavirenz	efavirenz	CYP2B6
CYP2B6 and methadone	methadone	CYP2B6
CYP2C19 and Clopidogrel	clopidogrel	<u>CYP2C19</u>
CYP2C19 and Proton Pump Inhibitors PPIs!	dexlansoprazole esomeprazole lansoprazole omeprazole pantoprazole rabeprazole	<u>CYP2C19</u>
CYP2C19 and Voriconazole	voriconazole	<u>CYP2C19</u>
CYP2C9 and NSAIDs NSAIDs!	aceclofenac aspirin celecoxib diclofenac flurbiprofen ibuprofen indomethacin lornoxicam lumiracoxib meloxicam nabumetone naproxen piroxicam tenoxicam	CYP2C8 CYP2C9
CYP2C9, HLA-B and Phenytoin	fosphenytoin phenytoin	CYP2C9 HLA-B
CYP2C9, VKORC1, CYP4F2 and Warfarin	warfarin	CYP2C9 CYP4F2 VKORC1
CYP2D6 and Atomoxetine	atomoxetine	CYP2D6

CYP2D6 and Ondansetron and Tropisetron	ondansetron tropisetron	CYP2D6
CYP2D6 and Tamoxifen	tamoxifen	CYP2D6
CYP2D6, ADRB1, ADRB2, ADRA2C, GRK4, and GRK5 and Beta-Blockers	acebutolol atenolol betaxolol bisoprolol carvedilol esmolol labetalol metoprolol nadolol nebivolol pindolol propranolol sotalol	ADRA2C ADRB1 ADRB2 CYP2D6 GRK4 GRK5
CYP2D6, CYP2C19 and Tricyclic Antidepressants	amitriptyline clomipramine desipramine doxepin imipramine nortriptyline trimipramine	CYP2C19 CYP2D6
CYP2D6, CYP2C19, CYP2B6, SLC6A4, HTR2A and Serotonin Reuptake Inhibitor Antidepressants SSRIs/SNRIs!	citalopram desvenlafaxine duloxetine escitalopram fluoxetine fluvoxamine levomilnacipran milnacipran paroxetine sertraline venlafaxine vilazodone vortioxetine	CYP2B6 CYP2C19 CYP2D6 HTR2A SLC6A4
CYP2D6, OPRM1, COMT, and Opioids Opioids!	alfentanil buprenorphine codeine fentanyl hydrocodone hydromorphone levomethadone methadone morphine naltrexone oxycodone remifentanil sufentanil tramadol	COMT CYP2D6 OPRM1

CYP3A5 and Tacrolimus	tacrolimus	CYP3A5
DPYD and Fluoropyrimidines	capecitabine fluorouracil tegafur	DPYD
HLA-A, HLA-B and Carbamazepine and Oxcarbazepine	carbamazepine oxcarbazepine	HLA-A HLA-B
HLA-B and Abacavir	abacavir	HLA-B
HLA-B and Allopurinol	allopurinol	HLA-B
IFNL3 and Peginterferon-alpha-based Regimens	peginterferon alfa-2a peginterferon alfa-2b ribavirin	IFNL3 IFNL4
MT-RNR1 and Aminoglycosides	amikacin dibekacin gentamicin kanamycin neomycin netilmicin paromomycin plazomicin ribostamycin streptomycin tobramycin	MT-RNR1
NAT2 and Hydralazine	hydralazine	NAT2
RYR1, CACNA1S and Volatile anesthetic agents and Succinylcholine	desflurane enflurane halothane isoflurane methoxyflurane sevoflurane succinylcholine	CACNA1S RYR1
SLCO1B1, ABCG2, CYP2C9, and Statins Statins!	atorvastatin fluvastatin lovastatin pitavastatin pravastatin rosuvastatin simvastatin	ABCG2 CYP2C9 CYP3A4 CYP3A5 HMGCR SLCO1B1
TPMT, NUDT15 and Thiopurines	azathioprine mercaptopurine thioguanine	NUDT15 TPMT
UGT1A1 and Atazanavir	atazanavir	UGT1A1

ND

G6PD

aminosalicylic acid aspirin chloramphenicol chloroquine chlorpropamide ciprofloxacin dabrafenib dapsone dimercaprol doxorubicin furazolidone gliclazide glimepiride glipizide glyburide hydroxychloroquine mafenide mepacrine mesalazine methylene blue moxifloxacin nalidixic acid nicorandil nitrofural G6PD nitrofurantoin norfloxacin ofloxacin pegloticase phenazopyridine primaquine probenecid quinine rasburicase sodium nitrite sulfacetamide sulfadiazine sulfadimidine sulfamethoxazole / trimethoprim sulfanilamide sulfasalazine sulfisoxazole tafenoquine tolazamide tolbutamide toluidine blue

trametinib vitamin c

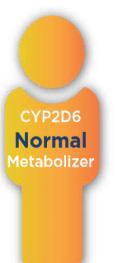
MORE THAN JUST PGX RESULTS

Phenoconversion

- A phenomenon by which an individual's genotype-predicted phenotype is transformed into another by factors such as drug interactions or diseases.
- Reversible upon discontinuation of offending medication
- Commonly Used Strong CYP2D6 Inhibitors:
 - Paroxetine, fluoxetine, bupropion

PHENOCONVERSION

Phenoconversion is a phenomenon that converts genotypic normal metabolizers into phenotypic poor metabolizers of medications.



Phenoconversion can be caused by many things, such as:

- Medications
- Smoking
- Alcohol
- Inflammation



She takes acetaminophen/codeine and is a genetically **normal** *CYP2D6* metabolizer. She is experiencing good pain relief with standard dosing.

She was then started on buPROPion. This causes phenoconversion of her **normal** *CYP2D6* metabolizer status to be transiently changed to *CYP2D6* **poor** metabolizer. Now she may not obtain adequate pain relief with codeine, so alternative therapies should be explored.

Common medications that cause phenoconversion:

- buPROPion (Wellbutrin*) (CYP2D6)
- FLUoxetine (Prozac*) (CYP2D6)
- PARoxetine (Paxil*) (CYP2D6)

Please reference the Flockhart Table™ for more medications: https://drug-interactions.medicine.iu.edu/MainTable.aspx

Phenoconversion is reversible upon discontinuing the causative medication

Phenoconversion Resources

itraconazole **

- Flockhart Table
 - https://drug-interactions.medicine.iu.edu/main-table
- UF PROP Calculator
 - https://precisionmedicine.ufhealth.org/how-to-interpret-results/phenoconversion-calculator/

Inhibitors

Inhibitors compete with other drugs for a particular enzyme thus affecting the optimal level of metabolism of the substrate drug which in many cases affect the individual's response to that particular medication, e.g. making it ineffective.

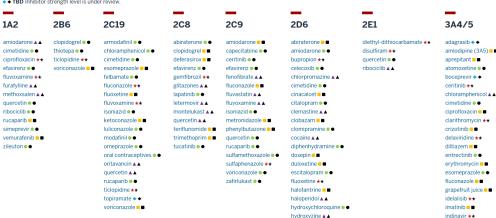
★ A Strong inhibitor is one that causes a ≥ 5-fold increase in the plasma AUC values or more than 80% decrease in clearance.

■ A Moderate inhibitor is one that causes a 2-fold to < 5-fold increase in the plasma AUC values or 50-80% decrease in clearance.

■ A Weak inhibitor is one that causes a ≥ 1.25-fold but < 2-fold increase in the plasma AUC values or 20-50% decrease in clearance.

A In-Vitro Only In-Vitro Only evidence only.

◆ TBD Inhibitor strength level is under review.



levomepromazine • •

CYP2D6 Phenoconversion Calculator



The PROP™ Pharmacogenetics Calculator is intended to help clinicians integrate a standardized method of assessing CYP2D6 phenoconversion into practice when a CYP2D6 genotype is available. The CYP2D6 drug metabolizing enzyme is susceptible to inhibition by concomitant drugs, which can lead to a clinical phenotype that is different from the genotype-based phenotype, a process referred to as phenoconversion. Phenoconversion is highly prevalent but not widely integrated into practice because of either limited experience on how to integrate or lack of knowledge that it has occurred.



Pharmacists Role

ASHP Statement on the Pharmacist's Role in Clinical Pharmacogenomics

- Knowledge gaps are a well-known barrier for both healthcare professionals and patients
 - Be the point of contact for patients and healthcare professionals in interpreting PGx test results and providing educational resources
- Pharmacists are broadly trained in a number of medication-related areas, including pharmacology, pharmacokinetics, and pharmacodynamics
 - This places pharmacists in a unique position in dealing with the complexities of pharmacotherapy in the era of PGx
- Guide PGx implementation efforts and educate healthcare professionals in the adoption of PGx testing
- Create and advocate for PGx clinical decision support services to minimize drugdrug interactions
- Provide consultations about PGx test results to patients
- Collaborate with healthcare providers from multiple disciplines (e.g. physicians, nurse, genetic counselors) to ensure their patients receive the best possible care
- Involvement in PGx research and facilitating the development of clinical practice guidelines



Emerging trend: adding PGx into clinical calculators and algorithms

Genetics is just one piece of the patient puzzle.

Important to consider other factors.



Clinical **Factors**

http://www.warfarin dosing.org/Source/ Home.aspx

WARFARINDOSING

User:

Patient:

www.WarfarinDosing.org

~

Required Patient Information Sex: -Select- ∨ Ethnicity: -Select-Age: -Select-Race: > Warfarin Dosing Weight: lbs or kgs Clinical Trial Height: inches) or (feet and cms) -Select- ∨ Liver Disease: -Select-Smokes: > Outcomes Indication: -Select-> Hemorrhage Risk **Baseline INR:** Target INR: Randomize & Blind Amiodarone/ mg/day Dose: > Patient Education Statin/HMG CoA Reductase Inhibitor: -Select-> Contact Us Any azole (eg. Fluconazole): -Select- V > References Sulfamethoxazole/ -Select-> Glossary **Genetic Information** VKORC1-1639/3673: Not available/pending > About Us CYP4F2 V433M: | Not available/pending Not available/pending GGCX rs11676382: Version 4.0 Not available/pending CYP2C9*2: Build: May 2, 2024 Not available/pending CYP2C9*3: CYP2C9*5: Not available/pending Not available/pending CYP2C9*6: Accept Terms of Use > ESTIMATE WARFARIN DOSE

Models of Delivering PGx Services

- Health-system Prescriber-led:
 - Sole provider-led
 - Physician, mid-level provider (genetic counselor, nurse practitioner, physician associate/assistant), pharmacist provides all PGx services to patient
 - Supported largely through clinical decision support (CDS) tools built into electronic health record (EHR)
 - Alert prescriber to offer PGx testing prior to prescription of PGx-relevant medication
 - Actionable recommendations for medication prescription
 - o Interdisciplinary team
 - Prescriber works collaborative with other members of interdisciplinary team who interact with patient to provide PGx services
 - Team may include a clinical pharmacist, genetic counselor, and nurses
 - Discusses PGx testing with patient and orders testing
 - PGx results are interpreted by a member of the team and recommendations are discussed with team members before a final decision is made about the medication



Models of Delivering PGx Services (cont.)

- PGx consultation service
 - Patient is referred to or independently decides to visit a consultation individual/team who provides PGx services
 - Team can include clinical pharmacists, genetic counselors, nurses, etc.
 - Consultation note with recommendations can be provided to prescriber
- Community pharmacist-led:
 - Pharmacist provides PGx services to patient and discusses recommendations with prescriber
 - Recommending PGx testing
 - Ordering the test
 - Interpreting PGx results
 - Provide recommendations to prescriber

Incorporating PGx into Community Pharmacy Practice

- Direct-to-consumer (DTC) PGx testing is become more readily available for patients
 - Testing that is not prescriber-ordered
 - Some downsides so use with caution
- The expansion of DTC testing in addition to prescriber-ordered PGx testing will continue to increase the awareness of PGx testing and desire for PGx interpretation services
- Community pharmacies are ideal locations to implement PGx services due to:
 - Easy access for many patients
 - Direct pharmacist to patient contact to provide knowledgeable PGx education to patients
 - Point of care PGx testing can be completed in the pharmacy
 - PGx services can be implemented into already existing medication therapy management (MTM) services



Incorporating PGx into Community Pharmacy Practice (cont.)

- Various steps can be taken to implement PGx services into pharmacy practice:
 - Assess pharmacy readiness
 - Establish a workflow
 - Collaborate with prescribers (if needed)
 - o Identify suitable patients for PGx testing
 - Obtain PGx testing and results
 - Interpret PGx test results
 - Provide a recommendation

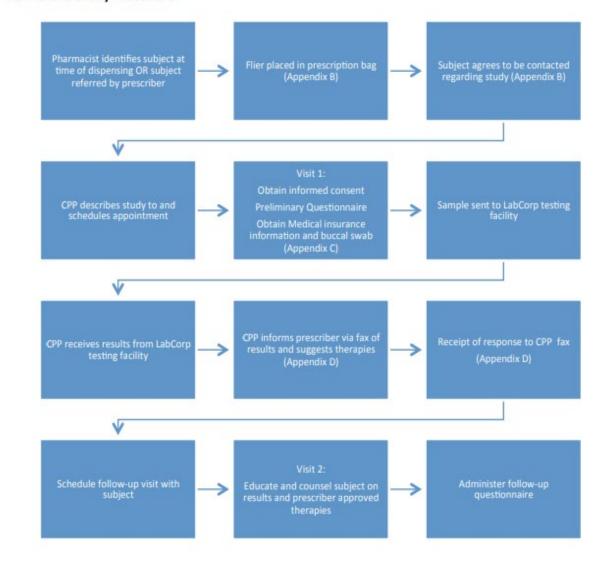
Community Pharmacy Foundation

- Implementation of a Personalized Medicine (Pharmacogenomics) Service in a Community Pharmacy
- Chapel Hill, NC

https://www.communitypharmacyfoundation.org/resources/grant docs/CPFGrantDoc 44468.pdf

Accessed: 10/31/2025

Flow Chart: Study Procedure





Assess Pharmacy Readiness

- Evaluate pharmacy's scope and whether PGx services can be implemented alongside other services offered
 - o Implementation alongside MTM can provider further optimization of pharmacotherapy
- Ensure pharmacists are properly educated about PGx
 - Lack of knowledge and confidence about PGx has been identified as a barrier for many pharmacists
- There are several options for pharmacists to educate themselves on PGx (including but not limited to):
 - ASHP Pharmacogenomics Certificate
 - NCPA Implementing Pharmacogenomics
 - ACCP Precision Medicine: Applied Pharmacogenomics
 - o Test2Learn

Caudle KE, Whirl-Carrillo M, Relling MV, et al. Advancing Clinical Pharmacogenomics Worldwide Through the Clinical Pharmacogenetics Implementation Consortium (CPIC). *Clinical Pharmacology & Therapeutics*. Published online July 18, 2025. doi:https://doi.org/10.1002/cpt.70005

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https://elearning.ashp.org/products/11488/pharmacogenomics-certificate.

https://www.test2learn.org/

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American College of Clinical Pharmacy. *Precision Medicine: Applied*Pharmacogenomics Certificate Program [online course], Release date

September 9 2025. Accessed October 20 2025. https://www.accp.com/PGX

Establish a Workflow

- Determining how to implement PGx services into the community pharmacy workflow is extremely important
- Factors to consider include:
 - Adequate staffing for services
 - Appropriate space for conducting testing (e.g. a consultation room)
 - Patient identification to be collected
 - (e.g. date of birth, gender, ethnicity, medication use, etc.)
 - Obtaining informed consent from patients
 - Time and staff to interpret PGx results and provide recommendations



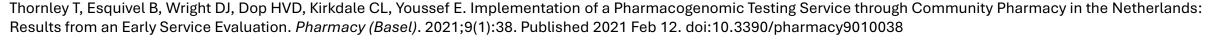
Collaborate with Prescribers

- Collaborating with prescribers is important to ensure that recommendations made by community pharmacists can be implemented
- Engaging with prescribers also:
 - Raises awareness of PGx services
 - Allows the prescribers to ask questions
 - Can ensure a reliable method of communication between pharmacy and prescriber is established



Identify Suitable Patients for PGx Testing

- Patients who are suitable for PGx testing can be recruited to the pharmacy in various ways:
 - Identification by community pharmacists
 - Referral from prescribers
 - Patient request of the service
 - Marketing materials can be created to display within the pharmacy
- Potential suitable candidates for PGx testing include patients who:
 - o Are on medications with actionable PGx recommendations (e.g. clopidogrel)
 - Have a lack of response to various medications (e.g. multiple antidepressants)
 - o Experience many side effects from their medication





Obtain PGx Test Results

- PGx test results can come from various sources:
 - Direct-to-consumer (DTC) PGx tests
 - PGx data located in electronic health records
 - Internal vs external labs
 - Healthcare provider-ordered PGx tests
 - Community pharmacist-ordered PGx tests

Direct-to-Consumer (DTC) Testing

- Direct-to-consumer (DTC) tests can be sold in pharmacies
 - Includes CYP2C19 DTC tests, which is clinically relevant for clopidogrel and citalopram dosing
- With DTC testing, patients can bring PGx results directly to the community pharmacy
- A pharmacist can interpret the results and provide information and recommendations to the patient's prescriber
- Consider collaborative practice agreement for access to more clinically relevant PGx tests

Healthcare Provider- and Community Pharmacist-Ordered PGx Testing

- PGx testing can be ordered by healthcare providers (e.g. physicians, nurse practitioners, etc.)
- Community pharmacists can establish collaborative practice agreements (CPAs) with prescribers that allows them to order PGx testing
 - Allowing pharmacists to order tests can increase efficiency and decrease clinic visits for patients
- DNA samples for testing can be collected in the pharmacy
 - After collection, samples can then be sent to a CLIA accredited lab who report the results



PGx Data in Electronic Health Records

- A patient's PGx information can also be accessed through electronic health records (EHR), if accessible
- For example, some EHRs can integrate CPIC guidelines into its system and provide:
 - Prescribing alerts
 - PGx clinical decision support
 - Therapeutic recommendations
- Pharmacists can use these tools and their knowledge to create their recommendations

COLLABORATION AND ADVANCEMENT IN PHARMACY

Interpret PGx Test Results

- Once the results are received, pharmacists can then interpret the results
- Perform a medication review with consideration of patient's genotypes and phenotypes
- Examples:
 - Patient's genotype is CYP2C19 *1/*1 and phenotype is a normal metabolizer
 - If this patient was taking clopidogrel, they would have the expected response to this drug in terms of efficacy and side effect profile
 - No action needed
 - Patient's genotype is CYP2C9 *2/*3 and phenotype is a poor metabolizer
 - If this patient was taking meloxicam, they would be at risk for increased plasma concentrations and adverse effects
 - Suggest an alternate medication
 - Patient's genotype is CYP2D6 *1/*2x2 and phenotype is ultrarapid metabolizer
 - If this patient was taking codeine, they would be at risk for increased formation of morphine and toxicity
 - Suggest an alternate medication

Provide a Recommendation

- After completing the medication review and interpreting a patient's PGx results, provide a recommendation with actionable steps
 - Examples:
 - Reduce medication dose due to increased risk of adverse effects
 - Increase medication dose to achieve desired clinical effect
 - Suggest an alternate medication that is not affected by the patient's specific PGx results
 - Increased monitoring
 - No action needed if no medications implicated
- CPIC or DPWG clinical guidelines and FDA labels can be helpful for determining recommendations
- Counsel patient on PGx limitations, their PGx results, including what the
 results mean, how it affects their current medications, recommended
 changes to pharmacotherapy, additional monitoring, how it may affect
 future medications, and how it may explain previous medication failures
- Communicate recommendation to prescriber via previously determined method of communication



Build on what has been done

► Pharmgenomics Pers Med. 2021 Jul 15;14:877–886. doi: 10.2147/PGPM.S314972 🗷

Independent Community Pharmacists' Experience in Offering Pharmacogenetic Testing

Susanne B Haga ^{1,™}, Rachel Mills ¹, Jivan Moaddeb ¹, Yiling Liu ¹, Deepak Voora ¹

► Author information ► Article notes ► Copyright and License information

PMCID: PMC8289463 PMID: 34290521

REVIEW · Volume 63, Issue 2, P459-476.E6, March-April, 2023



Experience

Making pharmacogenetic testing a reality in a community pharmacy

Shanna K. O'Connor PharmD, BCPS (professor), Stefanie P. Ferreri PharmD, CPP, BCACP, CDE, FAPhA (Clinical Associate Professor and Director)

Natasha M. Michaels PharmD, CPP (Clinical Coordinator), Rebecca W. Chater BSPharm, MPH, FAPhA (Executive Vice President), Anthony J. Viera MD, MPH (Associate Professor), Hawazin Faruki (Vice President), Howard L. McLeod PharmD, FCCP,

Mary Roederer (Research Assistant Professor)

Journal of the American Pharmacists
Association

Mapping the implementation of pharmacogenomic testing in community pharmacies 2003-2021 using the Theoretical Domains Framework: A scoping review

Heba A.T. Aref · Mark J. Makowsky · Janice Y. Kung · Lisa M. Guirguis 🖰 🖾

► Pharmacogenomics. 2017 Feb 22;18(4):327–335. doi: 10.2217/pgs-2016-0175 🗷

Assessing feasibility of delivering pharmacogenetic testing in a community pharmacy setting

Susanne B Haga 1,1,*, Jivan Moaddeb 1,1, Rachel Mills 1,1, Deepak Voora 1,1

► Author information ► Article notes ► Copyright and License information PMCID: PMC5558549 PMID: 28244804

Research Open access | Published: 22 March 2022

Co-designing a community pharmacy pharmacogenomics testing service in the UK

Tim Rendell ™, Julie Barnett & David Wright

BMC Health Services Research 22, Article number: 378 (2022) Cite this article



Key Takeaways

- PGx is the study of how a person's genes may affect their response to medications
- PGx seeks to:
- Improve drug safety (avoid toxicity) and increase drug efficacy
- Reputable resources are available for pharmacogenomics information and clinical recommendations (ClinPGx, FDA)

Case Study

YT is a 68 yof who had a PGx panel drawn preemptively. Their relevant past medical history is significant for hypertension, dyslipidemia, coronary artery disease, glaucoma, erosive esophagitis, and depressive disorder.

Drug allergies: lisinopril (cough)

<u>Current medications with PGx</u> <u>considerations:</u>

- Atorvastatin 40 mg once daily
- Metoprolol tartrate 50 mg twice a day
- Paroxetine 20 mg once daily
- · Pantoprazole 40 mg once daily

Results of PGx Panel

Gene	Genotype	Activity
CYP2B6	*1/*1	Normal metabolizer
CYP2C19	*1/*17	Rapid metabolizer
CYP2D6	*1/*2 (activity score of 2)	Normal metabolizer
CYP2C9	*1/*1	Normal metabolizer
VKORC1	c1639G>A	Intermediate warfarin sensitivity
СҮРЗА5	*1/*3	Intermediate metabolizer
HLA-B*57:01	Not present	Low risk
SLCO1B1	*1/*14	Normal function

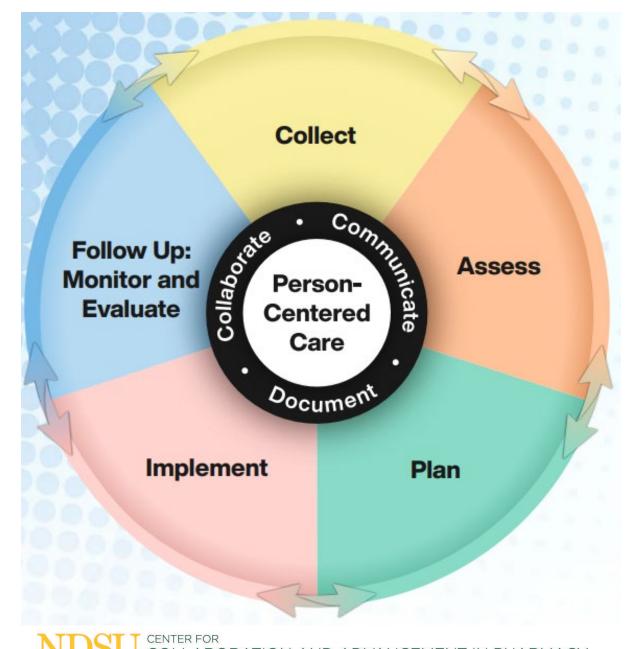
<u>Question:</u> Given that the patient is a CYP2C19 rapid metabolizer, which of the following options would be most appropriate?

- a) Increase the dose of atorvastatin from 40 mg to 80 mg due to SLCO1B1
- b) Switch metoprolol tartrate to bisoprolol due to CYP2D6
- c) Decrease the dose of paroxetine due to CYP2D6
- d) Increase the dose of pantoprazole by 50-100% due to CYP2C19

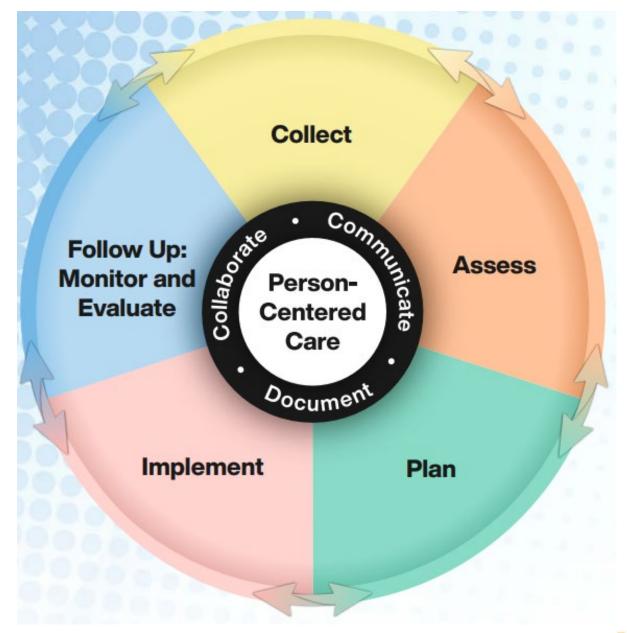


Collect

- Pertinent medical history in relation to PGx includes dyslipidemia, hypertension, depression and erosive esophagitis
- Genes of interest include CYP2D6, SLCO1B1, ABCG2, CYP2C19





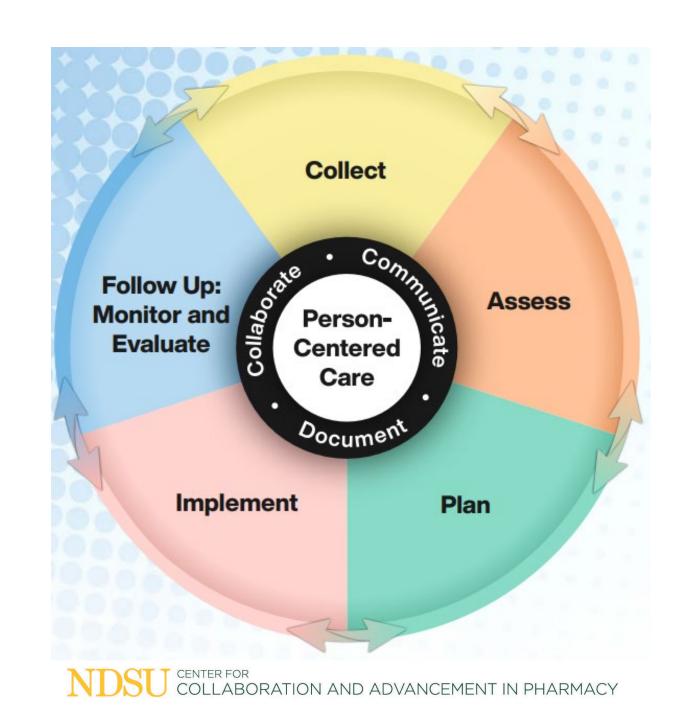


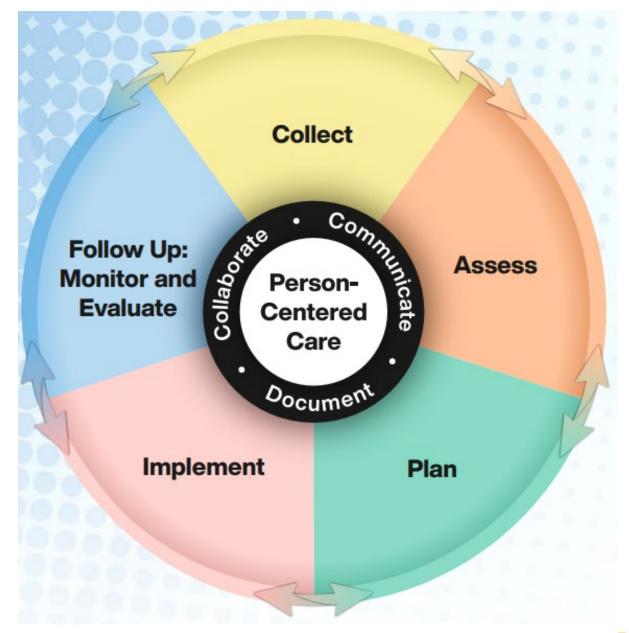
Assess

- Regarding dyslipidemia, the patient is SLCO1B1 normal function, suggesting that they are not at an increased risk of statin-associated muscle symptoms (SAMS)
- Regarding erosive esophagitis, the patient is a rapid metabolizer of CYP2C19, which is the primary metabolizer of pantoprazole
 - They are at a higher risk of therapeutic failure
- On metoprolol and paroxetine, CYP2D6 normal metabolizer – continue with usual care – but wait – paroxetine is a CYP2D6 strong inhibitor affecting metoprolol

Plan

- Patient's daily dose of pantoprazole should be considered for increase by 50-100% for erosive esophagitis
 - Can be given in divided doses
 - Could also consider rabeprazole or esomeprazole (less dependent on CYP2C19)
- Monitor for side effects on metoprolol





Implement

- Contact patient's prescriber to consider PPI recommendation (and monitoring of BP and HR with metoprolol)
- Counsel patient on CYP2C19 rapid metabolizer status and implications for PPI dosing as well as metoprolol monitoring

Follow Up: Monitor and Evaluate

- Resolution of symptoms and avoidance of side effects
- Development of adverse effects
 - Bradycardia, dizziness
 - Bone loss and fractures
 - ∘ Serum Mg²⁺, Ca²⁺
- Adherence and understanding





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CYP2D6	*1/*2 (activity score of 2)	Normal metabolizer
CYP2C9	*1/*1	Normal metabolizer
VKORC1	c1639G>A	Intermediate warfarin sensitivity
СҮРЗА5	*1/*3	Intermediate metabolizer
HLA-B*57:01	Not present	Low risk
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Special Thanks

- Nathan Carlson and Autumn Grasswick
- Sanford PGx Imagenetics Team
- CAP Center
- All of you!

Questions?

• Feel free to reach out: Natasha.Petry@ndsu.edu

Round Table Discussion Points

Pharmacogenomics

- 1. In what capacity do you feel you or the pharmacies you work with could participate in pharmacogenomics? Some options include sample collection, interpretation of results, screening for interactions, incorporation into MTM, and referral for pharmacogenomic consultation.
- 2. What additional resources would you need to make this happen?
- 3. Do you think patients would be interested in pharmacoeconomic services or hesitant?



Medicaid Billing in ND Pharmacies: Strategies for Accuracy and Service Expansion

LeNeika Roehrich, PharmD, BCGP Clinical Pharmacist – ND Medicaid



Disclosure

LeNeika Roehrich reports they have no relevant financial relationships with ineligible companies to disclose.

Objectives

- Review the Medicaid billing process for pharmacy services in North Dakota including eligibility criteria and documentation requirements
- Identify common billing challenges encountered by pharmacies and practical strategies to improve accuracy in Medicaid claims submission
- Describe opportunities for expansion of pharmacy services and leveraging Medicaid to improve patient health outcomes

Billing for Services

- Enrollment
- Determining Medicaid member eligibility
 - Traditional
 - Expansion BCBSND
- Covered services
 - Medical necessity
 - Pharmacist scope of practice
 - Code requirements
- Performing and documenting the service
- Submitting a medical claim



Provider Enrollment

Online Application

eneral Process Apply: How to

Required Information

Enrollment effective date NPI

Pharmacist license

<u>DEA license</u> (if applicable)

Service location info Billing provider info



Required Forms & Documents

Coversheet
Requirements checklist

Provider agreement Affiliation request

NPI registry copy RPh license copy



Online Application

- Gather required information PRIOR to starting the application
- Write down the Application Tracking Number (ATN)



Supporting Documents: "Paper" Application

- Complete required forms
- Submit required forms with supporting documents via email, fax, or mail



Health & Human Services



Medicaid Member Eligibility

Verify



- Always check prior to providing services
- Member Eligibility Instructions
- MMIS portal: mmis.nd.gov
- Provider Relations Call Center
- Automated Voice Response System

Information



- You need 3 of the 4 following pieces of member information
 - First name
 - Last name
 - Date of birth
 - Medicaid ID

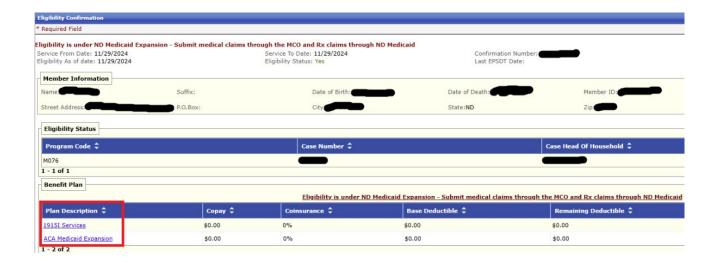
Medicaid Member Eligibility

Coverage



- Traditional Medicaid
 - Medicaid Fee for Service
 - Pharmacy and medical claims are billed to ND Medicaid
- Medicaid Expansion
 - ACA Medicaid Expansion
 - Pharmacy claims are billed to ND Medicaid
 - Medical claims are billed to the MCO







Covered Services

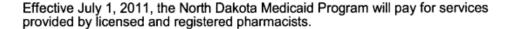
Scope of Practice

- Medication Therapy Management (MTM)

 Anticoagulation management
- Continuous glucose monitoring
- Drug/vaccine administration
- Tobacco cessation

Tools & Links

- ND Medicaid Provider Information
- Pharmacy Provider Manual
- Provider Guidelines, Manuals and Policies
- Procedure Code Look-Up Tool
- Fee Schedules







Disease State Management

Guideline-based therapy

MTM

Pharmacy Provider Manual



Medication Use

Adherence/Deprescribing
Transition of care
Health Literacy



Harm Reduction

Hepatitis C PA Risk of overdose PWID



CHAPTER 61-04-12 LIMITED PRESCRIPTIVE AUTHORITY FOR NALOXONE

CHAPTER 61-04-14 LIMITED PRESCRIPTIVE AUTHORITY FOR IMMUNIZATIONS CHAPTER 61-04-15 LIMITED PRESCRIPTIVE AUTHORITY FOR TOBACCO CESSATION THERAPIES

FDA NEWS RELEASE

FDA Approves First Over-the-Counter Naloxone Nasal Spray

Agency Continues to Take Critical Steps to Reduce Drug Overdose Deaths Being Driven Primarily by Illicit Opioids



For Immediate Release: March 29, 2023

CENTER FOR DRUG EVALUATION AND RESEARCH

DIVISION of DRUG INFORMATION

Your source for the latest drug information. Know the moment it happens.

FDA Approves First Nonprescription Daily Oral Contraceptive

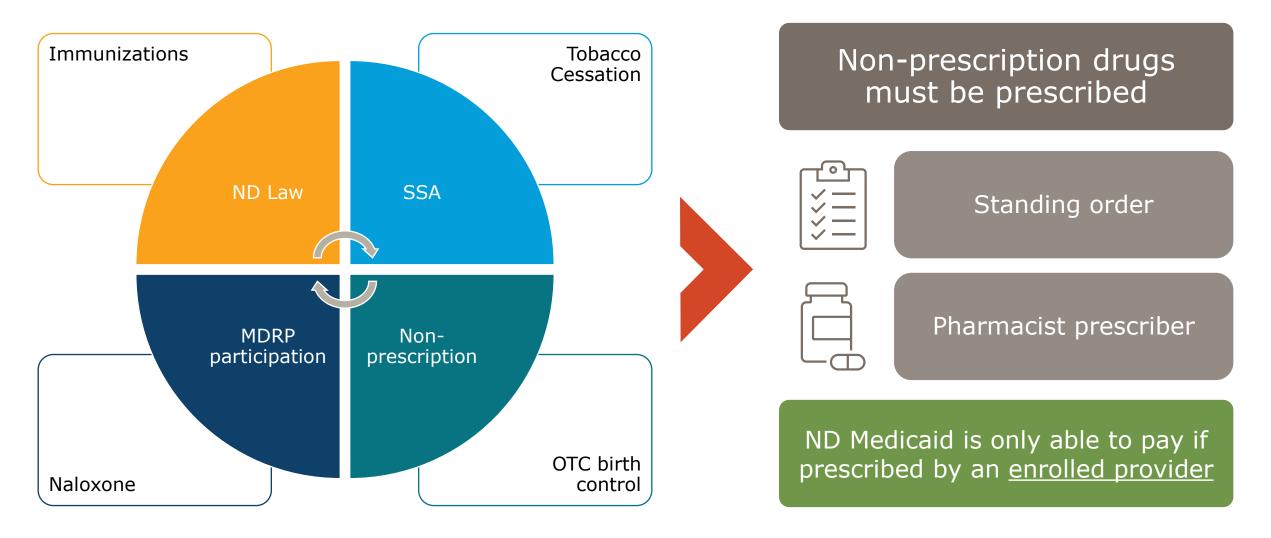
Today, the U.S. Food and Drug Administration approved Opill (norgestrel) tablet for nonprescription use to prevent pregnancy— the first daily oral contraceptive approved for use in the U.S. without a prescription. Approval of this progestin-only oral contraceptive pill provides an option for consumers to purchase oral contraceptive medicine without a prescription at drug stores, convenience stores, and grocery stores, as well as online.

 $\frac{https://www.fda.gov/news-events/press-announcements/fda-approves-first-over-counter-naloxone-nasal-spray}{counter-naloxone-nasal-spray}$

https://www.fda.gov/news-events/press-announcements/fda-approves-first-nonprescription-daily-oral-contraceptive?utm_medium=email&utm_source=govdelivery

https://www.nodakpharmacy.com/pdfs/lawbooknew.pdf





(4) Nonprescription drugs.—If a State plan for medical assistance under this title includes coverage of prescribed drugs as described in section 1905(a)(12) and permits coverage of drugs which may be sold without a prescription (commonly referred to as "over-the-counter" drugs), if they are prescribed by a physician (or other person authorized to prescribe under State law), such a drug shall be regarded as a covered outpatient drug.



Documentation

Pharmacy Provider Manual

ND Medicaid Billing and Policy Manual

Documentation includes:

- · Medical records including:
 - Member's name and date of birth;
 - Date of service;
 - Start and stop time spent with the member performing the service, to support payment for time-based billed services;
 - Name and title of provider rendering the service, if other than the billing practitioner;
 - o Chief complaint or reason for each visit;
 - Pertinent medical history;
 - Pertinent findings on examination;
 - o Medication, equipment and/or supplies prescribed or provided;
 - Description of treatment or service provided;
 - Recommendations for additional treatments, procedures, or consultations;
 - Diagnostic tests and results;
 - Dental photographs/teeth models;
 - Certification of medical necessity (if applicable);
 - Plan of treatment and/or care and outcome; and
 - Signature and date by the person ordering or rendering the service.
- Service authorization information;
- Claims, billings, and records of Medicaid payments and amounts received from other payers for services provided to members;
- · Records and original invoices for items that are prescribed, ordered, or furnished;
- Any other related medical or financial data that may include appointment schedules, account receivable ledgers, and other financial information; and
- Service-specific documentation requirements per policy.



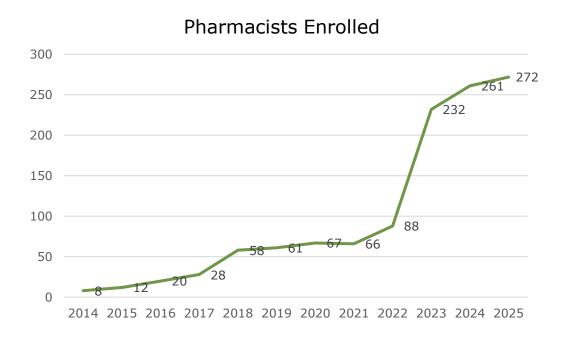
Submitting Claims for Services

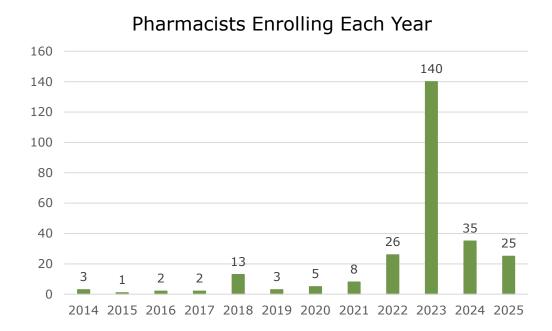
- Medical claim
- Coverage
 - Reimbursement
 - Procedure Code Lookup tool
- Improving accuracy in claims submission
 - O/R/P provider NPIs
 - Code definitions and billing parameters
 - Taxonomy and specialty for enrolled NPI
 - Service authorization number (if applicable)

Opportunities

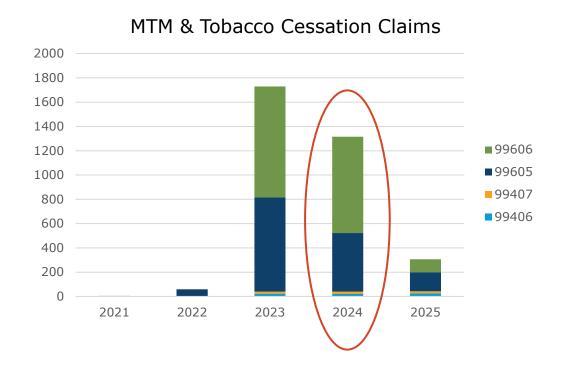
- Review point-of-sale messages on pharmacy claims
 - Paid claims and rejected claims
 - Identify potential interventions
- Leverage the monthly retrospective drug utilization review letters sent to the pharmacy
- Enroll, provide services, and bill for the work you do

Pharmacists Enrolled

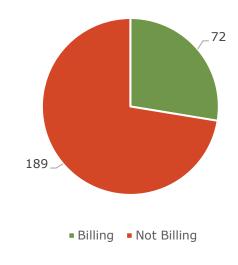




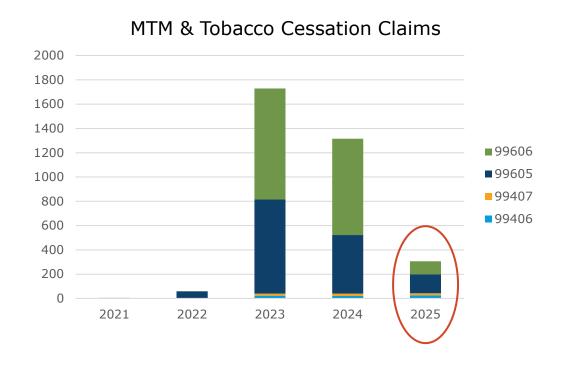
Pharmacists Billing



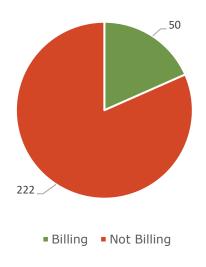
Enrolled Pharmacists Billing for MTM & Tobacco Cessation



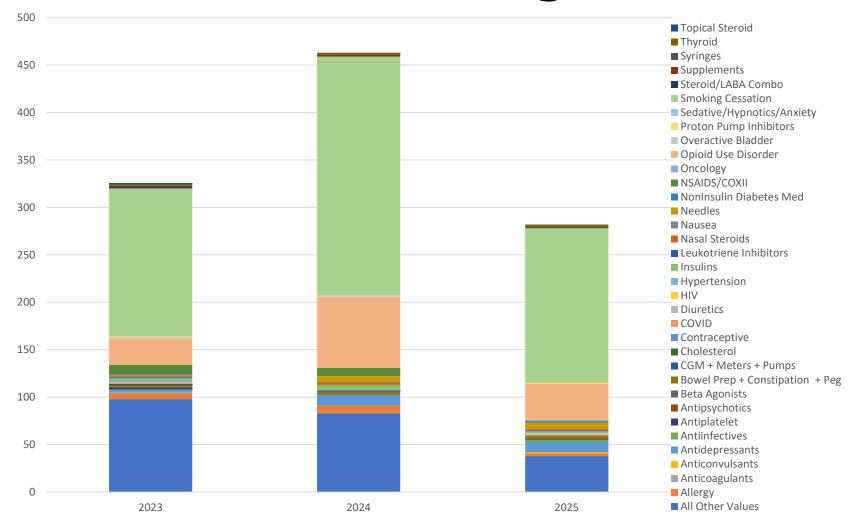
Pharmacists Billing



Enrolled Pharmacists Billing for MTM & Tobacco Cessation



Pharmacist Prescribing



Questions



Round Table Discussion Points

Medicaid

- 1. What Medicaid services are you currently providing/billing?
- 2. What tips do you have for others? (challenges you've had to navigate)
- 3. What additional resources would you need to start or expand your services?
- 4. What other payers besides Medicaid are you currently billing? What are the services? are providing/billing?

Implementing Collaborative Practice Agreements in North Dakota Pharmacies - Frameworks, Integration, & Action Steps

Carly Smithers, PharmD
Pharmacist/Pharmacy Manager
Dakota Clinic Pharmacy



Disclosures

Carly Smithers reports to have no financial relationships with ineligible companies to disclose.

Objectives:

- 1. Describe the structural framework and collaborative practice agreements available in North Dakota.
- Explain how test-to-treat services can be integrated into an existing pharmacy practice model and workflow.
- 3. Identify required resources, action steps, success and challenges to implement test-to-treat in a community pharmacy.

What is a collaborative practice agreement (CPA)?

- CDC defines a pharmacist CPA as "a formal agreement in which a licensed provider makes a diagnosis, supervises patient care, and refers patients to a pharmacist under a protocol that allows the pharmacist to perform specific patient care functions".
- ND lawbook describes it as "the written document signed by a physician and pharmacist which describes the limited prescribing authority granted to the pharmacist"

CPA's in North Dakota

- Agreement made between a NP (nurse practitioner) or MD (medical doctor) and a PharmD/RPh (pharmacist)
- Most often done at the hospital level or public heath
- Element Health- *NEW* CPA option for community pharmacists
 - No residency or board certification required for pharmacist
 - Partnership between a NP and pharmacist in ND
 - 11 different CPA's which allow pharmacist to prescribe
 - Must sign contract



Why are CPA's important?

- Closing gaps in care for patients
- Preventing delayed treatment
- Relieve burden of healthcare systems with simple disease state management
 - *NOT* a replacement for a PCP (primary care provider)
- Broader access for patient care
 - Community pharmacists = first direct line to health care in ND
 - Rural community access
- Patient affordability/decreasing financial burden
- Reimbursement decline new avenues for revenue
- Job satisfaction



Importance of CPA's cont.

- In 2021, data polled within the state to assess PCP needs within the state
 - 39% tobacco users
 - >10% living in poverty
- Rural areas of ND
 - 30% PCP's statewide work in these regions
 - PCP average age for rural zones higher than Midwest and US
 - Recruitment issues



Element Health

CPA Options

Test-to-treat CPA's	Other CPA's
Strep Throat (Antibiotics)	Albuterol Inhaler
Covid (Paxlovid)	Tobacco Cessation
Influenza (Oseltamivir)	Cold Sore Treatment
UTI (Antibiotics)	Birth Control
	GLP-1's
	Glucagon (CGM management)
	EpiPen

Getting started with Element Health- Step 1

- Point(s) of contact
 - Jesse Rue, Jesse Johnson
- CAP Center involvement
 - Elizabeth Skoy webinar on test-to-treat
- CLIA waiver
- Strategize with team
 - Designate leader
 - Refresh training

CLIA Waiver

- https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf
- https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf
- Form CMS 116
- \$248
- Good for two years
- Clialab@nd.gov
- Ph: 701-328-2352 Fax: 701-328-1890



CLINICAL			OVEMENT AMENDI OR CERTIFICATION	MENTS (C	LIA)
AL ENERAL INFORMATION	L APPLICA	BLE SECTIONS OF	THIS FORM MUST BE COM	PLETED.	4
Initial Application Anticipated Start Date		CLIA IDENTIFICATION NUMBER			
Change in Certificate Type			Description		
Change in Laboratory Direc	tor		(If an initial application leave bl.	ank, a number w	ill be assigne
Other Changes (Specify)					
ctive Date					
LITY NAME	YNAME		FEDERAL TAX IDENTIFICATION N	UMBER	
IL ADDRESS ECEIVE NOTIFICATIONS INCLUDING ELECTRONIC CERTIFICATES A EMAIL		TELEPHONE NO. (Include area code	FAX NO. (Incl.)	ude area code)	
LITY ADDRESS — Physical Locati icable.) Fee Coupon/Certificate will reporate address is specified	on of Laborate be mailed to t	ory (Building, Floor, Suite if his Address unless mailing	MAILING/BILLING ADDRESS (If diff or certificate	ferent from facility	address) send
MBER, STREET (No P.O. Boxes)			NUMBER, STREET		
	STATE	ZIP CODE	CITY	STATE	ZIP CODI
D FEE COUPON TO THIS ADDRESS CONE: Physical	SEND CERTIFICATE TO THIS ADDRESS PICK ONE: Physical		CORPORATE ADDRESS (If different from facility) send Fee Coupon or certificate	NUMBER, STR	EET
Mailing	Mailing		CITY	STATE	ZIP CODE
Corporate	Corpora	te			
		Laboratory Director's Phone Number			
DENTIALS			FOR OFFICE USE ONLY		
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Certificate of Waiver (Co	implete Se	ctions I – VI and IX	- X)		
			PM) must meet specific education, laboratory director must be submi		
ceremente for Provider P	eriormed	Microscopy Procedi	ures (PPM) (Complete Section	ns I-VII and IX	(-X)
Certificate of Compliance	e (Comple	te Sections I – X)			
laboratory is accredited l	on (Compl	ete Sections I – X) ar	nd indicate which of the follo nich you have applied for acc	owing organiz	ation(s) yo
	SAUGHBER BORRERS	Parposes, or 101 Mi	nun you have applied for acc	reditation for	CLIA purp
The Joint Commis	sion 📗				
The Joint Commis	sion	ACHC COLA	AABB A2LA		Tippe His Chine

dentify the waived testing (to be) performed by completing the table below. Include each analyte, test system, or device used n the laboratory.				
ANALYTE / TEST	TEST NAME	MANUFACTURER		
Example: Streptococcus group A	Ace Rapid Strep Test	Acme Corporation		
Check if no waived tests are performe	TEST volume for all waived tests performed and attach additional information usin			
VII. PPM TESTING If only applying for a C	ertificate for PPM, complete this section and ski	D section VIII (Non-Wayard Tortina)		
Listed below are the only PPM tests teach PPM procedure(s) to be perform Direct wet mount preparations for Potassium hydroxide (KOH) prepar Pinworm examinations Fern tests Post-coital direct, qualitative examulations Nasal smears for granulocytes Fecal leukocyte examinations	hat can be performed by a facility having a	a Certificate for PPM. Mark the checkbox by i, parasites, and human cellular elements		

CLIA approved supplies

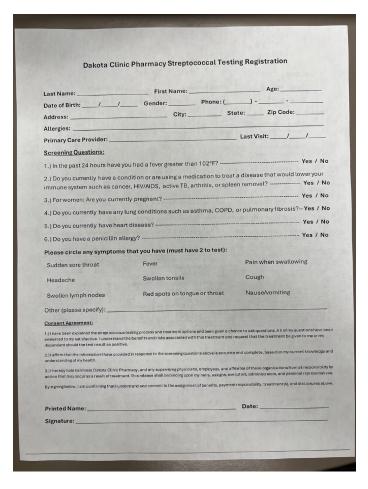
- Can contract with current wholesaler
 - Most wholesalers have direct CLIA sales information/additional resources such as advertising
- CAP center has list of options
 - No affiliations or discounts
- Cliawaived.com

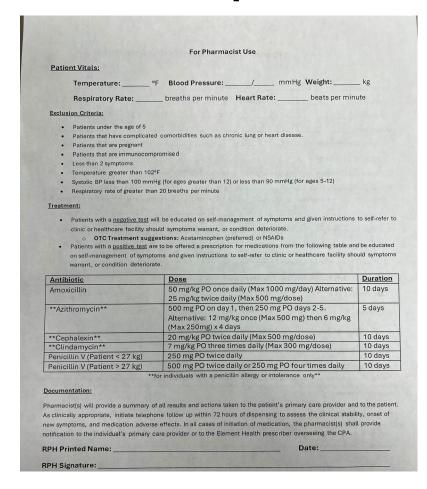
Getting started with Element Health- Step 2

- Decide on what protocols you'd like to initiate
- Sign contracts & submit payment (with provider associated with protocols, Element Health, Starfield)
- Read through protocols and assess other supply needs
 - Scale (weight-based treatment)
 - BP monitor (pediatric and adult)
 - Thermometer
 - Test to treat supplies (tests, UTI kits, tongue compressors, etc.)
 - Spill pads and appropriate PPE for staff
- Create templates (electronic or paper) and after visit summaries for all protocols involved
- Decide on patient out of pocket cost or billing strategies
 - Test to treat vs pharmacist office visit
 - Incorporate into software/platforms



Intake Form Example:

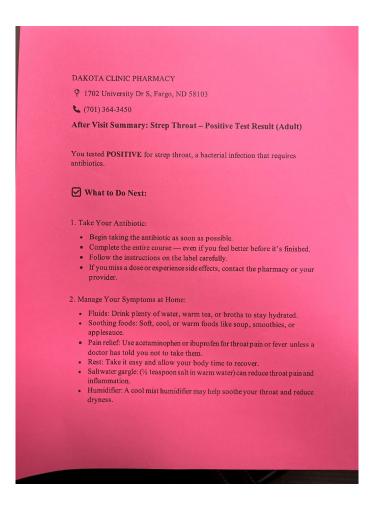


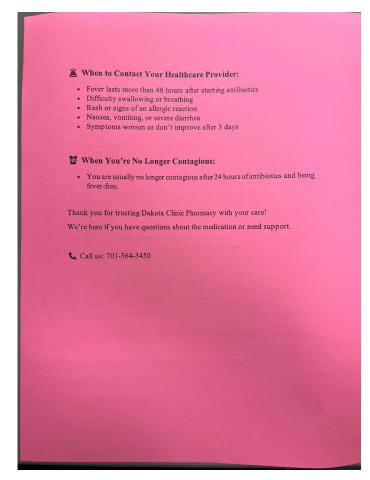


Helpful Tips:

- List exclusion criteria up top or screen upon patient inquiry
- Create spot for PCP information
- List medication allergies

After Visit Summary Example:





Helpful Tips:

- Color coded
- AVS both positive AND negative results
- AVS geared towards pediatrics vs adults

Getting started with Element Health: Step 3- Marketing and Implementation

- Strategize how you plan to market it
 - Social media, podcast, bag tags, signage, word of mouth
- Adding into workflow
 - Doing "test trials" to ensure process is smooth
 - Staff training days
- Tech involvement
 - Screen for candidates
 - Check patients in
- Student involvement
 - Create forms
 - Medical billing
 - Patient consultations



Medical Billing Options

- If credentialed, can choose to forgo self pay options and seek reimbursement from insurance
- Billed as an office visit
 - CPT code: 99202
- Could be a way to provide service for patients who can't afford out of pocket
 - NDMA

Barriers/challenges

- Local healthcare providers
 - Pushback of us taking over services/compensation
 - Downplaying validity of tests
- Patient not wanting to pay
- Office visit does NOT go into EMR (electronic medical record)
- Negative results
- Pediatrics
- Exclusion criteria
- Marketing
 - State level education to inform community and other health care workers of new pharmacy services



Patient Example 1:

MS is a 6-year-old female presented to the pharmacy with the following:

Fever 101, red irritated throat with white patches, pain when swallowing, upset stomach, swollen tonsils

*TIP: Parent fills out form and pays before throat swab

Pharmacist inspected throat, took vitals (BP 95/65, respirations 20 breaths per minute, temp 101, weight 55 lbs), and performed swab of the back of the throat

*TIP: distraction method for kids

Patient dismissed back to waiting area while test loads

Test was positive. Pharmacist evaluated antibiotic options based on protocol. Patient was prescribed Azithromycin due to Amoxicillin allergy. Azithromycin dosed appropriately based on weight and billed through insurance.

Patient/Parent given after visit summary, antibiotic, medication handouts, and given a pharmacist consult on symptom management and antibiotic use. Entire interaction was about 20 minutes.



Patient Example 2:

LP is a 55-year-old man with asthma who presented to the pharmacy in search of an albuterol inhaler. He had filled an albuterol inhaler with our pharmacy in the past, but the Rx had since expired. Patient worried about going without inhaler due to smoke content in environment.

Technician screened for possible CPA candidate and found he would be eligible if interested.

Patient filled out questionnaire, pharmacist met with patient in the office to review form and screen for any drug interactions such as beta blockers.

Pharmacist prescribed albuterol, and Rx was run through patient insurance. Patient provided AVS, Rx, and consultation.



What happens after?

- Documentation
- Alert provider in agreement as per their discretion
- Alert patient's PCP

References

- Centers for Disease Control and Prevention.
 Collaborative Practice Agreements and Pharmacists'
 Patient Care Services: A Resource for Pharmacists.
 Atlanta, GA: US Dept. of Health and Human Services,
 Centers for Disease Control and Prevention; 2013.
- North Dakota State Board of Pharmacy. Lawbook.
 Collaborative Agreement. September 2015.
- Bauman, Sonja; Kusler, Stacy; Will, Bobbie. "North Dakota Primary Care Office Needs Assessment". 2021.

Questions?



Round Table Discussion Points

Collaborative Practice Implementation

- 1. Has the pharmacy you work in implemented collaborative practice agreements?
- 2. If no, what CPAs do you think would be beneficial to your patient population?
- 3. What would some of the barriers be to implement a collaborative practice agreement?



Pharmacy Partnerships for Healthy Aging and Chronic Disease: Current Initiatives and Future Opportunities in North Dakota

Ryan McGrath, PhD Jayme Steig, PharmD

Before We Begin

- The off-label use of medications will be discussed during this presentation
- Conflicts and disclosures
 - None to report

Before We Begin

Learning objective

- 1. Describe current initiatives and opportunities for pharmacies to support the health and well-being of older adults
- 2. Describe pharmacy-led initiatives and opportunities to support individuals with chronic diseases, including those prescribed GLP-1 receptor agonists
- 3. Identify future opportunities for pharmacy involvement in research and collaboration with North Dakota State University to improve health outcomes

Greetings!

- Ryan McGrath, PhD
 - Associate Professor: Department of Health, Nutrition, and Exercise Sciences; North Dakota State University
 - Director of "Healthy Aging North Dakota" (HAND Lab) Healthy Aging Morth Dakota"
 - CAP Center Scientist
 - Department of Geriatrics; University of North Dakota
 - Fargo VA Healthcare System
 - Research agenda
 - Topics related to aging and health

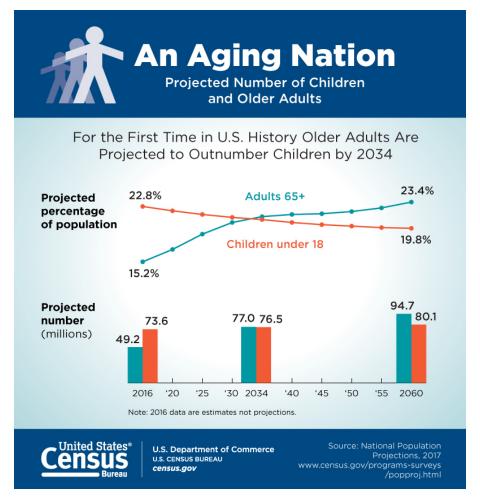


Greetings!

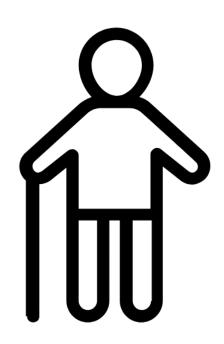
- Jayme Steig, PharmD
 - Assistant Professor of Practice
 - Department of Pharmacy Practice
 - Practice site at Southpointe Pharmacy
 - Research interests
 - Community pharmacy practice
 - Quality improvement
 - Medication therapy management





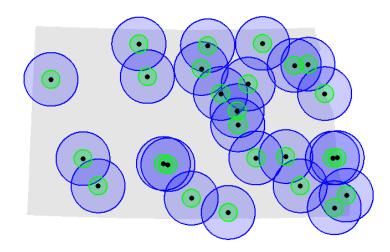


- What may come with a large older adult population demographic increase?
 - Examples
 - Need for healthcare providers (including pharmacists and related personnel)
 - Economic implications
 - Caretakers
 - Healthcare infrastructure
 - Reach to all older adults
 - Education on aging and health
 - Student and early career experiences working with older adults



Rural older adults

- Disproportionally reside in rural areas, but life expectancy might be lower
- Role of healthcare access
- Lack representation in research
- Part of rural health
- Approximately 97% of Americans live within 10 miles of a pharmacy

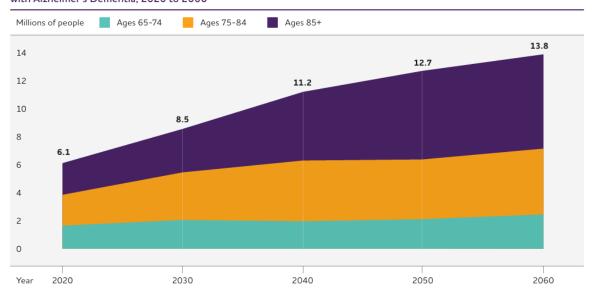


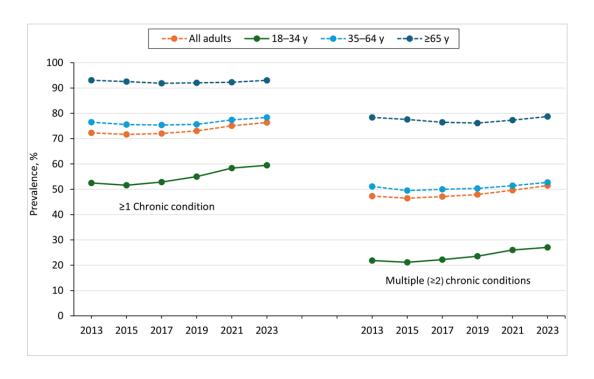


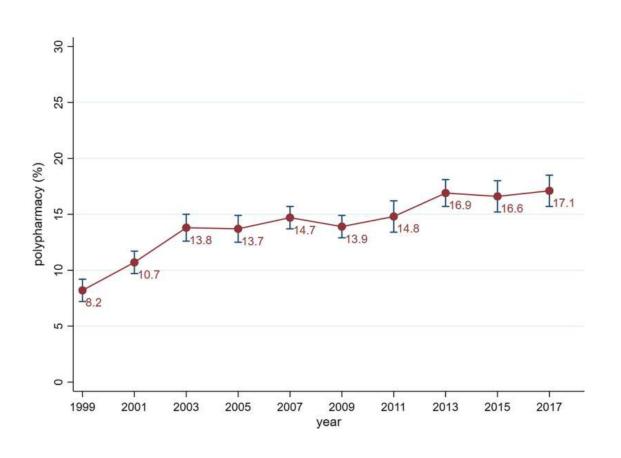
- Pharmacists and older adults
 - Older adults trust pharmacists
 - Viewed as a places of healthcare
 - Older adults are interested in talking about their medications
 - Location of pharmacy matters
 - Opportunity to communicate with prescribing physicians (fax/efax)
- Opportunities to interact
 - Medication therapy management
 - Distinct service or group of services that optimize therapeutic outcomes for individual patients (American Pharmacists Association)
 - Prevents adverse advents, lowers costs, patient benefit, delivery from pharmacist, Medicare

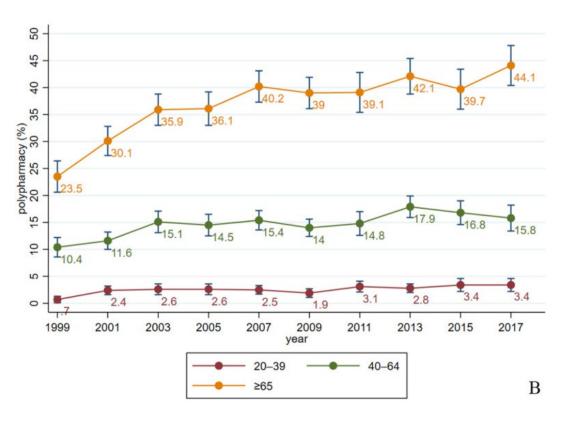


Projected Number of People Age 65 and Older (Total and by Age) in the U.S. Population with Alzheimer's Dementia, 2020 to 2060

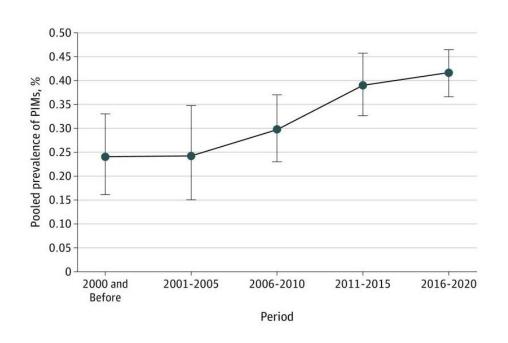








- Potentially inappropriate medications (PIM)
 - Medications that may present an elevated risk of adverse events or interactions in older adults
 - AGS Beers Criteria®
 - Rural areas
 - Age
 - Multimorbidity
 - Polypharmacy



- Examination of PIM use at local community pharmacies
 - Medication therapy management
 - n=42 older adults (age: 76.4 ± 7.9 years)
 - n=37 (88%) using a PIM
 - 9.7%: benefits outweighed risks
 - 83.9%: education on PIM risk provided
 - 1.1%: pharmacist recommended discontinuation
 - 5.3%: pharmacist contacted provider for deprescribing
 - Barriers and facilitators to implementing PIM review
 - Effective training strategies
 - Solidifying processes
 - Lessons for the future
 - Value to patients and pharmacies

Journal of the American Geriatrics Society

Journal of the American Geriatrics Society

RESEARCH LETTER

Integration of Potentially Inappropriate Medication Screening Into Community Pharmacies: A Pilot Study of Feasibility and Impact

Elizabeth Skoy¹ 💿 | Jayme Steig¹ | Heather Fuller² 🕤 | Rebecca Brynjulson¹ | Ryan McGrath³

¹Department of Pharmacy Practice, North Dakota State University, Fargo, North Dakota, USA | ²Department of Human Development and Family Science, North Dakota State University, Fargo, North Dakota, USA | ³Department of Health, Nutrition, and Exercise Science, North Dakota State University, Fargo, North Dakota, USA

Correspondence: Elizabeth Skoy (elizabeth.skoy@ndsu.edu)

Received: 4 August 2025 | Revised: 21 August 2025 | Accepted: 27 August 2025

Funding: This work was supported by North Dakota Economic Diversification Research Funds (FAR38182).

Keywords: community pharmacy | medication therapy management | potentially inappropriate medications





Figure 1. Percent distribution of adults aged 18 and over who met 2018 Physical Activity Guidelines for Americans for aerobic and muscle-strengthening activities: United States, 2020

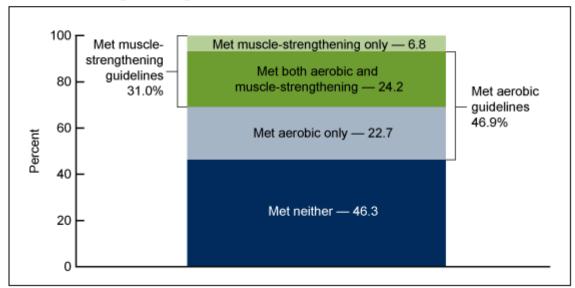
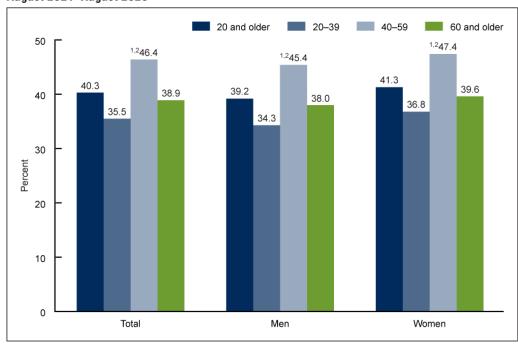


Figure 1. Prevalence of obesity in adults age 20 and older, by sex and age: United States, August 2021–August 2023



Significantly different from ages 20-39 (p < 0.05).

SOURCE: National Center for Health Statistics, National Health and Nutrition Examination Survey, August 2021-August 2021

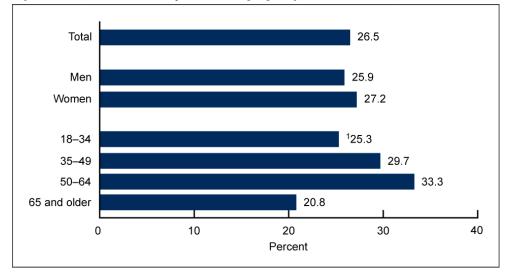


²Significantly different from age 60 and older (p < 0.05).

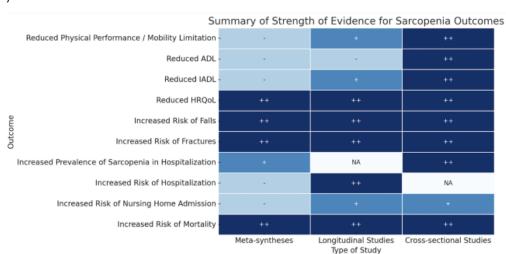
NOTE: Age-adjusted estimates for adults age 20 and older are 40.3% for the total population, 39.3% for men, and 41.4% for women and were age adjusted by the direct method to the U.S. Census 2000 population using age groups 20–39, 40–59, and 60 and older.

- Glucagon like peptide-1 receptor agonists (GLP-1RA)
 - Show promise for reducing body weight/mass
 - ~700% increase in use, including for off-label and cosmetic purposes
 - Risks
 - Many
 - Muscle mass loss

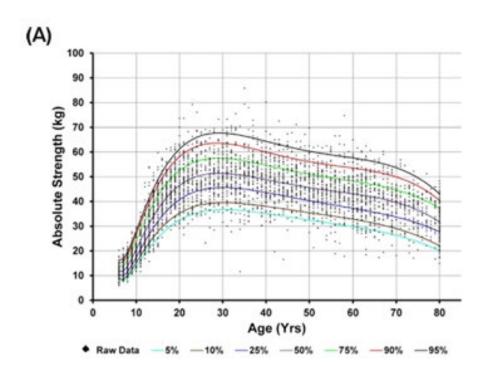
Figure 1. Percentage of adults with diagnosed diabetes who used GLP-1 injectables, overall and by sex and age group: United States, 2024

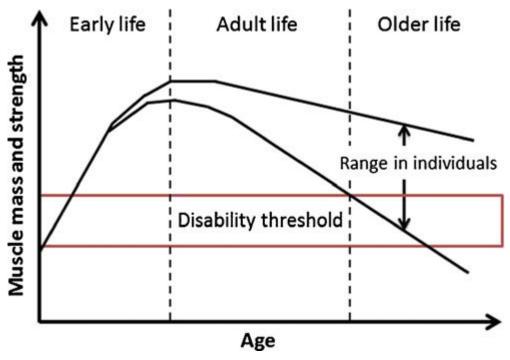


- GLP-1RA have shown promise
 - Adverse events are present
 - Strong consideration for risk-benefit balance
- Longer-term health implications should be examined
 - Sarcopenia
 - Age-related loss of muscle mass and strength/function
 - Sarcopenic obesity
 - Inclusion of obesity

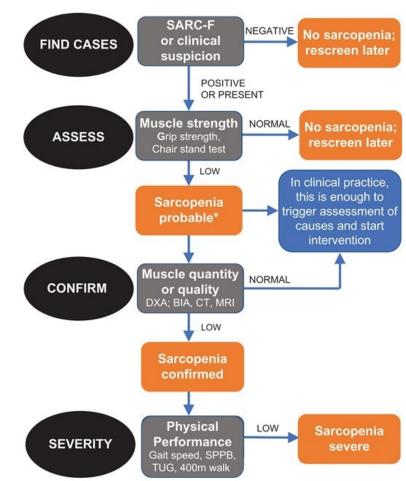








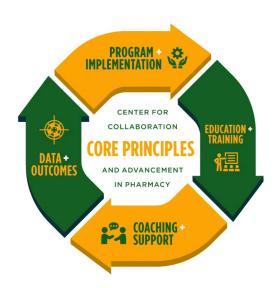
- Sarcopenia screening
 - Handgrip strength
 - Muscle mass
 - Physical performance



- Community pharmacies can connect patients with their healthcare providers
 - Heart, muscle, and brain health are all important for aging
 - Electrocardiogram (arrhythmia)
 - Handgrip dynamometer (weakness)
 - Cognitive assessment (cognitive impairment)
- n=106 older adults (age: 74.1±9.6 years; 57% female)
 - Arrhythmia referral: 8%
 - Weakness referral: 23%
 - Cognitive referral: 29%
 - Followed-up with healthcare provider: 24%



- I am interested; tell me more!
 - North Dakota State University and School of Pharmacy (only in state)
 - CAP Center is an excellent resource
 - Education and training
 - Programs and implementation
 - Consulting and support
 - Data and outcomes
 - Improve public health
 - Advance healthcare services including in rural areas
 - Engage in significant and meaningful research to advance human health
 - Improve pharmacy operations and patient care
 - Great and committed people
 - Opportunity to engage is excellent!



How may we answer your questions?



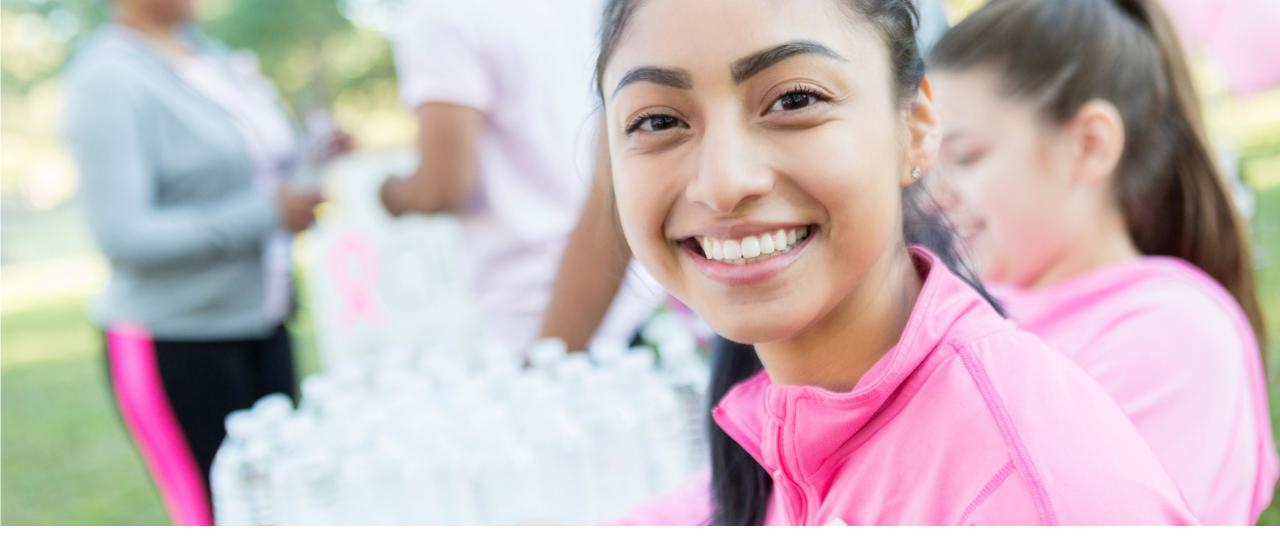
ryan.mcgrath@ndsu.edu jayme.steig@ndsu.edu



Round Table Discussion Points

Healthy Aging

- 1. What opportunities for research and quality improvement do you have through your observation and experience of work in your pharmacy?
- 2. What barriers exist for you to engage in research or provide additional healthcare services at your pharmacy?
- 3. How would you envision participating in a research opportunity at your pharmacy? What support would you need from the CAP Center?



Expanding the Role of Community Health Workers in North Dakota Pharmacies: Policy, Partnerships, and Practice Integration

Health & Human Services



Be Legendary.

Tiffany R. Knauf, MA

Health Systems and Pharmacy Coordinator, Health Promotion and Chronic Disease Prevention Unit

NACDD North Dakota Chronic Disease Director

• I have no financial relationships with ineligible companies to disclose.





Learning Objectives

- Describe current rules and regulations guiding the role and integration of Community Health Workers (CHWs) in North Dakota.
- Identify how the roles of the Community Health Worker align with and complement those of the pharmacy technician.
- Discuss funding mechanisms, training requirements, and policy support needed to expand the impact of CHWs in North Dakota.
- Explain opportunities for integrating CHWs into pharmacy teams to address social determinants of health and improve patient outcomes.





What is a CHW?

- Trusted frontline public health worker
- Connects people to care and resources
- Shares lived experiences with community
- Serves as advocate, educator, navigator



Key Functions:

- Health education, care coordination, resource navigation, and patient advocacy
- Address SDOH barriers affecting medication adherence and chronic disease outcomes

Evidence of impact:

- CHW interventions reduce A1c, improve BP control, increase preventive care uptake
- Integration with pharmacists leads to improved adherence and outcomes



American Diabetes Association. Resources for CHWs.
professional.diabetes.org
Health & Human Services Appual Review of Bublic Health / CHW Central CHW

Annual Review of Public Health / CHW Central. CHW Integration with Health Care.

https://doi.org/10.1146/annurev-publhealth-071521-031648



Pharmacy & CHWs: Working Together

Pharmacy Technicians

- Eligible to become Certified CHWs in North Dakota.
- May provide patient education, follow-up, and resource navigation as part of pharmacy workflow.

Pharmacists

- Can refer patients to Certified CHWs for follow-up, SDOH support, or chronic disease management.
- CHW services may be **reimbursed through Medicaid** when referred by a qualified provider, including pharmacists.
- Collaboration enhances care coordination and expands patient reach.





Legislative Action & Impact

2023 - HB 1028 Passed

- Required NDHHS to seek Medicaid state plan amendment for CHW reimbursement
- Created a time-limited CHW Task Force

2024 – Task Force Recommendations Due

- Scope of work, education and training
- Certification and regulation
- Medicaid reimbursement (including FQHCs)
- ND CHW Collaborative

2025 - Rules, SPA Certification

- ND Administrative Code Chapter 33-03-38 (rules for CHWs) approved.
- Medicaid State Plan Amendment submitted for CHW reimbursement
- Certification process and application launched on Oct. 1



Behind the Scenes: The Statewide Team Supporting CHWs



Certification

Four Pathways for Certification:

- 1. Training + Internship
- 2. Community Health Representative (CHR) Training
- 3. Supervised Work Experience
- 4. Reciprocity with Another State



Reimburseme nt Policy and Payment

- ND Medicaid coverage
- Monitor claims and utilization.
- Provider enrollment



Programmatic Support, Outreach, Association

- Develop supporting documents for adoption
- Provide education and TA
- Develop resources
- Establish Association

CHW Certification Pathways

- 1. Training + Internship
 - Complete a CHW Training Program + 200-hour internship
- 2. Community Health Representative (CHR) Training
 - Completed the Indian Health Service (IHS) Community Health Representative training
- 3. Supervised Work Experience
 - At least 1,000 hours of supervised work experience within past 3 years
 - Letter of recommendation from supervisor
- 4. Reciprocity with Another State

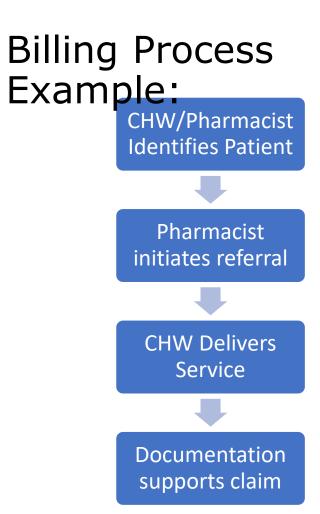


Funding and Reimbursement

Medicaid Reimbursement

- CHW services reimbursable under specific CPT codes
- Requires referral/order from qualified provider (including pharmacist)
- CHW must be certified and services documented

Grant and Programmatic
SUPPOMS working on CHW expansion, training, and integration through CDC-funded initiatives





Implementation Considerations

- Integrating CHWs into pharmacy teams
 - Workflow design (screen → refer → follow-up)
 - Communication and documentation protocols
- Training and continuing education opportunities
- Leveraging CHWs to meet quality metrics (BP control, adherence, A1c improvement)





Case Study & Discussion

- Example: Pharmacy CHW pilot improving hypertension control
- Open discussion:
 - How could CHWs fit into your workflow?
 - What barriers do you anticipate (space, billing, training)?







Questions?



Points of Contact



Certification

Tim Wiedrich

Health Response & Licensure

twiedric@nd.gov



Reimburseme nt Policy and Payment

Wendy Schmidt

Medical Services

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Programmatic Support, Outreach, Association

Tiffany Knauf

Healthy & Safe Communities

tknauf@nd.gov

701-328-2333

Round Table Discussion Points

Community Healthcare Workers

- 1. How do you see CHWs working within your current pharmacy workflow?
- 2. What impact do you think a CHW/technician could have on your patients and pharmacy?
- 3. Take a moment and imagine it's 2030. All the pharmacies you know of are fully staffed and have unlimited resources. What services, related to CHW work, is your pharmacy providing?

Thank You!

Please contact NDSU.CAPCenter@ndsu.edu
or Lisa.Nagel@ndsu.edu
If you have any questions!

