

The Outcomes of Implementing and Integrating Pharmacogenomics within Comprehensive Medication Management in Team-Based Care: A Review of the Evidence on Quality, Access and Costs, October 2020

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Annually, over \$528 billion is wasted, and 275,000 lives are lost due to non-optimized medication use. Misuse, overuse or underuse of medication therapy can lead to treatment failure, new medical problems or both. With over 80% of Americans taking at least one medication per week, and an increased percentage of hospital readmissions associated with a medication related problem, a strategy must be integrated that can ensure patients “get the medications right™.” Comprehensive medication management (CMM) is a patient-centered approach to optimizing medication use and improving patient health outcomes that is delivered by an interprofessional care team in collaboration with the patient.¹ To maximize the effectiveness of medication optimization, pharmacogenomics (PGx) should be integrated into a CMM program.

Pharmacogenomics is the study of how a patient's genetic profile determines their body's responses to

specific medications.² This care process, along with CMM, ensures each patient's medications are individually assessed to determine that each medication has an appropriate indication, is effective for the medical condition/patient goals, is safe given the comorbidities and other medications being taken and that the patient is able to take the medication as intended and adhere to the prescribed regimen.³ When integrated within a CMM program, PGx testing allows for precisely fitted and delivered medical care based on the unique characteristics of an individual patient's genetic profile plus their lifestyle and environment.

Value can be quantified by the overall effect of PGx testing integrated into CMM services. ***This document serves to summarize key findings from published literature supporting PGx integrated into CMM team-based care, producing decreased costs, increased provider education and patient satisfaction, access to care and outcomes.***

I. Summary of Data on Cost Outcomes from PGx within CMM

The effect of pharmacogenetic profiling with a clinical decision support tool on healthcare resource utilization and estimated costs in the elderly exposed to polypharmacy

- Patients older than 65 years were assigned to medication management as usual or pharmacogenetics-guided treatment utilizing a comprehensive medication management clinical decision support tool (CDST). This tool considers cumulative drug and gene interactions to predict the magnitude of drug level increases or decreases. Pharmacists utilized the information provided by this tool to make recommendations to prescribers. Four-month health care resource utilization (HRU) outcomes examined hospitalizations, emergency department (ED) visits, outpatient visits and provider acceptance of test recommendations.
 - **Reduced costs:** Patients in the PGx- and CDST-guided arm treated according to the personalized prescribing system had a significant decrease in hospitalizations and ED visits, resulting in potential cost savings estimated at \$218/patient.
 - **Better patient outcomes:** In the experimental, PGx-guided group, hospitalizations were 6.3% lower, ED visits 11% lower and outpatient visits 35.2% higher than the untested group. The rate of overall HRU was 72.2% in the tested group vs 49.0% in the untested group.
 - **Improved provider education:** Providers had a high satisfaction rate (95%) and considered the test helpful, and 46% followed CDST provided recommendations when appropriate.

Brixner D, Biltaji E, Bress A, et al. The effect of pharmacogenetic profiling with a clinical decision support tool on healthcare resource utilization and estimated costs in the elderly exposed to polypharmacy. J Med Econ. 2016;19(3):213-228. doi:10.3111/13696998.2015.1110160.

Combinatorial pharmacogenomic guidance for psychiatric medications reduces overall pharmacy costs in a 1-year prospective evaluation

- Researchers compared one year of pharmacy claims between a Pharmacogenomic (PGx) testing guided cohort and a treatment-as-usual (TAU) control group. Clinicians in the guided cohort reviewed the patient's history and, if applicable, ordered PGx testing while the treatment group retained normal medication management practices. Researchers analyzed total pharmacy spend per member, per year.
 - **Reduced costs:** Patients who received PGx testing saved \$1,035.60 in total medication costs over one year compared to the non-tested standard of care cohort ($p = 0.007$). Pharmacy cost savings averaged \$2,774.53 for patients whose medications were changed due to PGx testing, compared to those who were not ($p < 0.0001$).
 - **Better patient outcomes:** The number of patients in the PGx-guided arm that were on the most severe-risk medications decreased from 30.2% to 21.7%.

Winner JG, Carhart JM, Altar CA, et al. Combinatorial pharmacogenomic guidance for psychiatric medications reduces overall pharmacy costs in a 1-year prospective evaluation. Curr Med Res Opin. 2015;31(9):1633-1643. doi:10.1185/03007995.2015.1063483.

Cost-effectiveness of a pharmacogenetic test to guide treatment for major depressive disorder

■ Data from previous studies was used to model cost-effectiveness of PGx-guided medication management vs. standard of care (SOC) for major depressive disorder treatment. After undergoing PGx testing, providers followed-up with patients at four, eight and 12 weeks. Outcomes evaluated were total costs (direct and indirect), quality-adjusted life years (QALYs) and suicide rates.

- **Reduced costs:** The model predicted total cost savings of \$2,918 in direct and \$1,680 in indirect costs in PGx-guided treatment group when compared with SOC.
- **Better patient outcomes:** The model predicted lower probability of death from suicide (0.328% vs. 0.351%) and higher QALYs (2.07 vs. 1.97) for the PGx group when compared with patients receiving SOC. For a suicide death to be prevented, approximately 4,300 patients would need to be tested. (p-values not reported in this study)

Groessl EJ, Tally SR, Hillery N, Maciel A, Garces JA. Cost-Effectiveness of a Pharmacogenetic Test to Guide Treatment for Major Depressive Disorder. J Manag Care Spec Pharm. 2018;24(8):726-734. doi:10.18553/jmcp.2018.24.8.726.

Cost avoidance related to a pharmacist-led pharmacogenomics service for the program of all-inclusive care for the elderly

■ The team in this study consisted of prescribers, pharmacists, patients and residents. Prescribers referred patients to a clinical pharmacist for comprehensive medication management due to inadequate response to prescribed drugs. If necessary, pharmacogenomic tests were run and the pharmacists provided prescribers dosing recommendations based on these results.

- **Reduced costs:** Estimated cost avoidance when the study recommendation rate (70.5%) was utilized was \$162,031. Cost avoidance with a 100% acceptance rate was \$233,945. The mean cost avoidance per actionable drug-gene pair was \$1,983 per participant.

Bain KT, Knowlton CH, Matos A. Cost avoidance related to a pharmacist-led pharmacogenomics service for the Program of All-inclusive Care for the Elderly. Pharmacogenomics. 2020;21(10):651-661.

II. Summary of Data Improved Provider Education and Better Patient Satisfaction, Outcomes and Access to Care from PGx within CMM

Impact of pharmacogenomics on clinical outcomes for patients taking medications with gene-drug interactions in a randomized controlled trial

■ Patients diagnosed with major depressive disorder and at least one failed medication were randomized into either medication management treatment as usual (TAU) or medication management with a combinatorial pharmacogenomics approach. Patients had a minimum of three follow up visits during the 12 week study period. These patients had follow-up visits to evaluate the effectiveness of treatment. Symptom improvement (primary endpoint), response and remission were evaluated as clinical outcomes using the 17-item Hamilton Depression Rating Scale (HDRS).

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- **Better patient outcomes:** A significantly higher percentage of patients in the guided care arm switched to drugs with no drug-gene interactions by week eight, compared to the treatment-as-usual (TAU) arm. HDRS scores were significantly better (by 5%), response rate higher (by 8%) and remission rate lower (by 7.5%) at week eight of the study when the guided care arm was compared to TAU. These outcomes continued to improve significantly by the 24-week mark.

Thase ME, Parikh SV, Rothschild AJ, et al. Impact of Pharmacogenomics on Clinical Outcomes for Patients Taking Medications with Gene-Drug Interactions in a Randomized Controlled Trial. *J Clin Psychiatry*. 2019;80(6):19m12910. Published 2019 Oct 31. doi:10.4088/JCP.19m12910.

Assessment of the clinical utility of pharmacogenetic guidance in a comprehensive medication management service

- The evaluation of a collaborative pilot program aimed to demonstrate the benefit of incorporating pharmacogenetic information into CMM services. The pre- and post-interventional study evaluated 24 Hispanic patients who had a traditional CMM visit with a pharmacist prior to having pharmacogenetic testing. Genotyping was then performed to evaluate genetic variance in drug metabolizing enzymes. The pharmacist then incorporated the new pharmacogenetic information into the patient's management.
- **Better patient outcomes:** 129 medication-related problems were identified on the first visit, with a median of five conditions and three recommendations for medication regimen changes per patient. Genotyping revealed actionable variants in 96% of patients, with a median of three variants per patient. The care team was able to identify 22 additional medication-related problems and revised the medication action plans to incorporate the pharmacogenetic information.

Rodríguez-Escudero I, Cedeño JA, Rodríguez-Nazario I, et al. Assessment of the clinical utility of pharmacogenetic guidance in a comprehensive medication management service. *Journal of the American College of Clinical Pharmacy*. 2020;3:1028–1037. <https://doi.org/10.1002/jac5.1250>

Clinical impact of pharmacogenetic profiling with a clinical decision support tool in polypharmacy home health patients: A prospective pilot randomized controlled trial

- Patients were referred to the study at hospital discharge and were randomized to receive or not receive pharmacogenomic profiling. The control group only received medication management services while the experimental group additionally had a clinical pharmacist review the possible drug-drug gene interactions using a clinical decision support tool (CDST). The pharmacist then provided a medication recommendation to the physician.
- **Better patient outcomes:** The primary outcome measured was the number of re-hospitalizations and emergency department visits. Re-hospitalizations (RR=0.58, p=0.0007) and emergency department visits (RR=0.58, p=0.045) were lower in the tested group than the un-tested group. The tested group had an 85% reduction in the risk of death compared to the un-tested group (RR=0.15, p=0.054).

Elliott LS, Henderson JC, Neradilek MB, Moyer NA, Ashcraft KC, Thirumaran RK (2017) Clinical impact of pharmacogenetic profiling with a clinical decision support tool in polypharmacy home health patients: A prospective pilot randomized controlled trial. *PLoS ONE* 12(2): e0170905. doi:10.1371/journal.pone.0170905

Improved efficacy with targeted pharmacogenetic-guided treatment of patients with depression and anxiety: A randomized clinical trial demonstrating clinical utility

- Patients with depression and anxiety were randomized to one of two groups: a control group with medication management treatment as usual or an experimental group which incorporated PGx-guided medication management. Clinical psychiatric consultants developed a form used to analyze these patients and results were sent to the patient's prescriber. Patients had follow-ups with their providers at least three times during the study period.
 - **Better patient outcomes:** At eight weeks, remission rates for experimental vs. control groups were 25% vs 9%, and at 12 weeks rates were 35% vs. 13% ($p = 0.02$). A reduction in anxiety symptoms was also shown. The number of medication changes occurring in the experimental group was significantly higher than the control group.

Bradley P, Shiekh M, Mehra V, et al. Improved efficacy with targeted pharmacogenetic-guided treatment of patients with depression and anxiety: A randomized clinical trial demonstrating clinical utility. J Psychiatr Res. 2018;96:100-107. doi:10.1016/j.jpsychires.2017.09.024.

Incorporation of pharmacogenetic testing into medication therapy management

- Patients from a cardiology clinic attended medication therapy management sessions with clinical pharmacists and underwent pharmacogenomic testing. These results were then sent to the patients' cardiologists who made final prescribing decisions. The clinical team also created medication action plans which were distributed to the patients. Patients completed both pre- and post-intervention surveys.
 - **Improved patient satisfaction:** After intervention, about half of patients were able to accurately recall their PGx test results. Overall, patients were very satisfied with their PGX + medication management services, and 88% agreed they had a better understanding of their medication. All but one patient indicated they thought the medication action plan result card was useful.
 - **Better patient outcomes:** On average, 1.7 actionable variants were found per patient and every patient received at least one recommended change on the medication action plan.
 - **Improved access to care:** Before this study, patients had never had an interaction with a clinical pharmacist, and they did not have access to pharmacogenomic testing. After the study, patients were able to access the clinical team to discuss concerns about medications and descriptions of adverse responses.

Haga SB, Moaddeb J, Mills R, Patel M, Kraus W, Allen LaPointe NM. Incorporation of pharmacogenetic testing into medication therapy management. Pharmacogenomics. 2015 Nov;16(17):1931-41. doi: 10.2217/pgs.15.124. Epub 2015 Nov 10. PMID: 26555559.

Challenges and lessons learned from clinical pharmacogenetic implementation of multiple gene–drug pairs across ambulatory care settings

- Routine pharmacogenetic testing has been slow to translate to the clinic due to challenges such as the prescriber knowledge gap. This study identified challenges encountered in implementing pharmacogenomics to optimize medication use, including: lack of prescriber/patient knowledge, integrating PGx information into electronic health records, cost of testing and inadequate/variable reimbursement.

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Researchers solicited feedback from an inter-professional team with the clinical pharmacist as the medication expert that participated in three pragmatic clinical trials at UF Health. They identified challenges, successes and potential solutions.

- **Improved provider education:** Formal grand rounds presentations reached the largest number of prescribers. About 27% of prescribers underwent personal genotyping, and 100% of these individuals reported this was beneficial in the educational process. Prescribers also expressed that patient-centered, case-based educational programs were essential and effective in facilitating prescriber education and adoption of drug therapy recommendations.

Cicali EJ, Weitzel KW, Eley AR et al. Challenges and lessons learned from clinical pharmacogenetic implementation of multiple gene–drug pairs across ambulatory care settings. Genet Med. 2019;21(10):2264–2274. doi:10.1038/s41436-019-0500-7.

Impact of pharmacogenomics on clinical outcomes in major depressive disorder in the GUIDED trial: A large, patient- and rater-blinded, randomized, controlled study

■ A total of 1,398 patients diagnosed with major depressive disorder, with at least one failed medication trial, were included in a per-protocol analysis comparing two treatment selection methods: medication management treatment as usual and PGx-guided medication management. The clinical care team consisted of psychiatrists, primary care providers and pharmacogenomic experts. Symptom improvement, response and remission were evaluated as clinical outcomes using the 17-item Hamilton Depression Rating Scale (HAM-D17).

- **Better patient outcomes:** At week eight, patients in the PGx-guided-care arm had a statistically significant improvement in response (26.0% vs. 19.9%, $p = 0.013$) and remission (15.3% vs 10.1%, $p = 0.007$) compared to the treatment as usual arm.

Greden JF, Parikh SV, Rothschild AJ, et al. Impact of pharmacogenomics on clinical outcomes in major depressive disorder in the GUIDED trial: A large, patient- and rater-blinded, randomized, controlled study. J Psychiatr Res. 2019;111:59-67. doi:10.1016/j.jpsychires.2019.01.003.

Design and early implementation successes and challenges of a pharmacogenetics consult clinic

■ Primary care physicians (PCPs) were trained by a pharmacist to refer patients experiencing side effects/ineffectiveness from certain medications to an outpatient PGx consult clinic in internal medicine. At the clinic, the pharmacist verified the need for and ordered CYP2C19 and/or CYP2D6 testing, provided evidence-based PGx recommendations to PCPs and educated PCPs and patients on the results.

- **Improved provider education:** About 77% of the patients referred to the pharmacist had a phenotype that required a medication adjustment. This high referral percentage indicates that prescriber education was effective in educating PCPs of patients in need of medication optimization.

Arwood MJ, Dietrich EA, Duong BQ, et al. Design and Early Implementation Successes and Challenges of a Pharmacogenetics Consult Clinic. J Clin Med. 2020;9(7).

Effects of delivering SLCO1B1 pharmacogenetic information in randomized trial and observational settings

■ A total of 159 patients not taking a statin due to statin-related myalgia were randomized to receive SLCO1B1 Genotype Informed Statin Therapy (GIST) or receive usual care (UC). Pharmacogenomic experts made recommendations to the physicians who were encouraged to enter a shared decision making process with their patients. Patients received regular follow up for eight months and assessed for statin re-initiation, adherence and LDL lowering.

- **Better patient outcomes:** Patients in the GIST-arm were re-initiated on a statin more than the UC group (55.4% versus 38.0%, $p=0.04$) and had greater LDL decrease at three months (131.9 ± 42.0 versus 144.4 ± 43.0 mg/dL; $p=0.048$).

Peyser B, Perry EP, Singh K, et al. Effects of Delivering SLCO1B1 Pharmacogenetic Information in Randomized Trial and Observational Settings. Circ Genom Precis Med. 2018;11(9):e002228. doi:10.1161/CIRCGEN.118.002228.

Implementation of a pharmacogenomics service in a community pharmacy

■ A collaborative practice agreement was developed between a supervising physician and a clinical pharmacist practitioner. Appropriate patients underwent pharmacogenomic testing, and when results were obtained, the pharmacist formulated recommendations for the prescriber.

- **Improved provider education:** Almost 90% of clinical pharmacist recommendations were accepted by the prescriber after incorporation of the collaborative practice agreement. This number is much higher than expected, as typical studies have documented acceptances between 42% and 60%.
- **Better patient outcomes:** Half of patients had an allele with a recommended therapy change or increased monitoring. Collaboration between the pharmacist and prescriber allowed them to comprehensively review patient records and make the best prescribing decisions.

Ferreri SP, Greco AJ, Michaels NM, O'Connor SK, Chater RW, Viera AJ, Faruki H, McLeod HL, Roederer MW. Implementation of a pharmacogenomics service in a community pharmacy. J Am Pharm Assoc (2003). 2014 Mar-Apr;54(2):172-80. doi: 10.1331/JAPhA.2014.13033. PMID: 24632932.

CYP2D6-guided opioid therapy improves pain control in CYP2D6 intermediate and poor metabolizers: a pragmatic clinical trial

■ Patients with chronic pain (94% already on opioid) were enrolled using a cluster design into either a PGx-guided medication management arm or usual care arms. Clinical pharmacists assigned phenotypes based on genotype and CYP2D6 inhibitor use. These recommendations were then provided to physicians via EHR clinical consult note who made the final prescribing decisions. The primary outcome of interest was the change in composite pain intensity (the mean of the pain intensity current, worst and average on a 0-10 scale.)

- **Better patient outcomes:** Patients in the PGx-guided arm had better composite pain improvement compared to the usual-care arm (-1.01 vs -0.40 , $P=0.016$). Twenty-four percent of the patients in the

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guided arm reported more than a 30% reduction in the composite outcome compared 0% to the usual care arm. Twenty-four percent of the patients in the guided arm reported more than a 30% reduction in the composite outcome compared 0% to the usual care arm.

Smith DM, Weitzel KW, Elsey AR, et al. CYP2D6-guided opioid therapy improves pain control in CYP2D6 intermediate and poor metabolizers: a pragmatic clinical trial. *Genet Med.* 2019;21(8):1842-1850.

Implementation of a Standardized Medication Therapy Management Plus Approach within Primary Care

■ The multi-disciplinary team at this practice consisted of physicians, a nurse practitioner, physician assistants, a nurse manager, medical assistants, students of various disciplines and a pharmacist available to assist. A pharmacogenomic test was performed and a clinical pharmacist used this information, along with a clinical decision support system, to perform medication therapy management visits. The results of this were provided to the prescriber.

- **Better patient outcomes:** The pharmacist was able to identify almost three medication related problems per patient with 66% of patients having at least five actionable genetic variants. These potential therapy problems were then able to be addressed by the physician.
- **Better provider education:** The incorporation of the clinical decision support tool (CDST) allowed the pharmacist to make recommendations where 90.9% were accepted by the prescriber. This exceptionally high acceptance rate indicates that the tool was effective in allowing the pharmacist to effectively learn to make recommendations.

Schwartz EJ, Turgeon J, Patel J, Patel P, Shah H, Issa AM, Knowlton OV, Knowlton CH, Bain KT. Implementation of a Standardized Medication Therapy Management Plus Approach within Primary Care. *J Am Board Fam Med.* 2017 Nov-Dec;30(6): 701-714. doi: 10.3122/jabfm.2017.06.170145. PMID: 29180545.

Pain management using clinical pharmacy assessments with and without pharmacogenomics in an oncology palliative medicine clinic

■ Palliative medicine prescribers reviewed patient medication history and, if appropriate, referred the patients for pharmacogenomic testing as well as a visit with a clinical pharmacist. The results from this study were compared to a historical cohort.

- **Better patient outcomes:**
 - Of patients who underwent prescriber-ordered assessments by clinical pharmacists, 53% had pain improvement compared with 30% in historical control subjects (P<0.001).
 - Of patients with actionable genotypes, 73% experienced pain improvement.

Patel JN, Boselli D, Hamadeh IS, et al. Pain Management Using Clinical Pharmacy Assessments With and Without Pharmacogenomics in an Oncology Palliative Medicine Clinic. *JCO Oncol Pract.* 2020;16(2):e166-e174.

The effect of pharmacogenetic profiling with a clinical decision support tool on healthcare resource utilization and estimated costs in the elderly exposed to polypharmacy

■ Polypharmacy patients were assigned to one of three groups: normal medication therapy management, medication therapy management with a clinical decision support tool (CDST) software and medication therapy management with a CDST and pharmacogenomic (PGx) testing. On average, each patient had three drug therapy problems at the beginning of the study. Pharmacist utilized the CDST and PGx tests to make recommendations to prescribers in the intervention arms.

- **Better patient outcomes:** The percentage of drug therapy problems identified in the patients in the PGx + CDST arm categorized as serious was greater than in the other two arms (31% vs 4.6%).
- **Improved provider education:** Serious drug therapy problems were significantly more likely to be accepted by prescribers than less-serious problems (OR=1.96, p=0.05). The combinations of PGx, CDST and medication management allowed the pharmacist to make recommendations more likely to be accepted by the prescriber.

Brixner D, Biltaji E, Bress A, Unni S, Ye X, Mamiya T, Ashcraft K, Biskupiak J. The effect of pharmacogenetic profiling with a clinical decision support tool on healthcare resource utilization and estimated costs in the elderly exposed to polypharmacy. J Med Econ. 2016;19(3):213-28. doi: 10.3111/13696998.2015.1110160. Epub 2015 Nov 11. PMID: 26478982.

Feasibility of Integrating Panel-Based Pharmacogenomics Testing for Chemotherapy and Supportive Care in Patients With Colorectal Cancer

■ The multidisciplinary patient care team at this clinic consisted of a gastrointestinal oncologist, pharmacists, disease specialists and allied health staff. Patients underwent pharmacogenomic testing and clinical pharmacists used this information to create risk categories of red, yellow and green (major, moderate and minimal gene-drug interaction risk respectively). This assignment was provided to the care team who used this to make prescribing decisions for the patients.

- **Better patient outcomes:** The average patient had 40% of their potential medications flag as yellow or red and 94% of patients had at least one yellow or red medication in five or more therapeutic areas. Physicians were able to use these results to avoid prescribing medications that could have caused serious medication related problems.

Kasi PM, Koep T, Schnettler E, et al. Feasibility of Integrating Panel-Based Pharmacogenomics Testing for Chemotherapy and Supportive Care in Patients With Colorectal Cancer. Technol Cancer Res Treat. 2019;18:1533033819873924. doi:10.1177/1533033819873924.

Endnotes

- 1 McClurg, M., Sorensen, T., Carroll, J. The Patient Care Process for Delivering Comprehensive Medication Management (CMM): Optimizing Medication Use in Patient-Centered, Team-Based Care Settings. CMM in Primary Care Research Team. July 2018.
- 2 Table of Pharmacogenomic Biomarkers in Drug Labeling. U.S. Food and Drug Administration. Accessed Sept. 6, 2020. <https://www.fda.gov/drugs/science-and-research-drugs/table-pharmacogenomic-biomarkers-drug-labeling>
- 3 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, The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes.* www.pcpc.org/sites/default/files/media/medmanagement.pdf.