Original Research

The Clinical Benefits of Utilizing Pharmacogenomics In Long Term Care Facilities as Part of a Patient Center Care Plan of Action – An Implementation Analysis

Stephen Patton, M.D., Taylor Pierce, CNA

ABSTRACT

The utilization of Pharmacogenomic (PGX) Testing has long been debated as a tool to help provide personalized medicine in various care settings. Many studies have shown cost savings and improved patient outcomes when PGX testing results have been implemented in a clinical setting. However, we analyzed the clinical data for **295** patients in Long Term Care (LTC) settings from a Psychiatrist and Pharmacy Consultants' standpoint.

Our analysis shows that traditional prescribing methods of "trial and error" can never allow for the most precise, person centered care plans of action for collaborative care teams, physician, pharmacist and the nursing staff, in the LTC facility.

PGX can guide the physicians and pharmacists to a more accurate prescribing dosage and regimen that can aide the facility in decreasing the number of unnecessary medications, falls, polypharmacy related adverse drug events, and overall optimization of a patient centered care plan of action.

PGX testing is a tool that should be used in review of LTC residents' current medications and reviewed prior to adding any additional medications considered for future treatments.

BACKGROUND

Many studies have been written on the value of clinical utilization of pharmacogenomic (PGX) testing; however, very few have focused on the Long Term Care (LTC) setting. Furthermore, even fewer have provided insight or finding related to a Psychiatric Consulting Physician and a Doctor of Pharmacy in a LTC facility.

LTC facilities care for a population of patients that are older and frailer than the general population. The patients typically are prescribed multiple medications, have multiple co-morbidities and have limited mobility. These issues often manifest themselves in over-utilization of medication to treat a single disease state, more often in the treatment of behavioral medications.

Medicare, (CMS) through State Surveys have been trying to combat these issues with Psychiatric Medication Reduction [1] guidelines of 15%, then to 20% and currently up to 30% for each LTC facility. Oklahoma was one of the initially successful State; however, the reduction numbers are often seen as immeasurable given the patient population frequently changes in a LTC setting.

INTRODUCTION TO PHARMACOGENOMIC (PGX) TESTING

Pharmacogenomic testing is the study of a patient's unique genetic profile to determine the rate of metabolism for various medications. Most of the testing is historically devoted to cytochrome P450 (CYP) enzymes, which are involved in the metabolism of approximately 70%–90% of all prescribed drugs in the United States.

A patient's unique metabolization enzyme profile is reported in four classifications:
EM – Extensive (Normal) Metabolizer, PM – Poor Metabolizer, IM – Intermediate metabolizer, and UM – Ultra Rapid Metabolizer.
The association between one's gene variants and drug response rates or risks of adverse side effects to specific medications have been reported in many studies; in response, the US Food and Drug Administration (FDA) has updated the labels of nearly 120 drugs with recommendations for genetic testing prior to their use [2].
Pharmacogenetics is the implementation of personalized medicine, utilizing a process where patients are assessed and treated based on their genetic profile, allowing for more precise predictable outcomes of expected drug response and the risk of adverse side effects. Traditional medicine typically relies on the broad application of "standard of care" , "trial and error" and "one size fits all" treatments to LTC patients who are often given medications for their diagnosis, irrespective of their genetic context. Examples of this are the highly prescribed drugs: Duloxetine, Hydrocodone and Clopidogrel.
Utilizing a new approach may reduce the rate of adverse drug reactions (ADR), which may then prevent disease recurrence or the onset of secondary complications, leading to better clinical and economic outcomes [3].

MATERIALS AND METHODS

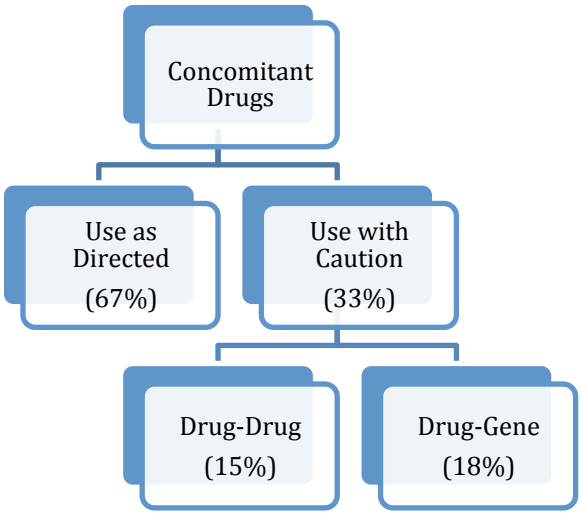
A comprehensive review of test results, physician and consulting pharmacist notes for several long-term care facilities allowed for a compiled database of information. Male and female patients taking one or more behavior medications, Polypharmacy (defined as taking five or more prescription medications per month), conditions assessed by a Psychiatrist were considered for participation.
Patient consent was obtained; sample was obtained with a buccal swab and tested at a selected pharmacogenomics laboratory. Test results were provided to the physician, consulting pharmacist and the LTC facility.
Goal was to review and consider various genetic factors compared to metabolization of medications, trends in common gene mutations, dosage recommendations or medications that were identified as dangerous or not able to provide any therapeutic value.
This study was retrospective and not meant to measure the difference in patient outcomes, hospital and emergency room usage, and patient satisfaction over a set period of time.
The buccal swab allowed the laboratory to provide pharmacogenomic targeted results for 17 genes, including CYP1A2, CYP2C9, CYP2C19, CYP2D6, CYP3A4/ CYP3A5, HTR2A, HTR2C, SLC6A4, SLC6A2, COMT, OPRM1, SLCO1B1, VKORC1, MTHFR, F2, and F5.
Test results generated three categories of intervention recommendations:
1) a *replacement* of one medication to another medication deemed better suited to the patient's genetic profile in which all available evidence indicated little or no effect from the genetic mutations identified; 2) *discontinuation* of a medication that was determined to be ineffective; and 3) *consolidation* of two medications into a single prescription. All three recommendation categories focused on maximizing the safety and efficacy profiles of each individual patient's drug regimen evaluated with an emphasis on better medication management and personalized care.

RESULTS

In our review of the pharmacogenomic data from our patient population, the test results showed that 33% had some form of "caution" or "alert" related to the patients' current distribution of concomitant drugs. These cautions were broken down into two categories, "Drug-Drug" and "Drug-Gene". *See Table 1*. The Drug-Drug category cautions were standard drug-drug, interactions, 15%, which we reviewed and also provided to the Pharmacy consultants and the facilities Director of Nursing for their review and assessments. The medications that were categorized as "Drug-Gene" cautions, 18%, were the true pharmacogenomic mutations. For our study group, the number of mutations per patient was also analyzed.

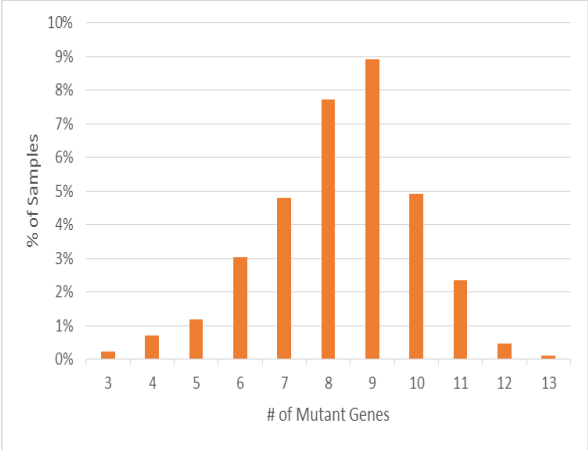
The findings, *See Table 2*, show that the number of mutations, for the "Drug –Gene" category, were calculated in the seven to ten range (7 – 10 mutations per patients).

Table 1 - Distribution of Concomitant Drugs



This piece of data further validates the value of having a full pharmacogenomic report with findings and recommendations. This patient group of 18%, had multiple mutations that would cross over to many different medications that would need to be considered avoiding or using with caution.

Table 2 - Distribution of Mutant Genes



DICSCUSSION

PGX testing is only performed once, and the unique genomic information can be utilized for guiding drug treatments for the patient's lifetime. Furthermore, once the patient's genotype is known, physicians and consulting pharmacists in a LTC setting can proactively select those drugs that match the patient's metabolic type.

Peter H. O'Donnell, MD, associate director for clinical implementation at the University of Chicago's Center for Personalized Therapeutics, was recently quoted saying, "It is my view that someday—probably not far in the future—we will look back on the idea of treating all patients who have the same 'disease' with the same drug as a simply archaic practice," [4]

The finding and evidences of this study further verify to the authors that the change can't come soon enough. Psychiatrists, Medical Directors, Pharmacist and Directors of Nursing working in LTC facilities that are utilizing PGX testing are in fact leading the way on genomic medicine in geriatrics.

One LTC specific study showed an average of $621 per patient in annual saving with Psychotropic drug changes accounting for the largest savings by drug class (61.3% of total savings).[5]

Those providers who remain uneducated on PGX testing or are close minded to the value of incorporating PGX results into their practices might find themselves behind the curve in the next 2 to 3 years as outcomes and clinical efficiencies will show it to be the new standard. There is a tremendous opportunity for clinicians to embrace a technology, which is no longer considered "new", which can help answer questions, impact patient care and have no downside. Knowledge is powerful, and pharmacogenomics knowledge for each patient can be beneficial.

FIVE KEY TAKE-A-WAYS

Utilizing PGX testing has shown positive impacts in our practice in the following ways.

1. PGX testing can improve patient outcomes by reducing trail and error and better managing severe side effects
2. PGX testing has the potential to directly reduce costs of drug treatments and overall clinical efficiencies in an LTC setting
3. PGX testing can have an immediate and long-term impact on patient outcomes and could substantially reduce both direct and indirect healthcare costs while improving quality of life
4. PGx implementation requires an implementation of science based Patient Centered Care Plans of Action related to each patient's drug regimen
5. Appropriate PGX testing with ethical laboratories that provide larger panels that report on large number of medications will provide added value and can be more cost-effective than current standard of care

CONCLUSIONS

Our retrospective data analysis and the clinical interactions notes highlighted that the elderly living in LTC facilities use high quantities of medications that are not being assessed with modern tools, thereby increasing the risk of adverse drug reactions and potentially dangerous outcomes for the patient and the LTC staff.

PGX testing further enhanced the clinical recommendations of the consulting pharmacist, that have never before had such test results available, to greater levels of efficiency and accuracy. Furthermore, the advantages of having a psychiatric consult physician interacting with the patients, staff and pharmacist lead to more precise assessments, medication regimen reviews and better outcomes for each patient in a more efficient timeline.

PGx testing is a tool that LTC facilities should consider implementing into their interdisciplinary team (IDT) processes to have a unique Patient Centered Care Plan of Action for each resident.

REFERENCES

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Correspondence:
Taylor Pierce
PH: (918)772-0095
FAX: (918)259-8708
PsyDoc,LLC
110 S Main Street, Suite 100
Broken Arrow, OK 74012

Disclosure:
PsyDoc, LLC, a private Oklahoma company owned by Dr. Patton, employees Ms. Pierce as CNA and COO.