Implementation of the GeneSight Pharmacogenetic Testing Guideline for Depression

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February 22nd, 2024

Abstract

The psychiatric nurse practitioners at the outpatient psychiatric clinic relied on trial and error to identify appropriate medication for patients with mental health disorders. Pharmacogenetic testing is effective in identifying appropriate medications that have low adverse effects and high efficacy for specific patients based on genetic factors. In this quality improvement project, the GeneSight pharmacogenetic testing guidelines were implemented to guide health care providers in identifying appropriate antidepressants for patients with depression at an outpatient psychiatric clinic. Eight nurse practitioners participated in comprehensive training on Gene Sight guidelines. The intervention involved providing the participants with comprehensive training on GeneSight guidelines using didactics and case studies. Independent samples *t*-test, Pearson Chi-square test of homogeneity, and Wilcoxon sign ranked test were conducted to evaluate the outcomes. The results of the post-intervention assessment indicated a statistically significant increase in participants' familiarity ($z = -2.598$, $p = .009$), knowledge ($z = -2.555$, $p = .011$), and confidence ($z = -2.414$, $p = .016$) after the implementation of the intervention. There was a statistically significant improvement in response to treatment ($t = -2.177$, $p > .05$) and a clinically significant decrease in the rate of reported side effects associated with antidepressants ($X^2 = 2.128$, $p > .05$) from 58.8% before to 36% after the implementation of GeneSight guidelines. The use of GeneSight guidelines were effective in improving treatment response, decreasing side effects, and enhancing patient satisfaction.

***Keywords*:** Pharmacogenetics, depression, antidepressants, educational intervention, GeneSight guidelines, knowledge, treatment response, side effects

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Mental disorders impact individuals' behavior, emotions, and thoughts, creating challenges in coping with life events (National Institute of Mental Health, 2020). Depression is a prevalent form of mental illness characterized by enduring feelings of sadness or a persistent loss of interest. This results in observable physical and behavioral symptoms, including changes in concentration, energy levels, appetite, and sleep patterns. Depression hinders individuals from effectively dealing with life events due to compromised thinking and a tendency toward inaction (Abbott et al., 2018). In the elderly population, depression often goes untreated and unrecognized, leading to heightened healthcare demands, diminished quality of life, and increased mortality (Devita et al., 2022; Kvalbein-Olsen et al., 2023). The problem of depression is exacerbated by behavioral changes such as suicidal ideation, which may escalate to attempts (Abbott et al., 2018). Additionally, clinicians face challenges in late-life depression treatment due to a lack of comprehensive knowledge, relying on a trial-and-error approach for determining the best medication and therapeutic interventions (Abbott et al., 2018). Consequently, there is a pressing need to enhance the treatment approach for depression, and this project explores the potential implementation of GeneSight pharmacogenetic testing guidelines to advance the diagnosis and treatment of depression.

Background of the Problem

The existing depression treatment guidelines use few clinically relevant data elements. As an example, the current recommended first-line monotherapy is the use of selective serotonin reuptake inhibitors (SSRIs) (Zeier et al., 2018). This first-line monotherapy has intolerable side effects, such as patient attrition and lack of requisite response (Srifuengfung et al., 2023). Other intolerable side effects include prolonged depression symptoms such as loss of interest, general

discontent, and hopelessness (Ekkekakis, 2020). Evidence-based recommendations have been suggested to improve depression treatment, such as switching to a different antidepressant, current SSRI dosage optimization, and use of a different pharmacological class medication to augment the initial medication (Zeier et al., 2018). However, these strategies are difficult to implement as there are no data available to clinicians to understand intolerable side effects such as prolonged lack of concentration, social isolation, mood swings, or likely benefits of evidence-based recommendations (Zeier et al., 2018). Thus, clinicians have to rely on the process of elimination and educated guessing rather than being guided by personalized prognostic data.

Depression is a common mental health disorder in the contemporary world. According to Corponi et al. (2019), depression affects 350 million people worldwide. It is among the leading causes of disability and a common cause of high economic and societal burden (Aboelbaha et al., 2021). There is a variety of pharmacological treatment options for depression in the contemporary market. Illustratively, there are over 40 compounds of antidepressant medications available for the treatment of moderate to severe depression (Corponi et al., 2019). However, there has been observed inter-individual variability in response to antidepressant medications. This inter-individual variability is due to single nucleotide polymorphisms (SNPs), which lead to DNA sequence changes and, thus, different responses to antidepressants. Nurses and other clinicians have to rely on a heuristic or "trial-and-error" approach as the current paradigm for depression diagnosis (Corponi et al., 2019). This heuristic approach to depression diagnosis and treatment has led to consequences such as overdose, underdose, or wrong dosage. The delayed recovery rate is linked to time wastage during antidepressant selection, which is based on individual clinical factors and safety profiles (Aboelbaha et al., 2021). This warrants the

exploration of well-rounded and more meaningful approach that accounts for genetic variations across patients taking antidepressants.

Studies have also revealed that 20%-30% of cases involving current antidepressants fail to show clinical improvement after the medication is recommended, this is an indication of depression treatment resistance (Aboelbaha et al., 2021). It is established that only 33% of patients with depression can achieve clinical remission within three years when using multiple treatments (Aboelbaha et al., 2021). Hence, current depression medication raises concerns about poor health outcomes among individuals with depression, leading to social functioning and productivity declines. In this regard, it is imperative to develop an effective treatment guideline for depression to improve patient health outcomes. The ramifications of this have been prolonged suffering, patient attrition, and other adverse effects (Zeier et al., 2018).

Conventional drug development is also a lengthy and expensive process, taking an average of 13-15 years with a development cost of about $2-3 billion (Corponi et al., 2019). Additionally, there is only a 10% chance that the developed drug can be approved by the government (Corponi et al., 2019). For this reason, it is paramount to embrace pharmacogenetics to achieve cost-effectiveness in drug development as well as drug efficacy in treating depression. The desire to improve the diagnosis and treatment of depression is a daunting task.

Researchers have utilized treatment response biomarkers to enable them to understand how they can establish and implement pharmacogenetic testing guidelines for depression to help in the effective treatment of this disorder (Corponi et al., 2019). In particular, the use of the multimarker approach uses genome-wide data to achieve drug repositioning to combat depression and associated complications (Corponi et al., 2019). It is established that antidepressant response clusters in families, which abets using pharmacogenetics to match a

patient's genetic profile with a medication pharmacological profile for optimized treatment (Corponi et al., 2019). Therefore, pharmacogenetics should be used for the achievement of precision medication selection for depression. Thus, it is pivotal to conduct pharmacogenetic tests to predict the side effects and response of antidepressants for improved treatment outcomes for depression.

Zeier et al. (2018) assert that pharmacogenetics has the potential to revolutionize depression treatment. It is a prelude to the selection of the most effective treatment option for depression by providing a customized and rational approach (Zeier et al., 2018). For instance, through genome-wide association studies (GWAS), it is established that genetic variants are associated with depression (Zeier et al., 2018). Pharmacogenetic decision support tools use algorithms for gene variation identification that is most relevant to patients and then match them with the most effective and safest pharmacotherapy (Zeier et al., 2018). Other than pharmacokinetic-relevant genes, pharmacogenetic tests also incorporate pharmacodynamics-relevant genes such as dopamine transporters and receptors and encoding serotonin (Zeier et al., 2018). The inclusion of pharmacodynamics-relevant genes enables the stratification of drugs or genes into color-coded categories. Nevertheless, for detailed matching of effective treatment regimens and genetic testing implementation for depression, consultations are required among nurses, pharmacists, and genetic counselors.

Pharmacotherapy, especially SSRIs antidepressants, is most frequently used for treating acute depression, while also there are other promising pharmacological options that health care practitioners can prescribe for the condition (Karrouri et al., 2021). Although antidepressant medication has shown to be effective, side effects are common and may result in discontinuation of treatment (Campos et al., 2021). The ultimate goal of depression treatment is to ensure the use

of the most effective medication with few side effects (Karrouri et al., 2021). Among the common risk factors contributing to the side effects of different antidepressants is the genetic factors of the patient (Campos et al., 2021). Therefore, it is essential to prescribe antidepressants with minimal gene interactions to minimize the associated side effects. Pharmacogenomic testing is a promising treatment procedure for identifying the best drug for a patient based on clinical symptoms (Tiwari et al., 2022; Oslin et al., 2021).

Identification of the Problem

Mental health issues are common in the contemporary world. In the outpatient psychiatric clinic in Frisco, Texas, depression is prevalent among patients visiting this facility. Presently, the psychiatric nurse practitioners at the outpatient psychiatric clinic in Frisco, Texas, rely on a "trial and error" for prescribing medication for depression, an approach that inhibits the identification most effective medication for the patient (Abbott et al., 2018; Corponi et al., 2019). As a result, patients reported increased side effects, poor treatment response, and prolonged remission. Therefore, there was a need for implementing an evidence-based intervention to help health care providers identify and prescribe antidepressants that are most effective and appropriate to the patient based on their genetic profile. Specifically, GeneSight pharmacogenetic testing was introduced at the facility as an evidence-based intervention to enhance the identification of appropriate antidepressants for patients with depression.

Project Question

The prevalent depressive symptoms, the socioeconomic burden associated with it, the existence of treatment resistance, and the side effects from the current antidepressant medications necessitate the implementation of the best pharmacogenetic testing guidelines. Therefore, it was essential to educate the providers on the GeneSight pharmacogenetic testing

guideline for a targeted or individualized treatment regimen that is effective for patients with depression. Consequently, the population, intervention, comparison, outcome, and timeline (PICOT) question was formulated to guide the implementation of this quality improvement project. The PICOT question is: In adults diagnosed with depression, does the integration of GeneSight pharmacogenetic testing guidelines into psychiatric treatment decision-making, compared to standard psychiatric treatment, improve treatment response, fewer side effects, and a higher level of patient satisfaction over 5 weeks?

P=Population: Outpatient psychiatric clinic nurse practitioner

I=Intervention: Implementation of an evidenced-based GeneSight testing guideline for depression treatment.

C=Comparison: Standard Psychiatric treatment.

O=Outcome: Treatment response, side effects, and patient satisfaction.

T=Timeframe: Five-week timeframe.

Literature Review

Search Methods

A comprehensive literature search was conducted across four health databases: CINAHL, Medline, PubMed, and Cochrane Library. Search terms derived from the PICOT question were used for the search process. These terms included psychiatric, nurses, pharmacogenetic, testing, GeneSight, pharmacogenomics, heuristic approach, improved treatment, outcomes, and depression. The search terms were typed on the search bars of each database, and Boolean operators "AND" and "OR" were used with search terms to filter the search process results to be as close to the clinical question as possible. Criteria for searching articles included peer reviewed, abstracts, articles published between the years 2017 and 2023, written in English, complete text, and GeneSight pharmacogenetic guideline were included. The search process yielded 54 research articles across the four databases. A total of 16 articles were kept and 38 articles were excluded due to non-relevance to the clinical question.

Review Synthesis

A review of the literature identified numerous research studies focusing on establishing the effectiveness of pharmacogenomics (PGx)-based testing for improving the clinical management of depression and patient outcomes. Most of the studies compared treatment outcomes between PGx-guided antidepressant treatment/prescription and trial and error approach. The outcomes relate to the efficacy and safety outcomes of PGx-guided and unguided antidepressant prescription/treatment. The significant themes derived from the review were treatment response, symptom remission, and tolerability of treatment.

In their editorial, Westrhenen and Ingelman-Sundberg (2021) highlight a noteworthy positive correlation between "trial and error" psychopharmacological treatment and a low response to drugs, particularly in depressive patients. The prolonged positive outcomes observed with psychopharmacological drugs indicate the need for a more efficient treatment approach. The authors express concern about serious side effects associated with "trial and error" treatments, including headaches and dizziness, leading many patients to discontinue medication. (Westrhenen and Ingelman-Sundberg, 2021). In contrast, the editorial suggests that pharmacogenetics offers a more positive approach with faster positive outcomes and is not associated with significant side effects.

A systematic review by Paykel (2022) showed that "trial and error" pharmacological treatments are associated with a high rate of partial remission, residual symptoms, and relapse into depression. Owing to factors such as the inefficacy of treatment, Major Depressive Disorder (MDD) patients have a high symptom remission rate. Patients would have to undergo multiple treatments for the medication to work. As such, this necessitates the implementation of pharmacokinetic treatment intervention for better patient outcomes. The review showed that pharmacogenetics was a more positive approach.

Treatment Response

The first theme derived from the literature entails the comparison of treatment response outcomes between PGx-guided Major Depressive Disorder (MDD) treatment and "trial and error" prescription. Various studies have shown that the treatment of depression through the "trial and error" approach is problematic due to poor outcomes in terms of treatment response. A randomized controlled trial (RCT) conducted by Rethorst et al. (2017) reported that the "trial and

error" approach leads to heterogeneous treatment response and prolongation of disease treatment, leading to a significant disease burden. As revealed by the study, only about one-third of MDD patients will achieve remission following the first treatment (Rethorst et al. 2017). Of the 122 participants in the study, only 29.5% were categorized as remitters based on the treatment response (Rethorst et al. 2017). Thus, Rethorst et al. (2017) demonstrated poor patient outcomes typical of the "trial and error" treatment approach.

A RCT by Han et al. (2018) in the Asian population also reported that "trial and error" MDD treatment results in inadequate treatment response even after prescribing adequate doses and duration of SSRI treatment. In the study, the researchers investigated the suitability and efficacy of pharmacogenomic–based antidepressant treatment of MDD. With a remission rate of 71.7%, the findings showed that PGx treatment was more effective and yielded better patient outcomes in treating MDD compared to "trial and error" interventions (Han et al., 2018).
A systematic review by Johnston et al. (2019) also confirmed this result by showing that in "trial and error" approach, about 30% of patients do not demonstrate clinical improvement after using two antidepressant medications at adequate dosage and duration of treatment. The researchers reviewed 35 epidemiological and economic articles on the burden associated with subsequent treatment steps owing to non-response in MDD patients. Nineteen of the studies showed a significant correlation between poor patient outcomes and multiple treatment steps owing to non-response (Johnston et al., 2019). Also, the problem poses a financial burden on patients as 12 of the studies showed a positive correlation between non-response and increasing costs (Johnston et al., 2019).

A meta-analysis performed by Vilches et al. (2019) also showed that the "trial and error" process of depression treatment has low response rates among patients. The meta-analysis

focused on three clinical studies done on the efficacy of commercial pharmacogenetic-based tools in the treatment of depressive patients. The three studies had a total of 450 eligible participants. The findings of Vilches et al. (2019) indicated that non-pharmacogenetic treatment resulted in inconsistent and poor outcomes, whereas the commercial pharmacogenetic-based tool demonstrated a higher remission rate.

In summary, the meta-analysis conducted by Vilches et al. (2019) revealed that the "trial and error" process of depression treatment, with a focus on three clinical studies evaluating the efficacy of a commercial pharmacogenetic-based tool, showed low response rates among patients. Specifically, the non-pharmacogenetic treatment led to inconsistent and poor outcomes, while the commercial pharmacogenetic-based tool demonstrated a higher remission rate. Transitioning to the discussion of symptom remission, further exploration into this aspect sheds light on the potential advancements and improved outcomes in depressive patient care.

Symptom Remission

The second theme derived from the literature entailed the comparison of symptom remission rates between PGx-guided MDD treatments compared to unguided prescription as measured by the Hamilton Depression Rating Scales HAM-D17 or HDRS-17 (Han et al., 2018). The RCT by Han et al. (2018) reported that the remission rates of antidepressant treatment based on trial-and-error approaches are not optimal. In the study, the researchers investigated the suitability and efficacy of pharmacogenomic–based antidepressant treatment of MDD. With a remission rate of 71.7%, findings showed that PGx-guided treatment was more effective and yielded better patient outcomes in treating MDD compared to "trial and error" interventions (Han et al., 2018).

A meta-analysis of RCTs conducted by Bousman et al. (2019) also reported that

approximately 50% of patients with MDD do not respond to antidepressant treatment, with remission rates being 37.5%. The researchers were concerned with investigating the correlation between pharmacogenetic-guided decision support tools and remission rates in MDD patients. Findings showed the use of PGx-guided approach in MDD patients was 1.7 times more likely to achieve symptom remission compared to the unguided approach (Bousman et al., 2019).

The RCT by Rethorst et al. (2017) also reported that only one in three MDD patients treated through "trial and error" approaches achieve remission, with the remission rates of SSRIs being about 35%. The purpose of the RCT was to identify clinical and biological parameters that would facilitate the increase in remission rates among MDD patients. On the other hand, studies have shown that PGx-guided treatment can achieve higher remission rates among patients with severe depression. An RCT conducted by Greden et al. (2019) reported a statistically significant higher remission, as indicated by the PGx-guided group compared to unguided treatment.

Treatment Tolerability

The theme of tolerability of treatment was derived from the context of the burden of side effects as measured between the PGX-guided and "trial and error" approaches. According to Westrhenen and Ingelman-Sundberg (2021), the "trial and error" process of antidepressant prescribing has been associated with an increased burden of side effects. The RCT by Han et al. (2018) reported that unguided or "trial and error" MDD treatment is associated with increased risk and burden of adverse drug events. In the study, the researchers investigated the suitability and efficacy of pharmacogenomic–based antidepressant treatment of MDD. With a remission rate of 71.7%, findings showed that PGX-guided treatment was more effective and yielded better patient outcomes in treating MDD compared to "trial and error" interventions (Han et al., 2018)

Additionally, the RCT by Thase et al. (2019) also reported that unguided antidepressant

prescription is associated with an increased risk of gene-drug interactions and, consequently, a burden of side effects. The purpose of the RCT was to evaluate the impact of pharmacogenomics on improving clinical outcomes for MDD patients under medications that have gene-drug interactions. The results of the study depicted significant improvement in outcomes for patients in the guided-care arm (Thase et al., 2019).

A review conducted by Abbot et al. (2018) reported that MDD patients treated using an unguided prescription approach were 1.13 times more likely to have medication intolerability events that led to a reduction of optimal dose or stop antidepressant treatment. The review provided a critical analysis of the current literature on the efficacy of pharmacogenetic support tools for geriatric depression management.

The GeneSight Testing intervention

The literature, as exemplified by Hays (2022), underscores the pivotal role of pharmacogenetic testing, such as the GeneSight testing guideline, in reshaping depression treatment paradigms. Hays's work establishes the analytic validity of this approach, affirming its precision in genetic profiling and its ability to categorize individuals based on metabolizer types. The clinical validity and utility of GeneSight testing have been robustly supported, with evidence demonstrating its capacity to accurately predict patient responses to psychotropic medications, particularly concerning the cytochrome P450 pathway and HLA-A/HLA-B gene variants (Hays, 2022). This evidence-backed tool offers clinicians a pathway to optimize drug dosages, ultimately contributing to more efficient and effective treatment processes. Hays's findings further emphasize the significant reduction in adverse drug reactions and improved overall patient remission rates when psychiatrists integrate pharmacogenetic information into their decision-making. In sum, the burgeoning body of evidence, epitomized by Hays's research, advocates for the routine

incorporation of GeneSight testing to enhance the precision and efficacy of depression treatment. Moreover, drawing from a systematic review conducted on GeneSight involving English language studies published before February 22, 2016, GeneSight testing emerges as a pivotal guide in the treatment of depression, as supported by compelling evidence. In the Health Quality assessment study, the primary outcomes of interest included suicide prevention, remission of depression symptoms, response to depression therapy, depression score, and quality of life. Secondary outcomes included the impact on therapeutic decisions, as well as patient and clinician satisfaction. The findings of the review suggest that patients who received the GeneSight test for guiding psychotropic medication selection showed improved responses to depression treatment, greater improvements in measures of depression, and higher levels of patient and clinician satisfaction compared to those who received usual care (Hays, 2022). However, no significant differences were observed in rates of complete remission from depression.

The Health Quality Ontario assessment in 2017 demonstrated that individuals undergoing GeneSight testing displayed not only enhanced responses to depression medication but also notable improvements in depression measures. Moreover, both clinicians and patients expressed greater satisfaction compared to those receiving standard care. This evidence underscores the instrumental role of GeneSight in refining treatment strategies for mood disorders, schizophrenia, and anxiety, showcasing its potential to significantly impact the personalization and efficacy of depression treatment. The findings collectively highlight GeneSight testing as a valuable tool in guiding clinicians toward more tailored and effective interventions for individuals struggling with depression (Health Quality Ontario, 2017).

Staff Education

Implementing GeneSight testing guidelines in clinical practice requires a concerted effort in staff education to ensure effective utilization and interpretation of genetic information. Staff members, including clinicians, nurses, and support staff, need comprehensive training on the principles of pharmacogenomics and the specific genes analyzed by GeneSight, such as CYP2D6, CYP2C19, CYP1A2, SLC6A4, HTR2A, and possibly CYP2C9. This education should cover the implications of genetic variations on drug metabolism and response, as well as the practical application of GeneSight results in guiding psychotropic medication selection (Boyle, 2021).

Additionally, staff should be educated on interpreting and communicating results to patients, fostering an understanding of how genetic information can inform personalized treatment plans. Given the evolving nature of genetic testing technologies, ongoing education, and updates are essential to ensure staff competency and confidence in utilizing GeneSight testing guidelines, ultimately enhancing the quality of patient care and treatment outcomes.

Implications of Findings

The literature shows that "trial and error" approach in depression treatment is associated with low treatment response, poor remission rates, high side effects burden, and medication intolerability that leads to dose reduction or cessation of antidepressant treatment. Evidence suggests that these could be overcome using pharmacogenomics testing to facilitate personalized prescriptions of antidepressants that are likely to be more effective in terms of achieving higher treatment response and symptom remission while avoiding antidepressants that are most likely to fail. Literature suggests that pharmacogenetic (PGx)-guided antidepressant prescription may also avert higher side effects burden and medication intolerability reported in "trial and error"

approach. In doing so, pharmacogenomics testing may help achieve better outcomes and improve treatment compliance due to low side effects burden. Currently, the facility lacks an evidence-based depression treatment guideline. Therefore, the literature is greatly essential for the facility as it supports the use of a pharmacogenetic-based depression treatment guideline such as GeneSight to improve outcomes of patients with severe depression. The literature offers strong evidence for using pharmacogenetic-guided therapy, such as GeneSight, to improve MDD treatment outcomes, including antidepressant treatment response, symptom remission, and medication tolerability, and has reduced the burden of side effects. Therefore, it is imperative to implement the GeneSight pharmacogenetics testing protocol in the facility in Texas.

Project Aim

This project aimed to evaluate the effectiveness of incorporating GeneSight pharmacogenetic testing guidelines into psychiatric treatment decisions for adults diagnosed with major depressive disorder. Specifically focusing on the roles of nurse practitioners in outpatient psychiatric clinics, the goal is to assess whether this integration results in superior treatment responses, reduces adverse reactions, and increases patient satisfaction over 5 weeks. By conducting this project, the project lead seeks to inform providers about the practical implementation of GeneSight testing guidelines, enhancing the ability of nurse practitioners to provide personalized and optimized care for individuals dealing with depression.

Project Objectives

- Introduce GeneSight Guidelines: Introduce and implement GeneSight pharmacogenetic testing guidelines into the decision-making process for psychiatric treatment within the clinical setting.
- Conduct Multidisciplinary Training: Administer comprehensive educational materials and

training sessions to the multidisciplinary team, focusing on nurse practitioners, to ensure a thorough understanding and effective application of GeneSight testing guidelines in psychiatric treatment.

- Enhance Provider Compliance: Enhance healthcare provider compliance with best practices by promoting the consistent adoption of GeneSight pharmacogenetic testing guidelines in psychiatric treatment decisions, specifically focusing on nurse practitioners.
- Mitigate Adverse Outcomes: Reduce the incidence of adverse outcomes in adults diagnosed with major depressive disorder undergoing psychiatric treatment decisions guided by GeneSight testing guidelines by a targeted percentage within a 5-week implementation period.

Implementation Framework

This study is an evidence-based practice project, making it necessary to employ an implementation framework for applying clinical evidence toward making patient care decisions. Therefore, the Iowa model was used as the implementation framework for the study. The Iowa framework was developed twenty-five years ago by nurses working at the University of Iowa Hospital and the faculty from the University of Iowa College of Nursing (Cullen et al., 2022; Duff et al., 2020; Iowa Model Collaborative et al., 2017). The framework is based on eight steps (Titler, 2018). (see Appendix A).

The first step entails determining the trigger where an EBP change is needed (Chiwaula et al., 2022). This trigger for the project is poor outcomes for depression patients due to the lack of testing when administering antidepressant medications to the patients. Healthcare providers in the psychiatric clinic currently rely on a trial-and-error approach, leading to errors in prescribing antidepressant medications. The second step entails establishing whether the problem identified

is a priority for the organization (Iowa Model Collaborative et al., 2017). The poor outcomes for depression patients are a priority for the facility since most patients treated at the psychiatric clinic are often diagnosed with depression.

The third step entails forming a team that develops, assesses, and executes the EBP change (Camargo et al., 2017). The project team comprised professionals with different backgrounds, including psychiatrists, nurses, and a physician. This is critical in ensuring better evaluation and execution of the change. The fourth step of the Iowa model entails collecting and examining research associated with the practice change (Iowa Model Collaborative et al., 2017). This has been met by conducting a comprehensive literature review on the benefits of having a testing procedure to help with the prescription of antidepressant medications.

The fifth stage entails critiquing and synthesizing the evidence obtained from the literature. The psychiatric clinic currently uses trial and error since there is no standard protocol to determine the correct antidepressant medication. The literature demonstrated that trial and error techniques are linked with an increased rate of residual symptoms, partial remission as well as relapse in depression (Paykel et al., 2022; Vilches et al., 2019; Westrhenen & IngelmanSundberg, 2021).

The sixth stage of the model entails examining whether adequate research exists to execute the practice change (Iowa Model Collaborative et al., 2017). The trial-and-error approach used by healthcare providers in the facility poses significant risks to patient safety. As a result, it is necessary to introduce a new technique, the GeneSight testing guideline, which is an evidence-based approach to help improve outcomes for patients with depression in the facility.

The seventh step involves using a pilot program to implement the change (Iowa Model Collaborative et al., 2017). For example, the program can target a unit to implement the intervention before introducing it to the entire organization. This can provide the opportunity to identify areas that need improvement to maximize the outcomes when executing the program in the whole organization. The final stage of the Iowa model program involves the evaluation of the results. If the results from the pilot program are favorable, then it is recommended that the change should be implemented in the entire facility.

In conclusion, the Iowa model can help guide how to implement the suggested intervention and ensure it achieves success. Implementing the GeneSight guideline will help increase the knowledge of psychiatric nurse practitioners on testing patients with depression. Consequently, the psychiatric nurse practitioners in the clinic were able to make informed decisions, thus reducing trial and error associated with antidepressant prescriptions.

Methodology

Population of Interest

The population of interest for this project includes direct and indirect populations. The direct population comprised the staff who were educated on the pharmacogenetics guidelines. Specifically, this population consisted of psychiatric nurse practitioners working at the psychiatric outpatient clinic. The indirect population included patients with a diagnosis of major depression between the ages of 15 to 70 being treated at the outpatient clinic. The inclusion criteria for the nurse practitioners included the ability to communicate in the English language, licensed nurses, and nurses working at the Frisco outpatient clinic at the time of the project implementation. The office scheduler and biller were excluded from the project because they have administrative and financial responsibilities rather than direct involvement in patient care. The inclusion criteria for patients included age between 15 and 70, diagnosed with depression. Patients below the ages of 15 and older than 70 were not included in the project due to the higher prevalence of comorbidities and may be on multiple medications.

Project Setting

This project was carried out in an outpatient psychiatric clinic not affiliated with any healthcare system. The clinic provides outpatient mental health services to patients with different psychological disorders. Its main specialty is psychiatry, and it offers mental health services to approximately 2000 – 3000 patients. The clinic is made up of staff with different professional backgrounds, including schedulers, billers, office managers, nurses, nurse practitioners, licensed professional counselors, and a psychiatrist. The patient load per nurse practitioner is 10-18 patients per day, ranging from ages 5-99. This clinic accepts a mix of private insurance, Medicare, Medicaid, and self-pay. It is also important to note that the clinic offers healthcare

services to children, adolescents, adults, and older adults.

Stakeholders

The current project engaged different sets of stakeholders. First, the project engaged the facility's chief executive officer (CEO), who was responsible for providing the organizational resources needed for the project. The organizational resources included creating time and a conducive environment for psychiatric nurse practitioners to participate in the project. Free sample test kits and a sample report was supplied by the pharmacogenetic testing company to the clinic for educational purposes.

The second set of stakeholders included the psychiatric nurse practitioners who were educated on the guidelines to implement pharmacogenetics testing to help provide better services to patients. Psychiatric nurse practitioners were critical to the project as the success of implementing the project is largely dependent on them. The project mentor is also a stakeholder and guides the project lead on how to conduct various activities throughout the project. The final stakeholder group included the patients. Patients are the primary recipients of healthcare services. They have an interest in the quality of care they receive, including the effectiveness of treatments, communication with healthcare providers, and overall patient experience. The CEO has granted permission, allowing the researcher to use the clinic as the project site without needing and affiliation agreement for the site.

Intervention

The intervention involved the implementation of an evidenced-based GeneSight testing guideline for depression treatment (see Appendix B). The guidelines were aimed at identifying the most appropriate antidepressant based on patient's genetic factors. The implementation involved a systematic approach in planned steps to ensure that there is effectiveness in its

application in clinical practice.

Step 1: Sending Invitations to NPs

The first step of the intervention is the invitation of the Nurse Practitioners, which was done within the organization. Also, the invitations were formulated and sent to the Nurse Practitioners together, which ensures that they are motivated to participate in the GeneSight Testing Initiative (see Appendix C). This step is considered a crucial part of the intervention and determines the effectiveness of the whole process.

Step 2: Engaging with Potential Participants

In ensuring that the intervention plans are effective, ensuring the participants are actively engaged in the process, such as, for instance asking them if they have any knowledge of the topic. Furthermore, through communication, one can identify gaps within the potential participants.

Step 3: Administering Pre-Education Test

In active engagement, one may identify knowledge gaps which also can be identified in the pre-education test. Also, this assists in identifying the baseline knowledge of the NPs participating in the project. Also, the pre-education test can serve as a tool for planning the subsequent education in form of training sessions within the facet of GeneSight Testing guidelines.

Step 4: Provide a PowerPoint Presentation

After the identification of the gaps in knowledge in both engagement and pre-education test phases, the training sessions involve PowerPoint presentations to ensure that they gain detailed knowledge on GeneSight testing guidelines and their impacts in reducing adverse drug reactions and their benefits in clinical practice application.

Step 5: Offering Overview and Implementation Details

In this step, the NPs participants are offered the GeneSight intervention guideline pamphlet with in-depth background knowledge. This offers the NPs a guideline on how it should be implemented daily in the clinical practice with expected patient outcomes, which is considered a timely intervention.

Step 6: Disseminating PowerPoint Presentation

Within the organizational departments, the PowerPoint presentations are spread throughout all departments to ensure that every health professional has access to the presentation, and this acts as a prior preparation for the implementation phase and also learning in subsequent training sessions. Furthermore, the disseminating of the PowerPoint presentations makes sure that the information on GeneSight testing guidelines is readily available and hence acts as a tool for clinical decision-making during clinical practice.

Planning Project Team

The success of the GeneSight Testing initiative relies on a dedicated and collaborative project team. Each team member played a crucial role in ensuring the smooth implementation of the project. The roles of project lead included educating participants about GeneSight Testing guidelines, overseeing activities related to the GeneSight Testing initiative, addressing issues and concerns regarding the intervention, providing support as needed, collecting, compiling, and analyzing data, and authorizing the project and facilitating the acquisition of necessary technology and resources. The roles of the human resource manager included analyzing current NPs' current workloads to inform training time allocation, supporting the implementation of the program by sending invitations and reminders to participants and providing logistical support, including toolkit distribution. This collaborative team, led by the Project Lead, ensured that the

initiative was not only well-executed but also supported at the organizational level.

Required Resources

The resources required for the successful implementation of this quality improvement project included GeneSight Testing Guidelines Handbook (comprehensive guide providing detailed information on the testing guidelines), Computers (used for electronic data collection, training sessions, and implementation support), a Dedicated Training Room for GeneSight Utilization (a physical space where training sessions and practical applications of GeneSight took place, and a PowerPoint presentations (used for educating participants).

How Resources Were Obtained

The GeneSight Testing Guidelines Handbook was acquired through existing organizational resources. Computers and the dedicated training room were allocated and facilitated by the Human Resource Office. PowerPoint presentations were developed using the facility's computer. The acquisition and allocation of these resources were coordinated through collaborative efforts between the project team and relevant organizational departments.

Timeline

The strategic implementation of the GeneSight Testing guidelines unfolded within a 5-week timeline, ensuring systematic execution of key project milestones (See Appendix D). In the first week, participants were informed about the project and recruited. Also, pre-education tests were administered in the first week and GeneSight PowerPoint presentations were used to educate the staff. The training and preparation were completed in the second week. The third to fifth weeks were used to implement GeneSight in psychiatric treatment decisions, conduct post-implementation surveys, and evaluate outcomes.

Tools and Instrumentation

Pre- and Post-Knowledge Survey

The Pre-and Post-Knowledge Survey (Appendix E) is a tool that was designed to evaluate the effects of the GeneSight Testing initiative training on health care staff's knowledge for use in clinical practice application. This survey was developed internally for the NPs in the organization as it was aimed at recording the quantitative change before and after training and education sessions. Also, after analysis, this survey tool offered the percentage of the NPs educated. Additionally, as the tool is developed internally, the research project basis has completed autonomy and no need for external permission to carry out the implementation.

Chart Audit Tool

The Chart Audit Tool (Appendix F) also is a tool used for the quantitative measure of the practical application of the implementation. For instance, it records the quantitative results and offers the chance to evaluate the implementation results of the GeneSight guidelines in the practical application in the clinical practice in the psychiatric treatment of depression. Furthermore, it is also developed internally; hence, it aligns with the organizational and project objective 1 and 3. Validation of the tool was done through expert consultation; hence, the approach for its use is focused and unique. This enabled the elimination of the external permission requirements, which offers flexibility and control over the utilization of the Chart Audit Tool.

PowerPoint Presentation

The PowerPoint Presentation was used to train health care staff at the facility about the intervention. The presentations were developed by the project lead to align with the needs of the intervention and implementation process. The educational content included in the PowerPoint presentation was developed based on the existing literature about the intervention.

Patient Health Questionnaire 9 (PHQ-9)

The Patient Health Questionnaire (PHQ-9) was used to measure levels of depression among the patients. PHQ-9 is a nine-item tool used to screen depression (see Appendix G). For each of the nine items, patients were asked to rate how they were bothered by given symptoms in the last two weeks (Schulte et al., 2021). PHQ-9 scale has four answer options for all nine items, ranging from not at all (0), several days (1), more than half of the days (2), and nearly every day (3). The PHQ-9 patient score is obtained by adding each item to achieve the total score. The total

sum score ranges from 0 to 27, indicating the extent of depression (Schulte et al., 2021).

Client Satisfaction Questionnaire (CSQ-8)

The Client Satisfaction Questionnaire (CSQ-8) was used to assess patients' satisfaction with care (see Appendix H). The tool is a valid and reliable questionnaire for measuring patients' experience with care. The tool has high internal consistency, with a Cronbach's alpha of .95 (Pedersen et al., 2022). Initially, CSQ-8 was developed to measure patient satisfaction with mental health care in outpatient settings (Pedersen et al., 2023).

Data Collection Plan Educational Intervention Evaluation

Both pre and post-implementation data were collected from health care providers to assess the knowledge base, attitude, and adoption of GeneSight-guided testing. Data were collected by administering surveys to the participants before and after the education sessions. The questionnaires for pre-implementation were sent prior to the education session within the 1st week of project implementation, and post-implementation questionnaires were sent during the final week of implementation. The outcome data collected included treatment response, side effects, and patient satisfaction with health care. Treatment responses were measured based on percentage changes in patients' health questionnaire (PHQ-9) scores from the first visit and return to the clinic after the initial prescription of antidepressants. Side effects were measured based patient's reported adverse effects resulting from the use of antidepressants, such as dryness of mouth, nausea, headache, drowsiness, insomnia, loss of appetite, blurred vision, sweating, and dizziness. Patient satisfaction was measured using the Client Satisfaction Questionnaire (CSQ-8). The baseline data for the outcome measures were collected through chart reviews retrospectively for five weeks before the implementation of the intervention. For the pretest, data were collected during return visits of patients.

Process Evaluation

To evaluate the effectiveness of the intervention, the process was observed for implementation and compliance by the health care providers using a checklist. NPs were monitored for compliance, and support was provided throughout the implementation. Reminders were used to remind health care staff about the time, date, and location of educational sessions. Nurses' knowledge, confidence, and familiarity with the use of GeneSight guidelines were evaluated before and after training. Training was provided to improve health care staff's knowledge and competencies with the use of the GeneSight guidelines to identify the most appropriate antidepressant for patients.

Participant Privacy

The protection of participants' privacy and confidentiality is one of the ethical principles in research (Friesen et al., 2017). To protect participant's privacy, information that reveals the identity of both the providers and patients was omitted while the collected data were secured in a folder with a password known to the Project Lead only. Identifiable patient and staff data were not collected. Instead, patients and staff were assigned different codes as means of identification. All charts and audit tools were kept at the project site, only accessible to the project lead. As such, responses were both confidential and anonymous while hard copies were filed and saved in cabinets only accessible by the Project Lead. If participants felt uncomfortable and discouraged from participating based on privacy concerns, they were excluded from participating.

Data Storage

Both soft and hard copy data were securely stored to enhance privacy and unauthorized access. Soft copy data were stored electronically in folders that are password-protected on the project lead's computer. Hard copy data were stored in a lockable cabinet accessed by the project

lead only. Data will be permanently destroyed after a period of two years.

Ethics/Human Subjects Protection

The providers were recruited by inviting them to participate in the project. The invitation contained relevant information such as benefits, date, and location (see Appendix C). The CEO of the clinic, as part of the organizational endorsement, encouraged NPs to join the project voluntarily. The project lead had a pep talk at the site to first introduce the project to NPs either at break time or a short session at the clinic as approved by the CEO to stimulate interest, then take down email contacts for onward sending of invites. Although the project did not include incentives, which were communicated to the NPs, the practitioners were well-informed of the benefits of the project. Benefits include knowledge gain on pharmacogenetic testing, which in turn improves their professional practice while providing efficient treatment to patients. The benefit to the clinic was communicated to them, which is a reduction in return patients because of patient's satisfaction with their care. To allay concerns and encourage full participation, the perceived risk of the project and measures for mitigating them were also communicated to the Providers. Participants with privacy concerns were removed from participating in the project. Participants were not incentivized or coerced to participate but were encouraged through education on the benefits of the intervention to them, which, for the providers, is an increase in knowledge base. Nurses have a role in ensuring optimal patient outcomes; therefore, they should know pharmacogenomics as a nursing competency (Cheek et al., 2015). For the patients, the effectiveness of treatment and a higher chance of reduction in return visits after medication are what they stand to benefit.

Ethics/IRB Process

The project site does not require review by Touro University Nevada's Institute of

Review Board because it is a Quality Improvement Project that has already been approved by the university. The project site does not have an IRB and the management has already approved the project to be implemented at the clinic (Appendix I). It is duly approved and supported by the clinic's management, as such, all providers were required to participate in the project. Permission to implement the project was obtained from the site (see Appendix I). In the process, their data were protected. Personally identifiable data were not included in the final report, and results were reported in aggregate only. Measures were taken to ensure data gathered were protected, secured, and not used for purposes other than intended.

Data Analysis Plan

A statistician was engaged to advise on the best statistical testing to measure and interpret the projected outcomes of the intervention. The project adopted a quantitative methodology for statistical data analysis. A quantitative methodology makes the generalization of project findings possible and facilitates the exploration of relationships between variables as well as the testing of hypotheses (Eyisi, 2016).

Both descriptive and inferential statistics were deployed to analyze the data collected. Descriptive statistics such as mean and standard deviations of continuous scores such as patient satisfaction scores and percentage changes in patients' PHQ-9 scores. Also, descriptive analyses involved computing frequencies for the number of patients who reported side effects five weeks before and after the implementation of the intervention.

Independent samples *t*-test were used to examine if there were statistically significant differences in means between the baseline and posttest data on treatment response. Independent samples *t*-test was appropriate for the project because the test is used to compare the means of two unrelated groups (Gerald, 2018). For changes in staff knowledge, confidence, and familiarity

with the use of GeneSight guidelines, the Wilcoxon signed ranked test was used because of a small sample size of health care staff at the facility who were trained on the guidelines. For the reported side effects, the Pearson Chi-square test of homogeneity was conducted to evaluate if the number of patients who reported side effects of antidepressants were homogenous 5 weeks before and after the implementation of the intervention. Pearson Chi-square test of homogeneity is suitable for examining if frequency is equally distributed among groups (Turhan, 2020). The inferential results were evaluated at a 0.05 level of significance. The statistical analysis was conducted using Statistical Package for the Social Sciences (SPSS) version 27. The results were presented in text, tables, and figures.

Analysis and Findings

Depression is the most prevalent mood disorder globally (Aboelbaha et al., 2021). There exist different pharmacological options for treating depression; therefore, the selection of appropriate antidepressants is based on safety profile and individual clinical factors (Aboelbaha et al., 2021). Pharmacogenomic testing is a promising treatment procedure for identifying the best drug for a patient based on clinical symptoms (Tiwari et al., 2022; Oslin et al., 2021). Health care professionals' knowledge and skills in using pharmacogenomic testing are essential in improving patients' health outcomes. The purpose of this project was to improve health care professional's knowledge and confidence in the use of pharmacogenomic testing through am educational intervention. This section contains the results of the project.

Descriptive Statistics

A sample of eight health care professionals participated in this project. The majority of the participants were psychiatric nurse practitioners (n = 4, 50%). Also, the majority of the participants were females (n = 6, 75%) and most had 0 and 5 years of experience (n=3, 37.5%) (see Table 1).

Table 1

Participants' Demographics

Variable	Category	*N*	%
Profession	Family nurse practitioner	3	37.5
	Psychiatric nurse Practitioners	4	50.0
	Psychiatrist	1	12.5
Gender	Females	6	75.0
	Males	2	25.0
Years of Experience	>15	1	12.5
	0-5	3	37.5
	11--15	1	12.5
	45611	1	12.5
	6--10	2	25.0

Inferential Tests

Considering the sample size was used, a non-parametric test was used to examine if there were statistically significant changes in participants familiarity, knowledge, and confidence in the use of pharmacogenomic testing before and after the intervention. The Wilcoxon sign ranked tests were conducted as a non-parametric equivalent of paired samples *t*-test. The results indicated that there was a statistically significant increase in participants scores across the three outcomes ($p <. 05$) (see Table 2).

Table 2

Wilcoxon Sign Ranked Test Results

Pair	Z	*P*
Post Familiarity – Pre-Familiarity	-2.598	.009
Post Knowledge – Pre-Knowledge	-2.555	.011
Post Confidence – Pre Confidence	-2.414	.016

Treatment Response

A total of 17 patient charts were reviewed to extract data on treatment responses for five weeks before the implementation of the intervention. Twenty-five charts were reviewed during the five weeks of implementation, making a total sample size of 42 patients. Independent samples *t*-test was conducted to examine if there was a statistically significant difference in the mean response to treatment of depression after administering antidepressants before and after the implementation of the intervention. Based on the PHQ-9 scores, the mean response to treatment 5 weeks before the implementation of the intervention was 40.02%, with a standard deviation of 9.90. However, the response to treatment increased to 48.90%, with a standard deviation of 14.66 after the implementation of the intervention. Based on the independent samples *t*-test, the increase in treatment response was statistically significant at a .05 level of significance (t = -2.177, p >.05)(see Table 3).

Table 3

Summary Statistics and Independent Samples t-Test Results

Timeline	*n*	Mean	Standard Deviation	*T*	*p*	Effect Size
Baseline	17	40.02	9.906	-2.177	.035	12.971
Posttest	25	48.90	14.663			

Side Effects

Pearson Chi-square test of homogeneity was conducted to evaluate if the number of patients who reported side effects of antidepressants were homogenous 5 weeks before and after the implementation of the intervention. The Pearson Chi-square test results indicated that there was no statistically significant difference in the number of patients who reported side effects related to antidepressants five weeks before and after the implementation of the intervention (X^2

=2.128, $p > .05$) (see Table 4). Despite the non-statistical significance, there was a clinically significant decrease in the rate at which participants reported side effects associated with antidepressants five weeks after the implementation of the intervention. Out of 17 patients five weeks before the implementation of the intervention, 10 reported at least one side effect of antidepressants, representing a rate of 58.8%. However, out of 25 patients, only 9 reported side effects of antidepressants 5 weeks after the implementation of the intervention, representing a rate of 36%. Therefore, the was a decrease in the rate of reported side effects from 58.8% before to 36% after the implementation of the intervention.

Table 4

Crosstabulation of Side Effects and Pearson Chi-square Test of Homogeneity Results

	Side Effects		Total	X^2	p
	No	Yes			
Baseline	7	10	17	2.18	.145
Post-Intervention	16	9	25		

Patient Satisfaction

Patient satisfaction with health care was collected by administering CSQ-8 during their return visits to the clinic. Considering the design of this project, it was not possible to collect baseline satisfaction because the clinic had not been collecting patient satisfaction scores. Therefore, only a descriptive analysis of the **post-intervention** patient satisfaction scores was conducted. Out of a maximum of 32 scores, the mean patient satisfaction score was 28.68, with a standard deviation of 1.909. The minimum score was 26, and the maximum of 32 (see Table 5).

Table 5

Summary of Patient Satisfaction Scores

Statistic	*n*	Range	Minimum	Maximum	Mean	Std. Deviation	Variance
Value	25	6	26	32	28.68	1.909	3.643

Summary

Pharmacogenetic testing is essential in identifying the most appropriate medication for a patient based on their genetic factors. Health care professionals' knowledge and skills in the use of pharmacogenetic testing are crucial in enhancing their skills and competencies to provide quality care by integrating evidence-based practices. The results indicated that health care professionals' familiarity, knowledge, and confidence in the use of Gene Sight pharmacogenetic testing guidelines significantly improved after the implementation of the intervention. In addition, there was a statistically significant improvement in response to treatment after the implementation of the intervention. Despite the non-statistical significance, there was a clinically significant decrease in the rate of patient-reported side effects associated with the use of antidepressants after the implementation of the intervention.

Limitations of the Project

Selection bias might have occurred during the recruitment of the participants. The selection bias may cause inaccurate conclusions and skewed results since the sample may need to reflect the characteristics of the population under study accurately. All mental health professionals at the facility were included to reduce the selection bias. The questionnaires used to collect data were self-administered. Therefore, there was potential that participants would give biased responses. A quasi-experimental design was used, which is not as robust as randomized controlled trials. No

confounding variables were collected and analyzed. Therefore, there were possibilities that other variables could have contributed to the changes in the outcome measures. A small sample size was used, which may limit the power of the project and the generalizability of results. Another limitation of this project was the use of a single facility. Conducting the project in more settings could have enhanced the sample size and generalizability of the findings. Also, the project was implemented for a short timeframe of five weeks. Implementing the project over a longer period, for example, three months will enable understanding of the sustained impacts of the intervention.

Efforts to Minimize and Adjust for Limitations

Efforts to minimize and adjust for the limitations of this project included recruiting all mental health care professionals at the facility, using evidence-based guidelines, and using appropriate data analysis methods. Selection bias was limited by ensuring that all mental health professionals at the facility participated in the project. Because of the small sample size, a non-parametric test was conducted instead of a parametric test. Evidence-based guidelines were used to strengthen the study design.

Conclusion

This quality improvement project aimed at evaluating the effectiveness of incorporating GeneSight pharmacogenetic testing guidelines into psychiatric treatment decisions for adults diagnosed with major depressive disorder. The GeneSight pharmacogenetic testing guidelines were implemented to guide health care providers in identifying appropriate antidepressants for patients with depression at an outpatient psychiatric clinic. The educational sessions were effective in enhancing health care providers' familiarity, knowledge, and confidence with GeneSight. Also, the GeneSight pharmacogenetic testing guidelines were effective in improving treatment response, decreasing side effects, and enhancing patient satisfaction with care. The

success of this project implies that pharmacogenetic testing is appropriate in identifying effective medication with few side effects for specific patients based on their genetic factors. Therefore, health care providers should consider using pharmacogenetic testing guidelines such as GeneSight to improve the quality of care delivered to patients, such as enhancing the effectiveness of drugs, decreasing the side effects associated with medication, and improving overall patients' satisfaction with health care.

Major limitations of this project included the use of a small sample size and a single facility. To mitigate the limitations, appropriate statistical analyses were conducted. The success of this project has positive implications for the quality of care delivered to patients through enhanced treatment response, decreased side effects of medication, and improved satisfaction with care. Also, the success of this project underscores the need for policy changes to integrate the use of GeneSight pharmacogenetic testing guidelines to enhance the identification of the most appropriate antidepressant medication for patients with depression. The use of the GeneSight pharmacogenetic testing guidelines will be sustained by advocating for the integration of the guidelines into care policy at the clinic and by providing regular training to enhance health care providers' knowledge and competencies about the guidelines. Also, regular monitoring and evaluations will be conducted to identify and address the implementation barriers. The next steps will be to present the results to the stakeholders, including providers at the facility, and liaise with the facility administrator and nurse manager to ensure the project is sustained.

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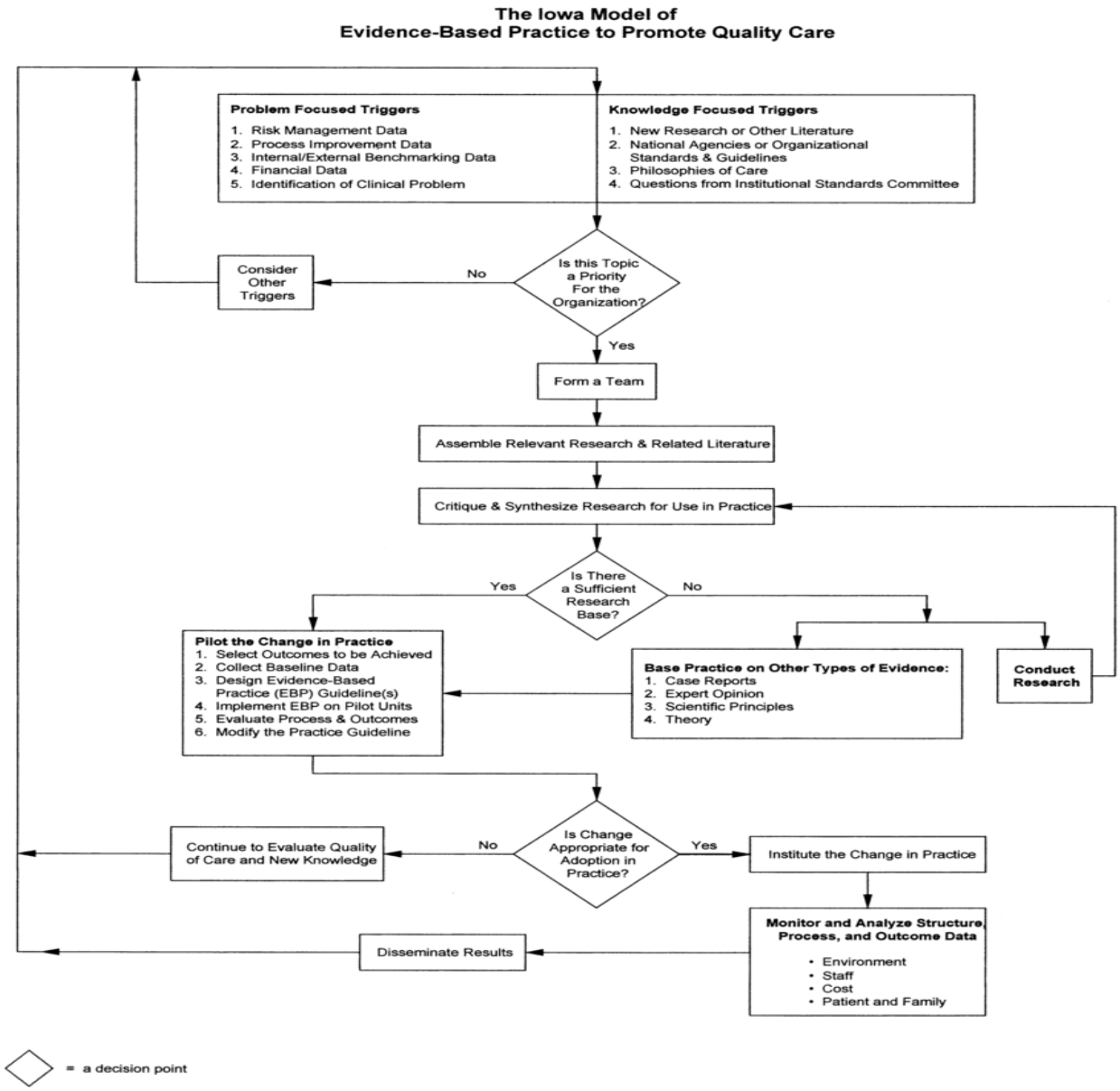
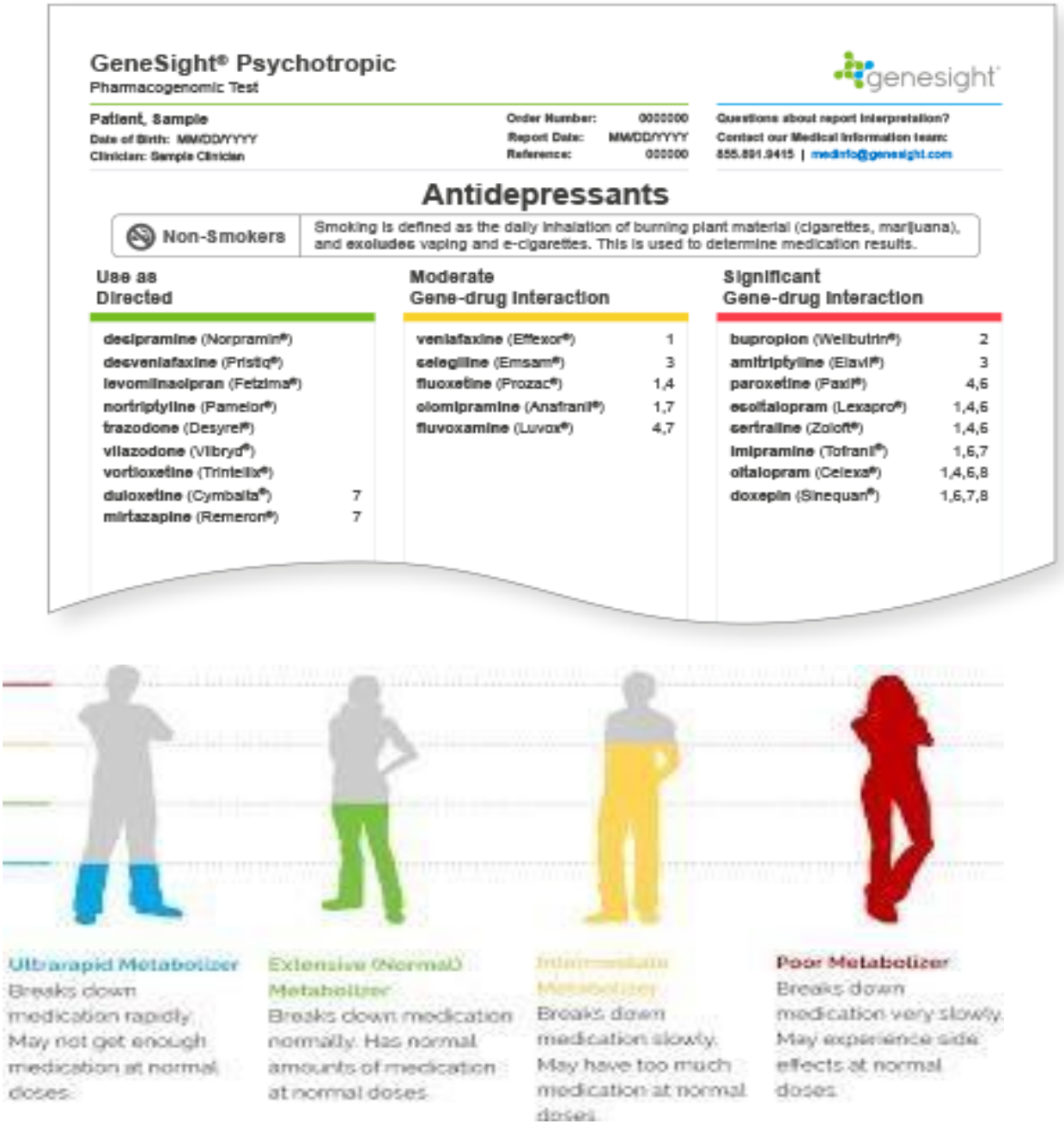
Appendix A

IOWA Model



Appendix B

GeneSight Guideline and Supporting Information



GeneSight® Psychotropic
Pharmacogenomic Test

genesight

Patient, Sample
Date of Birth: MM/DD/YYYY
Clinician: Sample Clinician

Order Number: 0000000
Report Date: MM/DD/YYYY
Reference: 000000

Questions about report interpretation?
Contact our Medical Information team:
855.891.9415 | medinfo@genesight.com

Antidepressants

Non-Smokers — Smoking is defined as the daily inhalation of burning plant material (cigarettes, marijuana), and excludes vaping and e-cigarettes. This is used to determine medication results.

Use as Directed		Moderate Gene-drug Interaction		Significant Gene-drug Interaction	
desipramine (Norpramin®)		venlafaxine (Effexor®)	1	bupropion (Wellbutrin®)	2
desvenlafaxine (Pristiq®)		escitalopram (Emsam®)	3	amitriptyline (Elavil®)	3
levomilnacipran (Fetzima®)		fluoxetine (Prozac®)	1,4	paroxetine (Paxil®)	4,6
nortriptyline (Pamelor®)		olomipramine (Anafranil®)	1,7	escitalopram (Lexapro®)	1,4,6
trazodone (Desyrel®)		fluvoxamine (Luvox®)	4,7	sertraline (Zoloft®)	1,4,6
vilazodone (Viibryd®)				imipramine (Tofranil®)	1,6,7
vortioxetine (Trintellix®)				citalopram (Celexa®)	1,4,6,8
duloxetine (Cymbalta®)	7			doxepin (Sinequan®)	1,6,7,8
mirtazapine (Remeron®)	7				

Ultrarapid Metabolizer
Breaks down medication rapidly. May not get enough medication at normal doses.

Extensive (Normal) Metabolizer
Breaks down medication normally. Has normal amounts of medication at normal doses.

Intermediate Metabolizer
Breaks down medication slowly. May have too much medication at normal doses.

Poor Metabolizer
Breaks down medication very slowly. May experience side effects at normal doses.

Appendix C

Invitation to GeneSight Testing Guideline Training

A call for all nurse practitioners to participate in the quality improvement training on Genecept assay testing guidelines.

Location: Outpatient Psychiatric Clinic, Frisco TX Time: 12:00 pm to 1:30 pm

Dates:

Purpose: Suggested guideline to enhance prescribing knowledge of nurse practitioners about the GeneSight testing guideline, eradicate trial and error testing approach for prescribing antidepressant medication.

Project lead: Ekaete Oyeka

Email: eoyeka@student.touro.edu

Appendix D

Project Timeline

Weeks	Dates	Activities
Week: 1		Welcome nursing practitioners interested in the initiative. Engage participants with an overview of the GeneSight implementation program. Administer the Pre-education test. - Present the GeneSight implementation PowerPoint. - Disseminate materials across relevant departments. Collaborate with the CEO to allocate and set up a dedicated room for project activities. Equip the room with necessary resources.

Week: 2		Roll out a comprehensive training curriculum for nurse practitioners. Conduct structured training sessions (theory and practical components). Incorporate interactive elements and case studies for hands-on learning. Address questions and concerns to ensure confidence in applying GeneSight guidelines. Complete NP training sessions

Week: 3		- Implement GeneSight in psychiatric treatment decisions. -Allocate time for additional data collection activities.
Week: 4		- Conduct post-implementation surveys and evaluate outcomes.
Week: 5		Launch a post-implementation survey for stakeholder feedback. Distribute the survey and ensure a high response rate. Analyze survey responses to assess implementation effectiveness. Identify areas for improvement, success stories, and lessons learned. Inform future initiatives based on the evaluation.

Appendix E

Knowledge Questionnaire

Welcome to the GeneSight Testing Educational Intervention Evaluation Survey. Your valuable insights are crucial in evaluating the impact of our educational initiative on knowledge acquisition related to GeneSight Testing guidelines in psychiatric treatment decisions. Please take the time to provide detailed and thoughtful responses to the following questions. Your feedback played a vital role in understanding the effectiveness of the intervention in enhancing knowledge.

Section 1: Demographic Information

What is your current role in the healthcare setting?

NP Student

Certified Nurse Practitioner

Other (please specify)

How many years of experience do you have as a Nurse Practitioner?

In which specialty area do you primarily practice as a Nurse Practitioner? (Open- ended)

Section 2: Pre-Education Knowledge Assessment

On a scale of 1 to 10, how would you rate your familiarity with GeneSight Testing guidelines before the educational intervention (1-Not Familiar at all to 10- Extremely Familiar)?

How confident were you in your understanding of the impact of GeneSight on psychiatric treatment decisions before the educational intervention?

(Not confident at all) to 10 (Extremely confident)

On a scale of 1 to 10, rate your confidence in applying GeneSight recommendations in clinical practice before the educational intervention (1-Not familiar at all to 10-Extremely Familiar).

Section 3: Educational Intervention Experience (Pre- and Post-Education Knowledge)

How many times did you engage with GeneSight Testing guidelines during the training sessions?

On a scale of 1 to 10, how clear were the educational materials provided during the sessions?

How many new insights or pieces of information did you gain from the educational intervention?

Section 4: Post-Education Knowledge Assessment

On a scale of 1 to 10, how would you rate your familiarity with GeneSight Testing guidelines after the educational intervention?

On a scale of 1 to 10, rate your confidence in applying GeneSight recommendations in clinical practice post-education.

How many new insights or pieces of information did you gain from the educational intervention?

Section 5: Additional Feedback and Future Intentions

What specific aspects of the educational intervention contributed the most to your knowledge acquisition?

How likely are you to recommend the GeneSight Testing guideline training to your colleagues for knowledge acquisition?

Very likely

Likely

Neutral

Unlikely

Very unlikely

Any additional comments or suggestions regarding the educational intervention's impact on your knowledge acquisition? (Open-ended)

Your thoughtful responses are crucial in shaping the future of GeneSight Testing guideline implementations. Thank you for your time and commitment to advancing evidence-based practices in psychiatric care.

Appendix F

Chart Audit Tool: GeneSight Testing Guideline Implementation

Objective: Assess the integration and application of GeneSight Testing guidelines in psychiatric treatment decisions through a comprehensive chart audit.

Patient Information:

Patient ID/Code: ____

Date of Chart Audit: _

General Information:

Healthcare Provider/Nurse Practitioner: Name: ____

Role: NP Student / Certified Nurse Practitioner / Other

Patient Demographics:

Age: __

Gender: Male / Female / Other

Diagnosis: ___

GeneSight Testing Guideline Implementation:

Was GeneSight Testing mentioned in the patient's chart?

Yes

No

If yes, specify the context:

Medication

selection o Dosage adjustment

Adverse reactions monitoring

Treatment response assessment

Other (please specify): _____

Documentation of GeneSight Testing Recommendations:

Were GeneSight Testing recommendations documented in the treatment plan or notes?

Yes

No

If yes, specify the type of recommendations documented:

Medication changes

Dosage adjustments

Monitoring plan

Referral to genetic counseling

Other (please specify): _____

Follow-up and Monitoring:

Were follow-up appointments scheduled based on GeneSight Testing recommendations?

Yes

No

If yes, specify the nature of follow-up:

Medication review

Symptom monitoring

Adverse reactions assessment

Genetic counseling follow-up

Other (please specify): _____

Overall Assessment:

Rate the level of adherence to GeneSight Testing guidelines based on the chart audit:

Low adherence

Moderate adherence

High adherence

Comments and Observations:

Provide any additional comments or observations related to the implementation of GeneSight Testing guidelines in this patient's chart. Include any challenges or successes encountered.

Recommendations for Improvement:

Based on the audit findings, suggest any recommendations for improving the integration of GeneSight Testing guidelines in future practice.

Appendix G

PHQ-9 Tool

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use "✔" to indicate your answer)*	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING 0 + _____ + _____ + _____

=Total Score: _____

Appendix H

Client Satisfaction Questionnaire (CSQ-8*)*.

Client Satisfaction Questionnaire (CSQ-8, v. TMS-180S)

(Larsen et al., 1979)

Instructions for participants:

Please help us improve our service by answering some questions about the help that you have received. We are interested in your honest opinions, whether they are positive or negative. Please answer all of the questions. We also welcome your comments and suggestions. Thank you very much. We appreciate your help.

1. How would you rate the quality of service you received?
   - ○ Excellent (4)
   - ○ Good (3)
   - ○ Fair (2)
   - ○ Poor (1)

2. Did you get the kind of service you wanted?
   - ○ No, definitely not (1)
   - ○ No, not really (2)
   - ○ Yes, generally (3)
   - ○ Yes, definitely (4)

3. To what extent has our service met your needs?
   - ○ Almost all of my needs have been met (4)
   - ○ Most of my needs have been met (3)
   - ○ Only a few of my needs have been met (2)
   - ○ None of my needs have been met (1)

4. If a friend were in need of similar help, would you recommend our service to him or her?
   - ○ No, definitely not (1)
   - ○ No, I don't think so (2)
   - ○ Yes, I think so (3)
   - ○ Yes, definitely (4)

5. How satisfied are you with the amount of help you received?
   - ○ Quite dissatisfied (1)
   - ○ Indifferent or mildly dissatisfied (2)
   - ○ Mostly satisfied (3)
   - ○ Very satisfied (4)

6. Have the services you received helped you to deal more effectively with your problems?
   - ○ Yes, they helped a great deal (4)
   - ○ Yes, they helped somewhat (3)
   - ○ No, they really didn't help (2)

   - ○ No, they seemed to make things worse (1)

7. In an overall, general sense, how satisfied are you with the service you received?
   - ○ Very satisfied (4)
   - ○ Mostly satisfied (3)
   - ○ Indifferent of mildly dissatisfied (2)
   - ○ Quite dissatisfied (1)

8. If you were to seek help again, would you come back to our service?
   - ○ No, definitely not (1)
   - ○ No, I don't think so (2)
   - ○ Yes, I think so (3)
   - ○ Yes, definitely (4)

Appendix I

IRB Approval

DNP 763–Project II

Touro University Nevada

DNP Project Team Determination

Quality Improvement or Evidence Based Practice Project or Research

All DNP Projects, regardless of methodology, must uphold the highest standards of ethical practice including confidentiality and privacy as described in the ANA Code of Ethics. Accordingly, basic principles of ethics, confidentiality, and privacy must be addressed and maintained in each phase of the DNP Project implementation. Methods for maintaining such should be described in full detail within the body of the DNP Project Paper.

If the determination is made that the DNP Project is a "Quality Improvement or Evidence Based Practice Project," then the project should be referred to as such in all future communications–both written and verbally. Quality Improvement or Evidence Based Practice projects should not be referred to as research or research projects and are not subject to any form of IRB review. Additionally, the student should not make any claims in writing or verbally of IRB exemption status, acceptance, or review in such projects.

Sections A and B should be completed and submitted by the student. **Section C** should be completed by the faculty.

SECTION A

Student Name: Ekaete Oyeka

DNP Project Title: **Implementation of the GeneSight Testing Guidelines for Depression**

DNP Project Instructor: Dr. Julie Astrella, DNP, RN, CNE

DNP Project Mentor: Yewande Wilson

Quality Improvement or Research Worksheet

Rachel Nosowsky, Esq.

ITEM	Issue and Guidance	Rating
1	Are participants randomized into different intervention groups to enhance confidence in differences that might be obscured by nonrandom selection? Randomization done to achieve equitable allocation of a scarce resource need not be considered and would not result in a "yes" here.	YES X NO
2	Does the project seek to test issues that are beyond current science and experience, such as new treatments (i.e., is there much controversy about whether the intervention were beneficial to actual patients – or is it designed simply to move existing evidence into practice?). If the project is performed to implement existing knowledge to improve care – rather than to develop new knowledge – answer "no".	YES X NO

5/22/2023

3	Are there any potential conflicts of interest (financial or otherwise) among any researchers involved in the project? If so, please attach a description of such in an attachment to this form.	_____YES __X___NO
4	Is the protocol fixed with a fixed goal, methodology, population, and time period? If frequent adjustments are made in the intervention, the measurement, and even the goal over time as experience accumulates, the answer is more likely "no."	_____YES __X___NO
5	Will data collection occur in stages with an effort to remove potential bias? If so, is there any potential for data skewing from this process?	_____YES __X___NO
6	Is the project funded by an outside organization with a commercial interest in the use of the results? If the answer to this question is "Yes" please also answer question 6a and 6b. If the project is funded by third-party payors through clinical reimbursement incentives, or through internal clinical/operations funds vs. research funds, the answer to this question is more likely to be "no."	_____YES __X___NO
6a	Is the sponsor a manufacturer with an interest in the outcome of the project relevant to its products?	_____YES __X___NO

6b	Is it a non-profit foundation that typically funds research, or internal research accounts?	_____YES __X___NO

Adapted from Hastings Center, "The Ethics of Using Quality Improvement Methods to Improve Health Care Quality and Safety" (June 2006) If the weight of the answers tends toward "yes" overall, the project should be considered "research" and approved by an IRB prior to implementation. If the weight of the answers tends toward "no," the project is not "research" and is not subject to IRB oversight unless local institutional policies differ. Answering "yes" to sequence #1 or #2 – even if all other answers are "no" – typically will result in a finding that the project constitutes research. It is important to consult with your local IRB if you are unsure how they would handle a particular case, as the analysis of the above issues cannot always be entirely objective and IRB policies and approaches vary significantly.

Obtained from: Quality Improvement or Research Worksheet

SECTION B

All projects, including student QI or EBP projects, are required to be registered with the Department of Research at TUN. Please register your project via this Qualtrics survey. Provide your information as the PI for your project.

_X___Yes, I registered my project with the Department of Research at TUN via the link above

5/22/2023

_____No, I did not register my project with the Department of Research at TUN. Please provide rationale.

SECTION C

Project Classification Decision:

The project instructor will select one of the three classifications listed below.

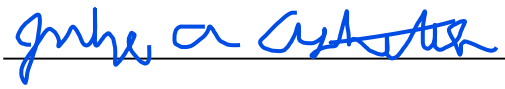
__x__This DNP Project is a quality improvement or evidence based practice project. Do not submit to IRB for review.

_____This DNP Project contains research methodology, and an IRB application should be submitted to the TUN IRB committee for exemption determination and/or full IRB review.

_____This DNP Project is not clearly delineated as quality improvement or research of discovery. Additional consultation were obtained from the IRB committee by the project team. The advice of the IRB committee regarding the need for review were noted in writing and the student were informed of such (Please attach any pertinent documentation from IRB review as an Appendix to this document.)

By signing below, the project instructor indicates that they agree with the above selection.

Printed Name of Project Instructor: Dr. Julie Astrella, DNP, RN, CNE

Electronic Signature of Project Instructor: 

5/22/2023

Appendix J

Site Approval Letter

HOPE
PSYCHIATRY & ASSOCIATES

9555 Lebanon Road, Suite #401.
Frisco TX 75035
469-840-5152
469-840-5200
1-866-986-1927
info@hopepsychiatry.org
Hopepsychiatry.org

Permission Letter for Project

To,
Ekaete Oyeka
Doctor of Nursing Practice
Touro University Nevada

November 7, 2023

Subject: Permission to complete project at site

Dear Ms. Oyeka,

I am pleased to inform you that I and Hope Psychiatry & Associates, PLLC grant you permission to conduct your project at our site. We feel that this project will be beneficial to our practice and aligns well with our clinic's mission and objectives. We look forward to collaborating with you.

All the best in your research.

Yours truly,

Bernard Marfo, APRN-BC
Managing partner