Implementation of the GeneSight Pharmacogenetic Testing Guideline for Depression

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This project is in partial fulfillment of the degree requirements for the Doctor of Nursing Practice at Touro University Nevada.

Overview

- The psychiatric nurse practitioners at the outpatient psychiatric relied on a "trial and error’.
- The purpose of this project was to evaluate the effectiveness of incorporating GeneSight pharmacogenetic testing guidelines into psychiatric treatment decisions for adults diagnosed with major depressive disorders.
- The GeneSight pharmacogenetic testing guidelines were effective in improving treatment response, decreasing side effects, and enhancing patient satisfaction with care.
- Health care providers should use pharmacogenetic testing guidelines to improve the quality of care.

Problem and Background

- Depression is among the leading causes of disability (Aboelbaha et al., 2021).
- There are several pharmacological treatment options used for treating acute depression (Karrouri et al., 2021; Corponi et al., 2019).
- Despite the effectiveness of medication, side effects are common and may result in discontinuation of treatment (Campos et al., 2021).
- Genetic factors of the patient is among the risk of side effects (Campos et al., 2021).

Problem Statement

- At the facility, ‘trial and error’ approach was used to identify appropriate antidepressants for patients.
- Most patients reported increased side effects, poor treatment response, and prolonged remission.
- Pharmacogenetics facilitates the selection of the most effective treatment option for depression (Tiwari et al., 2022; Oslin et al., 2021).

Literature Review

- **Treatment Response:** Pharmacogenetic testing is more effective than trial and error approach (Rethorst et al., 2017; Han et al., 2018; Vilches et al., 2019).
- **Symptoms Remission: P**harmacogenetic has higher remission rate than 'trial and error' approach (Han et al., 2018; Bousman et al., 2019; Rethorst et al., 2017; Greden et al., 2019).
- **Treatment Tolerability:** Pharmacogenetic testing is associated with fewer side effects than trial and error approach (Westrhenen & Ingelman-Sundberg, 2021; Han et al., 2018; Thase et al., 2019).

Literature Review (Cont')

- GeneSight Pharmacogenetic Guidelines are protocols for analyzing how patients' genetic composition may influence their response to some treatments.
- The GeneSight testing involve a simple cheek swab to collect DNA samples which are then analyzed to determine the best medication.
- The GeneSight medication results: Green (use as directed), yellow (moderate gene-drug interaction), and red (significant drug -drug interaction).
- GeneSight testing is effective in improving health outcomes (Abbott et al., 2018; Corponi et al., 2019; Hays, 2022).

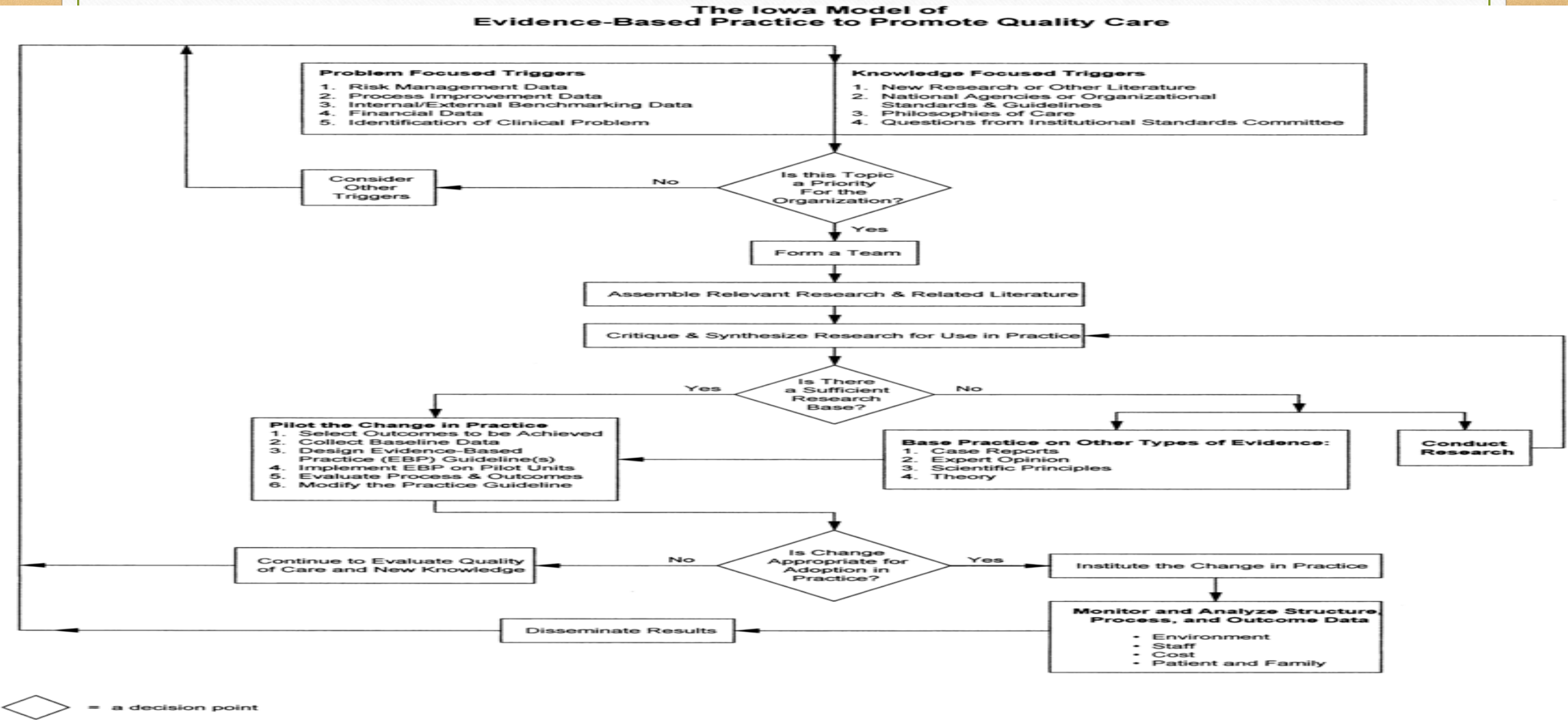
Aim and Objectives

- Aim: To evaluate the effectiveness of incorporating GeneSight pharmacogenetic testing guidelines into psychiatric treatment decisions for adults diagnosed with major depressive disorder.
- Objectives:
  - Introduce GeneSight Guidelines.
  - Conduct Multidisciplinary Training.
  - Enhance Provider Compliance.
  - Mitigate Adverse Outcomes.

Implementation Framework

- The Iowa model was used as the implementation framework for the study.
- The framework is based on eight steps: Identifying triggers, establishing if the problem is the priority, , developing, assessing, and implementing the change, reviewing and analyzing evidence, examining if adequate research exists, piloting the change, and evaluation of the results (Iowa Model Collaborative, 2017).
- The model was selected because it offered a structured approach to planning, implementation, and evaluation of the evidence-based practice change.
- The framework ensures all aspects of the project are systematically addresses.

Implementation Framework (Cont)

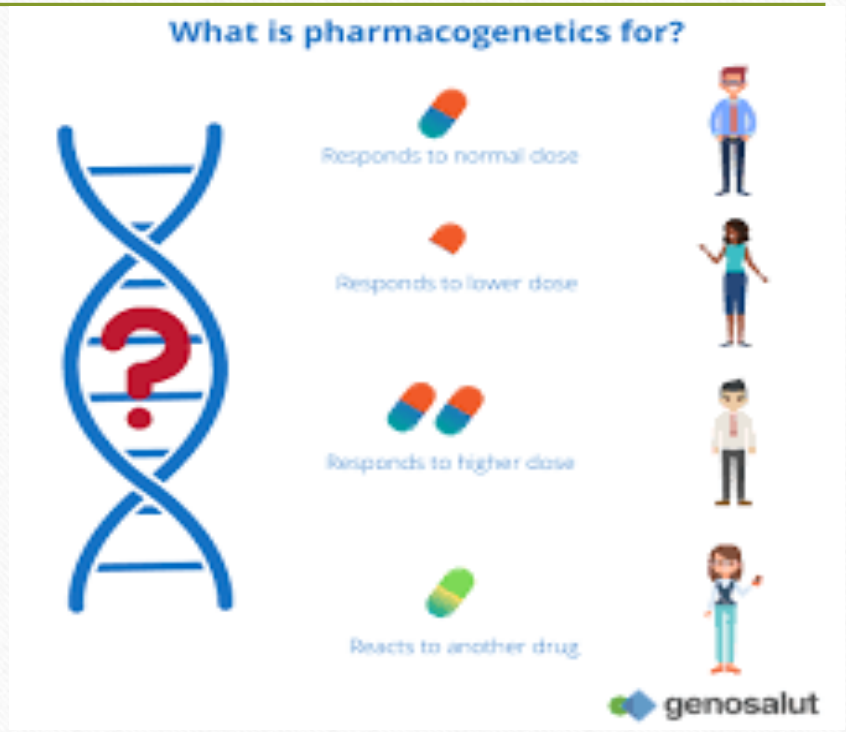


Methodology (Cont’)

- Required resources:
  - GeneSight Testing Guidelines Handbook.
  - Computers.
  - Dedicated Training Room for GeneSight utilization.
  - PowerPoint presentations.

Methodology (Cont’)

- Tools used:
  - Pre- and Post-Knowledge Survey.
  - Chart Audit Tool.
  - PowerPoint Presentation.
  - Patient Health Questionnaire (PHQ-9).
  - Client Satisfaction Questionnaire (CSQ-8).



Population and Setting

- The project was implemented in outpatient psychiatric clinic not affiliated with any healthcare system.
- The clinic provides outpatient mental health services to patients with different psychological disorders.
- Direct population comprised the staff who were educated on the pharmacogenetics guidelines.
- The indirect population was patients with a diagnosis of major depression between the ages of 15 to 70 being treated at the outpatient clinic.

Intervention

- GeneSight Testing guidelines were implemented.
- The guidelines are used to identify the most appropriate medication for patients based on their genetic factors.
- Health care staff at the clinic were educated about GeneSight Testing guidelines.
- Staff used the to guide the identification of most appropriate medication to prescribe to patients diagnosed with depression.

Ethics/Human Subject Protection

- No review from the Touro University Nevada's Institute of Review Board was required because it is a Quality Improvement Project.
- Permission to implement the project at the clinic was obtained.
- No identifiable information were collected.
- Data were protected by limiting access only to the project lead.
- No staff were incentivized or coerced to participate.

Results: Treatment Response

Table 1

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			

Results: Side Effects

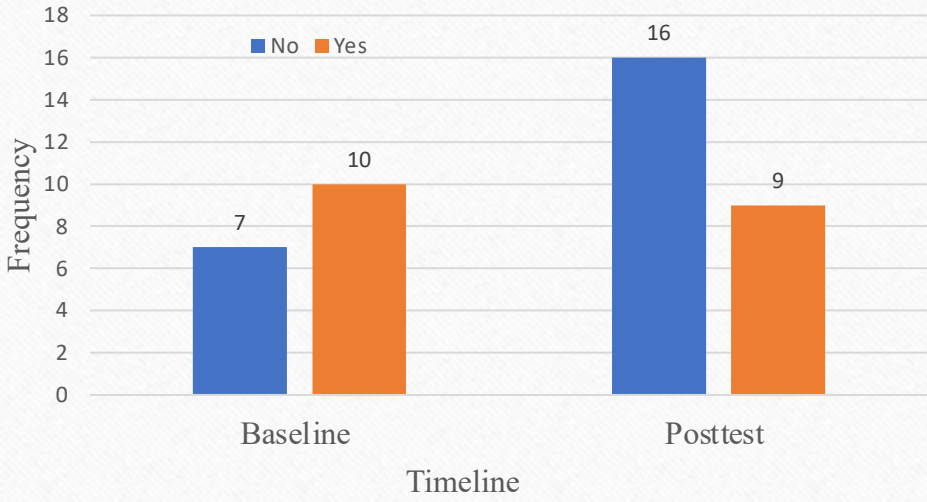
Table 2

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
Posttest	16	9	25		

Figure 1

Chart Showing Patient-Reported Side Effects

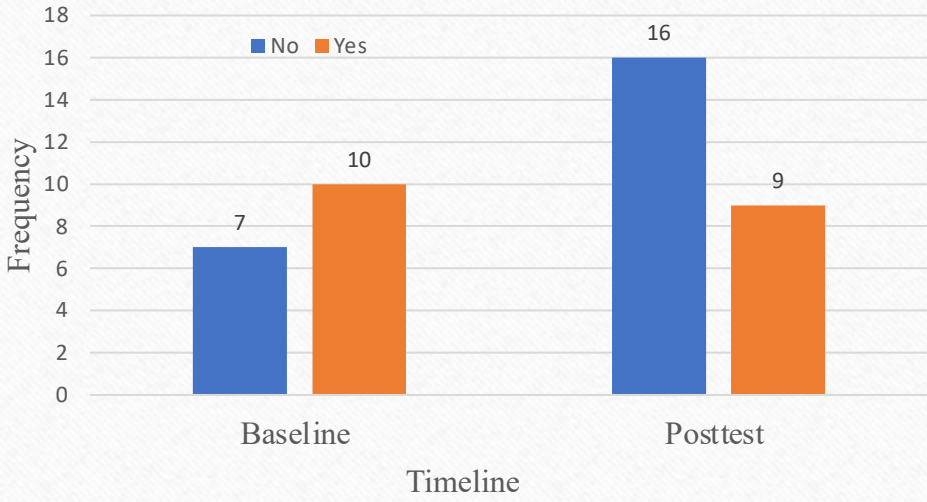


Results: Side Effects

- Out of 17 patients five weeks before the implementation of the intervention, 10 reported at least one side effect of antidepressant, representing a rate of 58.8%.
- out of 25 patients, only 9 reported side effects of antidepressants 5 weeks after the implementation of the intervention, representing a rate of 36%.
- There was a decrease in the rate of reported side effects from 58.8% before to 36% by 38.8% after the implementation of the intervention.

Figure 1

Chart Showing Patient-Reported Side Effects



Results: Patient Satisfaction

Table 3

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

Discussion and Conclusion

- The GeneSight pharmacogenetic testing guidelines were implemented to help providers identify best medication based on patients’ genes.
- Education sessions improved health care providers' familiarity, knowledge, and confidence with GeneSight.
- GeneSight guidelines were effective in improving treatment response, decreasing side effects, and enhancing patient satisfaction with care.
- Pharmacogenetic testing is appropriate in identifying effective medication with few side effects for specific patients based on their genetic factors.

Discussion and Conclusion (Cont')

- Main limitations of this project included the use of a small sample size and a single facility.
- Using GeneSight pharmacogenetic testing may improve the quality of care by enhancing treatment response, decreasing side effects, and improving satisfaction with care.
- The success of this project underscores the need for policy changes to integrate using GeneSight pharmacogenetic testing guidelines as among the care protocols.
- Project will be sustained by integration of the guidelines into care policy and through regular monitoring and evaluations.

References

Aboelbaha, S., Zolezzi, M., & Elewa, H. (2021). Effect of pharmacogenetic-based decision support tools in improving depression outcomes: a systematic review. *Neuropsychiatric Disease and Treatment*, *17*, 2397–2419. https://doi.org/10.2147/ndt.s312966

Campos, A. I., Mulcahy, A., Thorp, J. G., Wray, N. R., Byrne, E. M., Lind, P. A., Medland, S. E., Martin, N. G., Hickie, I. B., & Rentería, M. E. (2021). Understanding genetic risk factors for common side effects of antidepressant medications. *Communications Medicine*, *1*(1), 1-10. https://doi.org/10.1038/s43856-021-00046-8

Chiwaula, C. H., & Jere, D. L. (2022). Experiences of nurse managers and practitioners on implementation of an evidence-based practice intervention. *Health SA = SA Gesondheid*, *27*, 1597. https://doi.org/10.4102/hsag.v27i0.1597

Corponi, F., Fabbri, C., & Serretti, A. (2019). Pharmacogenetics and depression: a critical perspective. *Psychiatry Investigation*, *16*(9), 645–653. https://doi.org/10.30773/pi.2019.06.16

Han, C., Wang, S.-M., Bahk, W.-M., Lee, S.-J., Patkar, A. A., Masand, P. S., Mandelli, L., Pae, C.-U., & Serretti, A. (2018). A pharmacogenomics-based antidepressant treatment for patients with major depressive disorder: Results from an 8-week, randomized, singleblinded clinical trial. *Clinical Psychopharmacology and Neuroscience*, *16*(4), 469–474.

References (Cont’)

Hays, P. (2022). Evidence basis for pharmacogenetic testing in psychiatry. *Journal of Medical*480. https://doi.org/10.9758/cpn.2018.16.4.469

Iowa Model Collaborative, Buckwalter, K. C., Cullen, L., Hanrahan, K., Kleiber, C., McCarthy, L. A. A. (2018). Models for the implementation of evidence-based practice in hospital-based nursing: A narrative review1.

Karrouri, R., Hammani, Z., Benjelloun, R., & Otheman, Y. (2021). Major depressive disorder: Validated treatments and future challenges. *World Journal of Clinical Cases*, *9*(31), 9350-9367. https://doi.org/10.12998/wjcc.v9.i31.9350

Oslin, D. W., Lynch, K. G., Shih, M. C., Ingram, E. P., Wray, L. O., Chapman, S. R., ... & PRIME Care Research Group. (2022). Effect of pharmacogenomic testing for drug-gene interactions on medication selection and remission of symptoms in major depressive disorder: The PRIME care randomized clinical trial. *Journal of American Medical Association*, *328*(2), 151-161. https://jamanetwork.com/journals/jama/fullarticle/2794053

References (Cont')

Thase, M. E., Parikh, S. V., Rothschild, A. J., Dunlop, B. W., DeBattista, C., Conway, C. R., Forester, B. P., Mondimore, F. M., Shelton, R. C., & Macaluso, M. (2019). Impact of pharmacogenomics on clinical outcomes for patients taking medications with gene-drug interactions in a randomized controlled trial. *The Journal of Clinical Psychiatry*, *80*(6). https://doi.org/10.4088/JCP.19m12910

Titler, M. G. (2018). Translation research in practice: An introduction. *The Online Journal of Issues in Nursing*, *23*(2), 1. https://doi.org/10.3912/OJIN.Vol23No02Man01

Tiwari, A. K., Zai, C. C., Altar, C. A., Tanner, J., Davies, P. E., Traxler, P., Li, J., Cogan, E. S., Kucera, M. T., Gugila, A., Braganza, N., Emmerson, H., Zai, G., Müller, D. J., Levitan, R., Kloiber, S., Daskalakis, Z. J., Frey, B. N., Bowen, J. M., . . . Kennedy, J. L. (2022). Clinical utility of combinatorial pharmacogenomic testing in depression: A Canadian patient- and rater-blinded, randomized, controlled trial. *Translational Psychiatry*, *12*(1), 1-10. https://doi.org/10.1038/s41398-022-01847-8

Westrhenen, R., & Ingelman-Sundberg, M. (2021). Editorial: From Trial and Error to Individualized Pharmacogenomics-Based Pharmacotherapy in Psychiatry. *Frontiers In Pharmacology*, *12*. https://doi.org/10.3389/fphar.2021.725565