EXPLORING PHARMACOGENOMIC TESTING AND CLINICAL DECISION-MAKING IN LOCAL MENTAL HEALTH FACILITIES

By:

Nicole Feltz

Submitted in partial fulfillment of the
requirements for Departmental Honors in
the Department of Nursing
Texas Christian University
Fort Worth, TX

May 6, 2019

EXPLORING PHARMACOGENOMIC TESTING AND CLINICAL DECISION-MAKING IN LOCAL MENTAL HEALTH FACILITIES

Project Approved:

Supervising Professor: Lynnette Howington, DNP, RNC, WHNP-BC, CNL

Department of Nursing

Danielle Walker, PhD, RN, CNE

Department of Nursing

Molli Crenshaw, M.S.

Department of Biology

ABSTRACT

This research project addresses the clinical question: How are local mental health facilities using pharmacogenomic testing information to make clinical decisions? In order to answer this question, the student investigator conducted a descriptive study to explore the use of pharmacogenomic testing by local mental health facility providers. The student investigator and faculty chair created a data form including demographics and survey questions that included both open and closed-ended questions. The survey was sent to 40 providers at various MHMR (My Health My Resources) clinics. Nurse practitioners and physicians were asked questions pertinent to how they felt pharmacogenomic testing has impacted their clinical decisions and patient experience. Survey results reveal that very few providers implement pharmacogenomic testing regularly. Providers expressed concerns such as lack of scientific evidence, high cost, and lack of new information for treatment as reasons testing is not routine. Although a limited sample was used, the findings suggest a need for further research to determine barriers to pharmacogenomic testing and incorporation of results into clinical decision-making.

TABLE OF CONTENTS

Exploring Pharmacogenomic Testing and Clinical Decision-Making in Local Mental Health Facilities

This project aims to address the significance of pharmacogenomic testing and how it is used to guide best practice and clinical decision-making in mental health clinics. Existing research provides a framework of the benefits of genetic testing and how it can hypothetically be used in clinical settings; researchers and health care professionals often face the challenge of how to implement testing and training required in order to interpret pharmacogenomic testing results for patients (Takahashi et al., 2017). Studies also explain how genetic polymorphisms may produce alternations in metabolism or pharmacokinetics of some drugs or drug classifications. To date, over 150 Federal Drug Administration (FDA) labels contain guidance on genetic testing in order to better inform drug selection, dosing, and toxicity (David et al., 2015). A positive association exists between genetic polymorphisms (a variation in alleles) and risk of toxicity, tardive dyskinesias, and Parkinsonism in patients who are receiving antipsychotic medication regimen (Cavallari, Jeong, & Bress, 2011). Tardive dyskinesia is a neurological syndrome marked by slow, rhythmical, stereotyped movements, either generalized or in single muscle groups, which occur as an undesired effect of therapy with certain drugs (Venes, D., & Taber, C. W., 2013). The integration of pharmacogenomic testing in clinical practice presents a possible improvement in this area; testing typically involves a saliva test with results within two days to a week. However, current research specific to the mental health population is sparse due mostly to the complex nature of patient adherence and extensive medication regimens. The overarching goal of many researchers is to use genomics to guide drug therapy and efficacy as well as avoid adverse drug events (Bielinski et al., 2014).

Clinical Question

This research project addresses the clinical question: How are local mental health facilities using pharmacogenomic testing information to make clinical decisions? In order to answer this question, the student investigator conducted a descriptive study to explore the use of pharmacogenetics testing by local mental health facility providers, which include physicians and nurse practitioners.

Theoretical Framework

According to Rogers (2003), "diffusion is the process by which an innovation is communicated through certain channels over time among members of a social system" (p. 5). The messages communicated through diffusion of innovation are new ideas and a kind of alteration in a social system. Since an idea is new, there is an element of uncertainty about adoption. Rogers (2003) defines uncertainty as "the degree of the number of alternatives perceived by an individual or group with respect to the occurrence of an event and the probability of alternatives". The uncertainty of an idea suggests a lack of predictability, structure, or information; the most certain way to reduce uncertainty is to provide more information.

The adoption of a new idea, or diffusion of innovation, is complicated and may take a long period of time before the population adopts the idea. Additionally, whether an idea is accepted or rejected, social change within a system occurs due to the consequences from the adoption or rejection of the idea. Rogers (2003) defines diffusion as both planned and spontaneous spread of ideas. Rogers further explains his theoretical framework with four main elements including innovation, communication channels, time, and a social system. Innovation is a new idea, practice or object that typically contains five characteristics.

The characteristics of innovation include a relative advantage, compatibility, complexity, trialability, and observability. The relative advantage of an innovation is defined as the perceived benefit, measured in terms specific to the innovation such as economic terms, social prestige, or convenience (Rogers, 2003). Compatibility is the consistency with values, experiences, or needs already in place by the population or adopters of the innovation. Complexity is the perceived difficulty of the innovation to understand and apply by the user. The trialability refers to the degree to which the innovation can be implemented or experimented with, while observability is how visible the results are to others outside direct use of the innovation. The more ideal an innovation fits within these characteristics (i.e low complexity, high compatibility), the more likely users or participants are to adopt the innovation (Rogers, 2003).

. Diffusion is a very social process; communication channels convey information and evaluation of an innovation, mostly dependent on subjective information from one person to another. Objective information from studies is important as well; however, most people do not evaluate studies, but instead communicate study findings and evidence with others subjectively. Time of diffusion involves how long the decision-making process takes within a population. The decision-making process includes knowledge, persuasion, decision, implementation, and confirmation of the innovation (Rogers, 2003). At the end, the innovation-decision process typically leads to either adoption or rejection of an idea.

The social system involved in an innovation is an interrelated unit engaged in joint problem solving and accomplishment of a common goal. The structure of this social system affects diffusion and is defined as the patterned arrangements of the units in a system. A developed social system structure is predictable and gives individuals positions and orders to

carry out. The structure can both facilitate and impede the process of diffusion dependent on the social system. Decisions of the acceptance or rejection of an innovation happen in three ways: optional, collective, or authority (Rogers, 2003). Optional decisions are made by an individual and not influenced by other members of the system. Collective decisions are made by the members within a system and typically require a consensus. Authority decisions are made by few or the minority of powerful individuals within a system and do not require input from individual members (Rogers, 2003).

Operational Definitions

In this study, pharmacogenomic testing serves as the innovation. The student investigator administered surveys to health care providers asking their opinions regarding implementation of pharmacogenomic testing and the perceived impact of results on patient care management. The characteristic of innovation as defined by Rogers (2003), "compatibility" was used to explore the degree to which pharmacogenomic testing is perceived as consistent with values and needs of health care workers and patients within the mental health facility. Rogers' (2003) characteristic of innovation "complexity" was used to explore the perceived difficulty of pharmacogenomic testing to understand and apply among providers in the mental health facility.

Review of the Literature

The student researcher used the databases Medline, CINAHL, Joanna Briggs Institute, Scopus, and Nursing & Allied Health Database (ProQuest) to find literature using terms and combinations such as *personalized medicine, pharmaco** AND *test, antipsychotics, antidepressants, patient outcomes, mental health, drug dosage, clinical practice* AND *genetic testing.* The literature appraisal varied in levels of evidence and quality (Johns Hopkins, n.d.) (Appendix A)

Current Pharmacogenomics

Existing literature searched and reviewed what is known about pharmacogenomic testing and identifies the risks associated with basing medicine on a "one size fits all" approach (Abul-Husn, N. S., et al., 2014). Consequently, suggested doses of prescribed medications frequently lead to adverse effects, intolerance, or reduced effects. Although the suggested dose works for some, a patient-centered approach is desired and made possible to some effect by pharmacogenomic testing (Bielinski et al., 2014).

Pharmacogenomic testing encounters some hesitancy by providers due to scrutiny of genetic testing for diseases and associated disease risk factors. Cavallari, Jeong, and Bress (2011) reported genotyping for specific variants found in the P450 chromosome may carry less risk for discrimination and ethical concern compared to disease-association testing, but research is still limited. Lack of research can partially be attributed to the difficulty of identifying a valid sample of patients on mental health regimens; common mental health regimens include antidepressants or antipsychotics. Specifically, patients who are newly diagnosed with a mental illness and have not tried other medications are challenging to find. Patients with chronic mental health issues most likely have an extensive drug regimen history, which makes research in this population especially difficult (Malhotra, Zhang, & Lencz, 2012).

Identified Challenges

Much of the literature also explains challenges and shortcomings of current pharmacogenomics. One of the most prominent challenges is the lack of clinical utility data to suggest a necessary change in best practice, which introduces the need for more rigorous evaluation (Takahashi et al., 2017). Another common challenge researchers and providers face is lengthy return of results, which in turn affects implementation of results into practice.

However, certain biotech companies have started to develop and use point of care (POC) testing, which gives quicker test results, allowing providers to make decisions about medications (Abul-Husn, N. S., et al., 2014). Even if rapid testing were more readily available, very few health care settings provide professional guidelines regarding genomics to guide providers as to when and to what extent pharmacogenomic testing is necessary (Bielinski et. al., 2014). Additionally, the complexity of genomic testing is beyond the scope of practice for many health care professionals. For example, a substantial amount of patients with mental health conditions require polypharmacy, or concurrent use of a large amount of drugs, likely for multiple diagnoses that require treatment (McClay et al., 2011). This complexity makes interpretation of results, clinical decision-making, and acceptance of pharmacogenomic genomic testing by providers extremely difficult. Many current researchers state that investment in informatics and provider education is necessary to move forward in implementation of pharmacogenomic testing.

Current literature suggests evident gaps in research regarding success in basing mental health medication regimens on pharmacogenomic testing. However, evidence of success in other realms exists. The current research identifies four types of metabolizers: poor, intermediate, extensive, or ultrarapid (Malhotra et al., 2012). Specifically, anticoagulants such as Warfarin and antiplatelets such as Clopidogrel are widely investigated due to the known risks of over or under dosing dependent on their patients' metabolism rate. Considerable research in the use of certain beta-blockers and proton pump inhibitors also exists (Malhotra et al., 2012). However, pharmacogenomic testing to predict antipsychotic efficacy exploring CYP2D6 polymorphisms is limited (Cavallari et al., 2011).

Pharmacogenomic testing is becoming more prevalent in health care; however, there are still significant gaps in research. Ethical concerns of genomic testing as well as lack of knowledge

about interpretation of results contribute to the gap in the literature. In addition, researchers struggle to find eligible participants for studies specific to pharmacogenomic testing efficacy (Malhotra, Zhang, & Lencz, 2012).

Methods

Design

This is a descriptive study using anonymous survey methods designed for providers at several local mental health facilities to determine how they are using the results of pharmacogenomic testing to support medication management.

Procedures for Recruitment

Following Texas Christian University Nursing Review Board approval, the student investigator created an online survey via Survey Monkey and sent a link to the Program Director at MHMR to forward to providers. The email included a cover letter within the consent form document (Appendix C) explaining the study further and instructions on how to complete the survey. The survey was anonymous and the providers' completion of the survey served as their voluntary consent. Inclusion criteria are providers in MHMR Tarrant County clinics who are at least 18 years old, and make clinical decisions or directly impact patient care. Exclusion criteria are staff under 18 years old and staff with no direct contact or involvement with patient care decisions. The student investigator had the opportunity to establish relationships with providers last summer (2018) through an externship within various Tarrant County clinics.

Data Collection

The survey was the primary form of data collection. Prior to data collection, the student investigator and faculty chair created a data form including demographics and survey questions (Appendix D). The survey included both open and closed-ended questions.

Data Analysis

Descriptive statistics were used for demographic data and any questions that required categorical or dichotomous answers. The open-ended questions were analyzed using qualitative methods to learn more about the experience of collecting and using pharmacogenomic data to make clinical decisions, the ease of use, and benefits of implementation.

Results

Of the 13 respondents, the age of providers ranged from 26 to 64, with an average of 45 years of age. Eighty-five percent of respondents were female and the average time as a provider was 12 years. Most of the providers received information on pharmacogenomic testing from company representatives who visited the office or contacted the providers directly. Common barriers to testing implementation identified were cost or insurance, lack of strong scientific evidence, lack of clinical utility, and difficulty of incorporation of the process into a normal workflow. However, no resistance by patients was identified and providers stated that testing takes about five minutes, and results are typically received back within a week. Results are reported as "easy" (4) or "neither easy nor difficult" (2) to interpret to patients via the provider. Overall, very few providers (3) changed medication regimens because of test results; the providers who changed medication regimens reported less side effects and better efficacy with medication change. Five providers reported testing as helpful to their current practice.

Discussion

The results from the survey suggest very few providers in MHMR utilize pharmacogenomic testing products for their patients. Overall, providers appear knowledgeable of testing implications and how to test and read results for patients. Although providers acknowledge potential benefits of testing, barriers such as lack of insurance coverage affect

incorporation of testing into practice. Pharmacogenomic testing is not utilized on a regular basis within MHMR, which affects implementation related to a break in normal workflow. More research on the benefits and efficacy of testing is needed to incorporate pharmacogenomic testing into patient care.

Limitations

Limitations within this study include a low response rate (32.5%) as well as the number of skipped questions by providers. The survey included both open and closed-ended questions; many of the open-ended questions were left unanswered, however, almost all the closed-ended questions attained a response. In addition, contact via email may hinder response rate as the providers work with incredibly busy schedules.

Recommendations

For future research studies, the investigators recommend a more direct form of contact such as phone interviews or focus groups. This would encourage improved communication and participation particularly with open-ended questions.

Implications

More research on the efficacy and satisfaction rates of pharmacogenomic testing is needed. Although this survey suggests testing is generally reported as easy to perform and interpret, barriers such as cost interfere with widespread testing. The investigators suggest further studies to address specific barriers and possible solutions to these barriers.

Conclusion

Overall, providers have mixed attitudes of testing, and the use of testing in MHMR varies as related to prescribing practices. Although testing is reported to be a short process for patients

and providers, results may or may not give new information. In conclusion, further research is needed on the impacts of pharmacogenomic testing related to patient outcomes.

References

Abul-Husn, N. S., Owusu Obeng, A., Sanderson, S. C., Gottesman, O., & Scott, S. A. (2014). Implementation and utilization of genetic testing in personalized medicine. *Pharmacogenomics and Personalized Medicine, 7,* 227-240. doi:10.2147/PGPM.S48887

Bielinski, S., Olson, J., Pathak, J., Weinshilboum, R., Wang, L., Lyke, K., & Kullo, I. (2014). Preemptive genotyping for personalized medicine: Design of the right drug, right dose, right time-using genomic data to individualize treatment protocol. *Mayo Clinic Proceedings, 89*(1), 25-33. doi:10.1016/j.mayocp.2013.10.021

Cavallari, L. H., Jeong, H., & Bress, A. (2011). Role of cytochrome P450 genotype in the steps toward personalized drug therapy. *Pharmacogenomics and Personalized Medicine*, 4123-4136. doi:10.2147/PGPM.S15497

Dang, D., & Dearholt, S. (2017). Johns Hopkins nursing evidence-based practice: model and guidelines. 3rd ed. Indianapolis, IN: Sigma Theta Tau International.

David, S. P., Johnson, S. G., Berger, A. C., Feero, W. G., Terry, S. F., Green, L. A., & Phillips, R. J. (2015). Making personalized health care even more personalized: Insights from activities of the IOM genomics roundtable. *Annals of Family Medicine*, *13*(4), 373-380. doi:10.1370/afm.1772

Malhotra, A., Zhang, J., & Lencz, T. (2012). Pharmacogenetics in psychiatry: Translating research into clinical practice. *Molecular Psychiatry, 17*(8), 760-769. doi:10.1038/mp.2011.146

McClay J, Adkins D, Aberg K, Stroup S, Perkins D, Vladimirov, V. (2011). Genome-wide pharmacogenomic analysis of response to treatment with antipsychotics. *Molecular Psychiatry*, *16*, 76–85. doi:10.1038/mp.2009.89

Rogers, E. M. (2003). *Diffusion of innovations*. New York, NY: Simon and Schuster.

Takahashi, P. Y., Ryu, E., Pathak, J., Jenkins, G. D., Batzler, A., Hathcock, M. A., Bielinski, S. J. (2017). Increased risk of hospitalization for ultrarapid metabolizers of cytochrome P4502D6. *Pharmacogenomics and Personalized Medicine, 10*, 39-47 doi:10.2147/PGPM.S114211

Venes, D., & Taber, C. W. (2013). *Taber's cyclopedic medical dictionary, 22.* Philadelphia: F.A. Davis.

Zhang, J., Lencz, T., & Malhotra, A. (2010). D-2 receptor genetic variation and clinical response to antipsychotic drug treatment: A meta-analysis. *American Journal of Psychiatry, 167*(7), 763-772. doi:10.1176/appi.ajp.2009.09040598

Appendix A

Article Level and Quality of Evidence

Author/Date	Type of Study	Level of Evidence	Quality Rating
Abul-Husn, N. S., et al. (2014)	Literature Review	V	Good
Bielinski et al. (2014)	Non Experimental - descriptive	III	High
Cavallari, L. H., Jeong, H., & Bress, A. (2011)	Literature Review	V	High
David et al. (2015)	Clinical Practice Guidelines	IV	High
Malhotra, A., Zhang, J., & Lencz, T. (2012)	Literature Review	V	High
McClay et al. (2011)	Experimental Study (RCT)	I	High
Takahashi et al. (2017)	Non Experimental (Quantitative Descriptive)	III	High
Zhang, J., Lencz, T., & Malhotra, A. (2010)	Meta-Analysis	I	High

Model based on: Dang, D., & Dearholt, S. (2017). Johns Hopkins nursing evidence-based practice: model and guidelines. 3rd ed. Indianapolis, IN: Sigma Theta Tau International.

Appendix B

Texas Christian University
Fort Worth, Texas

DEPARTMENTAL PROTOCOL REVIEW (Student Version) HUMAN SUBJECTS

The TCU Institutional Review Board (IRB) is responsible for protecting the welfare and rights of the individuals who are subjects of any research conducted by faculty, staff, or students at TCU. Approval by the IRB must be obtained prior to initiation of a project, whether conducted on-campus or off-campus. Student research is encouraged at both the undergraduate and graduate level. Only Protocol Reviews submitted by TCU students as the Principal Investigator will be accepted for review by the Departmental IRB committee. Protocol Reviews submitted by faculty as Principal Investigators or projects that are considered above "minimal risk" need to be submitted to the TCU IRB Committee not the Departmental IRB Committee.

Please submit this protocol electronically to the Chair of your Department DRB committee. Also submit a consent document, HIPAA form if applicable, Protection of Human Subjects Training certificates, and any questionnaires, or other documents to be utilized in data collection. A template for the consent document and HIPAA form and instructions on how to complete the consent are available on the HCNHS website (www.harrisresearch.tcu.edu) at the Student Research link. Once the DRB protocol has been submitted, you must allow at least **two weeks** for the review and approval letter to be received.

1. **Date:** January 31, 2019 – January 31, 2020

2. **Study Title:** Exploring Pharmacogenomic Testing and Clinical Decision-Making in Local Mental Health Facilities

3. **Principal Investigator - must be a TCU student:** Nicole Feltz

4. **Department:** Harris College of Nursing and Health Sciences – Nursing

5. **Other Investigators - list the faculty mentor first as well as other faculty, staff, and students conducting the study including those not affiliated with TCU:** Dr. Lynnette Howington

6. **Project Period:** 1 year

7. **Funding Agency: (if not applicable - put "NA")** NA

8. **Amount Requested From Funding Agency: (if not applicable - put "NA")** NA

9. **Due Date for Funding: (if not applicable - put "NA")** NA
10. **Purpose - Describe the objectives and hypotheses of the study and what you expect to learn or demonstrate:**

    This project aims to address the significance of pharmacogenomic testing and how it can guide best practice and clinical decision-making. This research project will address the clinical question: How are local mental health facilities using pharmacogenomic testing information to make clinical decisions? In order to answer this question, the student investigator will conduct a descriptive study to explore the use of pharmacogenetics testing by local mental health facility staff such as physicians and nurse practitioners.

11. **Background - Describe the theory or data supporting the objective(s) of the study and include a bibliography of key references as applicable:**

    Existing research provides a framework of the benefits of genetic testing and how it can hypothetically be used in clinical settings; researchers and health care professionals often face the challenge of how to implement testing and training required in order to interpret pharmacogenomic testing results for patients. Studies also explain how genetic polymorphisms may produce alternations in metabolism or pharmacokinetics of some drugs or drug classifications. To date, over 150 Federal Drug Administration (FDA) labels contain guidance on genetic testing in order to better inform drug selection, dosing, and toxicity (David et al., 2015). A positive association exists between genetic polymorphisms and risk of toxicity, tardive dyskinesias, and Parkinsonism in patients who are receiving antipsychotic medication regimen (Cavallari, Jeong, & Bress, 2011). The integration of pharmacogenomic testing in clinical practice presents a possible improvement in this area. However, current research specific to the mental health population is sparse due mostly to the complex nature of patient adherence and extensive medication regimens. The overarching goal of many researchers is to use genomics to guide drug therapy and efficacy as well as avoid adverse drug events (Bielinski et al., 2014)

    References:

Bielinski, S., Olson, J., Pathak, J., Weinshilboum, R., Wang, L., Lyke, K., & Kullo, I. (2014). Preemptive genotyping for personalized medicine: Design of the right drug, right dose, right time-using genomic data to individualize treatment protocol. *Mayo Clinic Proceedings, 89*(1), 25-33. doi:10.1016/j.mayocp.2013.10.021

Cavallari, L. H., Jeong, H., & Bress, A. (2011). Role of cytochrome P450 genotype in the steps toward personalized drug therapy. *Pharmacogenomics and Personalized Medicine*, 4123-4136. doi:10.2147/PGPM.S15497

David, S. P., Johnson, S. G., Berger, A. C., Feero, W. G., Terry, S. F., Green, L. A., & Phillips, R. J. (2015). Making personalized health care even more personalized: Insights from activities of the IOM genomics roundtable. *Annals of Family Medicine*, *13*(4), 373-380. doi:10.1370/afm.1772

McClay J, Adkins D, Aberg K, Stroup S, Perkins D, Vladimirov, V. (2011). Genome-wide pharmacogenomic analysis of response to treatment with antipsychotics. *Molecular Psychiatry*, *16*, 76–85. doi:10.1038/mp.2009.89

Zhang, J., Lencz, T., & Malhotra, A. (2010). D-2 receptor genetic variation and clinical response to antipsychotic drug treatment: A meta-analysis. *American Journal of Psychiatry, 167*(7), 763-772. doi:10.1176/appi.ajp.2009.09040598

12. **Participant Population - Describe the characteristics of the participant population including the inclusion and exclusion criteria and the number of participants you plan to recruit:**
    Inclusion criteria are staff in MHMR Tarrant County clinics who are at least 18 years old, make clinical decisions or directly impact patient care. Exclusion criteria are staff under 18 years old and staff with no direct contact or involvement with patient care decisions. There will be up to 60 participants.

13. **Recruitment Procedure - Describe your recruitment strategies including how the potential subjects will be approached and precautions that will be taken to minimize the possibility of undue influence or coercion.**
    The student investigator will email MHMR providers a survey link through a staff manager offering participation. The email will include a brief cover letter (consent form document) explaining the study further and instructions on how to complete the survey. The MHMR providers will then complete the survey, and the student will receive the completed surveys back anonymously. In order to minimize the possibility of influence or coercion, the student investigator will not contact the providers directly.

14. **Consenting Procedure - Describe the consenting procedure, whether participation is completely voluntary, whether the participants can withdraw at any time without penalty and the procedures for withdrawing, whether an incentive (describe it) will be offered for participation. If students are used as subjects, indicate an alternative in lieu of participation if course credit is provided for participation. If a vulnerable population is recruited, describe the measures that will be taken to obtain surrogate consent (e.g., cognitively impaired subjects) or assent from minors and permission from parents of minors.**
    The survey will be anonymous and the staff's completion of the survey will serve as their voluntary consent. The participants can withdraw with no penalty by notifying the investigator in writing. No incentive is offered for participation.

15. **Study Procedures - Provide a chronological description of the procedures, tests, and interventions that will be implemented during the course of the study. Indicate the number of visits, length of each visit, and the time it would take to undergo the various tests, procedures, and interventions. If blood or tissue is to be collected, indicate exactly how much in simple terms. Flow diagrams may be used to clarify complex projects.**
    The student investigator and faculty chair created a data form including demographics and survey questions (see attached). The survey will include both open and closed-ended questions. The student investigator will email the survey link (via Survey Monkey) to the staff manager who will forward it to the MHMR providers. The email will include a brief cover letter (consent form document) explaining the study further and instructions on how to complete the survey. The one-time survey is expected to take about 20 minutes to complete. The MHMR providers will complete the survey, and the student will receive the completed surveys back anonymously.

16. **Data Analyses - Describe how you will analyze your data to answer the study question.**

Descriptive statistics will be used for demographic data and any questions that require categorical or dichotomous answers. The open-ended questions will be analyzed using qualitative methods to learn more about the experience of collecting and using pharmacogenomic data to make clinical decisions, the ease of use, and benefits of implementation.

17. **Potential Risks and Precautions to Reduce Risk - Indicate any physical, psychological, social, or privacy risk which the subject may incur. Risk(s) must be specified. Also, describe what measures have been or will be taken to prevent and minimize each of the risks identified. If any deception is to be used, describe it in detail and the plans for debriefing.**
    The potential risk is that privacy could be breached as some comments may identify the provider. No identifying information is required, including name of the staff member. All surveys will be received anonymously by the student investigator, which may minimize this risk. There is no physical, psychological or social risk within this survey.

18. **Procedures to Maintain Confidentiality - Describe how the data will be collected, de-identified, stored, used, and disposed to protect confidentiality. If protected health information is to be re-identified at a later date, describe the procedure for doing so. All signed consents and hard data must be stored for a minimum of 3 years in a locked filing cabinet (and locked room) in the principal investigator's office, or a storage closet at TCU. Your professional society may recommend keeping the materials for a longer period of time.**
    Surveys have no identifying information including the names of staff members. The student investigator will receive the surveys anonymously with no identifying information. All documents will be deleted from the investigator's laptop. While documents are on the laptop, the laptop will be password protected and the only person with the password is the investigator.

19. **Potential Benefits - Describe the potential benefits of the research to the participants, to others with similar problems, and to society.**
    A potential benefit to this research is the opportunity to express ideas and beliefs towards pharmacogenomic testing and contribute to research in this area.

20. **Training for Protecting Human Research Participants – Submit training certificates for all the study investigators. The training link is available on the TCU IRB webpage at: www.research.tcu.edu**

21. **Checklist for the Items that Need to be Submitted: Please combine all the files into one pdf document before submitting the materials electronically to the Departmental Committee Chair. To prevent any delay in the approval of your protocol, use the most recent template for the protocol, consent document, and HIPAA form by downloading them from www.research.tcu.edu or http://www.harriscollege.tcu.edu/research.htm each time you prepare your materials.**

Appendix C

Texas Christian University
Fort Worth, Texas

NURSING CONSENT TO PARTICIPATE IN RESEARCH
Cover Letter – Explanation of Study

Title of Research: Exploring Pharmacogenomic Testing and Clinical Decision-Making in Local Mental Health Facilities

Funding Agency/Sponsor: N/A

Study Investigators: Nicole Feltz and Dr. Lynnette Howington

What is the purpose of the research? This project aims to address the significance of pharmacogenomic testing and how it can guide best practice and clinical decision-making. This project project will address how local mental health facilities are using pharmacogenomic testing information to make clinical decisions.

How many people will participate in this study? There will be up to 60 participants in this study.

What is my involvement for participating in the study? Your involvement in this study is the completion of a survey. Please complete the provided survey and answer the question as best as you can. Please do not include your name.

How long am I expected to be in this study for and how much of my time is required? The time required is about 20 minutes or however long the survey takes to complete.

What are the risks of participating in this study and how will they be minimized? Your identity could be revealed through demographic data, even though the survey is de identified and anonymous. This risk is minimized because completed surveys will be de-identified.

What are the benefits for participating in this study? A potential benefit to completing this survey is that you have the opportunity to express ideas and beliefs towards pharmacogenomic testing and contribute your knowledge in this area.
Will I be compensated for participating in this study? No you will not be compensated for completing the survey.

What is an alternate procedure(s) that I can choose instead of participating in this study? Participation in this survey is voluntary, you can choose whether or not to participate in this survey. There is no alternative procedure.

How will my confidentiality be protected? Names are not required. No identifying information will be placed on the survey and all completed surveys will be kept anonymous.

Is my participation voluntary? Yes your participation is voluntary.

Can I stop taking part in this research? Yes, you may withdraw your participation in this study at any time. However, once all the surveys have been analyzed and the study is closed, you will not be able to withdraw from the study.

What are the procedures for withdrawal? Notify either of the investigators listed below either by email or phone.

Will I be given a copy of the consent document to keep? Yes you will be given a copy of the consent document.

Who should I contact if I have questions regarding the study?
Dr. Lynnette Howington, faculty advisor
(817) 257-7331, l.l.howington@tcu.edu

Nicole Feltz, student investigator
(402) 680-8432, nicki.feltz@tcu.edu

Who should I contact if I have concerns regarding my rights as a study participant?

Dr. Michael Faggella-Luby, Chair, TCU Institutional Research Committee, 817-257-4355

Dr. Tim Barth, TCU Research Integrity Office, 817-257-6429, t.barth@tcu.edu

Your completion of the survey indicates that you have read or been read the information provided above, you have received answers to all of your questions and have been told who to call if you have any questions, you have freely decided to participate in this research, and you understand that you are not giving up any of your legal rights.

Thank you so much for your completion of this survey!

Investigator Name: Nicole Feltz

Appendix D

Demographics

Age:

Gender:

Highest degree achieved:

What is your role at the clinic?

Length of time as a provider:

Length of time in MHMR:

Other experience:

Previous knowledge of pharmacogenomics:

Data Collection Form

Questions: Process and details of pharmacogenomic testing

1. How did you (the provider) get info about testing?
2. How long did it take to incorporate the testing/results?
3. Tell me about any resistance by staff, patients, insurance or other parties
4. Tell me about any other barriers to the implementation of testing

Questions: Results of pharmacogenomics and impact to patients

1. Did you (the provider) change medications because of the results? Explain.
    a. If the answer to question 1 is yes, did you notice a difference in the patient's health status after this change? Did their medication regimen stabilize after this change?

   b. If the answer to question 1 is no, what impacted your decision to keep the current medication regimen?

2. Are the results easy to explain/easy for the patients to understand? Are the results easy to interpret as a provider? Explain.
3. How did the patients react to results and/or the possible change in treatment?
4. Do you (the provider) believe PGX testing is helpful to you in practice and to the improvement of patient care? Why or why not?

Appendix E

Demographics	
Age	Range: 26-64 years
	Average: 45 years
Time as clinician	Range: 1-32 years
	Average: 12 years
Time at MHMR	Range: 1-26 years
	Average: 7.7 years
Degree	Masters: 10 Doctorate: 1 MD: 2

Appendix F

Email Script

Good afternoon,

My name is Nicki Feltz and I am a senior nursing student at TCU. I am also part of the Honors College and will be working to complete my project thesis this semester. This summer I had the opportunity to be an extern in MHMR clinics for 6 weeks and grew my interest in mental health even further. Therefore, my thesis involves exploring how pharmacogenomic testing impacts clinical decision-making in mental health facilities. My advisor Dr. Howington and I were hoping to include MHMR providers as our population, which involves a short anonymous survey. I would greatly appreciate your time to complete the attached survey, which should take about 15 minutes. I have also attached the consent form as well as my full protocol for the study for further clarification of your participation.

Thank you so much for your time and contribution to my project thesis.