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## Metabolic Monitoring for Veterans Newly Prescribed Antipsychotic Medications: Enhancing the Process with Nursing Interventions

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#### Abstract

People who have severe mental illness are known to experience comorbidities and have shorter lifespans than those in the general population. There are many confounding reasons for those in this population to experience comorbidities that shorten their lives. However, it is commonly recognized that metabolic changes caused by medications taken to treat severe mental illness play a major role in the development of comorbidities and early mortality in those who take them. Drug manufacturers and several major organizations recommend the close monitoring of the metabolic status of those prescribed drugs in the class of medications known as antipsychotics. However, literature suggests that metabolic monitoring guidelines are rarely followed. This project explores the role nurses can take to better monitor the metabolic status of those taking antipsychotic medications. With increased monitoring, prescribers have a clearer picture of the client's metabolic status, can be better aware of changes that may occur during initiation and continuation of treatment, and the opportunity to make interventions that lead to better health outcomes. This document describes a process improvement project designed to increase metabolic monitoring among Veterans newly prescribed an antipsychotic medication by providing a nurse case manager, working with a pharmacist, to assist with the metabolic monitoring process. The project is known as the Metabolic Ounce of Prevention. The setting is a mid-south Veterans Administration Medical Center [VAMC] and its outpatient mental health clinics.

## Metabolic Monitoring for Veterans Newly Prescribed Antipsychotic Medications:

### **Enhancing the Process with Nursing Interventions**

#### **Background and significance**

For patients who suffer from severe mental illness, medications are essential to function optimally in occupational, social, and other important aspects of day-to-day life settings. As with all medications, antipsychotic medications come with the potential for undesirable side effects. This drug class is empirically known to cause metabolic abnormalities in some who take them, leading to increased comorbidities and early mortality. The population that takes these medications are known to have significantly shorter lifespans. According to Houben, Janssen, Kellen, Alphen, & Meijel (2018), people with severe mental illness live about 15-20 years less than those in the general population. There are many confounding reasons this aggregate of the population has increased comorbidities and early mortality. For example, there are higher rates of suicide, higher rates of substance abuse, heavy smoking, decreased ability to make optimal healthcare choices, scarcity of healthy foods and housing (Jones et al, 2016).

Anyone taking antipsychotic medications has the common risk of metabolic abnormalities. Pillinger et al. (2019) reported that approximately one-third of those with schizophrenia have metabolic syndrome and that the prevalence of obesity, type 2 diabetes and hyperlipidemia is 3-5 times greater for them than those in the general population. Bomboy, Graber, and Wallace (2020) reported that the broader scope of people with severe mental illness, not just schizophrenia, have a metabolic syndrome prevalence of 52% as compared to the 23% of those in the general population. Working closely with these clients to monitor their metabolic status can help prevent or reduce the metabolic side effects some experience from taking their medications, thus leading to better health outcomes (Cooper et al., 2016). Early efforts of preventing or reducing metabolic side effects are crucial as 84.8% of older adults with severe mental illness have somatic comorbidities (Houben et al., 2019). Bostic & Murphy (2017) emphasized the need for metabolic monitoring due to patients having psychiatric illnesses receiving less frequent medical care. They noted that the psychiatrist is often the only healthcare provider that the patient sees, thereby making close adherence to metabolic monitoring vitally important. In a study by Dennis, Gittner, Payne, & Nugent (2020) greater than 90% of those taking antipsychotics reported having health insurance and a usual place for health care, but only about 76% reported having seen a mental health professional in the past year.

To standardize safe and effective monitoring of the metabolic status of those taking antipsychotic medications, a group of stakeholders assembled in 2004 to develop metabolic monitoring guidelines. The four major organizations were the American Diabetic Association [ADA], the American Psychiatric Association [APA], the American Association of Clinical Endocrinologists [AACE], and the North American Association for the Study of Obesity [NAASO]. Several drug manufacturers and the Food and Drug Administration [FDA] also participated in the joint effort to produce the seminal work that would become the standards of practice for those prescribing antipsychotic medications (Consensus Development, 2004). Table 1 displays the result of the consensus statement. Table 2 displays the guidelines and how they are interpreted for the purposes of this project. The guidelines recommend very close monitoring at the initiation of medication followed by a quarterly check for one year, then annually. This project director focused on the initial 12-week period and references it as the Metabolic Ounce of Prevention Project [MOPP]. It is during this 12-week period that metabolic changes may occur and be noted; consequently, interventions such as adding metformin, or changing antipsychotic medications can be implemented. These interventions following metabolic changes can reduce or

prevent comorbidities affecting the quality of life and length of years lived for those clients whose metabolic status is changed by their medication.

During the first 12-weeks after the initiation of an antipsychotic medication, the guidelines recommend a baseline personal and family history, a belly circumference, a body mass index [BMI], a fasting lipid level, and a fasting glucose level. Further BMI monitoring is recommended at weeks 4, 8 and 12. At week 12, all labs and measurements should be repeated. Although not covered in the scope of this project, the guidelines recommend repeating all measurements quarterly for 1 year, then annually.

Five years after the 2004 guidelines were published, a study was conducted to determine the impact and effectiveness of guideline adherence related to their publication. Morrato et al., (2009) studied 18,876 subjects in a commercial insurance plan to see if metabolic monitoring was performed on patients prescribed antipsychotic medications. This seminal study found that patients in the commercial insurance plan treated with antipsychotic medications had little metabolic monitoring performed. The study revealed that 75% of the subjects had no glucose monitoring at all at baseline and 90% had no baseline lipid levels, even though the consumers had health insurance and were twice as likely to develop diabetes. The study also found that antipsychotic medications were prescribed for off label uses such as sleep and anxiety.

In another study performed by Ward, Wynaden, and Heslop (2018) researchers followed 100 consumers for one year who were taking antipsychotic medications in an outpatient mental health clinic. Of the 100 consumers, 58% had no metabolic data collected at all and only one had all measurements taken as directed by the 2004 consensus guidelines.

These studies reveal a gap in practice that exists in the United States. Similar gaps in practice have been identified globally in other nations such as England, Canada, New Zealand,

and nations in sub-Sahara Africa (Greenwood & Shier, 2016; Hirsch et al., 2018; Keenan et al., 2020; Mugisha et al., 2020). Clearly, having guidelines for monitoring the metabolic status of those taking antipsychotic medications alone has not been effective in assuring guideline adherence.

There have been multiple efforts published in the literature describing various organizational efforts to perform metabolic monitoring on clients taking antipsychotic medications. Staff education is widely mentioned as a better way to ensure that measures are taken. Efforts include having methods such as a clinical decision support tool, pop-up orders that are autogenerated when a specific medication is prescribed, and electronic health records audits. Hibner et al. (2020) discussed a novel approach of using a pharmacist-and-nurse driven protocol. This protocol showed an increase of metabolic data gathered in four of the five categories listed in their study. However, no matter how plentiful the efforts were to increase the use of the metabolic monitoring guidelines, these guidelines were typically underutilized or not used at all (Bozymski, Whitten, Blair, & Overly, 2017; Greenwood & Shiers, 2016; Lee, 2016; Millar, Sands, & Elson, 2014; Stromski, Morrison, & Meehan, 2016).

Prescribers are ultimately responsible for monitoring the metabolic status of their clients. There are various barriers that prevent guideline adherence. These barriers include lack of an organizational policy, lack of a formal process to collect data, failure to designate a person responsible for gathering needed data, autogenerated labs and measurements not utilized, lack of standard data reports compiling the data, and lack of communication between primary care and mental health providers (Barnes et al., 2015; Bombay et al., 2020; Mangurian et al., 2013; Mwebe, 2017; Ward et al., 2017).

#### **Review of Literature**

A review of the literature was conducted using a university's online library, Google Scholar, and the Veterans Administration Medical Center [VAMC] library. Dates were selected between 2013 and 2022. Two exceptions were made for seminal works with the dates of 2004, when the consensus statement introducing the metabolic guidelines was published and 2009, when the study was conducted to evaluate the effectiveness of publishing the consensus statement. Key words and phrases used for the literature search included metabolic monitoring, antipsychotic metabolic, metabolic syndrome, antipsychotic metabolic side effects, metabolic monitoring guidelines antipsychotic, efficacy metabolic monitoring antipsychotic, international metabolic monitoring antipsychotic, metabolic syndrome antipsychotic, psychotropic medication monitoring. Articles were selected if they fell into seven key themes identified for the project. Themes include:

- 1. Increased morbidity and early mortality.
- 2. Metabolic monitoring guidelines.
- Early intervention for metabolic side effects of antipsychotic medication.
- 4. Underutilization of metabolic monitoring for antipsychotic medication.
- 5. Methodologies for increased utilization of metabolic monitoring.
- 6. Primary Care integration.
- 7. Miscellaneous articles pertinent to topic.

Of the plethora of articles that were generated by the above search, then further delineation by the seven key themes, twenty-eight articles were chosen to create the scientific underpinning of the project.

#### **Design and Theoretical Framework**

The PICO question for this project was: Does providing a nurse case manager working closely with the pharmacist to assist in the metabolic monitoring of Veterans newly prescribed antipsychotic medications, as directed by the consensus statement of 2004, increase the volume of data collected, increase provider awareness of guidelines, and improve the health outcomes for Veterans?

The affiliated University has determined that the project does not meet the requirement of research and that IRB oversight is not required. The VA Medical Center, where this project was conducted, also recognized that the project did not meet the definition of research and was deemed an operations activity. Operations activities at the VA includes-certain quality improvement endeavors that are necessary to support the VHA's mission of providing healthcare to the nation's Veterans. The VA's mission of providing healthcare to the nations Veterans is based upon President Lincoln's promise to care for him who shall have bourne the battle by serving and honoring the men and women who are American Veterans (Veterans Administration, 2021). Due to this project's classification as a process improvement project, consent of the participants was not required.

The Metabolic Ounce of Prevention Project used the framework of LEAN Innovation, which is the model the VA uses for process improvements. The process utilizes a PowerPoint template that describes the current state of an operation, describes the future state that is the desired outcome, and then maps out the steps to get to that future state. More information regarding the VA's use of LEAN Sigma Six can be found by following the link https://www.research.va.gov/resources/policies/oro-120811.cfm.

#### **Methodologies and Procedures**

The setting of the Metabolic Ounce of Prevention Project was a Veterans Health Administration Medical Center and its outpatient mental health clinics, all of which are in the mid-south United States. The catchment area of the medical center where the setting took place services over 45,000 Veterans. Sampling of the population was selected from a pharmacy report of Veterans newly started on antipsychotic medication. The formal name of the dashboard used to generate the report is the Identify Medications Newly Prescribed within Previous Month Dashboard [IMNNPPM]. This report populated 144 Veterans who were newly started on an antipsychotic medication or whose antipsychotic medication was changed from one antipsychotic medication to another. Sixty Veterans were identified who were newly started on an antipsychotic medication. The sample of sixty was then randomly divided into two different cohorts with equal numbers of thirty members each. At the end of 12 weeks, 29 Veterans remained in cohort 1 and 28 Veterans remained in cohort 2. One Veteran in each cohort was taken off their antipsychotic medications and one Veteran in cohort 2 died during the project. Cohort 1 was assigned to a nurse case manager to assist with metabolic monitoring using the 2004 consensus guidelines. Cohort 2 did not have a nurse case manager assigned to assist with metabolic monitoring. Cohort 1 was comprised of 24 males and 5 females with a mean age of 50 years, ranging from 27 years to 75. Cohort 2 was comprised of 28 males and 1 female with a mean age of 56 years, ranging from 22 years to 84. Seven medications were identified as newly initiated medications; however, each group was not stratified by specific medications. These medications included aripiprazole, lurasidone, olanzapine, paliperidone, quetiapine, risperidone, and ziprasidone. Table 3 displays each group and the number of Veterans prescribed each of these seven medications, along with gender and average age.

The following set of criteria was utilized to randomly select veterans for each of the two groups from the IMNNPPM report.

• Must be an established Veteran of the Veterans Health Administration. The VA considers a Veteran to be established if the Veteran has had an intake appointment and a treatment plan has been initiated.

• Must be receiving treatment at one of the Veterans Health Administrations community-based outpatient clinics [CBOC's].

• Must have a diagnosis of mental illness, mild, moderate, or severe, and treated by an antipsychotic medication.

• Must have been newly initiated on an Antipsychotic medication,

or, has been changed from one antipsychotic medication to another for any reason i.e., lack of efficacy or due to initial agent not well tolerated.

• Must have at least one follow-up appointment with the prescribing provider.

Due to the random nature of the selection process, and the limited number of subjects, each of the two groups was not matched based on which antipsychotic agents prescribed. All data was de-identified at the end of 12 weeks and no one individual can be traced. All conclusions from the project were based on de-identified information.

## Definitions of metabolic monitoring guidelines for the Metabolic Ounce of Prevention Project

Because the VA accepts both fasting glucose and HgA1c as part of its metabolic monitoring guidelines, the MOPP project accepts both readings; it is the providers' choice of use. Only the period from baseline through 12 weeks was included for the project scope. This 12week period following the initiation of medication is an important window, the time for which this project referenced as the Metabolic Ounce of Prevention period. Baseline measurements, including a personal and family history, body mass index (BMI), belly circumference, blood pressure, cholesterol, and glucose reading or A1C, were counted if they were collected within a three-month period prior to initiation of medication and 2 weeks before or after the intervals of baseline, 4 weeks, 8 weeks, and 12 weeks. For example, if a baseline lipid panel was obtained within three months prior to initiation of medication, this reading was counted as baseline. If the 12<sup>th</sup> week lipid reading was performed within two weeks before or after week 12, it was counted as performed. Table 2 describes the specific metabolic components recommended for monitoring based upon the 2004 guidelines; the measurements, the definition for the project, method of measurement and time frames are included.

#### Intervention

Surveys were directly sent to providers of all eight of the outpatient clinics and the inpatient psychiatric healthcare prescribing team of the mid-south VA Medical Center where the project took place prior to the initiation of the MOPP (See appendix A). There are approximately 30 providers in this group. This survey was attached to an email that contained a brief description of the project and a link to a six-minute video describing the project. Providers were requested to download and fill out the survey and to paste it to a reply email. Because no

provider surveys were returned and only two of the providers notified the case manager of Veterans meeting the project criteria, the project director met with the facility pharmacist and identified Veterans newly placed on an antipsychotic.

The project director served as the nurse case manager assisting with metabolic monitoring using the 2004 guidelines published by the American Diabetes Association (ADA); these guidelines represented the entire consensus group. Each electronic medical record of the thirty Veterans in cohort 1 was audited to assess for the baseline information required by the guidelines. A template was configured to display all data required by the guidelines, to determine if the specific component was completed or not, and the results for the specific components. For example, if the blood pressure was measured, the result of the reading was displayed. If there was missing data, the word *pending* was used to denote the information had not yet been collected. The template also contained the dates of the four-week intervals and what specific data was required for weeks 4, 8, and 12. The template was then transferred to each individual prescribing provider via encrypted email for review. After all templates were recorded for the twenty-nine Veterans in cohort 1 and sent to the prescribing providers, the project director divided clinical time into two areas of focus, collecting missing baseline data, followed by collecting data required by the guidelines at the required intervals, including week 4, week 8 and week 12 when all measurements should be repeated.

For cohort 1, there was an attempt to collect any missing baseline information notifying the prescribing provider and clinic nurse of the missing data. The focus then changed to setting up the collection of the recommended data to be collected at weeks 4, 8, and 12. A medical record review was conducted by the project director to assess for lab orders and future appointments. If no lab appointment or lab orders were found, the project director, serving as the

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nurse case manager, filled out lab orders and sent them to the prescribing provider for a signature. A return to clinic order was accompanied to ensure the labs would be collected. A notice would then be sent to the clinic nurse, alerting them that the Veteran would be in the clinic for a lab draw and would need a blood pressure, weight, and belly circumference obtained prior to the Veteran leaving the clinic. Upon completion of the 12<sup>th</sup> week of the initiation of an antipsychotic medication, a two-week period was given for the collection of any missing measurements. A second template was designed to display all 12 weeks of data collected. Where data was missing, the words *not assessed* were used to indicate the data was missing. The templates were then copied into the Veterans electronic health records and forwarded to the prescribing provider for review.

#### **Data Analysis**

Following the completion of the 12<sup>th</sup> week of all 57 members of the two cohorts, the following analyses were performed:

- The percentage of data collected at baseline, weeks 4, 8, and 12. These were compared to assess the efficacy of having a nurse case manager to oversee metabolic monitoring of those taking antipsychotic medications.
- Baseline information was averaged in both groups and compared with the 12<sup>th</sup> week measurements and compared within each group.
- Baseline information was averaged in both groups. Week 12 information was averaged, and the two groups' data was compared between the two groups.
- The baseline and post-intervention providers' surveys compared to measure the intervention's ability to raise providers awareness of the guidelines.

• Potential for improved health outcomes with patient-specific interventions for detected metabolic abnormalities.

#### Results

#### Volume of data collected

At the end of the 12<sup>th</sup> week, cohort 1 had 67.7% of the data required to meet the 2004 metabolic guidelines collected. In contrast, cohort 2, who did not have a nurse case manager working with the pharmacist, had 36.2% of the data required by the 2004 guidelines. This represents a 53.8% increase in the amount of data that was collected by having a nurse case manager/pharmacist assist with the metabolic monitoring of Veterans newly prescribed an antipsychotic medication. Table 4 displays the total volume of data that was collected for each of the two groups during the entire 12-week period. Tables 5-8 compare groups' volume of data by categories. Belly circumference was not measured in either group, which is addressed in the limitations section.

#### **Provider Awareness of Guidelines**

None of the prescribing providers returned the projects surveys. At the end of the project, there was no data to be compared and therefore no after-project survey was sent to the providers. This is a limitation of the project that is addressed in the limitations section.

#### **Health Outcomes**

Metabolic monitoring is designed to identify metabolic changes in the individual participant. There were four participants who showed an increase in one of the four measurements that could have triggered an intervention to mitigate the increase (see APPENDIX B). There was one participant who showed decreasing BMI after being switched from one antipsychotic to another antipsychotic medication (see APPENDIX B and C).

#### **Detection of Increase in BMI**

Participants T16 and T29 had increases in their BMIs greater than 4 kg/m<sup>2</sup>; approximately greater than a 10% increase in BMI. Participant T16 began with a BMI of 31.47 and at the end of the 12<sup>th</sup> week following the initiation of medication had a BMI of 35.31. Participant T29 began the project with a BMI of 27.43 and at the end of the 12<sup>th</sup> week had a BMI of 32.15. According to Cooper et al., 2016, for every increase of 1kg/m<sup>2</sup> in the BMI, the likelihood of developing diabetes increases by 8.3%. Using this information as a guide, participants T16 and T29 have approximately a 33.2% increased risk of developing diabetes than before they were initiated on an antipsychotic medication. Participant T29 also had an increase in HgA1c from 4.8 to 5.3 by the end of the 12<sup>th</sup> week. By detecting this early change in BMI and HgA1c, the clinician could then take the appropriate actions to prevent or reduce further metabolic damage. Cooper et al., (2016) list the following possible interventions for weight gain and insulin resistance caused by an antipsychotic medication:

- Begin with lifestyle changes as first line treatment for weight gain.
- Consider adjunctive aripiprazole or Metformin, or topiramate.
- Consider switching antipsychotic agents.

## **Detection of Increase in Total Cholesterol**

Participants T19 and T22 had increases in their total cholesterol levels >30 points mg/dl, representing an increase in over 15%. Having higher levels of total cholesterol can cause cholesterol deposits in the arteries that can lead to the development of atherosclerosis, chest pain, heart attack, and stroke (Mayo Clinic, 2021). Participant T19 began the project with a total cholesterol level of 191mg/dl and at the end of the 12<sup>th</sup> week following the initiation of medication had a total cholesterol level of 223 mg/dl. Participant T22 began the project with a

total cholesterol level of 143 mg/dl and at the end of the 12<sup>th</sup> week following the initiation of medication had a total cholesterol level of 185 mg/dl. Knowledge of an increase in cholesterol following the initiation of an antipsychotic medication can give clinicians the tools needed to prevent or reduce further increases in cholesterol. Cooper et al., (216) also encourages lifestyle interventions as the first line treatment of increasing cholesterol. Ojaka, Repo-Tilhonen, and Niskanen, (2008) reported that the use of a statin drug can be effective in reducing LDL levels in people taking antipsychotic medications. In their study of 28 patients, the use of a low to moderate dose of a statin drug was effective in 84% of the participants in reaching their target goal in just one month.

#### Use of Guidelines to Monitor the Efficacy of Switching Antipsychotic Medication

Participant T3 had been placed on an antipsychotic medication approximately one year prior to the study period. The participant gained greater than 50 pounds in the 12-month period following the initiation of medication. This participant had no metabolic data collected in the mental health clinic following the initiation of medication. This participant was seen by a different provider at the onset of the project, and the participant's medication was switched to a different antipsychotic, making participant T3 eligible for the MOPP project. Participant T3's BMI began to track downwards from 37.19 to 36.16 during the 12-week period of the project. Having the metabolic data collected following a change in antipsychotic medications has demonstrated a downward trend in this participant's BMI. Although outside of the 12-week window of this project, the guidelines recommend that data be collected every three months for one year, then annually.

#### **Barriers to Implementation and Sustainability**

Metabolic monitoring requires weights and measures. To assess these measurements has traditionally required in-person interaction with the client and the provider. COVID-19 profoundly altered the clinical setting in which this project took place. The project was conducted during the height of the COVID pandemic. The use of video visits was the preferred method of getting mental healthcare to the Veterans served by the Veterans Health Administration during the pandemic. This greatly reduced the ability of the nursing staff to collect weights, belly circumference, and blood pressure. Although labs could still be drawn at the primary care sites and main campus lab, many Veterans were reluctant to obtain any inperson treatment. In addition to this large barrier, other barriers to the project and its sustainability are listed below:

- Although metabolic guidelines have been available for almost 2 decades, there is no policy that requires the guidelines to be followed.
- Despite being a part of prescribing providers performance evaluations, metabolic monitoring is not weighted sufficiently to provide incentive.
- Lack of oversight, auditing, and management of metabolic monitoring exists.
- There is no one person assigned to case manage metabolic monitoring.

#### Discussion

It is noteworthy that when comparing the two groups, both cohorts had personal and family histories present 100% of the time. A personal and family history is defined in this project as a chart entry associated with the initiation of an antipsychotic that is dedicated, or has a dedicated section, discussing client and client family history of conditions pertinent to metabolic health status. Conversely, there were no belly circumferences obtained in either group. Personal and family histories and belly circumferences, two of the recommended metabolic indicators were not compared as both had 100% of the personal and family histories and both groups had 0% of belly circumferences assessed. The difference in compliance in these two components might be explained by the fact that the personal and family history is required by policy but belly circumference, while being a recommendation in guidelines, is not required by policy. This emphasizes the importance of having policies in place to ensure compliance with important guidelines.

The Metabolic Ounce of Prevention Project was successful in increasing the amount of metabolic monitoring that took place at a mid-south VAMC. This result occurred by providing a nurse case manager in collaboration with the pharmacist to work closely with prescribing providers and the clinic nurses at the main hospital and eight outpatient clinics. For providers to intervene when abnormalities occur, they must first be able to detect an abnormality. Having a nurse case manager who assists with gathering the recommended measurements at the prescribed timeframes and then compiling the information into a report can better ensure that metabolic issues are detected, even before weight gain is visibly apparent. Changes to metabolic status do not always manifest as weight gain. Insulin resistance and hyperlipidemia are changes that can occur with the use of an antipsychotic medication and cannot be detected by observation alone. This project was successful in detecting four Veterans that had changes in weight, insulin resistance, and total cholesterol, giving the clinicians the opportunity to intervene.

A key lesson learned with the project is that metabolic changes do not take place as a group but rather with the individual. A more patient-centered approach would have been to place parameters on each of the four key metabolic components and flag changes that fall outside of those parameters. For example, with the use of BMI, a parameter could be placed that would flag a result if one of the four BMI readings of the 12-week period increased by a pre-determined level, or whatever level suggested by the providers. Once the change is detected, a flagged report could be sent to the provider by the clinic nurse using an encrypted email (an acceptable form of communication at the VAMC). By utilizing this process, it would increase the providers' awareness of the guidelines. Once a clinician is made aware of a flagged piece of data, the clinician could then work with the client, the pharmacist, and clinic nurses to initiate first line lifestyle modifications and other interventions developed by the clinic team.

The use of baseline and week 12 templates made communication with the provider and clinic nurse possible. The baseline template was key in assessing what information had been gathered and what information was still needed. The week 12 template displayed all 12 weeks measurements and served as a repository for information that could be visualized in one place. The 12-week template can also be shared with other providers, such as with the primary care provider, thus increasing the potential for communication between mental health and primary care. Appendix C demonstrates how some Veterans taking antipsychotics can rapidly gain weight following the initiation of medication. Appendix C also serves as a strong indicator that the guidelines are effective in tracking the efficacy of making an intervention of switching antipsychotic medications. Participant T3 weight, featured in appendix C, is shown to be tracking down following the switching of medication; suggesting that switching medications was an effective intervention.

The project created an effective process improvement strategy for improving the Veterans' metabolic outcomes. The potentials are there to reduce or prevent metabolic comorbidities associated with their medications, medications needed for optimal functionality. The process designed in the MOPP project gives prescribers and clinic staff the tools to detect metabolic changes and the opportunity to intervene offers many possibilities. These possibilities include the following:

- Greater job satisfaction for clinicians.
- Reduced healthcare costs, saving the American Taxpayer.
- Increased productivity in the job market.
- Increased quality of life for the individual Veteran.
- Increased years of life lived.
- Less caregiver stress on family.
- Increased time that loved one has with their family.

## Limitations

Waist circumference was not measured for any of the 60 subjects across both groups. Future studies may explore this phenomenon. A speculative reason includes the possibility that nursing staff in the clinics are not accustomed to measuring the waist circumference of their clients; lack of measuring tapes provided for the nursing staff; lack of education of the landmarks used to measure waist circumference; lack of oversight/audits to provide feedback and accountability.

Lack of a formal policy requiring the compliance of metabolic monitoring may explain the resistance to the changes made by having a nurse case manager to assist the clinicians with a task for which they do not otherwise have to participate. This may explain why 33.6% of the data required to meet guidelines was still missing despite the presence of a nurse case manager.

Due to pandemic conditions, clinicians were adapting to providing much of their care via remote methods. Clients were also adapting to receiving much of their care remotely and many were resistant to being seen face-to-face for labs and measurements.

Lack of participation by providers to the survey may be due to the stress of the clinics having to transition to pandemic conditions. The complexity of the survey return process is also a likely cause of poor response.

#### **Considerations for Future Studies**

The MOPP was able to show an improvement/increase in the quantity of data collected in metabolic monitoring of Veterans who are newly prescribed an antipsychotic medication. Future studies could expound on other methods of increasing the quantity of data collected and what can be done with that data to further mitigate metabolic abnormalities when identified. Working with pharmacists and prescribing staff to set parameters that would flag clinicians when an abnormality is detected could increase awareness of the need for intervention. Education for clinicians and clients could be studied to measure the efficacy education has on the client's ability to selfadvocate and the clinician's ability to respond when necessary. Since pandemic conditions are uncertain, the use of facility-issued scales, measuring tapes, blood pressure machines, point of service A1C and lipid monitors, could be studied to measure the efficacy of having clients selfmeasure and report information to their clinician. This system may facilitate involving patients in their own care, giving them control of metabolic monitoring. An easier process of filling out and returning a survey, such as Microsoft Forms surveys, could have improved provider participation. Getting permission to contact the providers directly, such as in TEAMS, could also prove to be a more effective way to get surveyed information. Finally, a study could measure the efficacy of having a one-page metabolic guidelines poster-style tool, that clinicians and patients could reference, with a list of possible interventions to mitigate abnormalities detected.

#### Conclusion

People living with severe mental illness are at higher risk for comorbidities and early mortality. Diagnoses of severe mental illness are lifelong conditions. There are no cures, only treatment. Medications are required for those who have severe mental illness so that they may function optimally in occupational, social, and other important aspects of life. Medications that treat psychosis are known to have the propensity to cause metabolic abnormalities in some who take them. These abnormalities can only be addressed if they are detected. Guidelines to detect metabolic abnormalities have been available for nearly two decades and have been largely disseminated. However, literature suggests that the guidelines are rarely utilized. In an editorial published in Current Psychology (2012) Dr. Nasralla discussed how it is ethically and morally obligatory of prescribers to provide proper care to the people for whom they prescribe antipsychotic medications, many of whom are mentally and physically impaired and rely upon them for care. In addition to moral and ethical considerations, legal considerations are to be considered as well. In an article written by Marret & Mossman (2016) the authors discussed the medicolegal issues that can be associated with not following practice guidelines. The article was specifically discussing metabolic monitoring of patients taking antipsychotic medications. The authors noted that while most psychiatrists would prefer for their patients not to experience metabolic issues with their medications, many neglect the proper monitoring or have limited records of it being performed. In the case of malpractice suits, laws in many states allow clinicians and patients to invoke practice guidelines for defense or egregious claims.

Having the guidelines themselves has not been effective in ensuring compliance. Gaps in practice have been identified as a global problem. There are many barriers implementing metabolic monitoring as recommended by the guidelines. Having a nurse case manager working with the pharmacist to assist with the process of monitoring the metabolic status of those taking antipsychotic medications has been shown to be effective in increasing the amount of data collected. The use of templates allowed clinicians to view all the information gathered in the monitoring process, instead of them having to search for the information in the electronic health records. This gives the clinicians a convenient place to view the metabolic status of their clients, giving them the opportunity to intervene when indicated. Resources for having a nurse case manager (an ounce of prevention) can reduce or prevent years of expensive comorbidities and lengthen the lifespan of the person on anti-psychotic medications (the proverbial pound of cure).

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### TABLE 1

ADA Screening Measures for Patients Initiating Atypical Antipsychotic Medications

	Baseline	Week 4	Week 8	Week 12	Quarterly	Annually
Personal &	Х					
Family HX.						
BMI	Х	Х	Х	Х	Х	X
Waist Cir.	Х					
Bloop Pressure	Х			Х		Х
Fasting glucose	Х			Х		
Fasting Lipids	Х			Х		

Note: Adopted from the American Diabetes Association et al., 2004

Table 2 Guidelines	and MOPP Interpretation for Pro	oject				
Guideline Item to	Definition for Project	Method of	Time Frame(s)			
be measured		Measurement				
Personal and Family History	A chart entry associated with the initiation of an antipsychotic that is dedicated, or has a dedicated section, discussing client and client family history of conditions pertinent to metabolic health status such as diabetes, BMI, hypertension, insulin resistance, hyperlipidemia, or any other significant historical aspect pertinent to the clients personal or family metabolic status. Does not have to be an exhaustive or all- inclusive note.	Charted, Not Charted	within three months prior or two weeks after the initiation of medication.			
Body Mass Index (BMI)	Height and weight at baseline/weight at weeks 4,8,12	Charted, Not Charted	Within three months of baseline and within 2 weeks before and after weeks 4, 8, 12.			
Waist Circumference	A waist circumference collected by provider or clinic nurse.	Charted, Not Charted	Within three months of initiation of medication.			
Blood Pressure	A blood pressure reading captured at any encounter i.e., primary care, mental health, inpatient.	Charted, Not Charted	Within three months of initiation of medication and two weeks before or after week 12.			
HgA1c Result or fasting glucose.	A result of a lab ordered by any provider.	Charted, Not Charted	Within three months of initiation of medication and two weeks before or after week 12.			
Fasting Lipids	A result of a lab ordered by any provider.	Charted, Not Charted	Within three months of initiation of medication and two weeks before or after week 12.			

Note: Developed by project director of the Metabolic Ounce of Prevention to define timelines and definitions.

	Cohort 1 (Intervention)	Cohort 2 (No Intervention)	
Male	24	27	
Female	5	1	
Mean Age	50	56	
Aripiprazole	9	7	
Lurasidone	5	3	
Olanzapine	3	12	
Paliperidone	0	1	
Quetiapine	7	5	
Risperidone	6	2	
Ziprasidone	2	0	

## Table 3 SAMPLE DEMOGRAPHIC AND MEDICATIONS INITIATED

Note: Displays demographic and drug specific data per subjects of each group





NOTE: Table displays results of metabolic data collected per group. The blue bar represents cohort 1, the group that had a nurse case manager, and the orange bar represents cohort 2, the group that had no case manager.



NOTE: A display of the percentages of each cohort's BMI collection at each of the 4-week intervals.



NOTE: A display of the percentages of each cohort's blood pressure collection at baseline and week 12.





NOTE: A display of the percentages of each cohort's glucose readings collection at baseline and week 12





NOTE: A display of the percentages of each cohorts's lipid readings collection at baseline and week 12



*NOTE:* Increased BMI detected from data gathered in the MOPP, demonstrating the processes' success in detecting abnormalities that need to be mitigated. These two Veterans BMI increased during the 12-week period. Without the monitoring process, these changes would have otherwise gone undetected.



*NOTE:* An increase in HgA1c detected from data gathered by the MOPP, demonstrating the processes' success in detecting abnormalities that need to be mitigated. This Veterans HgA1c increased during the 12-week period. Without the monitoring process, these changes would have otherwise gone undetected.



*NOTE:* Increased total cholesterol detected from data gathered in the MOPP, demonstrating the processes' success in detecting abnormalities that need to be mitigated. These two Veterans total cholesterol increased during the 12-week period. Without the monitoring process, these changes would have otherwise gone undetected.

## APPENDIX A

Provider Perception of Support and Comfort Level

On a Scale of 1-10

1. Please provide the level of comfort you have with using the guidelines for metabolic monitoring of Veterans who are newly prescribed atypical antipsychotic medications.

2. How do you rate your knowledge/familiarity with metabolic monitoring guidelines for initiation and first 3-months of the initiation of an atypical antipsychotic medication?

3. Please rate your perception of the level of clinical support you get when performing metabolic monitoring.

4. Please list any barriers you may have to effectively perform metabolic monitoring when your clients are initiated on an atypical antipsychotic medication.

5. Please list anything you feel would make metabolic monitoring more user friendly in your work area.

## APPENDIX B

## Subjects with demographics and metabolic data collected at each interval

Su bje ct ID	Group	Se x	Age	BL BMI	BL_ SysB P	BL_ DiasB P	BL Lipid	BL GLU COS E	BL Ha1 c	WEEK 4 BMI	WEEK 8 BMI	WEEK 12 BMI	WK12 - SysBP	WEEK 12 DiasB/ P	WEEK 12 Lipid	Week 12 Glucos e	Week 12 HgA1 c	NUMBER OF DATA COLLECTE D IN MH
1T	INTERVENTION	М	63	41.45	178	88	169		7.3	40.3 6	40.7 5	41.2 7	112	62	х	189		0
2T	INTERVENTION	Μ	57	39.81	136	84	99	162		Х	38.2 2	39.4 8	125	71	54.4	171		0
3T	INTERVENTION	F	50	37.19	119	189	266	97	5.3	36.5 1	36.1 6	Х	Х	Х	Х	Х		0
4T	INTERVENTION	М	51	32.52	136	87	Х	Х		Х	33	Х	Х	Х	121	100		0
5T	INTERVENTION	Μ	31	29	134	85	297	87	4.9	Х	Х	26.2 8	119	78	248	92	4.7	0
6T	INTERVENTION	Μ	58	33	139	88	Х	195		Х	35.2 8	35.0 7	118	77	131	148	10.4	2
7T	INTERVENTION	Μ	65	23.29	164	84	Х	х	Х	23.3 9	Х	24.2 6	134	82	Х	Х		0
8T	INTERVENTION	Μ	33	Х	Х	Х	Х	х		Х	Х	30.3 6	145	82	Х	Х		0
9T	INTERVENTION	Μ	69	26.67	119	80	216	100		Х	Х	24.8 7	166	79	180		5.1	4
10 T	INTERVENTION	F	27	Х	103	71	226	107		4.5	Х	27.1 8	115	80	162		4.8	4
11 T	INTERVENTION	F	55	33.36	136	89	202	x	6.4	Х	X	33.7 2	125	89	193		6.7	2
12 T	INTERVENTION	Μ	33	27.17	117	76	X	x		Х	X	24.1 2	122	88	175	98	4.6	0
13 T	INTERVENTION	Μ	30	27.81	126	79	301	x		X	X	29.0 2	121	79	159	89	5.5	4

14 T	INTERVENTION	Μ	70	38.98	169	75	165		5.8	Х	40.7 5	39.3 9	Х	х	145	145	6.2	4
15 T	INTERVENTION	Μ	40	32.91	131	85	Х	265		Х	Х	32.4 7	145	100	222	156	8.5	0
16 T	INTERVENTION	Μ	72	31.47	152	193	257		5.4	31.4 7	Х	35.3 1	129	57	214	93	5.6	0
17 T	INTERVENTION	Μ	48	34.95	111	72	Х	х		Х	Х	Х	Х	Х	Х	Х		0
18 T	INTERVENTION	Μ	61	26.04	128	189	Х	х		х	Х	25.8 2	100	70		88	6.4	0
19 T	INTERVENTION	F	56	36.11	132	89	191		5.9	37.3 3	37.2 1	34.7 4	111	77	223	95		10
20 T	INTERVENTION	F	31	23.97	98	64	197	х		Х	Х	24.4 3	109	69	Х		4.9	1
21 T	INTERVENTION	Μ	37	34.78	130	83	150		5	х	Х	Х	Х	Х	163		5.1	2
22 T	INTERVENTION	Μ	52	25.69	118	81	143		5.2	Х	Х	26.4	133	77	185	95	5.1	0
23 T	INTERVENTION	Μ	51	43	144	95			6.8	42.0 6	Х	Х	Х	Х	Х	Х		0
24 T	INTERVENTION	Μ	75	30.94	125	84	292	96	5.6	30.9 4	31.5 6	31.4 4	109	71	Х	Х		0
25 T	INTERVENTION	Μ	43	36.09	118	182	202	90		Х	Х	Х	Х	Х	Х	Х		0
26 T	INTERVENTION	Μ	40	30.41	129	79	189	96	5.5	х	Х	Х	Х	Х	Х	Х		0
27 T	INTERVENTION	Μ	30	31.04	133	81	205		5.1	х	Х	Х	Х	Х	Х	Х		0
28 T	INTERVENTION	Μ	75	Х	Х	Х	127	90		Х	Х	30.8 9	157	81		98		2
29 T	INTERVENTION	Μ	60	27.43	123	77	210		4.8	32.1 3	32	32.1 5	124	76	191		5.3	2
1C	NO- INTERVENTION	Μ	71	30.25	135	78	Х	Х	х	Х	Х	Х	Z	х	х	х		0

2C	NO- INTERVENTION	Μ	58	32.1	135	86	108	87		Х	Х	31.5 6	117	80	X	84	6.2	0
3C	NO- INTERVENTION	F	31	Х	Х	Х	196	Х	5.2	х	х	х	Х	Х	x	Х		0
4C	NO- INTERVENTION	Μ	50	45.3	164	106		269		46.0 8	Х	Х	130	89	Х	Х		0
5C	NO- INTERVENTION	Μ	77	18.23	120	63	79	63		19.3 2	Х	19.3 2	119	60	Х	Х		0
6C	NO- INTERVENTION	Μ	84	х	Х	Х	Х	Х		23.7	Х	х	х	х	х	х		0
7C	NO- INTERVENTION	Μ	57	39.61	139	61	Х	Х		Х	Х	х	х	х	х	х		0
8C	NO- INTERVENTION	Μ	78	32.82	119	77	94.6	133		Х	Х	х	Х	Х	x	Х		0
9C	NO- INTERVENTION	Μ	40	Х	х	Х	Х	х		х	27.7 9	Х	Х	Х	Х	Х		0
10 C	NO- INTERVENTION	Μ	32	38.08	124	74	Х	94		х	Х	Х	Х	Х	Х	Х		0
11 C	NO- INTERVENTION	Μ	62	Х	х	Х	Х	89	Х	х	Х	Х	Х	Х	Х	Х		0
12 C	NO- INTERVENTION	Μ	48	33.71	145	84	Х	х	Х	Х	Х	Х	Х	Х	Х	Х		0
13 C	NO- INTERVENTION	Μ	60	33.86	95	59	198	79		Х	Х	33.8 3	121	80	Х	Х		0
14 C	NO- INTERVENTION	Μ	53	24.33	141	63	Х	99		24.6 8	Х	24.7 1	116	77	Х	X		0
15 C	NO- INTERVENTION	Μ	48	33.59	122	86	Х	х		Х	Х	Х	Х	Х	Х	Х		0
16 C	NO- INTERVENTION	Μ	40	32.91	131	85		265		Х	Х	32.4 7	145	10	Х	156		2
17 C	NO- INTERVENTION	Μ	22	30.48	126	84	Х	85		Х	Х	Х	Х	Х	X	Х		1
18 C	NO- INTERVENTION	Μ	38	24.32	114	63	Х	115		Х	Х	Х	Х	Х	X	X		0

19 C	NO- INTERVENTION	Μ	80	Х	145	105	Х	144	Х	Х	Х	Х	Х	Х	Х	0
20 C	NO- INTERVENTION	Μ	62	Х	Х	Х	Х	х	Х	Х	Х	Х	Х	Х	Х	0
21 C	NO- INTERVENTION	Μ	35	Х	х	х	х	х	х	Х	Х	Х	Х	Х	Х	0
22 C	NO- INTERVENTION	Μ	65	Х	х	х	100	176	х	Х	Х	Х	Х	Х	Х	0
23 C	NO- INTERVENTION	Μ	63	32.63	139	90	201	114	31	29.6 7	Х	Х	Х	Х	Х	0
24 C	NO- INTERVENTION	Μ	73	24.49	176	96	Х	170	24.2 8	Х	Х	Х	Х	Х	Х	0
25 C	NO- INTERVENTION	Μ	71	33.84	108	62	Х	х	29.9	Х	Х	Х	Х	Х	Х	0
26 C	NO- INTERVENTION	Μ	41	25.28	127	80	173	92	х	24.5	25.2 8	123	80	Х	Х	0
27 C	NO- INTERVENTION	Μ	73	26.74	159	77	х	92	х	х	х	Х	Х	X	Х	0
28 C	NO- INTERVENTION	Μ	60	23.44	144	85	Х	85	25.1 6	Х	X	Х	X	Х	Х	0

Note: Yellow highlighted area indicates the participants were referenced in the body of the text. Green highlighted areas indicate a decrease in the BMI of participant T3, who had been switched from one medication to a different medication due to an increase in weight >50 pounds. Red highlighted areas indicate increases in the BMI or total Cholesterol of those highlighted participants.

Key: M=Male; F=Female; X=No Data collected; BL=Baseline; SysBP=Systolic blood pressure; DiasBP=Diastolic blood pressure

### **APPENDIX 3**



NOTE: Table represents participant T3's increase in weight over a 12-month period followed by a decrease in weight following the intervention of changing the participants medication to a different antipsychotic agent