Reducing the Incidence of Antipsychotic Induced Dystonic Reactions in Children

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Abstract

Dystonic reactions are a source of great distress to patients and can lead to increased morbidity and mortality. Antipsychotics are among the most reported causes of drug related dystonic reactions in children. While antipsychotics are generally FDA approved psychosis, bipolar disorder and autism, they are used off label for sleep disorders, oppositional defiant disorder, ADHD and other conditions. The prevalence of antipsychotic induced dystonic reactions in children can be as high as 90% with certain medications and the presence of other risk factors. The purpose of this project is to determine if provider education and updated prescribing guidelines can reduce the incidence of dystonic reactions in children being prescribed antipsychotics in the psychiatric hospital. This is an evidence-based practice project. An education program based upon FDA guidelines for the most commonly prescribed antipsychotics at the project setting was developed and reviewed with providers. Data on the incidence of dystonic reactions was collected for 91weeks prior and 4 weeks after the provider education. Charts were was also collected to assess for provider compliance with the prescribing guidelines. The number of dystonic reactions averaged 1.09 per week prior to the intervention and 3 per week post intervention. Provider compliance with the prescribing guidelines was 95%. The project was limited by small sample size and short duration of data collection in the post implementation period. The data collection should be continued for an additional 87 weeks following the implementation phase to match the pre-implementation time frame and the results then reexamined.

Key words: extrapyramidal syndromes, dyskinesia, dystonia, movement disorders, side effects, antipsychotics, Risperdal, Abilify, dystonic reactions

Reducing the Incidence of Antipsychotic Induced Dystonic Reactions in Children

Dystonia is an involuntary motor syndrome that causes contractions of muscles (Knopf et al., 2021). In rare cases, dystonia can affect the larynx and be lethal (Alkharboush & Alsalamah, 2020). The incidence of antipsychotic induced dystonic depends on the presence of risk factors (van Harten et al., 1999). With certain risk factors, the incidence can be as high as 90% (van Harten et al., 1999). Antipsychotics are among the most reported causes of drug related dystonic reactions in children (Knopf et al., 2021).

The use of antipsychotics has increased in children and adolescents in recent years (Knopf et al., 2021). This might be due to the Food and Drug Administration's (FDA) approval of these drugs for children with schizophrenia, bipolar disorder, autism-related irritability, Tourette syndrome, and bipolar depression (Knopf et al., 2021). It may be due to the increase in off-label use of these medications as well. Antipsychotics are now used to treat sleep disorders, attention-deficit/hyperactivity disorder, oppositional defiant disorder, major depressive disorder, and posttraumatic stress disorder (Knopf et al., 2021). The increased utilization of antipsychotics in children places them at higher risk for this adverse drug reaction.

Dystonic reactions are a source of great distress to patients and leads to medication non-adherence (DiBonaventura et al., 2012; American Medical Association, 2020). Medication non-adherence also contributes to higher utilization of health services, increased medical costs, and an increased burden on the healthcare system (Oates et al., 2020). The need to reduce the incidence of dystonic reactions cannot be overstated.

The project setting is a large in-patient pediatric psychiatric unit in New York serving children, as young as age five. When antipsychotic induced dystonic reactions are observed, the providers will generally intervene by ordering an IM injection of either Cogentin or Ativan. The

offending agent will then be either decreased, discontinued or augmented with an anticholinergic such as Cogentin to prevent future occurrences. Symptoms generally resolved within 30 minutes of treatment. Dystonic reactions should be largely preventable since the risk factors are known, as discussed above. The incidence of dystonic reactions could be decreased with provider education highlighting FDA prescribing guidelines.

Project Question

Among pediatric patients being prescribed antipsychotic medications, can provider education highlighting FDA prescribing guidelines reduce the incidence of dystonic reactions in a psychiatric hospital?

Search Methods

A literature review was conducted utilizing the Touro University – Nevada library electronic search engine and Google. Databases searched include Academic Search Complete, Health & Medical Collection, Free Medical Journals, PubMed, DOAJ Directory of Open Access, Psychology Database, Journals@Ovid Ovid Full Text, Research Library, MEDLINE, ClinicalKey Flex, Wiley Online Library, Nursing & Allied Health Database, SD College Edition Journals and Academic Search Elite. The search terms used were dystonic reactions, children, pediatric, adverse drug reactions, antipsychotics, medication adherence, risk factors, Risperdal and Abilify. The search was limited to the last 10 years and articles were chosen for review based on availability of full text online and the likelihood of similarity to the population at the hospital where the DNP project is being completed. The initial search using term “dystonic reaction” yielded 361 results. Search terms “dystonic reactions children” yielded 67 articles. Search terms “dystonic reactions children antipsychotic” yielded only 14 articles. The term ‘antipsychotic’ was removed and the 67 articles were examined individually for the presence of

data pertaining to antipsychotic induced dystonic reactions. Articles with research limited to dystonic reactions unrelated to antipsychotics were excluded. Next, a search using the terms "antipsychotic best practices children" yielded 56 results. In total, 23 of 123 sources were selected for inclusion in the literature review. Several were not included in this project due to redundancy. Additional publications cited by the aforementioned articles were reviewed and then included in this project.

When searching for the protocols for the proper administration of antipsychotics and prescribing guidelines, several methods were used. First, the project lead reviewed the database articles already downloaded for protocols and national guidelines for the prevention and treatment of antipsychotic induced dystonic reactions. Four articles were identified. In addition, Prescribing Information documents published by several antipsychotic drug manufacturers were downloaded from the FDA's website. Prescribing Information includes data from the FDA's clinical trials regarding adverse effects, including dystonic reactions.

Review of Study Methods

The types of studies that are included in the project are meta-analysis of randomized controlled trials, retrospective, and observational studies such as retrospective chart reviews and systematic review of peer-reviewed research studies. These methods are relevant to the aim of the studies performed and are relevant to this DNP project because they are reliable, valid and measure the incidence of dystonic reactions due to antipsychotic use in children.

Review Synthesis

The literature review identified several important facts surrounding antipsychotic induced dystonic reactions. The predictors of dystonic reactions are known and there is sufficient knowledge whereby the incidence of dystonic reactions can be reduced. Dystonic reactions are a

source of great distress to patients. Dystonic reactions can cause medication non-adherence. Interventions such as provider education highlighting FDA prescribing guidelines will likely be effective in reducing the incidence of dystonic reactions in children on antipsychotics.

Historical Context of the Nursing Profession

Historians often considered the field of professional nursing to have begun when Florence Nightingale led a group of nurses to the Crimean Peninsula in 1854 to deliver nursing services to British soldiers (University of Pennsylvania School of Nursing, n.d.). Nightingale later returned to England and established nursing education programs. Since then, the nursing professional has evolved. The scope of practice for nurses will vary by region and level of education. The American Nurses Associated reports that, at a minimum, modern nurses perform physical exams, provide health promotion and education, administer medications and other interventions and coordinate care with other health care professionals (American Nurses Association, n.d.). In the context of antipsychotic induced dystonic reactions, registered nurses with a basic nursing education will administer the antipsychotics and then monitor for dystonic reactions, implement nursing interventions and administering medications such as Cogentin when prescribed. Advanced Practice Nurses with prescription authority might prescribe the antipsychotics and Cogentin as well.

Incidence of Dystonic Reactions

One study from Tural Hesapcioglu et al. (2020) involving 441 children ages 4 -19 receiving treatment with antipsychotics revealed a 6.8% prevalence of acute dystonic reactions. Further analysis indicated that the incidence amongst children treated with one antipsychotic was 2.8% and 38.0% for those treated with two antipsychotics (Tural Hesapcioglu et al., 2020). The incidence of dystonic reactions in patients treated with a single first-generation antipsychotic was

10.5% and 2.2% with a second-generation antipsychotic (Tural Hesapcioglu et al., 2020). Another study involving 50 children ages 8 – 19 from Sikich et al. (2003) revealed that more than half of those treated with haloperidol (67%), olanzapine (56%) or risperidone (54%) required low-dose anticholinergics to control their extrapyramidal symptoms (EPS). Between the groups, haloperidol demonstrated the most frequent and severe symptoms. Similarly, high potency antipsychotic drugs such as haloperidol, fluphenazine, and pimozide cause dystonia more frequently than low potency drugs such as chlorpromazine (van Harten et al., 1999).

Predicators of Dystonic Reactions from Antipsychotics

A study examining Medline and Embase databases for the period between 1980 and 1998 using the key terms extrapyramidal syndromes, dyskinesia, dystonia, movement disorders, side effects, and antipsychotics found that 10-19 years of age is a strong risk factor for dystonic reactions (van Harten et al., 1999). In contrast, patients over age 45 have a very low risk. Other risk factors include male sex, a history of dystonic reactions, and cocaine use (van Harten et al., 1999). Another risk factor is the initiation of a new antipsychotic or dose increase. In fact, 95% of all cases of acute dystonia appeared either within 96 hours of initiating a new treatment or after a large increase in antipsychotic dose (van Harten et al., 1999). Other risk factors include high doses and intramuscular administration (Yamamoto & Inada, 2012).

Consequences of Dystonic Reactions

Antipsychotic induced dystonic reactions are a significant problem. They are a source of great distress to patients (Yamamoto & Inada, 2012). They also lead to medication non-adherence (DiBonaventura et al.,2012). Aside from the medical risks to each patient, it is known that medication non-adherence contributes to higher utilization of health services, increased medical costs, and an increased burden on the healthcare system (Oates et al., 2020).

Patient Distress

The project lead has observed and treated patients experiencing dystonic reactions and has observed the distress it creates first hand. Surveys conducted in different regions throughout the world have also found that dystonic reactions are distressing and frightening for the patient (Yamamoto & Inada, 2012) One study involving 202 people diagnosed with psychosis between July 1998 and February 1999 assessing patient satisfaction with antipsychotics found high rates of dissatisfaction. Nearly all patients reported unwanted side effects. Around half were dissatisfied with their medication (Fakhoury et al., 2001).

Medication Non-Adherence

A study from DiBonaventura et al. (2012) involving 876 patients with schizophrenia revealed that 86.19% of patients reported at least one side effect. Most side effects were associated with a significantly reduced likelihood of medication compliance. In fact, less than half of the 86.19% of patients experiencing side effects (42.5%) reported taking their medication as prescribed (DiBonaventura et al., 2012). Similarly, the American Medical Association (2020) reports that side effects and fear of side effects are often a reason for medication non-adherence. Non-adherence is a significant problem since it reduces the therapeutic effects of medication therapy, can lead to drug resistance and reactions, diminished quality of life, and increase morbidity and mortality (Oates et al., 2020).

Interventions

Primary interventions include adhering to prescribing practices least likely to results in dystonic reactions. Secondary interventions involve close monitoring of patients and treating the dystonic reaction as early as possible. Provider education should be provided to ensure these guidelines are adhered to.

Provider Education

Provider education needs to be tailored to the population a facility is treating. Traditional prescribing guidelines for antipsychotics may not be appropriate in all settings. For instance, the recommended starting and target dose for Abilify is 10 or 15 mg/day for adults according to the drug's manufacturer (aripiprazole, n.d.). For children, the starting dose is 2 mg/day. The project lead has observed that providers employed by settings treating primarily with adults are often not familiar with these nuances. Provider education specific to the population seen at the setting is critical.

Prescribing Guidelines

Primary interventions to prevent acute dystonic reactions include following gradual rather than rapid dose titration (van Harten et al., 1999). The project lead has observed that this can often be accomplished by following the manufacturer's dosing guidelines. For example, when Abilify is prescribed for Autism in children ages 6-17, the manufacturer's recommendations are: Dosing should be initiated at 2 mg/day (aripiprazole, n.d.). The dose should be increased to 5 mg/day, with subsequent increases to 10 or 15 mg/day if needed. Dose adjustments of up to 5 mg/day should occur gradually, at intervals of no less than 1 week. For Bipolar I in children, it can be increased faster: The recommended starting dose in pediatric patients (10 to 17 years) as monotherapy is 2 mg/day, with titration to 5 mg/day after 2 days, and a target dose of 10 mg/day after 2 additional days (aripiprazole, n.d.). Secondary interventions include dose reductions or discontinuation of the offending agent (Fakhoury et al,. 2001). Other treatment strategies may include switching from a first generation antipsychotic to a second generation antipsychotic and administration of anticholinergic agents, dopamine agonists and benzodiazepines (Fakhoury et al,. 2001).

Impact of the Problem

To summarize, the risk factors for dystonic reactions are known. Dystonic reactions are a source of great distress, can be lethal in certain situations, lead to medication non-adherence and increase the burden on the healthcare system. The rationale for conducting this project was to safely reduce the number of dystonic reactions and all its consequences by implementing provider education tailored to specific needs of the patient population at a given site.

Project Aims

The project aim was to improve the quality of care at the project site by reducing the incidence of antipsychotic induced dystonic reactions. Data was collected on the incidence of dystonic reactions at the project site. Best practices for antipsychotic administration for the population at the project site was reviewed. A provider education program reinforcing the FDA guidelines was developed and taught to providers.

Project Objectives

In the timeframe of this DNP Project, the project lead:

1. Developed an evidence-based practice guideline for the safe administration of antipsychotics for the population served at the practice site. The practice guidelines were to follow FDA approved guidelines whenever available. For instance, manufacturer of Abilify states that dosing for adolescents with bipolar disorder should be 2 mg per day at the beginning and then titrated to 5 mg after 2 days (aripiprazole, n.d.).
2. Administered education materials to providers highlighting FDA prescribing guidelines.

3. Aimed to improved provider compliance with best practices for administering antipsychotics to pediatric patients.
4. Aimed to reduce rates of dystonic reactions in pediatric patients taking antipsychotics by 10% within a 5-week implementation frame.

Implementation Framework

This evidence-based practice DNP project utilized the IOWA model. This can be found in Appendix A.

Historical Development of the Framework

The IOWA Model of Evidence-Based Practice was developed by the University of Iowa Hospitals and Clinics in 1990s (Cabarrus College of Health Sciences, 2022). It serves as a guide for nurses to use research to help improve patient care. It is a step-by-step process that starts by determining if change is warranted. The steps then guide the project leader in forming a team, gathering and analyzing research related to the desired practice change, implementing the change and then evaluate the results (Cabarrus College of Health Sciences, 2022).

Application to DNP Project

The application of the IOWA Model to this project is illustrated in Appendix A and described below. The project lead formed a team consisting of a DNP mentor, pharmacist, medical director and director of research at the project site. The pharmacist provided the team with the number of dystonic reactions over a 2-year period. The project consulted with the director of research to determine the time period from which this data should be collected. Project lead researched overall incidence of dystonic reactions. Project lead researched best practices for the administration of antipsychotics for the population serviced at the project site. Project lead compared this to current practices at the project site. Project lead worked with the

DNP mentor to design and pilot the education program. The program was implemented and then results evaluated.

Setting

The venue where the project was implemented is large in-patient pediatric psychiatric unit in New York serving children ages 5 - 17. The project site uses paper medical records but will be implementing an EMR in mid-2023. As a facility that treats children, it is subject to scrutiny from the Office of Mental Health and other regulatory bodies.

Stakeholders

The project involved multiple stakeholders each with unique roles:

- Director of Research: Reviewed project and ensures all research ethics guidelines were followed
- Director of Compliance: Ensured HIPAA guidelines are followed
- Hospital Medical Director: Approved evidence-based guidelines
- Project Mentor: Assisted with project implementation as needed
- Director of Pharmacy: Provided data on the incidence of dystonic reactions.

Approval from the hospital administration was required in order for this project to be completed. An affiliation agreement with TUN is not needed to complete the project. Approval from the hospital was granted. IRB approval from the school is not required since the project does not involve human-subjects research. Documentation of this decision is provided in Appendix B.

Interventions

There were 4 objectives and interventions:

Develop the Evidence-Based Practice Guidelines and Educate Providers

The project lead developed an evidence-based practice guideline for the safe administration of antipsychotics for the population served at the practice site. The practice guidelines recommended that providers consider using the FDA guidelines whenever available (aripiprazole, n.d.; risperidone, n.d.). The provider education was limited to the antipsychotics Abilify and Risperdal. The project lead proposed an education program highlighting FDA prescribing guidelines. The FDA guidelines can be found in Appendix C.

Evaluate Provider Compliance

The project lead evaluated provider compliance with adherence to the FDA prescribing guidelines. This was accomplished by reviewed charts in the post implementation period for patients receiving treatment with Abilify and Risperdal for an FDA approved indication. For each condition, the manufacturer provides dosing guidelines. The project lead completed chart reviews to assess providers were compliant with these guidelines.

Evaluate Rates of Dystonic Reactions

The project lead evaluated the rates of dystonic reactions in pediatric patients taking antipsychotics in the pre and post implementation periods. The goal was to reduce the incidence of dystonic reactions by 10% within a 4-week time frame. The project lead completed pre and post chart reviews to determine if there was a reduction in dystonic reactions. The project lead collected data for approximately 2 years prior to implementation and then 1 month post implementation. Notably, the number IM Cogentin injections orders were used as the marker for dystonic reactions. The typical indication for Cogentin is Parkinsonian disorders, however, since the setting was a psychiatric unit, the only likely indication for Cogentin was to treat dystonic reactions. Hence, this was used as the marker for when dystonic reaction occurred.

Resources

A number of resources were required. This includes access to databases such those available at Touro Library, drug manufacturer prescribing guidelines published on pdr.net, UpToDate subscription. The project lead also required access to the hospital's medical records from the pharmacy. The project lead obtained access to these resources through the relationship with Touro College, the FDA's website and his paid subscription to UpToDate. No human resources were required other than those listed above.

Timeline

A graphic of this timeline can be found in Appendix D.

Tools

FDA Guidelines

The project lead provided the Assistant Director of Nurse Practitioner Education with a summary of the FDA approved prescribing guidelines for the medications Abilify and Risperdal (Appendix C). This was taught to the majority of providers on the unit.

Chart Review Tool

The project lead developed a chart review tool to review charts and gauge if providers adhered to the FDA prescribing guidelines. The chart review process can be found in Appendix E. The chart review data collection tool can be found in Appendix F.

Data Collection Plan

Data Collection Timeline

The data collection process occurred immediately after provider education is completed, over the 4-week period from 11/13/2022 to 12/10/22. The data collection timeline can be found in Appendix D.

Evaluate Provider Compliance

The project lead collected data by reviewing 5 charts per week for 4 weeks. The 5 charts were assessed for provider compliance with the updated prescribing guidelines. Providers were considered compliant when Abilify and Risperdal were prescribed according to the FDA guidelines. The guidelines differ based upon the age, weight and diagnosis of the patient and, hence, for each chart selected, the patient's age, weight and diagnosis were reviewed. The project lead then assessed if the medications were prescribed according to the FDA guidelines specific to each patient. The chart review process is described in Appendix E.

Evaluate Rates of Dystonic Reactions

The pharmacy provided the project lead with the number of IM Cogentin injections administered from 1/5/2021 through 10/5/2022 and then again for each week from 11/13/2022 to 12/10/2022. As discussed earlier, IM Cogentin is rarely, if ever, used at this facility for any condition other than acute dystonic reactions. Hence, this is how the project lead assessed for a change in the rate of dystonic reactions in the post intervention period.

The project lead collected data for 4 weeks. Five charts for pediatric patients prescribed Abilify or Risperdal for an FDA approved indication were selected for review each week. The number of IM Cogentin injections administered each week were provided by the pharmacy. The data was documented on the chart tool found in Appendix F. The chart review process tool can be found in Appendix E.

Data was reported in aggregate only and not by individual charts or individual providers. No protected health information ("PHI") or patient/provider identifiers were be collected. Data was collected electronically using a Microsoft Word document with the Data Collection Tool found in Appendix F. The Word document is stored on the project lead's computer at the facility

which is password protected. No protected health information was or will be taken off premises. The data will be stored until 3/1/2023 and will then be deleted from the computer.

Ethics/Human Subjects Protection

Participants

This was an archival study. No humans subject research was conducted. The healthcare providers were the participants. Providers were not be required to change their practice and were advised to continue to use their clinical judgement. The providers benefited from increased provider knowledge. The education was provided during the course of their normal working hours. They did not receive additional compensation for this education.

IRB Approval Process

A project determination form was submitted to the TUN project repository. Several meetings were held with hospital administration provider including the CEO and director of research. A formal request for the study was requested. A research committee convened to discuss the request. The request was approved.

Data Analysis Plan

The project lead assessed the data for clinically significant outcomes. It should be noted that this was an evidence-based practice project and not a quality improvement project. Hence, no data related to the prescribing practices during the pre-implementation stage of this project was collected. The project lead assumed that best practices for administering antipsychotics to pediatric patients were not fully adhered to prior to the project implementation date. This was be a limitation of the project.

The project objectives are described above in the Project Objectives section. Objectives # 1 and # 2 are process measures and involve the development and implementation of a prescriber

education program. Objectives # 3 and # 4 was analyzed for significant outcomes as follows:

- Objective # 3 (Improve provider compliance with best practices for administering antipsychotics to pediatric patients): Data was analyzed using descriptive statistics. Five charts were collected each week from 11/13/2022 to 12/10/2022 and assessed for provider compliance with the recommended prescribing guidelines. The frequencies and percentages of the number of charts that are in compliance was presented using a 95% confidence interval.
- Objective # 4 (Reduce rates of dystonic reactions in pediatric patients taking antipsychotics by 10% within a 4-week implementation frame): Data was analyzed using descriptive statistics. The average number of dystonic reactions from the pre-implementation compared to the average number of dystonic reactions in the post-implementation period was presented. The results were demonstrated using a mean and confidence interval. Statistical tests were avoided.

Analysis of Results

Objective # 3 was to improve provider compliance with best practices for administering antipsychotics to pediatric patients. Data was analyzed using descriptive statistics. Five charts were collected each week for 4 weeks from 11/13/2022 to 12/10/2022. They were assessed for provider compliance with the recommended prescribing guidelines. The frequencies and percentages of the number of charts that are in compliance are presented using a 95% confidence interval. The compliance rate in the 20 charts reviewed was 95% This was generalized to hospital as a whole. Compliance results are shown in Table 1.

Table 1: Provider Compliance Results

Standard Deviation (s)	0.2236068
Variance s2	0.05
Count n	20
Mean $\bar{x}$	0.95
Sum of Squares SS	0.95
The confidence interval falls between	0.852% and 1.048%.
Margin of error	0.097998

Objective # 4 was to reduce rates of dystonic reactions in pediatric patients taking antipsychotics by 10% within a 4-week implementation frame. The number of dystonic reactions in the pre-implementation stage, from 1/30/2021 through 10/5/2022, approximately 91 weeks, was 99: Approximately 1.09 per week. Post-implementation, from 11/13/2022 to 12/10/2022, over 4 weeks, there were 12 dystonic reactions: Approximately 3 per week.

Modifications to Timeline

It should be noted that the timeframe for the project was adjusted. The Director of Nurse practitioner Education at the project site was unable to provide the provider education on the date initially anticipated. Provider education was initially scheduled for 11/4/2022. Data collection was scheduled to start 11/6/22. Provider education was postponed until 11/11/2022 and, hence, the data collection phase also delayed until 11/13/22. In order to meet the project deadlines, the data collection phase was decreased from 5 weeks to 4 weeks.

Another significant change was the number of charts collected. The hospital uses paper records and not an electronic medical records system ("EMR"). It took the project lead hours to search through the hospital's charts to find patients that met the inclusion criteria outlined in the

Chart Review Process found in appendix E. Due to time constraints, the number of charts to be reviewed each week was reduced from 10 to 5. Hence, the total sample of charts decreased from 50 to 20. The difficulty in finding suitable charts for review was not anticipated.

Discussion and Interpretation of Results

Provider Compliance

Objective # 3 was to improve provider compliance with best practices for administering antipsychotics to pediatric patients. Pre-implementation compliance data was not available as previously stated. However, a 95% compliance rate (19 out of 20 charts) in adherence to FDA guidelines is high. There is no research data available on the rates of compliance with FDA guidelines. In this case, the project lead considers this high in the context of this project for the following reasons. Providers were permitted to deviate from the manufacturer guidelines when necessary, using their clinical judgement. In the one case where the provider deviated from the guidelines, the deviation was minor and there were no adverse effects.

Dystonic Reactions

Objective # 4 was to reduce rates of dystonic reactions in pediatric patients taking antipsychotics by 10% within a 4-week implementation frame. This objective was not achieved during this time frame. Prior to implementation, there was an average of 1.09 dystonic reactions per week. This increased almost 3-fold post implementation to 3 per week. Further investigation is needed to determine why the number of dystonic reactions were higher during the post-implementation period compared with the previous two years. This may support the previously published literature, may contradict it or, most likely, have no correlation at all due to the weaknesses discussed below. To illustrate, the increased use of antipsychotics in children is

known (Knopf et al., 2021). The increased number of dystonic reactions may be due to the increased use of antipsychotics and are not necessarily because they were prescribed differently than in the past.

Strengths and Weaknesses

The project had a number of weaknesses:

- There was no data available on the level of compliance with FDA approved guidelines prior to project implementation. Hence, it was not possible to determine whether provider education affected compliance. The project lead assumed that compliance was poor and improved post implementation with provider education.
- Data was collected for 91 weeks prior to implementation. Post implementation, only 4 weeks of data was collected. Furthermore, the number of dystonic reactions during the course of these timeframes was not evenly distributed. For instance, in the 4-week post implementation period, there was 1 week with 5 dystonic reactions and another with just 1 dystonic reaction. This can impact results of the study. Ideally, the time frames from before and after implementation should be consistent in order to make a true comparison. Furthermore, in order to observe a true pattern, more than 4 weeks of data collection is needed. Furthermore, a sample size larger than 20 charts would carry more significance.

The primary strength of the project lies in the its design and setting: A large pediatric psychiatric unit. The facility has data related to antipsychotic use for a large volume of pediatric patients each year. The project lead was not able to utilize the data due to time constraints. The facility still uses a paper based medical record system. Searching through paper charts to find a

large sample of patients that met the criteria for inclusion required more time than the project lead was able allocate for the project. Notably, the facility expects to upgrade to a modernized electronic medical records system ("EMR") in 2023 (Medical Director, New York, personal communication, September 2022). If the medical records system is updated as planned, it would be easier and less time consuming to collect the needed data for this project. If a team would agree to continue this research project after the EMR has been implemented, it should be able to obtain a much larger sample and use this data to determine a true cause and effect relationship between adherence with prescribing protocols and the number of dystonic reactions.

Impact on People and Systems

The providers are now more aware of the FDA approved prescribing guidelines. The providers are also aware of the need to take precautions that would lower the risk for them.

Differences Between Observed and Anticipated Outcomes

The number of dystonic reactions were much higher in the post implementation period. The project lead expected them to decrease. As discussed above, antipsychotics are one of the leading causes of drug induced dystonic reactions in children (Knopf et al., 2021). One way to decrease the risk of dystonic reactions is to follow a gradual rather than rapid dose titration (van Harten et al., 1999). The FDA guidelines recommend this as well and indicate clearly that children often require a slower titration schedule and have a lower maximum daily dose than adults (aripiprazole, n.d.; risperidone, n.d.). The project lead would have expected provider education on the prescribing of antipsychotics to children to decreased the number of dystonic reactions. This was not demonstrated though in 4 weeks of data collected.

Costs and Strategic Trade-offs

The decision was made to reduce the data collection period from 5 weeks to 4 weeks since the Director of Nurse Practitioner Education was not able to train the provider on schedule and due to project time constraints. The decision was made to decrease the sample of charts each week from 5 to 4 due to the difficulty in finding a sample that met the required criteria and using a paper based medical records system. The changes had to be made so that the project can be completed by its deadline. The tradeoff was a small sample size that may have little statistical significance. While this trade off will affect the project at its current state, were a team to agree to continue the data collection over a longer period of time, a sample of 5 charts per week may be sufficient to generate data that is more generalizable.

Limitations

The project was free of bias (including selection, survivorship, omitted variable, recall, observer and funding). Limitations related to design include:

- Design limitation. The project lead did not collect pre and post data for dystonic reactions over an equal period of time. Hence, there was limited ability to perform statistical analysis, such as a paired t test, and determine significance of change in patient outcomes.
- Data collection. Time constraints prevented an adequate sample over an adequate time period from being collected. Data was collected for 91 weeks prior to the project implementation. The project guidelines set forth by Touro University – Nevada only allowed for 4 – 5 weeks of data collection after the implementation phase.
- Sample size. With a small sample of 20 charts in the post implementation phase, there may not be enough data to identify significant relationships between adherence to prescribing guidelines and the prevalence of dystonic reaction.

- Not all providers attended the education session.

To compensate for these limitations the project lead will assign the project to an individual or team after the project due to date with recommendations to collect an additional 87 weeks of data. This will increase the sample size and the time frames for the pre and post-implementation periods will then match. Additional education programs should be scheduled to compensate for providers not present at each session.

Conclusion

Dystonic reactions due to psychiatric medications at a psychiatric hospital are common, a source of great distress, can be lethal in certain situations, lead to medication non-adherence and increase the burden on the healthcare system. The purpose of this project was to improve the quality of care at the project site by reducing the incidence of antipsychotic induced dystonic reactions in children that are prescribed antipsychotics. This would be accomplished by providing the provider with updated prescribing guidelines. Data was collected on the incidence of dystonic reactions at the project site from both before and after the provider were educated with manufacturer prescribing guidelines. The incidence of dystonic reactions from before and after the provider education program were compared. The incidence of dystonic reactions did not decrease in the 4 weeks following provider education. There an unexpected increase. Provider were 95% complaint with the FDA approved guidelines. Further study and analysis are needed to determine why incidence of dystonic reactions increased in the post implementation period.

Sustainability

The project is sustainable since the cost minimal, provider education is part of the normal workflow at the facility and it's in the facility's interest to reduce the incidence of dystonic reactions to a minimum.

Implications for Practice

Should the project demonstrate that provider education related to manufacturer prescribing guidelines reduces incidence of dystonic reactions, this may be a reason for advance practice nurses and other prescribing healthcare providers to focus more on FDA approved guidelines for prescribing practices and rely less on recommendations that may not be evidence based. Provider education should likewise be based upon these guidelines. Provider education that occurs at the time of hiring or whenever a new drug is introduced in the hospital's formulary would be based upon the FDA guidelines.

Suggested Next Steps

It is noted that the sample in the project was likely too small and the data collection phase of 4 weeks was too short to draw any conclusions. The data collection should be continued for another 87 weeks to match the pre-implementation time frame of 91 weeks. Furthermore, provider education on the manufacturer guidelines for prescribing antipsychotics would need to be provided at regular intervals until the project's completion.

References

Alkharboush, G. A., & Alsalamah, M. A. (2020). Risperidone-induced acute laryngeal dystonia: A case report. *The American Journal of Case Reports*, *21*, e922393. https://doi.org/10.12659/AJCR.922393

American Medical Association. (2020, December 2). *8 reasons patients don't take their medications*. https://www.ama-assn.org/delivering-care/patient-support-advocacy/8-reasons-patients-dont-take-their-medications

American Nurses Association. (n.d.). *What is Nursing & What do nurses do?* https://www.nursingworld.org/practice-policy/workforce/what-is-nursing

aripiprazole - Drug Summary. (n.d.). www.pdr.net. http://www.pdr.net/drug-summary/Abilify-aripiprazole-103

Cabarrus College of Health Sciences. (2022, June 16). *Cabarrus College of Health Sciences Library: IOWA Model.* Cabarrus College of Health Sciences Library. https://cabarruscollege.libguides.com/c.php?g=465666&p=5283295

DiBonaventura, M., Gabriel, S., Dupclay, L., Gupta, S., & Kim, E. (2012). A patient perspective of the impact of medication side effects on adherence: Results of a cross-sectional nationwide survey of patients with schizophrenia. *BMC Psychiatry*, *12*(1). https://doi.org/10.1186/1471-244x-12-20

Fakhoury, W. K. H., Wright, D., & Wallace, M. (2001). Prevalence and extent of distress of adverse effects of antipsychotics among callers to a united kingdom national mental health helpline. *International Clinical Psychopharmacology, 16*(3), 153-162. https://doi.org/10.1097/00004850-200105000-00004

Knopf, A. (2021). Multiple antipsychotics linked to acute dystonic reactions in 7% of children. *Brown University Child & Adolescent Behavior Letter*, *37*(2), 9–10. https://doi.org/10.1002/cbl.30525

Oates, G. R., Juarez, L. D., Hansen, B., Kiefe, C. I., & Shikany, J. M. (2020). Social risk factors for medication nonadherence: Findings from the CARDIA study. *American Journal of Health Behavior*, *44*(2), 232–243. https://doi.org/10.5993/ajhb.44.2.10

risperidone - Drug Summary. (n.d.). www.pdr.net. https://www.pdr.net/drug-summary/Risperdal-risperidone-977

Sikich, L., Hamer, R. M., Bashford, R. A., Sheitman, B. B., & Lieberman, J. A. (2004). A pilot study of risperidone, olanzapine, and haloperidol in psychotic youth: A double-blind, randomized, 8-week trial. *Neuropsychopharmacology: Official Publication of the American College of Neuropsychopharmacology, 29*(1), 133–145. https://doi.org/10.1038/sj.npp.1300327

Tural Hesapcioglu, S., Ceylan, M. F., Kandemir, G., Kasak, M., Sen, C. P., & Correll, C. U. (2020). Frequency and correlates of acute dystonic reactions after antipsychotic initiation in 441 children and adolescents. *Journal of Child and Adolescent Psychopharmacology*, *30*(6), 366–375. https://doi.org/10.1089/cap.2019.0123

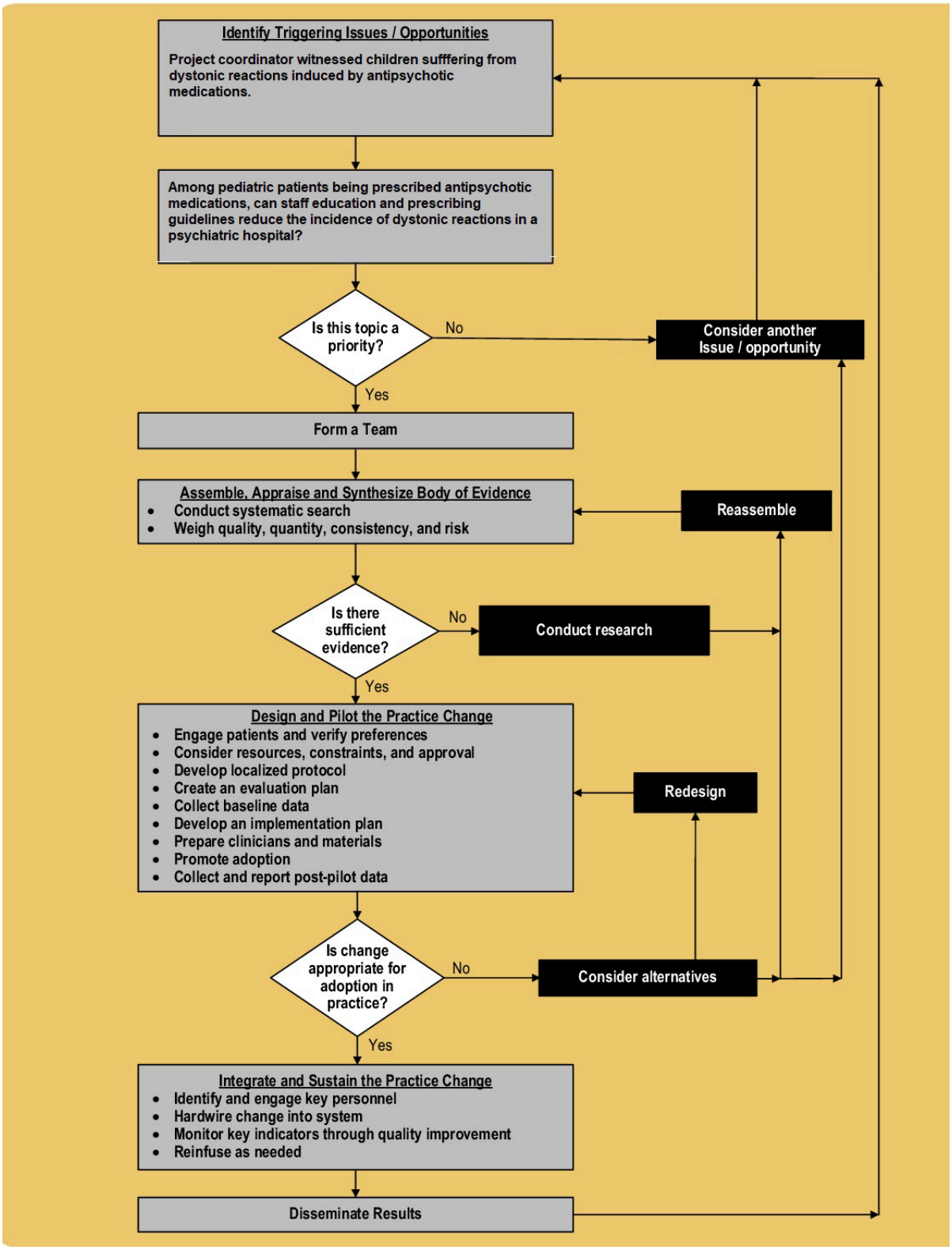
University of Pennsylvania School of Nursing (n.d.). *American Nursing: An Introduction to the Past*. (n.d.). https://www.nursing.upenn.edu/nhhc/american-nursing-an-introduction-to-the-past/

van Harten, P. N., Hoek, H. W., & Kahn, R. S. (1999). Fortnightly review: Acute dystonia induced by drug treatment. *BMJ, 319*(7210), 623–626. https://doi.org/10.1136/bmj.319.7210.623

Yamamoto, N., & Inada, T. (2012). Dystonia secondary to use of antipsychotic agents. *Dystonia - The Many Facets*. https://doi.org/10.5772/27559

Appendix A

IOWA Model



Appendix B

IRB Waiver

Touro University Nevada

DNP 763–Project II

DNP Project Team Determination: Quality Improvement Project or Research

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

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

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

SECTION A

Student Name: Micah B. Engel

DNP Project Title: Reducing the Incidence of Antipsychotic Induced Dystonic Reactions in Children

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

DNP Project Mentor: Jessica Kilbride, DNP

Quality Improvement or Research Worksheet

Rachel Nosowsky, Esq.

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

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

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

Obtained from: Quality Improvement or Research Worksheet

SECTION B

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

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

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X___ No, I did not register my project with the Department of Research at TUN. Please provide rationale.

SECTION C

Project Classification Decision:

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

X____ This DNP Project is a quality improvement project. Do not submit to IRB for review.

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

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

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

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

Electronic Signature of Project Instructor: Julie A Astrella

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Appendix C

FDA Guidelines *

- Abilify
    - Schizophrenia
        - Age 13-17: Initially, 2 mg PO once daily. After 2 days increase to 5 mg PO once daily, and after 2 more days increase to the target dose of 10 mg PO once daily. Then, titrate in 5 mg increments, usually every 2 weeks to allow assessment of effectiveness and tolerability. Max: 30 mg/day PO.
    - Bipolar d/o (acute)
        - Age 10 and older: Initially, 2 mg PO once daily. Titrate to 5 mg once daily after 2 days, and then titrate to a target dose of 10 mg/day after an additional 2 days. Subsequent increases should occur in increments of 5 mg/day. Max: 30 mg/day PO.
    - Autism:
        - Age 6-17: Initially, 2 mg PO once daily. Increase dose to 5 mg PO once daily after 1 week. Further titration should occur in increments of 5 mg/day at intervals of no less than 1 week. Recommended dose range: 5 mg to 10 mg PO once daily. Individualize regimen based upon response and tolerability. Max: 15 mg/day PO.
- Risperdal
    - Schizophrenia
        - Age 12-17: 0.5 mg PO once daily initially. May administer in divided doses to increase tolerability. Adjust dose at intervals of at least 24 hours and in increments of 0.5 to 1 mg/day as tolerated to the recommended target dose of 3 mg/day. Max: 6 mg/day PO.
    - Bipolar d/o (acute)
        - Age 10 - 17: Initially, 0.5 mg PO daily. Adjust dose at intervals of at least 24 hours and in increments of 0.5 mg/day to 1 mg/day as tolerated to the recommended target dose range of 1 mg/day to 2.5 mg/day PO. Max: 6 mg/day PO.
    - Autism:
        - Age 5-17 weighing between 33 and 42 LBS: 0.25 mg PO once daily, initially, for at least 4 days. Then may increase to recommended dose of 0.5 mg PO daily. Maintain this dose for at least 14 days. Thereafter, adjust as clinically necessary at intervals of at least 2 weeks and increments of 0.25 mg/day PO. Max: 3 mg/day PO.
        - Age 5-17 weighing 42 LBS or more: 0.5 mg PO once daily, initially, for at least 4 days. Then may increase to recommended dose of 1 mg PO daily. May administer in divided doses to increase tolerability. Maintain this dose for at least 14 days. Thereafter, adjust as clinically necessary at intervals of at least 2 weeks and increments of 0.5 mg/day PO. Max: 3 mg/day PO.

* Adopted from Prescriber's Desk References

Appendix D

Timeline

Reducing the Incidence of Antipsychotic Induced Dystonic Reactions in Children

The project was implemented over the course of 4 weeks from 10/31/22 to 12/6/2022:

- Week 1 (11/11/22): Educate provider
- Weeks 2–5 (11/13/22-12/10/22): Collection of compliance data. The project lead reviewed 5 charts each week. Criteria for inclusion will be pediatric patients treated with Risperdal or Abilify for an FDA approved indication for which there are prescribing guidelines. The project lead will assess if these prescribing guidelines were followed.
- Week 6 (12/12/22): The project lead requested the medical record for patients that received IM Cogentin injections during weeks 2 to 5 of the project implementation. The project lead assessed if the number of dystonic reactions has decreased since project implementation.

Appendix E
Chart Review Process

1. Is the patient age 17 or less and taking Abilify for Risperdal? (if not, then chart is excluded)
2. If the patient is taking Abilify, then what is the age and diagnosis?
    a. Based upon his age and diagnosis, is the child taking Abilify for an FDA approved indication? (If not, then the chart will be excluded)
    b. Were the manufacturer's dosing recommendations followed while in this hospital based upon the patient's age and diagnosis?
3. If the patient is taking Risperdal, then what is the age, weight and diagnosis?
    a. Based upon the age, weight and diagnosis, is the child taking Risperdal for an FDA approved indication? (If not, then the chart will be excluded)
    b. Were the manufacturer's dosing recommendations followed while in this hospital based upon the patient's age, weight and diagnosis?

Appendix F
Chart Review Tool

	Number of charts that followed prescribing guidelines	Number of charts that **did not** follow prescribing guidelines	Number of dystonic reactions in hospital
Week 1 (11/13/22 – 11/19/22)	5	0	1
Week 2 (11/20/22-11/26/22)	5	0	5
Week 3 (11/27/22-12/3/22)	5	0	3
Week 4 (12/4/22 to 12/10/2022	4	1	3