SUSTAINABILITY AND BENEFITS OF INDEPENDENT COMMUNITY PHARMACY LONG-ACTING INJECTABLE ANTIPSYCHOTIC MEDICATION SERVICES

A report submitted to the

University of Minnesota College of Pharmacy

Postgraduate (PGY1) Pharmacy Residency Program

by

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Abstract

On July 1st, 2019, new legislation went into effect in Minnesota that expanded the scope of practice for pharmacists to include the administration of long-acting injectable (LAI) antipsychotic medications in order to increase access to care. However, the benefits and sustainability of community pharmacies to offer this service is unknown. This project was designed to answer the unknow by increasing the number of patients receiving long-acting injectable (LAI) antipsychotics from a total of 0 to 3 per month by April 24th, 2020 at GuidePoint Pharmacies.

Eligible patients were >18 years and prescribed a LAI. Interventions and data were collected at each visit with a comprehensive medication review at the first visit. Patients were followed up with monthly or at next appointment; whichever was sooner.

Two patients were included in the study. One of the patients dropped out due to cost of medication and interventions were made on behave of the other patient. Patients' weight, blood pressure, CQI, AIMS score, and lipids did not have enough data to perform analysis.

Many barriers were present when initiating the new service of administering long-acting antipsychotic injectables in a community pharmacy which resulted in the study not being robust or sustainable. Once sustainable, pharmacists can begin to demonstrate a benefit in administering LAI.

I. Introduction

In rural communities, patients struggle to gain access to medical care due to geographical distance leaving some to have pharmacies their only entry point into the system; behavioral health being no exception. It is estimated that 69% of counties in the North West Central Region of the United States, which includes Minnesota, do not have access to a psychiatric provider. (1) Adding the service of administering long-acting injectable (LAI) medications to rural Minnesota will increase access for patients. Along with increased access to LAI, patients with serious and persistent mental illness will have continuity of care through comprehensive medication management, wellness checks, and continuous follow-up during the same visit as the injection.

GuidePoint pharmacies aim to bring specialized and individualized care to patients in rural communities. This is achieved by providing enhanced pharmacy services including pharmacogenomic screening, comprehensive medication management, point-of-care screenings, immunizations, and American Association of Diabetes Educations (AADE) - accredited Diabetes Self-Management Education. Offering a wide variety of enhanced pharmacy services to rural communities has helped patients achieve the best possible outcomes for their health through increase access to medical care.

Pharmacist administration of LAI is relatively new to the United States with Minnesota recently expanding the scope of pharmacy practice July 1, 2019, which has resulted in limited data as to the benefits pharmacists could provide. A study from June 2019 (2) in a multi-state supermarket-based community pharmacy determined that

percentage pharmacy-administered patients' adherence, which is the proportion days covered ≥80%, to LAI 78%. Since non-adherence is estimated to cost the United States more than $290 billion yearly and many LAI are expensive, increases the adherence rate could help decrease this yearly cost.

Another study, Mooney et al. (3), was a prospective study that sought to evaluate patient satisfaction with pharmacist-administered LAI in the community pharmacy. The small study found that patients had a positive response to the pharmacist led service with to 86% of the patients reporting that it was convenient to schedule an appointment and the service provided by the community pharmacy was more convenient than a similar service at a different healthcare setting. Ultimately, this new service will be an example of how Minnesota community pharmacy can increase access to care and adherence through LAI administration

II. Methods

Evaluation of the new service was focused on the sustainability and benefits of LAI offered in community pharmacies. To evaluate sustainability; the cost of medication, administration fee, and other services rendered were documented. Reimbursement for all services provided, including comprehensive medication reviews, were also recorded for each visit.

The Clinical Global Impression (CGI) severity and improvement scales are tools for the clinician to quantify and track patient progress and response over time (Appendix II). (4) This scale provides a studied method to determine severity of mental health

conditions. A movement disorder assessment (AIMS) and lipid panels were performed as indicated by the flowchart in appendix III when patients consented. (5)

Patient Appointments

Prior to the first patient encounter, verbal permission to administer the LAI was acquired from the provider whom ordered the medication. A review of the patient's medication list was performed, and a call was made with the patient to set an appointment date.

At the initial visit the patient received a comprehensive medication review (CMR) and a wellness check. Each appointment also included the signing of the consent form (Appendix I), medication review, collection of vitals, and completion of a CGI (Appendix II). The collection of vitals was stopped in March 2020 due to COVID-19 pandemic. Assessment if the LAI was indicated, safe, and effective was performed prior to injection.

After all the previous requirement were completed the patient received the injection following the administration instructions set forth in the package insert for each individual medication. Once the appointment was completed the prescribing provider was notified by either fax or phone.

III. Results

The goal of three patients receiving LAI from GuidePoint pharmacy was not met. Only two patients received injections with one continuing to receive the service.. Patient 1 received two injections of Sustenna Invega, and Patient 2 received six injections haloperidol decanoate. Each of the patients are examined individually below.

The third-party reimbursement rate for each LAI dispensed is listed in Table I. This does not include any administration fee and at the time of this manuscript no third part has reimbursed the administration fee for LAIs. A positive reimbursement was found for the Invega Sustenna. Following December 2019, dispensing haloperidol decanoate resulted in a negative reimbursement. The total LAI reimbursement was $154.79. Given the administration fee of $25 the total administration fees that were billed were $200. This results in a negative balance of $45.21.

Patient 1

Patient 1 was prescribed Invega Sustenna 234 mg every 3 weeks. She received two injection but had to discontinue the service due to the inability to pay for the injection following a change in insurance. If the patient were to continue to receive the injection following the insurance change the patient would have had to pay ~$600 every 3 weeks. Since she received only two injections there is limited data on the patient.

Patient 2

Patient 2 received six injections of haloperidol 50 mg. The patient has two interventions made on her behave with the timeline shown in Figure I. The first intervention was to change the interval from every 4 weeks to every 3 weeks. Change was made due to increase in patient symptoms. The second intervention was due to a shortage of haloperidol decanoate 50 mg/mL. She was switched to the haloperidol decanoate 100 mg/mL with 0.5 mL injected. She completed three Patient Health Questionnaire – 9 (PHQ-9) which increased each time. (Table II). The patient did not have a trend with her CGI results.

IV. Discussion

There was not enough data collected during the allotted time for analysis to be conducted. The results provide some anectodical evidence towards the interventions that can be made on the patient's behalf as well as the many barriers that are present to initiate the service in the community pharmacy. The barriers experienced are discussed in a section below.

Some data was collected for patient 2. A possible explanation for her increase is PHQ-9 is that her mood was affected by the isolation caused by COVID-19. The patient has struggled with paranoia in the past in regard to germs and she stated she was experiencing an increase in symptoms due to the pandemic. The patient's CGI-S most likely did not have a trend due to the limited data as well as the interventions needed to be made. The patient was late with her last injection to which she realized when her symptoms increased. The pharmacist was unable to reach the patient to schedule the appointment until she reached out to the pharmacy.

All but one of the injections were administered by the author. The pandemic caused one of the injections to be given by a different pharmacist and not all data was collected at that visit. Vitals were also stopped once the pandemic began to decrease contact time. The pandemic resulted in less data being able to be collected.

Barriers

Starting a new service brought to light the many barriers to starting administration of LAI in the community pharmacy. One of these barriers is Provider awareness of the expansion of the scope of pharmacists' practice. To increase awareness the following was performed: the pharmacy faxed letters to all the psychiatric providers that have a

patient fill a prescription at the pharmacy; explained new service over the phone; attending a psychiatric providers lunch; and face-to-face interactions with two providers. In the future more times could be dedicated to face-to-face interactions with providers as this seemed to be the best way to develop pharmacy-provider relationships.

Reimbursement of services is needed for the new service to be sustainable. At this time there has not been reimbursement for the administration fee. With time this should improve due to the law being less than a year old but until there is something in place the practice will not be able to take off across pharmacies in Minnesota.

The current pandemic has caused significant changes. Shortened visits and other precautions had to be in place to administer an injection. By having the visit with minimal contact some of the data was unable to be collected. This resulted in less monitoring of side effects. With the future uncertain it is unclear how to overcome this barrier.

In the future it may be beneficial to increase patient awareness. Individual patients who were prescribed LAI were approached but there was not any other outreach. Increasing patient awareness would target the patients that are currently going to the clinic to receive their injections; switching to the pharmacy setting may be more convenient for those patients.

V. Conclusion

Adding the service of administering long-acting antipsychotic injectable is not currently sustainable with current reimbursement. There was not enough patients or data collected to determine how pharmacists can benefit patients' access to care and side

effect management. There are many barriers to overcome and further research is needed.

VI. References

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VII. Tables

Table I – Third Party Reimbursement:

Reimbursement from third party after billing the medication only.

Date	**Patient 1: Invega Sustenna**	**Patient 2: Haloperidol vial**
12/3/2019	79.69	------
12/24/2019	79.69	------
12/31/2019	------	2.39
1/29/2019	------	-1.12
2/26/2020	------	-1.12
3/17/2020	------	-1.12
4/7/2020	------	-1.12
5/1/2020	------	-2.50
TOTALS:	159.38	-4.59

Table II – Patient 2 PHQ-9 and CGI

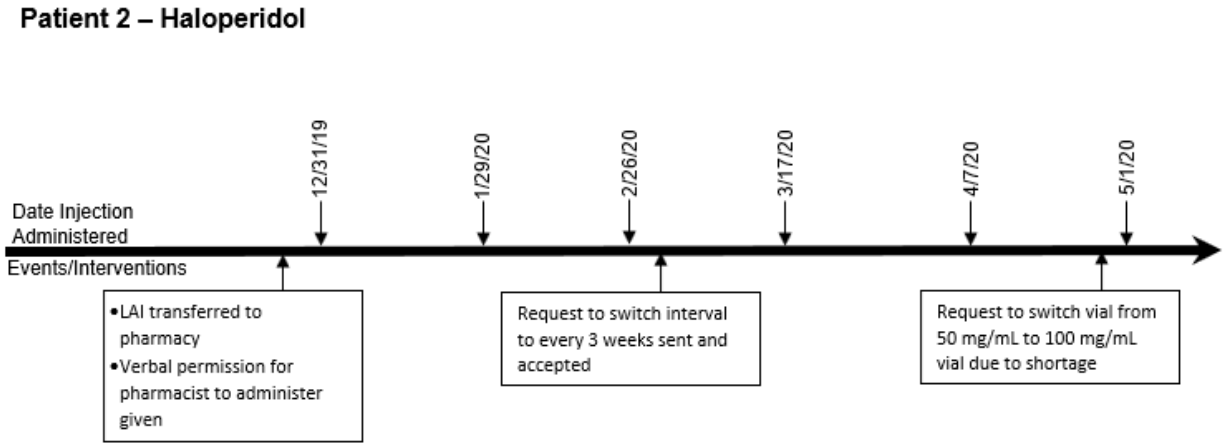
Results for Patient 2 with dates. Dashed lines mean that data was not collected on that date.

Date	**PHQ-9**	**CGI - S**
12/31/2019	13	------
1/29/2019	------	4
2/26/2020	14	6
3/17/2020	------	2
4/7/2020	------	------
5/1/2020	16	5

VIII. Figures

Figure I – Patient 2 Injections and Event Timeline:

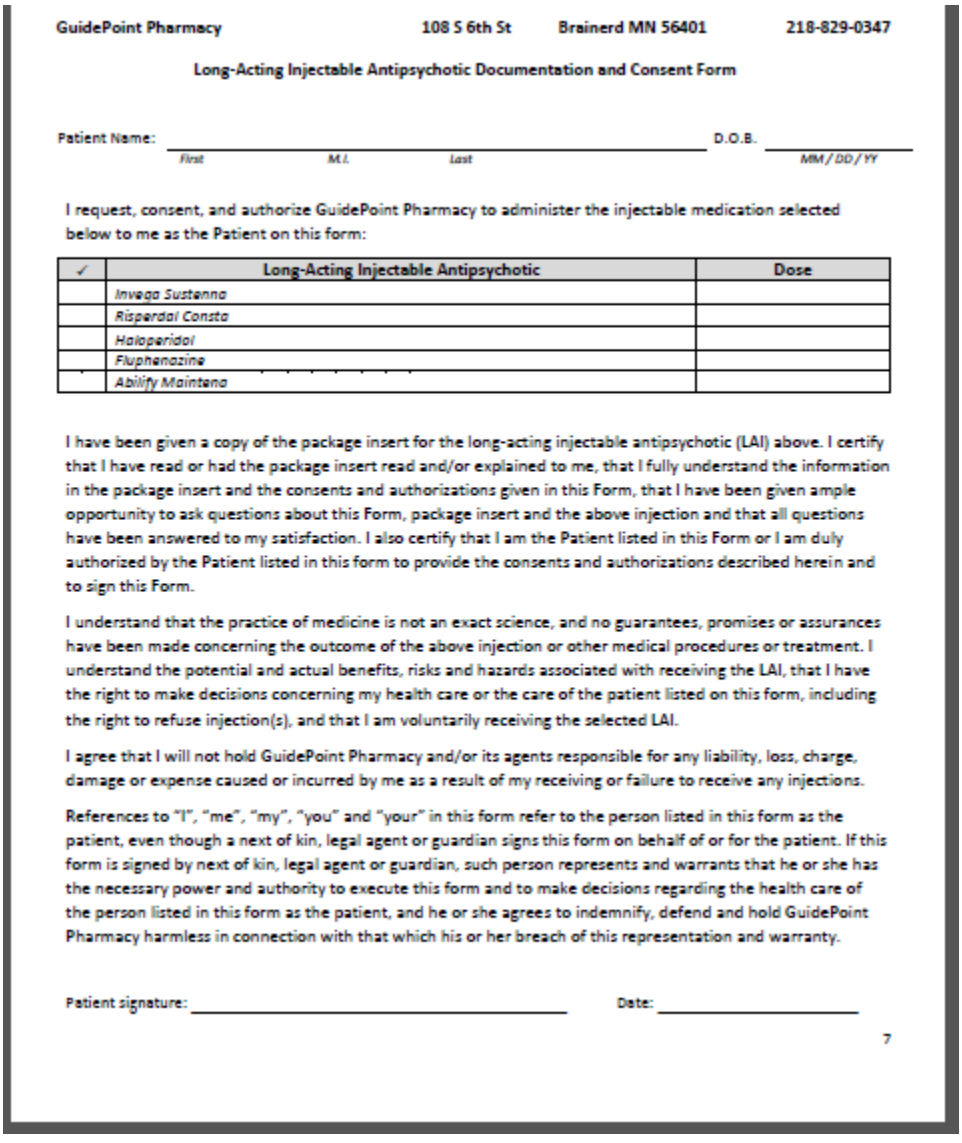
The number above the line are dates that haloperidol was injected into the patient. Below the line are events and interventions performed on behalf of the patient.



IX. Appendices

Appendix I – Documentation and Consent Form

Front Page



GuidePoint Pharmacy **108 S 6th St** **Brainerd MN 56401** **218-829-0347**

Long-Acting Injectable Antipsychotic Documentation and Consent Form

Patient Name: _____ D.O.B. _____
First *M.I.* *Last* *MM/DD/YY*

I request, consent, and authorize GuidePoint Pharmacy to administer the injectable medication selected below to me as the Patient on this form:

✓	Long-Acting Injectable Antipsychotic	Dose
	Invega Sustenna	
	Risperdal Consta	
	Haloperidol	
	Fluphenazine	
	Abilify Maintena	

I have been given a copy of the package insert for the long-acting injectable antipsychotic (LAI) above. I certify that I have read or had the package insert read and/or explained to me, that I fully understand the information in the package insert and the consents and authorizations given in this Form, that I have been given ample opportunity to ask questions about this Form, package insert and the above injection and that all questions have been answered to my satisfaction. I also certify that I am the Patient listed in this Form or I am duly authorized by the Patient listed in this form to provide the consents and authorizations described herein and to sign this Form.

I understand that the practice of medicine is not an exact science, and no guarantees, promises or assurances have been made concerning the outcome of the above injection or other medical procedures or treatment. I understand the potential and actual benefits, risks and hazards associated with receiving the LAI, that I have the right to make decisions concerning my health care or the care of the patient listed on this form, including the right to refuse injection(s), and that I am voluntarily receiving the selected LAI.

I agree that I will not hold GuidePoint Pharmacy and/or its agents responsible for any liability, loss, charge, damage or expense caused or incurred by me as a result of my receiving or failure to receive any injections.

References to "I", "me", "my", "you" and "your" in this form refer to the person listed in this form as the patient, even though a next of kin, legal agent or guardian signs this form on behalf of or for the patient. If this form is signed by next of kin, legal agent or guardian, such person represents and warrants that he or she has the necessary power and authority to execute this form and to make decisions regarding the health care of the person listed in this form as the patient, and he or she agrees to indemnify, defend and hold GuidePoint Pharmacy harmless in connection with that which his or her breach of this representation and warranty.

Patient signature: _____ Date: _____

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Back Page

Injection	Site	Location	Lot #	Pharmacist Name
	☐L ☐R ☐IM	☐Deltoid ☐Gluteal ☐Other: _____		

PHARMACY USE:

Vitals:

Height (inches)	
Weight (lbs)	
Blood pressure	
Heart rate	
Respiratory Rate	

AIMS

Last AIMS score:_____ Date:_____

Frequency of assessment*:_____

AIMS

Last AIMS score: _____ Date:_____

Frequency of assessment*:_____

*per AIMS flowchart in LAI binder

Date of next AIMS score:_____

Lipid Panel:

Date of Last lipid panel:_____

Frequency of panel*:_____

*per LIPID flowchart in LAI binder

Date of next panel:_____

If lipid panel is due. Attach documentation to form.

Before Injection:

( ) Review above information

( ) Review medication list with patient

( ) Collect vitals

( ) Fill out information regarding AIMS & lipid panel

After Injection:

( ) offer updated medication list to patient

( ) Give patient Next Appointment card

( ) Scan Form, medication list, and any supplemental material into patient documents

( ) Create task for patients next injection date

( ) Fax Form & Medication list to provider

Notes:_____

_____

_____

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Appendix II – Clinical Global Impression (CGI) Scale

Clinical Global Impressions (CGI) Form*

*Detailed scales available in Busner et al. (6)

Date: _____

Patient Name: _____ **DOB:** _____

Directions: Rating scales are located under CGI tab in LAI binder. Must be done at each visit.

CGI-S: _____

CGI-I: _____

Justification:

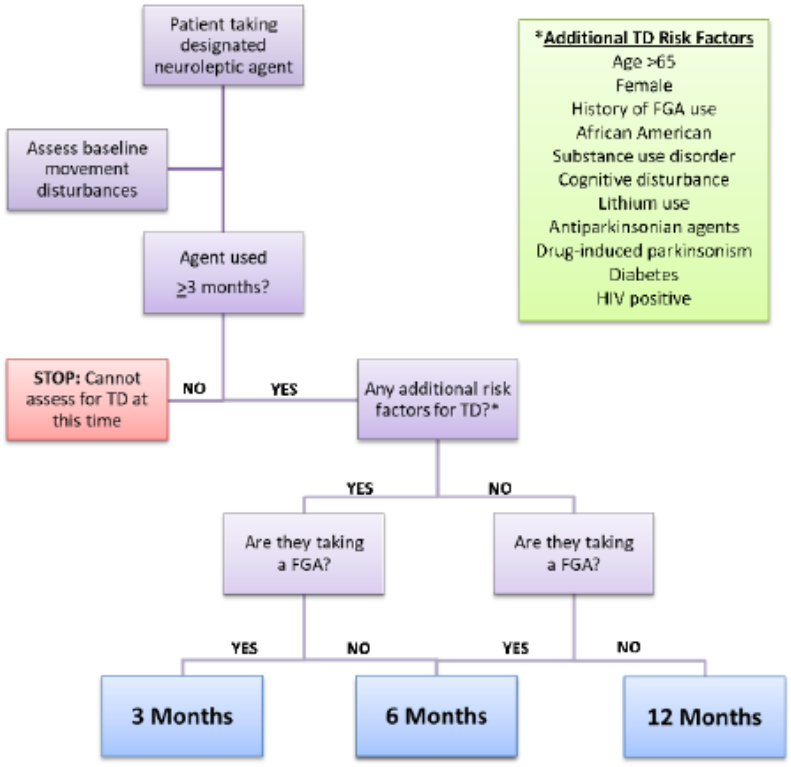
_____

_____

_____

Appendix III – Frequency of AIMS & Lipids

Recommended Frequency of AIMS Assessment



Abbreviations: TD – tardive dyskinesia; FGA – first generation antipsychotic

Table 5. Metabolic monitoring protocol for children and adolescents on second-generation antipsychotic medications.

Clinical evaluations								
	Tools	**Baseline**	**1 month**	**2 months**	**3 months**	**6 months**	**9 months**	**12 months**
Family and personal history*		x						
Height, weight, BMI, and age- and sex-specific percentiles	www.cdc.gov/growthcharts/	x	x	x	x	x	x	x
Waist circumference (at the level of the umbilicus) and percentiles	www.idf.org/webdata/docs/Mets_definition_children.pdf (pages 18-19); use adult cut-off (page 10) if lower	x	x	x	x	x	x	x
Blood pressure and percentiles	http://keltymentalhealth.ca/sites/default/files/HighBPGuidelines.pdf	x	x	x	x	x	x	x
Neurological examination for monitoring extrapyramidal symptoms	• AIMS (Abnormal Involuntary Movement Scale) www.mhsip.org/library/pdfFiles/abnormalinvoluntarymovementscale.pdf • SAS (Simpson-Angus Scale) www.outcometracker.org/library/SAS.pdf • ESRS (Barnes Akathisia Rating Scale) http://keltymentalhealth.ca/sites/default/files/BARS.pdf	x			x	x		x
Laboratory evaluations								
		Baseline	**1 month**	**2 months**	**3 months**	**6 months**	**9 months**	**12 months**
Fasting plasma glucose		x			x	x		x
Fasting insulin†		x			x	x		x
Fasting lipids (total cholesterol, LDL-C, HDL-C, triglycerides)		x			x	x		x
AST and ALT		x				x		x
TSH (quetiapine only)		x						x
Prolactin‡		x						x

Adapted from the Metabolic Assessment, Screening and Monitoring Tool and used with permission of Drs C. Panagiotopoulos and J. Davidson.
*Family history of diabetes (type 1, type 2, gestational), hyperlipidemia, cardiovascular disease, schizophrenia, schizoaffective disorder, psychosis not otherwise specified, bipolar disorder; personal history of smoking, physical activity, screen time, and sugar-sweetened beverages.
†Note that this assessment is *not* recommended for aripiprazole or ziprasidone, but is appropriate for all other second-generation antipsychotic medications.
‡Assessment of prolactin levels should be completed according to protocol except when the patient is displaying clinical symptoms of hyperprolactinemia (i.e., menstrual irregularity, gynecomastia, or galactorrhea), in which case more frequent monitoring may be warranted. Please also note that risperidone is the SGA with the greatest effect on prolactin.