

Molly Everett
Manuscript

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2 **Title: Adherence to Antipsychotic Medications- The Role of the Community Pharmacist**

3 **Principal Investigator**

4 Molly Everett, PharmD
5 PGY-1 Community-Based Pharmacy Resident
6 Jewel-Osco/Albertsons Companies, Chicago, IL

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8 **Co-Investigators**

9 Chandni Clough, PharmD
10 Residency Program Director, Patient Care Services Manager
11 Jewel-Osco/Albertsons Companies, Chicago, IL

12

13 Jeffrey Hamper, PharmD, BCACP
14 Academic Relations Manager
15 Albertsons Companies, Boise, ID

16

17 Jay Highland, PharmD
18 Patient Care Pharmacist, Residency Coordinator
19 Jewel-Osco, Chicago, IL

20

21 Brittany Hoffmann-Eubanks, PharmD, MBA
22 Pharmacy Manager, Patient Care Pharmacist
23 Jewel-Osco, Chicago, IL

24

25 Christina J. Cross, Pharm.D., BCACP
26 Pharmacy Manager, Residency Coordinator
27 Jewel-Osco, Chicago, IL

28

29 Chigozirim Obiekwe
30 Pharmacy Manager, PGY1 Residency Preceptor
31 Jewel-Osco, Chicago, IL

32

33 Beatrice Drambarean, PharmD, BCPS, BCACP
34 Clinical Pharmacist, Ambulatory Pharmacy Services
35 Clinical Assistant Professor, Pharmacy Practice
36 UIC College of Pharmacy, Chicago, IL

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40 **Abstract (295/300)**

41 Purpose: The purpose of this study is to assess the adherence rates of oral antipsychotics with
42 long-acting injectable (LAI) antipsychotic formulations among patients within a community
43 pharmacy setting. Nonadherence to antipsychotic medications can lead to devastating outcomes
44 for patients. There is a gap between identifying nonadherence in this patient population and
45 implementing interventions in the community setting. This study will provide data to assist
46 pharmacists in having a better understanding of how to help patients improve adherence for
47 antipsychotic medications.

48

49 Methods: This is a retrospective review that will analyze data from January 1, 2018 through
50 January 1, 2020 to assess the adherence rates of oral antipsychotic medications with LAI
51 formulations within select pharmacy locations in Illinois of a national grocery store chain. The
52 medications will be identified via their National Drug Code, and are paliperidone, aripiprazole,
53 and risperidone. The refill history of oral antipsychotic medications for patients who are 18 years
54 of age and older and have taken one of the selected medications for a minimum of 6 months will
55 be included. The proportion of days covered (PDC) will be calculated for each patient to
56 determine adherence rate.

57

58 Results: The average PDC rate calculated for this study population was 82%. A PDC >80% is
59 considered adherent, and this average is higher than what was expected. However, 35% of
60 patients analyzed had a PDC of less than 80%, and 50% of patients had a PDC of <90%.

61

62 Conclusion: Pharmacists have demonstrated their ability to increase patient adherence and long-
63 term outcomes for a variety of medications. When it comes to mental health outcomes,
64 adherence to medications can decrease the chance of relapse and improve quality of life. This
65 study will shed light on adherence to medications that have long-acting injectable formulations; a
66 potential solution to improve adherence.

67

68 **Introduction (422)**

69 Medication nonadherence can have serious effects on patients across all disease states,
70 especially when patients are taking these medications chronically. In the case of antipsychotic
71 medications, the consequences of medication non-adherence can be especially severe.
72 Nonadherence can lead to decompensation or exacerbation of symptoms, relapse,
73 rehospitalization or greater use of emergency psychiatric services, functional decline, and
74 increased risk of death.¹ Pharmacists are often the first to recognize the red flags of
75 nonadherence, late or missed refills. When pharmacists have the full refill history for patients,
76 the proportion of days covered (PDC) rate for each patient can be calculated to show how
77 adherent patients are to medications, including oral antipsychotic medications. PDC is calculated
78 by taking the number of days in the period “covered”, dividing by the number of days in the
79 period, and multiplying by 100%.

80 Clinical evidence shows that the ideal threshold for PDC is 80%, according to the Pharmacy
81 Quality Alliance.² Currently, PDC is assessed for other chronic disease state medications, such as
82 statins and diabetic medications, to ensure that patients are remaining adherent and obtaining the
83 maximum benefit of those medications. If the PDC is low, pharmacists can implement
84 interventions such as automatic refills, reminder phone calls, and periodic check-ins to identify
85 any barriers to adherence. Patients taking oral antipsychotics who have a low PDC should also
86 have these interventions in place. There is currently a gap between identifying nonadherence in
87 this patient population and implementing interventions in the community setting.

88 As of January 1, 2020, pharmacists in the state of Illinois were authorized to administer long-
89 acting-injectable antipsychotic medications to patients who had an active prescription from their
90 doctor. In states where pharmacists are authorized to administer injectable medications, it is
91 important to understand the trends in adherence and to recognize where pharmacists can make
92 appropriate recommendations to prescribers. It is crucial that pharmacists have a clear
93 understanding of their patients' adherence to oral antipsychotics, and that they can make
94 appropriate interventions and recommendations to switch to LAI antipsychotics when necessary.
95 Pharmacists have the potential to improve outcomes for their patients and the healthcare system.
96 In contrast to existing literature that is focused on oral adherence to antipsychotic medications,
97 this study will focus on oral antipsychotics that have an injectable dosage form available. By
98 collecting this information, pharmacists will have a better understanding of how to help patients
99 improve their adherence for antipsychotic medications. The purpose of this study is to assess the
100 adherence rates of oral antipsychotic medications with LAI equivalents among patients within a
101 community pharmacy setting.

102

103 **Objectives (42)**

104 The primary objective of the study was to assess adherence rates of oral antipsychotics
105 with LAI equivalents among patients within a community pharmacy setting. The secondary
106 objective of this study was to assess characteristics of patients with both high and low adherence.

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108 **Methods (111)**

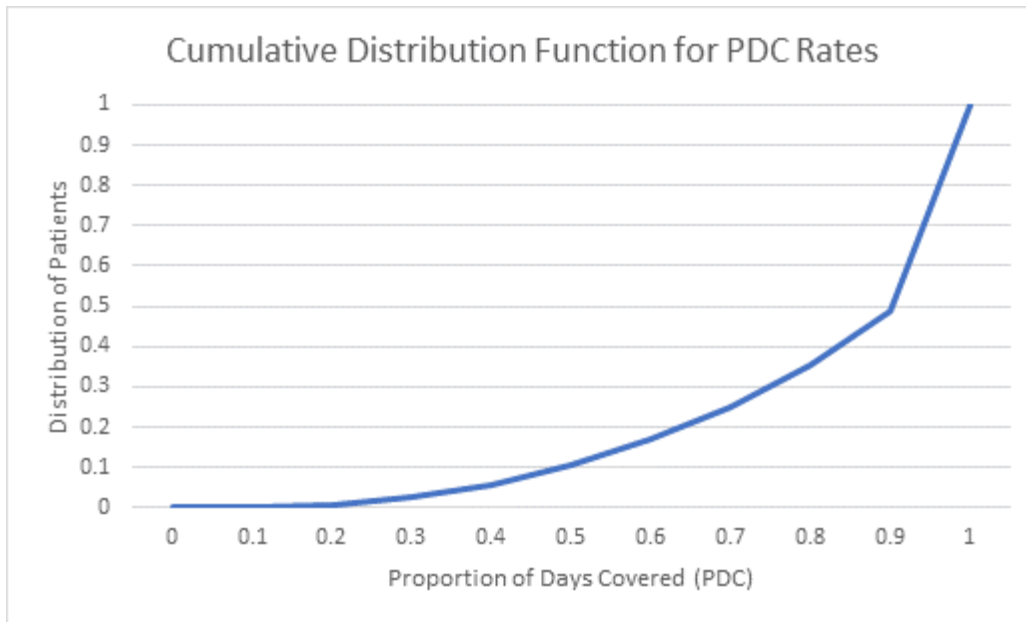
109 A retrospective review of oral antipsychotic medication adherence rates with LAI
110 equivalents was conducted from January 1, 2018, until January 1, 2020. Any patient 18 years of
111 age and older receiving oral antipsychotic medications that have an available long-acting
112 injectable formulation during the study period and have taken the medication for a minimum of 6
113 months was included in the study. Those excluded from the study included patients younger than
114 18 years of age, patients receiving oral antipsychotics that do not have a long-acting injectable
115 formulation or those patients who have been taking an oral antipsychotic medication for <6
116 months. Proportion of days covered (PDC) was calculated for each patient analyzed.

117

118 **Results (151)**

119 There were 212,744 prescription records collected for the purposes of this studying. After
120 grouping the records by patient, and applying the inclusion and exclusion criteria, the
121 prescription records of 16,784 patients were analyzed. The average PDC rate calculated among
122 the patients analyzed was found to be 82%, with PDC ranging from 39%-100%. Analysis also

123 showed that 35% of patients had a PDC of <80%. PDC calculations were capped at 100%,
124 despite the possibility of early refills, since a PDC of >100% was not feasible for the purposes of
125 this study.



126

127 **Figure 1. The Cumulative Distribution Function for PDC Rates.** This graph describes
128 the proportion of patients at each PDC percentage, from 0 to 1. For example, 50% of the patients
129 had a PDC of 90% or lower. 35% of the patients had a PDC of 80% or lower, and approximately
130 10% of the patients analyzed had a PDC of 50% or lower.

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132 Discussion (390)

133 When looking at PDC as a tool to measure adherence, PDC >80% indicates that a patient
134 is adherent to their medications.³ The PDC found in this study was higher than anticipated in this
135 patient population, based on past literature and preliminary data results. One study conducted in
136 2018 found the adherence rate for oral antipsychotics to be 32% for patients taking medications
137 for early psychosis.⁴ According to previous studies, adherence rates for second-generation
138 antipsychotics typically hover between 50-60%.⁵ Although the average PDC was higher than
139 initially expected, there is still a large number of patients that are not being adherent to their
140 antipsychotic medications.

141 The study did encapsulate a large group of patients, therefore the 35% (n of 5906) of
142 patients that had a PDC <80% is still substantial. Additionally, patients who are achieving the
143 minimum recommended PDC score of >80% can still benefit from converting to an LAI
144 antipsychotic to further increase their PDC, and potentially improve convenience by decreasing
145 their pill burden.

146 The final results indicate that in 35% of the patients assessed, it would be appropriate for
147 the pharmacist to intervene in order to improve adherence. Regarding mental health outcomes,

148 adherence to antipsychotic medications can greatly decrease the chance of relapse and potentially
149 improve quality of life. Pharmacists have demonstrated their ability to increase patient
150 adherence and long-term outcomes for a variety of medications. With patient consent,
151 pharmacists have the ability to discuss with prescribers the switch to injectable alternatives for
152 patients and provide education and administration of these medications.

153 One of the key limitations of this study is the assumption that all patients should be
154 continuously taking their antipsychotic oral medications. As this is a retrospective study, there
155 are several reasons why a patient may have temporarily discontinued a medication, such as
156 hospitalization, adverse drug events, changing providers, or other barriers. By determining the
157 average PDC for each patient and simply looking at their refill history, it leaves out potentially
158 vital details that may have led to the appearance of “poor adherence”. Another limitation of the
159 study is one that commonly occurs when using PDC as a measure of adherence. While PDC of
160 oral medications implies that medications are picked up on time, the pharmacist does not have
161 the ability to measure that the patient is actually taking the medication daily in a community
162 pharmacy setting.

163 164 **Conclusion (106)**

165 This study has important implications regarding adherence to an important class of
166 medications. Although the results showed that adherence was higher than expected, LAI
167 antipsychotics may still help to improve PDC and decrease pill burden for patients; even for
168 those patients who show >80% PDC adherence. This study sheds light on adherence to
169 medications that have alternative long-acting injectable formulations, which could be a solution
170 to improve adherence for this patient population. If an alternative exists for a patient that
171 minimizes barriers to adherence, the community pharmacist is the most suitable health care
172 professional that can make that recommendation and greatly improve outcomes for the patient.
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