

pandemic [3]. On March 13, the U.S. government declared a national emergency [4]. Following these declarations, and in response to rising COVID-19 infection rates [5], many jurisdictions implemented guidelines and policies to limit interactions between people: physical distancing, limits to the number of individuals who could legally gather, closure of indoor entertainment and recreational venues, among numerous others. Simultaneously, healthcare providers were implementing significant changes to the practice of medicine: canceling or deferring elective and non-urgent in-person appointments and procedures, [6] implementing virtual (telehealth) visit technology, (APA) reducing office hours and patient volume, [7] adopting more aggressive infection prevention and control procedures (CDC) and physical distancing guidelines, [8] and re-allocating hospital beds for COVID-19 patients [9]. The potential for COVID-19 infection and the associated changes in health care delivery practices raised concerns among mental health care providers [10,11]. Individuals with pre-existing serious mental illness, and in particular, those with schizophrenia, were deemed at particularly high risk for negative outcomes following COVID-19 infection [12, 13], including hospitalization [14] and in-hospital mortality [15]. These concerns were raised, in part, because individuals with schizophrenia have high rates of psychiatric comorbidity, [16] and have a therapeutic regimen that requires routine engagement with healthcare providers, including psychiatry, primary care, pharmacy, and psychotherapy, to achieve optimal outcomes. Previous studies have explored the pandemic's impact on the mental health of individuals with schizophrenia [17], reported changes in health care resource utilization among individuals with pre-existing mental health conditions overall [18, 19, 20] and for specific health care services such as inpatient hospitalizations [21,22] outpatient mental health services [23], telehealth use [18,19], or antipsychotic medication use [24]. However, to our knowledge no studies have evaluated comprehensive changes in outpatient, inpatient, and prescription drug utilization among a nationally representative sample of individuals with schizophrenia or schizoaffective disorder in the United States. The objective of the current study was to evaluate those changes in the early months of the pandemic.

Materials and Methods

This study was a retrospective cohort study among individuals with schizophrenia comparing healthcare resource utilization in the six months prior to (September 1, 2019, through February 28, 2020) and six months following (March 1, 2020, through August 31, 2020) the COVID-19 pandemic onset in the United States.

Data Sources

Individuals were identified and selected from the medical and pharmacy claims data licensed from Clarivate (www.clarivate.com/products/real-world-data/) and linked, at the

county level to the Area Health Resources Files (AHRF) available from the Department of Health and Human Services (www.data.hrsa.gov/topics/health-workforce/ahrf). Participant-specific age, sex, state of residence, 3-digit ZIP, insurance provider (Medicaid, Medicare, commercial, or VA/other), and healthcare resource utilization measures were identified and calculated from claims data. Other demographic characteristics were defined by county of residence and assigned as a continuous variable based on the county's mean value from AHRF data. Individuals were assigned to a county based on a combination of their 3-digit ZIP code, linked to the 5-digit ZIP code associated with their provider, assigned hierarchically beginning with the primary care provider, then the mental health care provider or clinic. State policy regarding the pharmacist authorization for administering LAI formulations of antipsychotic medications was identified from the National Alliance of State Pharmacy Associations website (NASPA). Pharmacist authorization was categorized as: not allowed to administer LAI antipsychotics, allowed to administer LAI antipsychotics, and allowed to administer LAI antipsychotics under a physician's supervision via a collaborative practice agreement. A collaborative practice agreement is a formal agreement between a prescriber and pharmacist that authorizes the pharmacist to deliver a specific set of patient care services, which can include authorization to administer an LAI antipsychotic.

Identification and Selection of Study Participants

Eligible individuals met each of the following criteria: diagnosis of schizophrenia or schizoaffective disorder (ICD-10-CM: F20.x, F25.x) defined by two or more outpatient claims (or one inpatient claim) between January 1, 2019 and June 30, 2020, 18 years of age or older as of January 1, 2019, a resident of the 50 United States or District of Columbia, and continuous use of healthcare services as measured by at least one medical or pharmacy claim between each of January 1, 2019 and June 30, 2019; January 1 and June 30, 2020; and July 1 to September 30, 2020.

Data Management and Analysis

The index date for the pandemic in the United States was defined as March 1, 2020. Outcome measures for all-cause and psychiatric-specific healthcare utilization included office visits for primary care, ED visits, and inpatient hospitalizations. Outcome measures for schizophrenia-specific (defined by an ICD-10 code for schizophrenia or schizoaffective disorder in the primary position) healthcare resource utilization included office visits for psychiatry, psychotherapy, community mental health centers (CMHC), partial-day hospitalizations, and inpatient hospitalizations. Visits were measured per thousand patients per month (PkPPM) and prescription use measured per thousand patients per week (PkPPW). Office visits and psychotherapy sessions categorized by delivery method: in-person, telehealth,

and total. Prescription medications were categorized by therapeutic class (antipsychotics, antidepressants, mood stabilizers, and anxiolytics), and characterized by route of administration (oral vs. injectable), by days' supply per prescription (<90 days' supply vs. 90+ days' supply), and by claims. Psychotherapy visits were defined by a claim for CPT 90832, 90834, 90837, 90839, 90840, 90845, 90847, 90849, 90853, or 96152. Psychiatric and medical comorbidities were identified from claims between April 1, 2019, and March 30, 2020. Psychiatric comorbidities included anxiety (F41.x), adjustment disorders (F43.2x), bipolar depression (F30.x, F31.x), obsessive-compulsive disorder (F42.x), PTSD (F43.1x), sleep-wake disorders (G47.x), alcohol and substance use disorders (F10.x – F19.x), F32.x, F33.x, F34.1), and depressive disorders (F32.x, F33.x). Medical comorbidities were measured by the Charlson Comorbidity Index [25]. COVID-19 infection was defined by ICD-10-CM B97.29 (from January 1 – March 31, 2020) and by U07.1 (from April 1 through September 30, 2020).

Analysis

Rates were calculated for each outcome variable, by month for outpatient and inpatient services and by week for prescription medication fills. March through August 2020 defined the pandemic period, while September 2019 thru February 2020 defined the pre-onset period, allowing a comparison between the six months prior to and following pandemic onset. Post-onset percent changes in utilization were calculated for the entire six-month period and by month, compared to the six-month average during the pre-onset period. Monthly average changes were tested for statistical significance using t-tests with standard error calculation methods depending on equal/unequal variance tests. Results are based on independent sample testing rather than paired testing, as the former is more conservative given that utilization pre- and post-onset are correlated within an individual. Post-pandemic onset changes in prescription drug utilization were also examined within regression models. The period between September 2019 and August 2020 was split into four three-month calendar quarters, labeled as Fall (September–November 2019), Winter (December 2019 – February 2020), Spring (March–May 2020), and Summer (June–August 2020), and with the COVID-19 pandemic represented by two consecutive periods: Spring 2020 and Summer 2020. These temporal indicators entered the model as a categorical variable to compare the utilization during the pre- and post-onset periods. Dependent variables included each outcome measure referenced above. The models controlled for the following time-invariant covariates: age (continuous, in years), sex, insurance type, indicator for each psychiatric comorbidity, and county-level median household income, county-level race-ethnicity characteristics (percentages of Black/African American, Hispanic, Asian/other), and county-level indicators distinguishing between metro, urban, or rural

areas. State policy regarding the pharmacist authorization for administering LAI formulations of antipsychotic medications is included in the pharmacy utilization models. To determine if the pandemic's association with changes in utilization differed by race/ethnicity or by state-level policy regarding pharmacist authorization to administer LAI antipsychotics, models also included interaction terms between these variables and calendar quarter. All analyses were performed using SAS v9 (Cary, NC). The research protocol was approved by the Advarra Institutional Review Board.

Results

A total of 493,796 (69.5%) individuals met study eligibility criteria (Table 1), with most qualifying with unspecified schizophrenia (29.1%), followed by bipolar type schizoaffective disorder (25.5%), unspecified schizoaffective disorder (14.5%), paranoid schizophrenia (13.6%), and depressive type schizoaffective disorder (10.8%). The population was 55.2% male, with an average age of 50.1 years, and 68.2% of the population was insured by Medicaid. The sample included residents of all 50 U.S. states and the District of Columbia, with most from New York (10.7%), followed by California (8.8%), Florida (6.9%), Ohio (6.6%), and Texas (5.8%). The most common mental health comorbidities were anxiety disorder (31.5%), followed by depressive disorders (29.7%), bipolar depression (24.5%), and sleep-wake disorders (16.7%). The Charlson Comorbidity Index score was 1.27 (SD: 1.88).

Outpatient Services

In the pandemic's first six months in-person primary care office visit rate declined by 32.5% (declining by 56.9% in April 2020), remaining below pre-pandemic levels through August 2020 (Table 2, Figure 1). During this period, telehealth-delivered primary care visits increased dramatically, peaking at 62.4% of all primary care visits in May 2020, remaining elevated through August (34.0%). The increase in primary care telehealth visits more than offset the reduction in in-person visits. The total primary care visit rate recovered to pre-pandemic levels by May 2020 and stayed elevated through September.

The post-pandemic onset psychiatry visit rate increased rapidly, up 9.7% in March, reaching a peak increase of 48.1% in June 2020, while remaining elevated through August (up 31.7%). Telepsychiatry was uncommon prior to March 2020, representing approximately 7% of all visits; however, the percent of psychiatry visits delivered via telehealth increased to more than 70% between April and August 2020. Psychotherapy sessions increased by 17.2% overall. Prior to the pandemic, less than 2% of psychotherapy sessions were delivered via telehealth, a rate which increased to 77.8% in April 2020 before declining steadily to 67.3% by August 2020. (Table 2, Figure 1). CMHC visits declined by an average of 15.1%, with in-person visits declining by 21.6%.

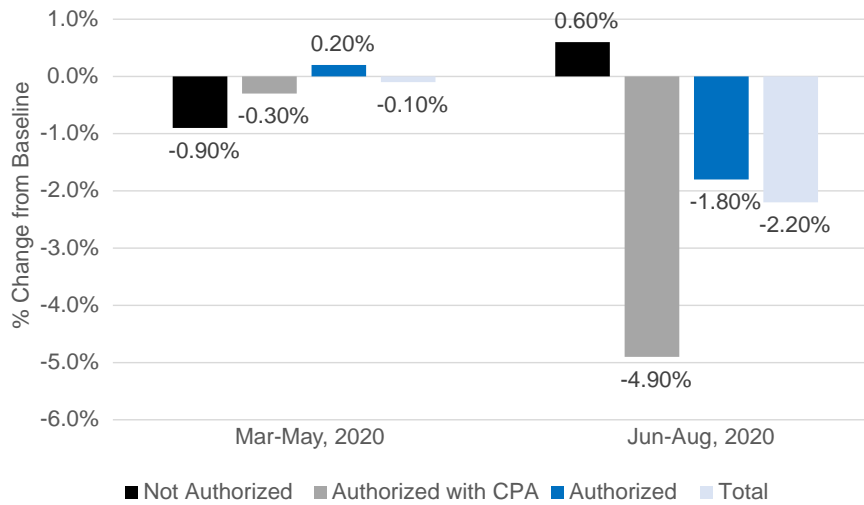


Figure 2: 3HUFHQW FKDQJH LQ DYHUDJH /\$, DQWLSV\FKRWLF SUHVFU... & 29,' SDQGHPLF FRPSDUHG WR SUH RQVHW OHYHOV E\ VWDWH S... DXWKRULJDWLRQ WR DGPLQLVWHU /\$, DQWLSV\FKRWLFV

Table 3: \$GMXVWHG DVVRFLDWLRQ EHWZHHQ WLPH LQ PRQWK SHULRGV DQG DQV... DPRQJ LQGLYLGXDOV ZLWK VFKL]RSKUHQLD RU VFKL]RDuHFWLYH GLVRUGHU "

	LAI Antipsychotic Claims		Oral Antipsychotics (Days Supply)		Oral Antipsychotics (90+ Days)	
	& R H ^ FLH Q \	P-value	& R H ^ FLH Q \	P-value	& R H ^ FLH Q \	P-value
Base Terms						
Pandemic Q1 (Mar - June 2020)	-	-	1.47	<0.001	0.01	<0.001
Pandemic Q2 (Jul - Sept 2020)	-	-	-	-	0.01	<0.0001
Pharmacist Authorization (No)	0.05	<0.0001	-	-	-0.01	<0.0001
Pharmacist Authorization (CPA)	0.05	<0.0001	7.69	<0.0001	-	-
\$ IULFDQ \$ PHULFDQ & RXQW \	0.13	<0.0001	-22.2	<0.0001	-0.04	<0.0001
\$ VLDQ & RXQW \	0.08	<0.01	-	-	-0.07	<0.0002
+ LVSDQLF & RXQW \	-	-	-15.36	<0.0001	-0.03	<0.0003
Interaction with Pandemic (Q1: Mar - June 2020)						
African American*Pandemic Q1	-	-	-	-	-0.01	<0.05
Asian*Pandemic Q1	-	-	-	-	-	-
Hispanic*Pandemic Q1	-	-	-	-	-0.01	<0.05
Pharmacist Authorization (No)*Pandemic Q1	-0.02	<0.01	-	-	-	-
Pharmacist Authorization (CPA)*Pandemic Q1	-	-	-	-	-	-
Interaction with Pandemic (Q2: July - Sept 2020)						
African American*Pandemic Q2	0.06	<0.0001	3.03	<0.05	-	-
Asian*Pandemic Q2	-	-	8	<0.01	-	-
Hispanic*Pandemic Q2	-0.03	<0.05	-	-	-	-
Pharmacist Authorization (No)*Pandemic Q2	-0.02	<0.01	1.23	<0.05	-	-
Pharmacist Authorization (CPA)*Pandemic Q2	-0.01	<0.01	-	-	-	-

" & RPSDUHG WR XWLOLJDWLRQ LQ WKH WKUHH PRQWKV SUHFHGLQJ WKH SDQGHPLF 'HFHP

individuals with pre-existing mental health conditions. In a recently published systematic literature review and meta-analysis, Vai, et al. [27] reported that individuals with pre-existing psychotic disorders or mood disorders were at increased risk of COVID-19 mortality and individuals with pre-existing mental health conditions were at increased risk of hospitalization. This result was confirmed by a subsequent systematic literature review which reported that individuals with pre-existing schizophrenia had a risk of mortality that was 2.2 times higher compared to individuals without schizophrenia [28]. In regard to the impact of the pandemic on mental health, however, a recently published systematic literature review that included eight longitudinal studies of individuals with schizophrenia spectrum disorder concluded that there is no consistent evidence that the pandemic led to worsening symptoms [17]. Further, a survey of 32 individuals with schizophrenia spectrum diagnoses reported consistent following of COVID-19 health and safety precautions and no post-pandemic worsening of schizophrenia symptoms [29].

Post-pandemic Changes in Healthcare Resource Utilization

Our results document rapid implementation and sustained use of telehealth-delivered psychiatric outpatient services. Despite the initial decline in in-person visits that occurred during the ramp-up of telehealth, overall outpatient care service rates for primary care, psychiatry, and psychotherapy all increased during the first six months of the pandemic. These results are consistent with clinical reports that individuals with serious mental illness, especially those with stable illness, continued to utilize preventative healthcare services [30]. Psychotherapy is perhaps the most complex healthcare service included in our analysis. Psychotherapy includes various therapeutic techniques and effectiveness is profoundly dependent upon both the continuity of care and the development and maintenance of an effective interpersonal relationship between provider and patient. This complexity is coupled with practical challenges, including differences in available technologies and limited access to private locations. Without a roadmap to guide this transition, providers have found success by personalizing transitions on a patient-by-patient basis. In combination with the well-documented reduction in missed appointments, [31] several of these approaches may contribute to the overall increase in psychotherapy contacts, including reducing visit duration but increasing frequency, offering flexible telehealth options (audio only vs. video calls), and implementing a between-visit call schedule to better monitor patients. [32,33,34]. Though in-person visits to community mental health centers declined and telehealth-delivered visits increased during the pandemic, the overall visit rate declined and as of September 2020 had not returned to pre-onset levels. These results are consistent with the challenges faced by community mental health centers [35] to maintain adequate care coordination

during the pandemic. Further, our results document the substantial and sustained use of telehealth for psychiatry visits, psychotherapy services, and community mental health center services, overall and specifically for care related to schizophrenia. This conforms with calls for psychiatric and psychosocial care to be delivered via telehealth [26, 36] and with evidence of significant increases in remote contacts in psychiatry [31]. Despite evidence that behavioral health services delivered via telehealth are effective, the use of telehealth-delivered psychiatry services has raised concerns about privacy, information security, different levels of access to technology, and other issues [37, 38].

In contrast, acute care services – including all-cause ED visits, inpatient and partial-day hospitalizations – show a modest but consistent decline in post-pandemic utilization. These results compare to studies conducted in the U.K. and Australia which noted 20% and 12% drop-in psychiatric inpatient admission rate, respectively [39, 40].

Antipsychotic medication use increased during the pandemic period, driven primarily by an increase in 90-day supply prescriptions. Patel et al. [31] noted changes in the delivery of psychiatric care with significant increases in remote care did not significantly influence the prescribing of antipsychotic or mood stabilizer medications. In a brief report MacLaurin et al. [41] profiled various methods used to successfully ensure continuation of antipsychotic pharmacotherapy during the early stages of the pandemic. Their model included a patient-by-patient review and personalized plan with options for switching to an LAI with a longer interval, switching to oral antipsychotics, and transition to at-home administration by a visiting nurse. The modest changes in overall LAI antipsychotic utilization in the present study are consistent with a report on antipsychotic medication use in a Canadian population [42] and with a recent survey of LAI prescribers who reported little change in oral and LAI antipsychotic prescribing practices during the COVID-19 pandemic [43]. In the U.S. and worldwide, the pandemic highlighted the important role of pharmacists in ensuring continuity of care and led to an array of expanded roles and responsibilities in patient care [44]. Specific to the care of individuals with schizophrenia, the most relevant issue in the U.S. may relate to the impact of state-level policies authorizing pharmacists to administer LAI antipsychotics. According to NASPA [45], 34 states authorize pharmacists to administer LAI antipsychotics, four states and the District of Columbia do not, and 12 states authorize pharmacists to administer LAI antipsychotics with a collaborative practice agreement [46]. States that require a collaborative practice agreement to allow pharmacists to administer LAI antipsychotics were associated with less utilization of LAI antipsychotics and more utilization of oral antipsychotics following the pandemic's onset. As LAI antipsychotic use among individuals with schizophrenia is associated with lower rates

of acute care services, including hospitalization, readmission, and ED visits [47], and higher levels of medication adherence [48], ongoing innovation in and evaluation of pharmacist scope of practice may be warranted. Finally, the current study indicates a modest association between race/ethnicity and post-pandemic changes in antipsychotic medication use. Our results contribute to a growing body of evidence regarding the impact of the pandemic by racial and ethnic populations. As an example, there is compelling evidence that racial and ethnic minority populations had less access to monoclonal antibody treatment for SARS-CoV-2 infection [49] and had higher rates of COVID infection, hospitalization, and mortality [50]. Other research has reported on the association of socioeconomic and demographic factors associated with healthcare inequalities during the COVID-19 pandemic [51, 52]. In contrast, however, a recent study of over three million U.S. adults concluded the pandemic did not increase disparities in access to surgical care [53]. Despite this variability, there continue to be calls to address inequalities through policy [54] and by systematically incorporating social determinants into the healthcare delivery model [55].

Strengths and Limitations

The study population of 493,796 individuals, represents a substantial proportion of all individuals with diagnosed schizophrenia in the United States, increasing the generalizability of results. The population included individuals across a spectrum of ages, insurance types, and geographic regions. The study included both healthcare utilization and social determinants of health data, though it's important to note that social determinants are measured at the county, rather than individual, level and only approximate individual's specific situations. The most significant limitation is the open dataset, which does not include insurance eligibility information and thus may result in incomplete measures of healthcare utilization. Further, the dataset does not include mortality information and the criteria to ensure ongoing utilization excludes individuals who died during the pandemic from the study population.

Conclusions

In the early months of the pandemic, individuals with schizophrenia experienced a significant shift in the way primary care, psychiatric care, and psychotherapy was delivered. The dramatic and sustained increase in primary care, psychiatry, and psychotherapy delivered via telehealth indicates this is a viable delivery model in this population. Use of 90-day supply prescriptions for oral antipsychotic medications increased dramatically while LAI antipsychotic use decreased 1.3%. Further, changes in LAI antipsychotic use varied by state-level policy regarding pharmacist authorization to administer this medication. Given the requirement for ongoing in-person visits with a healthcare provider to receive LAI antipsychotic medication, both issues

warrant further investigation. Declines in outpatient services, such as partial-day hospitalizations, may have long-term implications for mental health.

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