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A model for timely dissemination of critical information: Clozapine toxicity during the COVID pandemic

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Abstract

Clozapine is the only medication approved for treatment-resistant schizophrenia. Clozapine toxicity associated with COVID-19 infection could be amplified by concomitant nirmatrelvir/ritonavir. Knowledge gaps among clinicians and patients led to patient safety concerns and the implementation of a quality improvement (QI) project focused on rapid education dissemination. This QI project focused on clinicians, patients, and caregivers. Steps included clinician education at system, regional, and national levels and patient/caregiver education at system and regional levels. Optimization of electronic health record (EHR) tools facilitated efficient clinical workflows, targeted patient education to facilitate shared decision making, and promoted best practices. Education concerning risk for COVID-19, clozapine toxicity, and nirmatrelvir/ritonavir drug interactions was distributed to more than 1400 clinicians via e-mail and conference presentations. Enduring continuing education materials had more than 1200 views. Verbal or written education was rapidly delivered to 231 patients/caregivers and documented via autotext, an EHR tool. Following presentation of this QI project at a schizophrenia conference, more than 95% of attendees, including health care clinicians and patients/caregivers, rated their understanding of COVID-19, clozapine toxicity, and the interaction with nirmatrelvir/ritonavir as "very high" or "high." Separately, web-hosted continuing education platforms indicated that more than 75% of clinicians rated their understanding of these 2 issues as "very high" or "high" upon module completion. By educating patients/caregivers and clinicians about COVID-19 infection and nirmatrelvir-/ritonavir-associated toxicity risks, this project helped ensure safe prescription of clozapine during the COVID-19 pandemic. This project could serve as a rapid risk mitigation dissemination model of patient safety education.

Keywords: clozapine toxicity, COVID-19, nirmatrelvir/ritonavir, patient safety, rapid clinician education and dissemination, quality improvement

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Introduction

During the COVID-19 pandemic, expeditious dissemination of education on the manifestations, effect, and treatment of COVID was paramount, including in psychiatry. Clozapine is the gold standard for treatment-resistant schizophrenia, and case reports of COVID-19–associated clozapine toxicity evoked serious patient safety concerns in the clinician community.[1-3] Symptoms of clozapine toxicity include sedation; sialorrhea; speech and gait disturbances; and more seriously, hypotension, delirium, and seizures. Toxicity is likely mediated by elevation of clozapine concentrations via significant inhibition of hepatic cytochrome P450 (CYP) isoenzymes, primarily CYP1A2 and, to a lesser degree, CYP3A4/5, CYP2C19, and CYP2D6.[4] The most commonly prescribed oral COVID-19 treatment, nirmatrelvir/ritonavir, strongly inhibits CYP3A4, leading to early concerns about clozapine toxicity and initial contraindication of coprescription of the 2 agents.[5] Additionally, COVID-19 infection itself inhibits clozapine metabolism and may amplify the effect of nirmatrelvir/ritonavir. In working with our patients and colleagues, it was clear that this critical information on clozapine toxicity, COVID-19, and nirmatrelvir/ritonavir was not widely known. Therefore, the goal of this quality improvement (QI) initiative was to disseminate needed safety information on clozapine toxicity and these potentially important interactions to increase awareness, improve patient safety, and optimize management of clozapine in the setting of an active COVID-19 infection.

Methods

This project was a multistep, multidisciplinary, structured, clinical QI project focused on providing interdisciplinary health care professionals, patients, and patient caregivers education on the risks of clozapine toxicity and the potential drug-drug interaction between nirmatrelvir/ritonavir and clozapine during the COVID-19 pandemic. Targeted clinicians included physicians, pharmacists, advanced practice providers, and nurses. Patients/caregivers were, in part, targeted to bridge knowledge gaps in which clozapine is not frequently prescribed and psychiatric services are not consistently embedded, for example, in primary care offices, urgent cares, and emergency departments. The project was approved by the University of Pittsburgh Medical Center (UPMC) Quality Improvement Review Committee and, thus, no separate institutional review board approval was needed.

System and Statewide Clinical Education

A succinct slide set was developed with a summary slide recommending clinical actions, documentation, and additional resources based on the clinical scenario. These scenarios included (1) a patient taking clozapine who contracted COVID-19; (2) a patient taking clozapine who contracted COVID-19 and a nirmatrelvir/ritonavir prescription was being considered; and (3) a patient not taking clozapine but taking other medications that were metabolized by or were substrates of CYP 1A2, 3A4, and/or 2C19, was COVID-19 positive, and nirmatrelvir/ritonavir was being considered. This resource was distributed through email by leadership of the UPMC Western Behavioral Health (WBH) network, including multiple hospitals and ambulatory divisions, and by the chief psychiatric officer at the Department of Human Services, Office of Mental Health and Substance Abuse Services, to all state hospital clinical staff. Subsequently, 2 enduring and archived continuing education (CE) offerings were developed, one on COVID-19 and clozapine toxicity and a second on nirmatrelvir/ritonavir, COVID-19, and clozapine. These were disseminated across the behavioral health network (BHN), including to clinicians working in medical settings, and accessible to all interested health care professionals within and outside of the system.[6,7]

Facilitating Best Practice and Documentation Via the Electronic Health Record (EHR)

System EHR drug-drug interaction checkers were optimized with information technology to include up-to-date interaction information on clozapine and nirmatrelvir/ritonavir. Autotexts (also called dotphrases or smartphrases) were developed to facilitate documentation of patient/caregiver education provided on (1) risks of clozapine toxicity with COVID-19 infection, (2) monitoring for clinical signs/symptoms of clozapine toxicity, (3) possible interaction with coadministration of nirmatrelvir/ritonavir, and (4) instructions to seek emergency care for clozapine toxicity symptoms. Autotexts encourage incorporation of standard text into patient notes with an efficient mouse click or key stroke. These texts also reminded documenting clinicians of recommended practice and reinforced patient education between appointments in Open Notes systems, in which patients have full access to their medical record. Use of autotexts is reportable via structured query language (SQL) query. Clinicians were educated about this autotext via BHN leadership communication. Smaller groups of known clozapine clinicians affiliated with the academic psychosis specialty service line Comprehensive Recovery Services (CRS) were also directly contacted by project staff.

Promoting Patient and Caregiver Education in a Targeted Population Receiving Clozapine

Patient and caregiver education was targeted to the BHN's largest clozapine-prescribing entity, a multidisciplinary clozapine clinic within UPMC WBH Western Psychiatric Hospital (WPH) CRS that served 172 patients in 2022 and includes colocated phlebotomy, pharmacy, and nursing services. During the pandemic, as previously described,[8] many clozapine clinic patients did not regularly come into the clinic and instead used telehealth. Given these constraints, and need for rapid dissemination, clozapine clinic patients and caregivers were targeted by phone call between June 1, 2022, and November 8, 2022, for education as described. Patient lists were developed through pharmacy records and cross-validated with reports from Sigmund, a Qlik Software data warehouse visualization dashboard supported by UPMC Clinical Analytics. If patients/caregivers were not reached after the first phone call, a subsequent call was later attempted. Voicemails, if available, were left with callback information with each missed call. When an outreach attempt was successful, it was recorded in the patient's EHR using the autotext and was tracked through spreadsheets cross-referenced with an autotext SQL query. When 2 phone outreach attempts did not yield a successful contact, an educational letter was sent to the patient's address.

Efforts at Regional and National Dissemination

Health care entity leadership and individual clinicians were contacted at neighboring medical centers, and links to the durable CE resources were provided gratis. A presentation was given at the 39th UPMC WBH Schizophrenia Conference, which disseminates research and clinical advancements in schizophrenia to regional clinicians, health care and insurance administrators, and patients and caregivers. The conference was held online and incorporated well-used question-and-answer periods. Project posters were presented at the annual BHN Quality Improvement Fair.

National dissemination first occurred by way of a published, peer-reviewed, clinical case report on clozapine concentrations and toxicity in a patient with COVID-19.[2] A subsequently published, peer reviewed case series detailed clozapine concentrations and clinical presentations of patients taking clozapine and experiencing repeated COVID-19 infections.[3] A clinical tip, expert-reviewed and published online by SMI Adviser,[9] which is administered by the American Psychiatric Association to promote best practices in the treatment of patients with serious mental illness, was also published. The clinical tip focused on monitoring for and management of clozapine toxicity with COVID-19 infection. An earlier clinical tip had been separately authored regarding the precautions of clozapine and nirmatrelvir/ritonavir combination.[10] Further dissemination occurred through a panel at the 2023 annual meeting of the American Society of Clinical Psychopharmacology (ASCP).

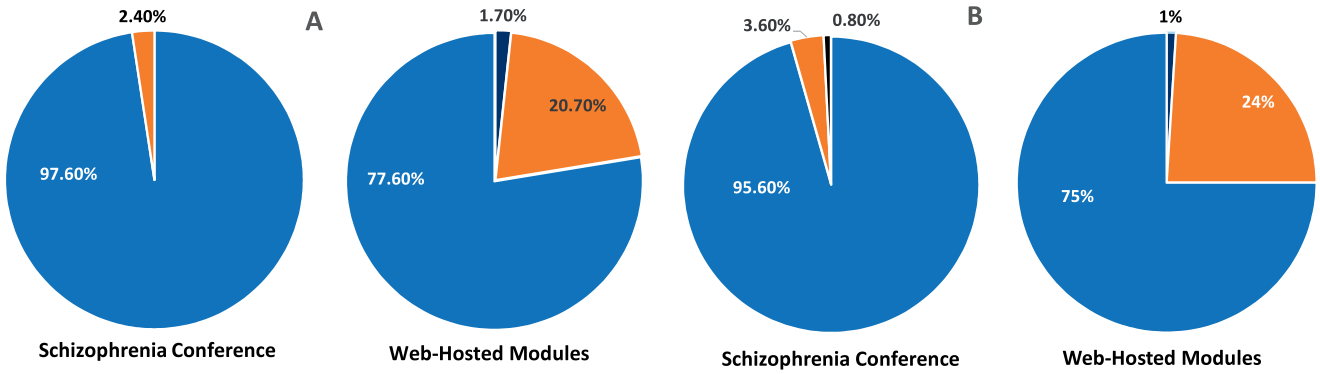
Results

The slide set was emailed to 310 clinicians in our health care system and to 738 in the state hospital system. The 2 CE videos had a combined 329 views by December 7, 2023. The UPMC WBH Schizophrenia Conference had 304 attendees; the Quality Improvement Fair had more than 190. Please see the Table. The CE evaluations from the UPMC WBH Schizophrenia Conference were available for 165 attendees and incorporated 2 key questions. For the first question, "As a result of participating in this CE activity, to what degree were you able to evaluate the medical and nursing management of clozapine toxicity using the illustrative case?", 97.6% rated their understanding as "very high" or "high" and 2.4% as "moderate" (Figure). For the second question, "As a result of participating in this CE activity, to what degree were you able to understand the significant precautions of using Paxlovid (nirmatrelvir/ritonavir) in clozapine-treated patients who experience mild to moderate COVID-19?", 95.6% rated it "very high" or "high," 3.6% as "moderate," and 0.80% as "low" (Figure). Summary reports were available from 1 CE web-hosted platform. Among the 76 participants who answered the above question 1, 77.6% rated it as "very high" or "high," 20.7% as "moderate," and 1.7% as "low," and for

TABLE: Results based on local, regional, and national dissemination efforts

	Forum	Dissemination Activity	Learners
Local	Behavioral Health Network	5 slide set succinctly describing COVID-19, clozapine toxicity, & nirmatrelvir/ritonavir drug interaction	Distributed to psychiatrists and APPs. $n = 310$
State	State Hospital System	5 slide set as above	Distributed to physicians, nurses, and pharmacists n = 738
Enduring Material (CME/CE Videos)	Medical Center Continuing Education Platform & Medical Center Physician Resources Platform	Two CME/CE Faculty Video Presentations – 30 minutes each	Combined views updated December 7, 2023 $n = 329$
Regional Conferences	1. Annual Schizophrenia Conference	Two Faculty CME/CE Presentations	$n = 304$ attendees
	2. Behavioral Health Network QI Fair	Poster	$n = 190$ attendees
National Conference	Annual Psychopharmacology Professional Society Meeting	Panel: 4 Faculty CME/CE Presentation	$n = 35$ attendees
Nationally Disseminated Web Resource	SMI Adviser- SAMHSA Funded and American Psychiatric Association administered	Clozapine Center of Excellence Experts Reviewed Clinical Tip and updated Tip (December 11, 2023)	Updated January 2024 $n = 843$ views
Patients, Families, & Caregivers	• Clozapine Clinic—within the psychosis specialty service line • Patients receiving clozapine in psychosis specialty service line outside the Clozapine Clinic	• Phone calls • Letters to those patients not reached by phone.	$n = 231$
Peer-Reviewed Journal	Schizophrenia Research	2 peer-reviewed articles[2,3]	Subscribers, Google, and PUBMED searches

APP = advanced practice providers; CME = continuing medical education; CE = continuing education; SMI = serious mental illness; SAMHSA = Substance Abuse & Mental Health Services Administration.



A. As a result of participating in this CE activity, to what degree will you be able to evaluate the medical and nursing management of clozapine toxicity using the illustrative case?

B. As a result of participating in this CE activity, to what degree will you be able to understand the significant precautions of using Paxlovid (nirmatrelevir/ritonavir) in clozapine treated patients who experience mild to moderate COVID-19?

FIGURE: CE evaluations for presentations on clozapine toxicity, COVID-19, and nirmatrelvir/ritonavir drug interactions; schizophrenia conference *n* = 165, web-hosted modules *n* = 76

question 2, 75% said "very high" or "high," 24% said "moderate," and 1% said "low" (Figure). In comparing question 1 results between the live UPMC WBH Schizophrenia Conference and the recorded CE videos, results were significantly different with "very high" or "high" ratings being more common among conference attendees (Fisher exact test $P < .00001$). Significant differences also were observed for question 2 with more conference attendees giving "very high" or "high" ratings (Fisher exact test $P < .00001$). The SMI Adviser clinical tip received more than 843 views by January 2024.

Phone counseling of 149 (86.6%) clozapine clinic patients/caregivers was completed via the project workflow as described. Clozapine clinic patients/caregivers who were not successfully contacted by phone ($n = 23$, 13.4%) were sent letters. An additional 59 out of a total 66 clozapine patients/caregivers not served by the clozapine clinic, but by other office- or community-based CRS services, received verbal counseling as part of standard care delivery. Clinicians working in these settings chose to provide the project-recommended patient education and use the documentation autotext as part of routine clozapine care delivery, demonstrating successful practice change without additional workflow support. In total, verbal counseling of 208 clozapine patients/caregivers was completed as confirmed by SQL query generated report of autotext usage.

Discussion

Rapid dissemination of education on clozapine toxicity and putative interaction with COVID-19 infection and treatment was needed during the pandemic to help ensure continued safe prescribing of this critical medication. Combined local, regional, and national efforts led to education of more than 2000 health care professionals and more than 200 local patients/caregivers, all of whom helped promote shared decision making and patient safety during a time of strained health care resources. Clinicians rated their understanding of the topics as quite high after engagement with project-generated CE. Interestingly, statistically significant differences in learner evaluations were observed between the virtual schizophrenia conference and the prerecorded CE videos, suggesting that the schizophrenia conference may have more optimally achieved its learning objectives. During the pandemic, opportunities in synchronous and asynchronous medical education grew exponentially with some studies suggesting superiority of synchronous learning,[11] including in case-based style approaches as were used in this project.[12] This may at least partially account for differences in perceived learner benefit between modalities. Furthermore, EHR optimization through autotexts and of drug-drug interactions checkers further enhanced education and safety. Given these findings, our efforts, as outlined, may be used as a road map for expedient patient, caregiver, and continuing medical education during pandemics and similar emergencies.

There are a few limitations of this project. Given the need to quickly integrate this information into practice and the challenges of the pandemic, we did not collect pre-post measures of knowledge, nor could we objectively track COVID-19-related changes in clozapine dose that occurred subsequent to knowledge gain. Evidence of practice change was limited to capturing use of the autotext. High rates of

patient/caregiver engagement may be a product of the high-intensity, well-resourced clozapine clinic model. However, clozapine-prescribing clinicians and nurses not affiliated with the clozapine clinic did educate patients and caregivers without additional staff support. This supports the principle that the uptake of novel clinical interventions can be best facilitated when perceived as both clinically important and efficient.

Conclusion

This QI project led to the successful, rapid education of health care professionals, patients, and caregivers about the risks of clozapine toxicity associated with COVID-19 infection and potential drug-drug interactions between nirmatrelvir/ritonavir and clozapine. Professional education and EHR workflow change was demonstrated through a model that may be modified to support other practice changes that require rapid adoption.

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