

# Developing written educational materials for patients on the effects of COVID-19 infection and Paxlovid on clozapine levels

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## Background

- Paxlovid is an antiviral combination product of nirmatrelvir and ritonavir that has received emergency use authorization by the FDA for patients with mild to moderate COVID-19 symptoms at risk of progression.
- Due to ritonavir’s inhibition of CYP3A4 enzymes, clozapine has been associated with increased clozapine levels in the blood to potential toxicity <sup>(1)</sup>.
- COVID-19 infection itself has also been associated with increased clozapine blood levels <sup>(2)</sup>.
- Although there is literature on developing and evaluating written educational materials, evidence suggests that these guidelines and tools are underutilized.

## Specific Aims

The primary aim of this project is to use published guidelines and evaluation tools to develop an evidence-based written educational handout for patients taking clozapine regarding the effects of COVID-19 and Paxlovid.

Secondary aims are to establish a method by which future written educational materials may be created for other issues targeting similar patient populations, and to add to the literature on the effective use of these guidelines and evaluation tools.

## Design and Methods

1. We developed an initial educational leaflet using established guidelines.
2. We evaluated this initial draft with an established readability tool, the **Flesch Reading Ease Score** <sup>(3)</sup>, which estimates the reading level of the leaflet.
3. We are obtaining expert evaluation of the product using the **DISCERN tool** <sup>(4)</sup>, which has been previously validated and widely used in the literature. Feedback is being solicited from members of the SMI Adviser National Clozapine Center of Excellence.
4. Next, we intend to obtain feedback from patients in our clinic who are diagnosed with schizophrenia or schizoaffective disorder and treated with clozapine. Patient evaluation will utilize the **USE tool** <sup>(5)</sup>, which measures the perceived usefulness of the product to patients. Patients will also be assessed on knowledge obtained from the brochure and qualitative data will be obtained in a focus group format.
5. We will distribute our final brochure to our patient population by mail and at clinic appointments, as well as making it available online through the SMI Adviser website.

## Expected Outcomes

- The finalized educational leaflet
- Patients’ perceived usefulness of the final product as measured by USE scores
- Measurement of patient knowledge pre- and post- exposure to the educational leaflet
- Qualitative data describing patient perception of the educational leaflet

## Future Directions

We hope that this project will serve to establish a standardized, valid, and replicable method that can be used to create additional written patient education materials from which this patient population could benefit.

## References

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**What does COVID-19 have to do with clozapine?**

When you take a medication like clozapine, it goes into your blood. Over time, your liver removes the medication from your body.

The amount of clozapine that your doctor gives you is based on your liver working normally.

COVID-19 can change how your liver works so that it takes longer to remove the clozapine from your blood.

This means that the amount of clozapine in your blood can increase and could become too high if you have COVID-19.

**If I get COVID-19, should I stop taking clozapine?**

No! You should not stop taking clozapine even if you get COVID-19, unless your doctor tells you to do so.

You should talk to both your primary care provider (PCP) and the doctor who prescribes your clozapine.

**Do you know the warning signs of too much clozapine?**

- Feeling tired, much more than usual
- Feeling confused
- Having trouble walking
- Drooling more than usual
- Muscle movements that you can't control

**What should I do if I have warning signs of too much clozapine?**

- Go to the nearest emergency room.
- Try to bring a list of all your medication.
- Tell the doctor you take clozapine.
- Tell the doctor if you have COVID-19 and if you are taking Paxlovid.

**What is Paxlovid?**

Paxlovid is the brand name for a combination of two medicines that can help people feel better from COVID-19 more quickly.

Paxlovid is used for people who have COVID-19 with mild-to-moderate symptoms and certain other factors that might increase their risk severe illness. In these cases, Paxlovid may reduce the risk of bad outcomes, such as having to go to the hospital.

**If I'm taking clozapine, can I take Paxlovid?**

Maybe, but you need to be extra careful. Paxlovid might increase clozapine in your blood, just like the COVID-19 infection does.

This means you need to talk to your doctors – the one that gives you clozapine and the one treating you for COVID-19. Usually, this is two different doctors.

**Are there any other treatments for COVID-19?**

Yes, there are other options. Some of them work sort of like Paxlovid. They're not for everyone, however. Ask the doctor treating you for COVID-19 for details.