Use of HIEs to Access Clinical Information for COVID-19 Test to Treat Services

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HI+ Pharmacy Health Information Technology Collaborative

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1. INTRODUCTION

Federal and state government agencies are expanding pharmacists' authority for test to treat programs to meet patient health care needs and close access gaps. One important program addresses the COVID-19 pandemic by encouraging practitioners to pair patient assessment, which may include point-of-care testing and treatment in a seamless encounter. Pharmacists who prescribe COVID-19 treatments offer timely access for patients who test positive for COVID-19. As a result, the number of pharmacists in test to treat programs is increasing. Data access and documentation using electronic standards in an interoperable way are crucial for proper implementation of test to treat programs. It is essential for success of the test to treat programs for pharmacists to have the ability to access clinically relevant information. The purpose of this document is to guide pharmacists in a standardized way on how to access clinically relevant information to utilize in test to treat programs.

2. DISCUSSION

Sufficient clinical data for test to treat programs can be available with access to electronic health records (EHRs) by connecting to state and regional health information exchanges (HIEs). According to the Pharmacy HIT Collaborative's guidance document on HIEs, "these exchanges ensure that the meaningful use of the information being shared remains accurate and readily interpretable. The goal of HIE is to ensure that health care professionals are able to receive and submit clinical information through electronic data exchange with current work processes in the delivery of care for all patients. This process enables stakeholders to better leverage data to facilitate patient care and therapeutic outcomes."[1] Adoption of HIE ensures patient health and safety by allowing providers a comprehensive view into the patient's medical history. To obtain and share clinical information in test to treat programs, pharmacies will need to establish a contractual relationship between the pharmacist's clinical documentation system or pharmacy management system and an HIE. The 21st Century Cures Act, passed in 2016, established the Trusted Exchange Framework and Common Agreements (TEFCA), for HIE guidance.[2]

In order to exchange personal health information (PHI), a practitioner (actor) does not necessarily have to use a certified EHR but must have a contractual agreement with a HIE; however, if the practitioner receives payment from Medicare, Medicaid, or another Centers for Medicare & Medicaid Services program, use of certified EHR may be required. Under a recent Food and Drug Administration (FDA) Emergency Use Authorization (EUA),[3] pharmacists are authorized to prescribe COVID-19 oral PAXLOVID™ antiviral therapy. If a patient suspects they have COVID-19, they can seek test to treat services from a pharmacist. The pharmacist can test the patient, and if positive for COVID-19, the patient is then assessed by the pharmacist who prescribes the COVID-19 antiviral Paxlovid™, if the patient is eligible. The pharmacy can then dispense the medication. Because COVID-19 treatments must be started early in order to work, quick access to care that pharmacists provide can greatly help patients quickly get tested and begin treatment in one visit.

Looking to the future, the 21st Century Cures Act, passed in 2016, established the Trusted Exchange Framework and Common Agreements (TEFCA), in which entities can now apply to be designated as Qualified Health Information Networks (QHINs). QHIN is an independent network of separate organizations that seek to work together and connect to each other and can enable their participants to engage in exchange of health information.

"A certified EHR is an EHR that's demonstrated the technological capability, functionality, and security requirements required by the Secretary of Health and Human Services and has received certification by the Office of the National Coordinator (ONC)".[4]

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[1] "Integrating Pharmacists into Health Information Exchanges," Pharmacist Health Information Technology Collaborative (PHIT), August 22, 2014, pg. 3. http://www.pharmacyhit.org/pdfs/workshop-documents/WG3-Post-2014-02.pdf

[2] ONC Completes Critical 21st Century Cures Act Requirement, Publishes the Trusted Exchange Framework and the Common Agreement for Health Information Networks, U.S. Department of Health and Human Services, January 18, 2022. https://www.hhs.gov/about/news/2022/01/18/onc-completes-critical-21st-century-cures-act-requirement-publishes-trusted-exchange-framework-common-agreement-health-information-networks.html.

[3] "Fact Sheet for Healthcare Providers: Emergency Use Authorization for Paxlovid," Food Drug and Administration, December 2021. https://www.fda.gov/media/155050/download.

[4] "What is a certified EHR? EHR Certification from CMS and ONC." Practice Fusion Blog. September 30, 2015. https://www.practicefusion.com/blog/what-is-a-certified-ehr/

In the test to treat scenario for dispensing PAXLOVID™, pharmacists need current renal and liver function test results. This example shows the need for timely exchange of clinical data that should be provided through HIE. Pharmacists also need to document potential drug interactions and obtain other necessary medical information, such as patient symptoms.

According to the FDA's EUA for PAXLOVID™, data access is an essential element to prescribe treatment. The requirements for treatment include that sufficient information is available, such as

> "access to health records less than 12 months old or consultation with a health care provider in an established provider-patient relationship with the individual patient, to assess renal and hepatic function; and sufficient information is available, such as through access to health records, patient reporting of medical history, or consultation with a health care provider in an established provider-patient relationship with the individual patient, to obtain a comprehensive list of medications (prescribed and non-prescribed) that the patient is taking to assess for potential drug interaction." [5]

Having an established HIE in this scenario would greatly reduce the burden on pharmacists and other providers in test to treat programs by removing the barriers that otherwise occur.

The American Society of Health-System Pharmacists [6](ASHP) developed a Pharmacists Paxlovid Prescribing Guide, which is a use case for test to treat for the use of PAXLOVID™ (Nirmatrelvir/Ritonavir) for specific treatment of COVID-19.
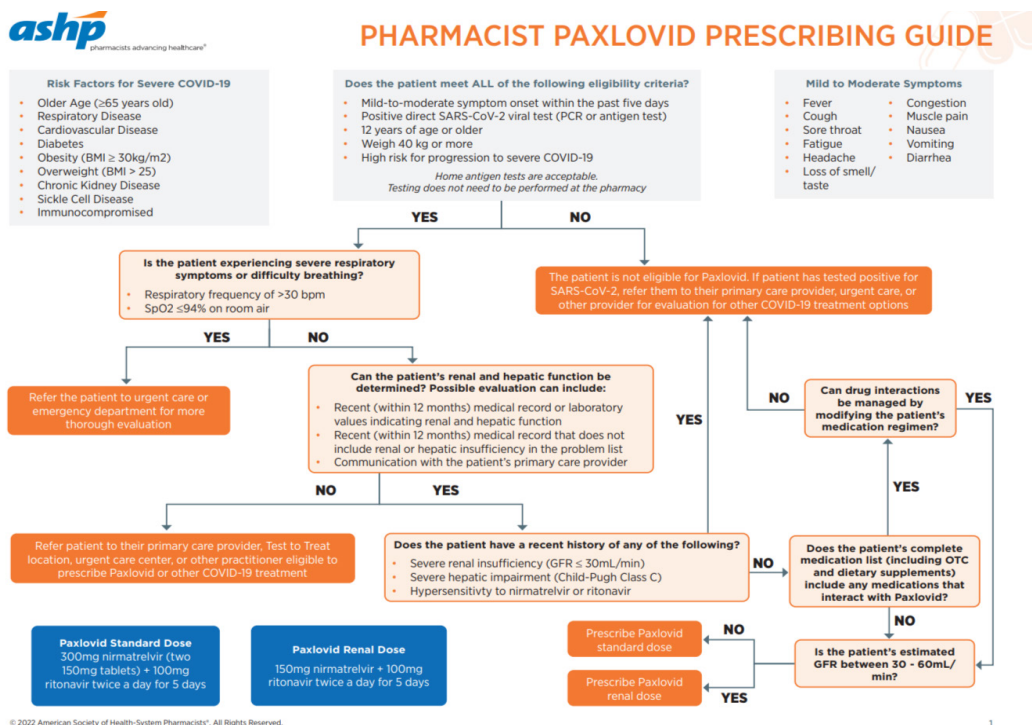
Pertinent clinical information needed. Can the patient's renal and hepatic function be determined?

Possible evaluation can include:

• Recent (within 12 months) medical record or laboratory values indicating renal and hepatic function

• Recent (within 12 months) medical record that does not include renal or hepatic insufficiency in the problem list

• Communication with the patient's primary care provider

PHARMACIST PAXLOVID PRESCRIBING GUIDE

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5
FDA response to Pfizer regarding EUA 105, August 5, 2022. https://www.fda.gov/media/155049/download.

6
https://www.ashp.org/-/media/assets/COVID-19/docs/Paxlovid-Prescribing-Guide.pdf

Prescribing & Dispensing

- Prescribing pharmacists are responsible for mandatory reporting of all serious adverse events and medication errors potentially related to Paxlovid **within 7 calendar days** from their awareness of the event using FDA Form 3500

- Complete and submit the MedWatch report online

- Prescribing pharmacists are also asked to submit a copy of the report to Pfizer Safety Reporting

- A copy of the Fact Sheet for Patients, Parents, and Caregivers must be provided with Paxlovid

Paxlovid Contraindications

- Paxlovid is a strong inhibitor of CYP3A and may increase plasma concentrations of drugs that are primarily metabolized by CYP3A

- Paxlovid is contraindicated with drugs that are highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions

Paxlovid cannot be started immediately after discontinuation of any of the following medications due to the sustained CYP3A induction of recently discontinued inducers

- Apalutamide
- Carbamazepine
- Lumacaftor/ivacaftor
- Phenobarbital
- Primidone
- Phenytoin
- Rifampin
- St. John's Wort

Notable Drug-Drug Interactions

- Alfuzosin
- Amiodarone
- Clozapine
- Colchicine
- Dihydroergotamine
- Dronedarone
- Eletriptan
- Eplerenone
- Ergotamine
- Finereone
- Flecainde
- Flibanserin
- Ivabradine
- Lomitapide
- Lovastatin
- Lurasidone
- Methylergonovine
- Midazolam, oral
- Naloxegol
- Pethidine
- Pimozide
- Propadenone
- Quinidone
- Ranolazine
- Sildenafil when used for pulmonary arterial hypertension (PAH)
- Silodosin
- Simvastatin
- Triazolam
- Tolvaptan
- Ubrogepant
- Voclosporin

This list may not be all inclusive

Resources for Evaluating Drug Interactions

- Fact Sheet for Healthcare Providers

- University of Liverpool COVID-19 Drug Interactions Checker

- COVID-19 Advisory for Ontario What Prescribers and Pharmacists Need to Know

Other Resources

- ASHP Paxlovid Resources

- NIH COVID-19 Treatment Guidelines

- CDC: COVID-19

- Test to Treat Locator

- PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers

- AHFS Nirmatrelvir Monograph

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3.   CONCLUSION

Pharmacists' ability to access data to assess and document clinical information related to delivery of test to treat programs is essential. Connecting pharmacy systems to HIEs is a critical component for test to treat programs. Utilization of pharmacists in test to treat programs is increasing, and having access to clinical information through an HIE will help facilitate interoperability.

4.   RESOURCES

https://www.ashp.org/-/media/assets/COVID-19/docs/Paxlovid-Prescribing-Guide.pdf

https://aspr.hhs.gov/TestToTreat/Documents/Fact-Sheet.pdf.

https://www.cardinalhealth.com/en/services/retail-pharmacy/patient-care-solutions/point-of-care.html

https://www.cdc.gov/coronavirus/2019-ncov/php/electronic-case-reporting.html. "Starting on January 1, 2022, eCR will be required by CMS Promoting Interoperability Program external icon for eligible hospitals and critical access hospitals and the Merit-Based Incentive Payment System (MIPS) Promoting Interoperability Performance Category external icon for eligible clinicians."

https://covid-19-test-to-treat-locator-dhhs.hub.arcgis.com/

https://www.healthit.gov/topic/information-blocking

https://naspa.us/resource/pharmacist-prescribing-for-strep-and-flu-test-and-treat/

https://ncpa.org/sites/default/files/2022-01/COVID-19_antivirals_billing_for_NCPA_members.pdf

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7645892/

List of HIE's https://strategichie.com/membership/hie-members-list/

https://pharmacist.com/Practice/COVID-19/Test-to-Treat-for-Paxlovid

SARS-COV-2 DIAGNOSTIC USE CASES https://www.finddx.org/dx-use-cases/

Sykes, Kenneth D., "Health Information Exchanges in The Community Pharmacy Setting," April 2019. https://dc.uthsc.edu/cgi/viewcontent.cgi?article=1062&context=hiimappliedresearch.

5.   ACKNOWLEDGEMENTS

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