Ambulatory care pharmacist evaluation of drug-drug interactions with nirmatrelvir/ritonavir: Managing workload and ensuring patient safety during the COVID-19 pandemic

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Abstract

Background: Nirmatrelvir/ritonavir, an oral antiviral for COVID-19, was released under an Emergency Use Authorization in December 2021. Its complex drug-drug interaction (DDI) profile, combined with limited initial guidance on DDI management, created a critical need for pharmacist-led interventions to ensure safe use.

Objectives: The objective of this study was to evaluate the frequency, type, and interventions for DDIs identified by an ambulatory care pharmacist in a rural clinic during a period when comprehensive guiding literature on nirmatrelvir/ritonavir was unavailable.

Methods: A retrospective electronic medical record review was conducted at a rural South Dakota clinic for patients seen January 1 to September 12, 2022. Adult patients with confirmed COVID-19 who were assessed by the pharmacist for antiviral therapy eligibility were included. Pharmacist-identified DDIs and interventions were categorized by type, and time spent per evaluation was recorded.

Results: Of the 141 included evaluations, 103 (73.0%) had at least one DDI identified, with a total of 195 interactions across 73 drugs. Most common drug classes involved were statins, opioids, and calcium channel blockers. Multiple DDIs were found in 52 evaluations and 32 evaluations required more than one drug intervention. Time spent on evaluations averaged 35 minutes. Despite incomplete guidance, pharmacist assessments aligned with later published data.

Conclusion: In the absence of comprehensive resources, the ambulatory care pharmacist played a critical role in identifying and managing potential DDIs. This study highlights the clinical value and workload burden of pharmacists practicing in settings where DDI evaluation occurs prior to prescribing, such as this clinic-based model. These findings underscore the importance of recognizing and appropriately reimbursing pharmacist contributions within ambulatory care practices.

Keywords: nirmatrelvir/ritonavir, COVID-19, ambulatory care pharmacist, drug-drug interactions, pharmacist workload, patient safety

Background

Coronavirus disease 2019 (COVID-19) led to a World Health Organization-declared viral pandemic.[1] COVID-19 symptoms ranged from mild upper respiratory symptoms to severe, potentially life-threatening symptoms, which usually occurred in patients with one or more risk factors; increased severity resulted in COVID-19 treatment becoming a health care priority for patients with several risk factors.[1]

Nirmatrelvir/ritonavir, a dual ingredient antiviral medication, was developed in response to COVID-19. It was used to treat mild to moderate COVID-19, especially in those patients with certain risk factors for COVID-19 progression.[2,3]

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The nirmatrelvir dose requires adjustment for renal dysfunction, while ritonavir is a known inhibitor or inducer of various metabolic CYP enzymes, uridine diphosphate-glucuronyltransferase, P-glycoprotein, and organic anion transporting polypeptides.[2,4,5] These inhibitive and inductive effects resulted in the potential for drug-drug interactions (DDIs) between nirmatrelvir/ritonavir and many drug classes due to their impact on several drug metabolism pathways.[3,4,6] Nirmatrelvir/ritonavir use was originally indicated for patients who were at high risk for progression to severe COVID-19, defined as age 65 and older and with certain underlying medical conditions; as such, these patients also typically had extensive medication regimens.[2] Pharmacists are uniquely trained as drug experts in the health care system and possess the knowledge and evaluation skills to understand and minimize the impact of nirmatrelvir/ritonavir DDIs on patients' medication regimens, health, and safety.[7-10]

Nirmatrelvir/ritonavir was released for use in the United States in December 2021 under an Emergency Use Authorization (EUA) and marketed under the trade name Paxlovid™.[2] The EUA meant it had not been reviewed through standard FDA approval processes, thus limited information was readily available to health care prescribers about its efficacy and coadministration.[2,3,10] Due to their comprehensive

expertise in medications, pharmacists were often relied upon to ensure appropriateness of nirmatrelvir/ritonavir therapy since published literature and guidance was lacking.[3,5,6] Nirmatrelvir/ritonavir was a novel drug to many pharmacists, and although extensive information was available about ritonavir interactions, very little information was available about the drug combination. The absence of comprehensive published guiding literature necessitated careful review of patients' home medications through full medication reconciliations to identify and address any potential DDIs to avoid adverse reactions that might result in the need for additional medical care.[2,3,5,6,10] The severity of adverse reactions resulting from DDIs range from minor (e.g., hypotension, glycemic changes, increased sedation) to major (e.g., toxic drug levels, reduced efficacy due to decreased drug levels, increased platelet aggregation, myopathy, rhabdomyolysis, encephalopathy, renal damage, death), all of which would jeopardize patient safety.[2,3,5,10]

Although pharmacists possessed the skills and expertise to use multiple incomplete and frequently updated resources to ensure patient safety (e.g., the Liverpool COVID-19 Interaction Checker[11], Paxlovid™ fact sheets for health care providers[12]), comprehensive nirmatrelvir/ritonavir DDI literature was not available until late 2022, approximately one year after EUA release.[2,4,6] During the period when comprehensive guiding literature was unavailable, pharmacists in various practice settings spent significant amounts of time performing these evaluations, which were necessary to ensure patient safety and facilitate proper nirmatrelvir/ritonavir administration and DDI management.[4-6] However, the amount of time spent by pharmacists on these complex evaluations is not well documented in existing literature. This unaccounted-for time can have significant workflow and financial implications, and the pharmacist time is often not compensated for through third-party billing.[4-6,13-15]

Avera Medical Group Brookings clinic is a single clinic in rural South Dakota and part of a multi-state health system consisting of 32 billable providers and serving over 35,000 patients. A clinical ambulatory care pharmacist who was 0.5 FTE at the clinic (3.5 hours daily, Monday through Friday, dedicated to direct patient care hours) conducted chronic disease state management under a broad collaborative practice agreement. Prior to the EUA of nirmatrelvir/ritonavir, the pharmacist primarily conducted diabetes management appointments but pivoted to assessing COVID-19-positive patients for antiviral therapy after the EUA. During the period described below, the clinic stocked the majority of nirmatrelvir/ritonavir available in the county; patients were dispensed the medication directly from the clinic and patient counseling was provided solely by the pharmacist at the clinic. Patients were referred to the pharmacist by other providers in the clinic for evaluation for treatment with nirmatrelvir/ritonavir after experiencing a positive home COVID-19 test or a positive polymerase chain reaction (PCR) test/lab-verified COVID-19 infection. Upon receipt of the referrals, the pharmacist confirmed the patients were eligible for treatment based on nirmatrelvir/ritonavir's eligibility criteria and use guidelines.[2]

Objective

The objective of this study was to evaluate the frequency and type of interventions for DDIs with nirmatrelvir/ritonavir identified by a single ambulatory care pharmacist during the period when comprehensive guiding literature was unavailable. This will allow for better understanding of the workload of a pharmacist as a subject matter expert in the complex evaluations following ongoing nirmatrelvir/ritonavir prescribing and the potential billing implications.

Methods

This study was a retrospective, single-center electronic medical record review to determine nirmatrelvir/ritonavir DDIs identified by an ambulatory care pharmacist in a rural clinic. Patients were included if they were 18 years of age or older, received primary care at the clinic, had a positive home COVID-19 test or positive PCR test/lab-verified COVID-19 infection, were referred to the pharmacist for evaluation within five days of COVID-19 symptom onset, and their case was reviewed by the pharmacist between January 1, 2022 and September 12, 2022. Patients were excluded from the study if they were pregnant, hospitalized at the time of referral to the pharmacist, had an eGFR < 30 mL/min/1.73m^2, or had Child-Pugh Class C hepatic impairment. The study was approved by the Avera Health Institutional Review Board.

This study described the number and type of identified DDIs with nirmatrelvir/ritonavir identified by the ambulatory care pharmacist during the period while comprehensive guiding information about DDIs with nirmatrelvir/ritonavir was not available. Medical records of every patient who received nirmatrelvir/ritonavir after evaluation by the pharmacist during the study period were evaluated for pharmacist documentation and subsequent pharmacist interventions for DDIs. Pharmacist interventions were classified into four categories: medication discontinuation (for duration of treatment), medication dose adjustment (for duration of treatment), additional monitoring (without medication adjustment), and no medication adjustments or additional monitoring required. Identified DDIs were also classified into interaction categories as defined by later published comprehensive guiding literature, and these categorizations were compared to the pharmacist's interventions based upon their clinical judgment.[4] In addition, the time the pharmacist spent evaluating DDIs, if documented, was collected.

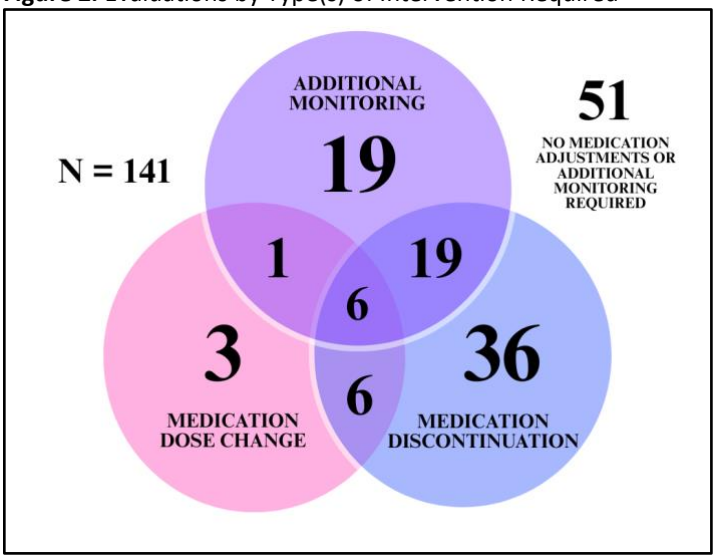
Results

The ambulatory care pharmacist completed 142 nirmatrelvir/ritonavir patient evaluations during the study period. One evaluation was excluded due to concurrent pregnancy, resulting in 141 evaluations (99.3%) included for

analysis. During the 141 evaluations, the pharmacist identified a total of 195 DDIs with nirmatrelvir/ritonavir involving 73 distinct drugs and 36 classes of drugs. Drug classes (and drugs that are not easily categorized into a class) in which DDIs were found during the evaluations are included in Figure 1. The most commonly identified DDI drug classes were with HMG-CoA reductase inhibitors (statins, n = 42), opioid analgesics (n = 20), and calcium channel blockers (n = 18).

Of the 141 evaluations, 103 (73.0%) had at least one identified DDI with nirmatrelvir/ritonavir that required intervention by the pharmacist. Multiple DDIs were found in 52 medication regimens, with an average of 1.38 DDIs found per evaluation. As shown in Figure 2, 32 evaluations required multiple types of interventions (e.g., medication dose change, medication discontinuation, and/or additional monitoring), and 51 evaluations did not require any intervention.

Figure 2. Evaluations by Type(s) of Intervention Required



Three set Venn Diagram shows three areas of intervention (medication dose change, medication discontinuation, additional monitoring) in the 141 evaluations. 90 evaluations required medication adjustments or additional monitoring. 32 evaluations required >1 type of counseling.

Of the 195 identified DDIs with nirmatrelvir/ritonavir, the pharmacist discontinued 73 (37.4%) medications for the duration of nirmatrelvir/ritonavir therapy. Table 1 describes interventions completed by the pharmacist during the study period and how the identified DDIs with nirmatrelvir/ritonavir were categorized, both during the study period and after publication of guiding literature.[4] Of the drugs reviewed, 12 drugs were not covered in the categorization reference, so interaction information from the University of Liverpool COVID-19 Drug Interactions tool was extrapolated to assign category of interaction.[11]

Table 1. Pharmacist Interventions for Identified DDIs During Study Period Compared to Types of DDIs Based on Guiding Literature Published After the Study Period

Pharmacist Interventions for Identified DDIs (Before Published DDI Data Available)		*Types of DDIs Based on Published Literature (After Published DDI Data Available)*	
Pharmacist Intervention	Number Identified (*n* = 195)	Category of Interaction with Nirmatrelvir/Ritonavir	Number Identified (*n* = 195)
Medication Discontinuation (For duration of treatment)	73 (37.4%)	Do not coadminister (Do not use nirmatrelvir/ritonavir - use alternative COVID-19 therapy - strong inducer can compromise efficacy)	2 (1.0%)
		Do not coadminister (nirmatrelvir/ritonavir use ONLY possible if drug is paused or replaced by a noninteracting drug)	41 (21.0%)
Medication Dose Adjustment	17 (8.7%)	Potential interaction (dose adjustment and/or close monitoring required)	63 (32.3%)
Additional Monitoring* (Without medication adjustment)	65 (33.3%)	Potential interaction (manageable by counseling)	49 (25.1%)
No Medication Adjustments or Additional Monitoring Required	40 (20.5%)	Weak interaction	15 (7.7%)
		No interaction expected	25 (12.8%)

*Additional monitoring recommendations included blood pressure, blood glucose, increased sedation, INR following course of treatment, and using additional birth control method
Abbreviations: DDI(s), drug-drug interaction(s)

The range of pharmacist time spent per evaluation was 30 to 60 minutes, with an average of 35 minutes per evaluation. Two evaluations did not include documentation of pharmacist time spent, leaving 139 evaluations with time-related data. Evaluation times were longer during the initial period following the nirmatrelvir/ritonavir EUA, when the pharmacist was still developing efficient workflows and all relevant clinical and medication information required thorough review. Time recorded for each evaluation included reviewing the patient's

chart and medication list, assessing potential drug–drug interactions using the most current nirmatrelvir/ritonavir guidance, counseling the patient, and coordinating medication pick-up with a non-COVID-positive individual.

Discussion

This study shows the critical, but potentially unquantified, role of the ambulatory care pharmacist in managing DDIs during the early availability of nirmatrelvir/ritonavir therapy for COVID-19. Ambulatory care pharmacists were crucial to reviewing patient medication regimens, evaluating evolving literature to identify DDIs, and intervening to prevent negative outcomes due to DDIs. In comparing the DDIs identified before and after comprehensive literature was available, the DDIs identified were similar. When compared to expected rates of intervention, discrepancies between the identified DDIs (Table 1) were due to lack of clinical data and gaps in literature and the pharmacist opting for the most cautious approach when addressing the DDI. As such, the pharmacist was more likely to hold a medication for the duration of nirmatrelvir/ritonavir treatment than to reduce the dose or suggest or provide additional monitoring. For example, although not every statin needed to be held for the duration of nirmatrelvir/ritonavir therapy, the pharmacist opted to temporarily discontinue all statins as a deliberate form of clinical accuracy in a low-information environment as the increased relative risk of cardiovascular events from temporarily discontinuing the statin did not outweigh the potential precipitating adverse events of continuing that statin. Thus, the pharmacist discontinued drugs for 37.4% of the 195 DDIs found, whereas the later-published comprehensive guiding literature would recommend "do not co-administer" for only 22.0% of the 195 DDIs identified.[4] However, the pharmacist opted to make no medication adjustments or recommend additional monitoring in 40 drugs, which is consistent with the later published literature.[4] This indicates that, despite absent or inconsistent resources, the pharmacist made an appropriate determination of what medications did not need additional monitoring or dose adjustments based on their clinical knowledge and judgment.

Of the 141 evaluations, 32 evaluations required more than one type of intervention (i.e. dose reduction and discontinuation) and 52 resulted in the need to intervene on more than one DDI (i.e. multiple medications), so they took more time for the pharmacist to complete. Although 51 evaluations did not require medication adjustments or additional monitoring, counseling by the pharmacist was still required to educate the patient on how to use nirmatrelvir/ritonavir, potential side effects, and to confirm absence of identified DDIs with their current medication regimen. Given that COVID-19 evaluations required on average 35 minutes, they resulted in a significant workload increase during this period for the 0.5 FTE ambulatory care pharmacist.

While it is evident that the DDI evaluations completed by the pharmacist were substantial, they do not encompass the full scope of work completed by the pharmacist for nirmatrelvir/ritonavir. As the landscape for nirmatrelvir/ritonavir was ever changing in the initial months after EUA, the pharmacist continually reviewed the most current literature, educated clinic personnel on updates, and completed curbside consults. To increase the clinic's efficiency for nirmatrelvir/ritonavir evaluations, the pharmacist created resources and 'quick sheets' to help non-pharmacist providers determine eligibility for the medication, quickly screen for DDIs, and modify medication regimens accordingly. This intervention became increasingly critical as nirmatrelvir/ritonavir supply became more widely available in community pharmacies and prescribers sent nirmatrelvir/ritonavir prescriptions to community pharmacies for dispensing versus dispensing from the clinic's stock. The pharmacist also communicated with local community pharmacies dispensing nirmatrelvir/ritonavir about its criteria for use and DDIs. The time spent educating other health care providers and addressing curbside consults is not accounted for in this study.

Describing the full impact of the pharmacist on the clinic is incomplete without a review of the fiscal impact. As nirmatrelvir/ritonavir evaluations and subsequent appointments were conducted telephonically, the clinic could not bill third party payers for the pharmacist-delivered services, so no actual revenue was generated. This lack of revenue generation resulted in an under-estimation of the pharmacist's contribution to clinic operations during this time of significantly increased actual work. If usual clinic billing policy were followed and in-person appointments were conducted, each evaluation would have resulted in billing of a Current Procedural Terminology (CPT®) code 99211 because pharmacists are not recognized providers under Medicare Part B or in South Dakota.[13-17] This code is one of the least revenue-generating codes used to bill for outpatient evaluation and management services and would have resulted in approximately $3,286.71 in clinic revenue if applying the 2022 Physician Fee Schedule (South Dakota Medicare Administrative Contractor and non-facility designation).[18] However, CPT® 99211 does not accurately reflect the work completed by the pharmacist, as complex Medical Decision Making (MDM) occurred with each appointment. A previous study demonstrated that this type of visit performed by a pharmacist would result in a CPT® code 99214 if billing using the full 2021 American Medical Association Level of Medical Decision Making–CPT® codes.[19] When applying the 2022 Physician Fee Schedule and the higher code, the clinic pharmacist would have generated $13,572.66 for the clinic; an approximately four-fold increase in revenue generation.[19] The time other clinicians saved through the delivery of this service by the pharmacist also has a fiscal impact, but isn't captured by the data presented. The pharmacist was likely more efficient and thorough in evaluating the medication-related

nuances in prescribing nirmatrelvir/ritonavir for patients. The impact of this service on other clinicians' ability to do other work was also not captured. While the potential revenue generation (for both full scope of billing and incident-to-provider billing) is helpful to translate impact, it does not comprehensively convey other impacts of pharmacist services, such as quality of care, avoided events (e.g., hospitalization), patient safety, or prescriber access to drug information experts.

Although ambulatory care pharmacists are not yet able to realize this type of revenue under Medicare, an accurate reflection of clinical work completed in the outpatient setting is crucial to advance the practice of pharmacy and prevent burnout. Accurately quantifying and qualifying work completed allows for open conversations with other health care prescribers and non-medical staff on the benefit of an ambulatory care pharmacist and preventing over-assigning workload due to the intangibles also expected of an ambulatory care pharmacist.[20] Overall, ambulatory care pharmacists are a critical asset to the outpatient health care team as they are able to quickly pivot clinical responsibilities as seen during the COVID-19 pandemic, rapidly adjusting focus from chronic disease state management to conducting evaluations for appropriate use of nirmatrelvir/ritonavir. During a period of inconsistent resources and an ever-evolving environment, ambulatory care pharmacists continued to provide exceptional patient care and serve as the cornerstone of clinical drug information.[6] Despite all of the challenges, pharmacists ensured the safe evaluation, prescribing, and dispensing of COVID-19 antivirals such as nirmatrelvir/ritonavir.[6]

Due to the retrospective and single-center nature of the study, some limitations exist. Only the available medical records from one facility were reviewed, thus full medication regimens, especially over the counter medications, may not have been evaluated by the pharmacist, although every effort was made to mitigate this issue. Knowledge and recommendations for DDIs with nirmatrelvir/ritonavir were evolving during the study period as new information was published, so the DDI categorization and pharmacist recommendation for specific drugs potentially varied throughout the study period. Furthermore, patients may not have been referred to the pharmacist due to an informal consult and quick determination that the patient was not eligible for nirmatrelvir/ritonavir therapy, so the true number of patients evaluated is likely underestimated. While it is also possible that some patients were treated without review by the pharmacist, this data is not available, so a comparison between patients with and without pharmacist review is not feasible.

Areas for future research include quantifying DDI interventions with nirmatrelvir/ritonavir and time spent by pharmacists in other practice areas (e.g., community pharmacy) and documenting time spent by ambulatory care pharmacists to include all activities related to in-clinic nirmatrelvir/ritonavir dispensing.

Conclusion

Ambulatory care pharmacists spent significant time identifying and intervening on DDIs associated with nirmatrelvir/ritonavir, relying on extrapolating clinical knowledge to ensure patient safety during COVID-19. Despite evolving literature and limited billing opportunities, ambulatory care pharmacists continue to serve as drug information experts.

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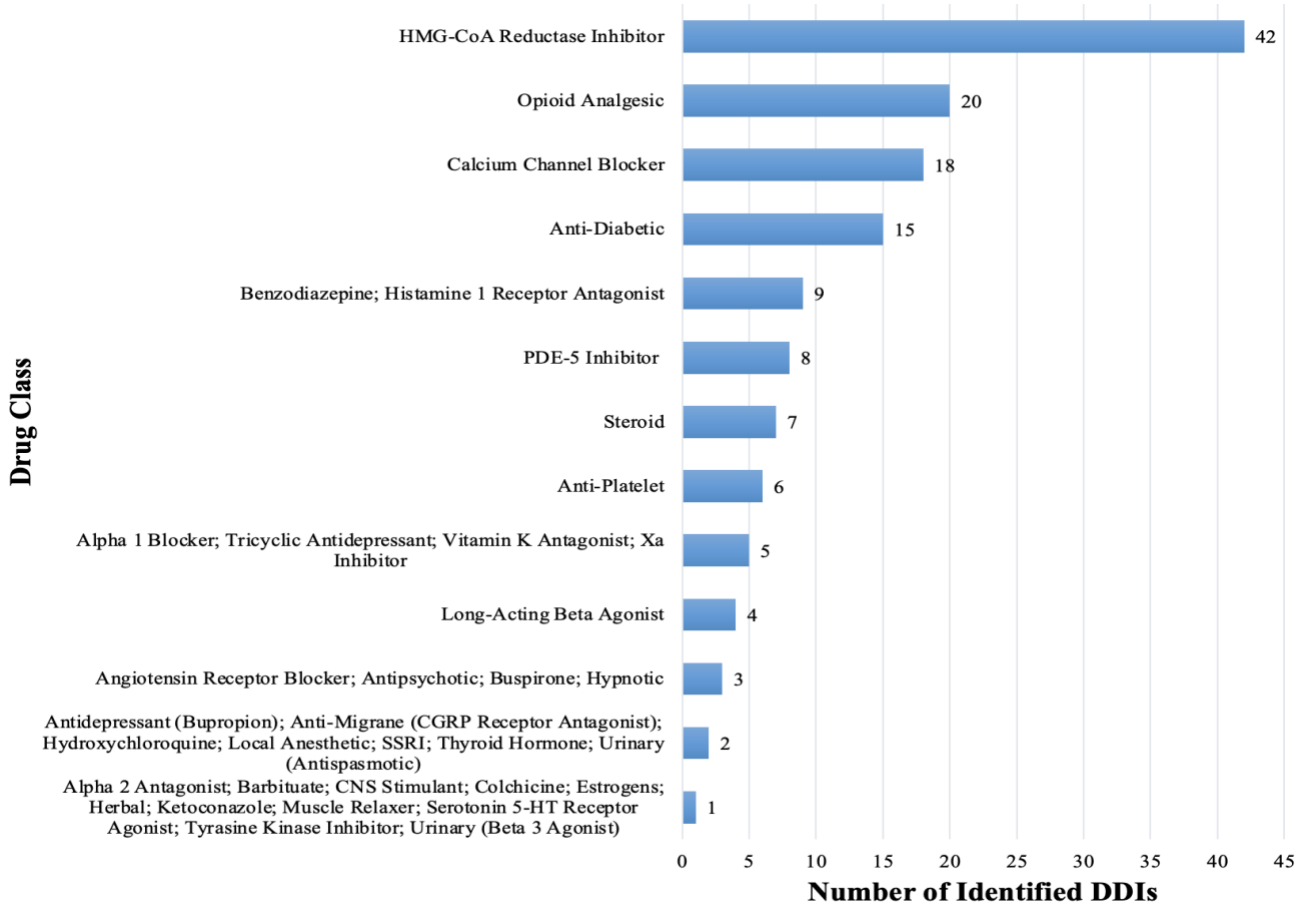
Figure 1. DDIs with Nirmatrelvir/Ritonavir Identified by a Single Ambulatory Care Pharmacist, by Drug Class



Abbreviations: HMG-CoA, hydroxymethylglutaryl CoA; PDE-5, phosphodiesterase type 5; CGRP, calcitonin gene-related peptide; SSRI, selective serotonin reuptake inhibitor; 5-HT, serotonin