

PHARMACY FOCUS

JOURNAL OF THE VALLEY HOSPITAL PHARMACY

FORMULARY UPDATES



ADDITIONS

Rubidium-82 (CardioGen-82).

This radiopharmaceutical is used in positron emission tomography (PET) imaging to assess myocardial perfusion and detect coronary artery disease. It is injected into the bloodstream, where it emits positrons, allowing for detailed imaging of blood flow to the heart muscle.

Oligonucleotide (Imetelstat).

This agent inhibits telomerase activity to selectively induce apoptosis in malignant cells with high telomerase activity while sparing normal cells. Indicated for the treatment of adult patients with low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring 4 or more red blood cell units over 8 weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESA). Restricted to Luckow Infusion.

Zolbetuximab-clzb (Zyloy).

CLDN18.2- directed monoclonal antibody which targets CLDN18.2 positive cells via antibody-dependent and complement-dependent cytotoxicity pathways. Indicated in combination with fluoropyrimidine and platinum containing chemotherapy, for the first line treatment of adult patients with locally advanced or unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma whose tumors are CLDN18.2 positive. Restricted to Luckow Infusion.

Hexaminolevulinate (Cysview) for Blue Light Cystoscopy

This agent is used during cystoscopy to help visualize abnormal tissue in the bladder by highlighting cancerous or precancerous areas. It is administered prior to the procedure and absorbed by the bladder, where it fluoresces under specific lighting, aiding in more accurate detection of bladder cancer.

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DRUG INFORMATION CORNER

Jasmine Takach, PharmD

Question: How can Lupkynis (voclosporin) reduce the decline of kidney function in patients with lupus nephritis (LN)?

Response: Lupus is an autoimmune disease that causes the immune system to attack its own tissues rather than only infections and diseases. Lupus nephritis (LN) is a serious complication of lupus that occurs when the immune system attacks the kidneys leaving it damaged. This damage to the kidneys will reduce the normal functions such as removing waste from blood, maintaining body fluids, and regulating hormone levels. Symptoms of LN include swelling, polyurea, foamy urine, hematuria, and elevated blood pressure. If left untreated, patients may need to be treated with dialysis or a kidney transplant. To prevent LN from occurring or progressing, patients need to be compliant with their lupus treatment that often includes immunosuppressive drugs and corticosteroids. A newly approved medication, Lupkynis (voclosporin) was approved in 2021 as the first and only FDA-approved oral medication for the treatment of LN. Prior to this approval, Benlysta (belimumab) was a non-oral option for the treatment of LN.



Voclosporin is a calcineurin-inhibitor immunosuppressant that is used in combination with immunosuppressive therapy for lupus such as mycophenolate mofetil and corticosteroids. The approval was based on overall outcomes of two late-stage studies, the AURORA Phase III study and the AURA-LV Phase II study. The AURA-LV study randomized patients to receive voclosporin 23.7mg or 39.5mg twice daily or placebo in combination with mycophenolate mofetil (2g/day) and tapered low-dose corticosteroids. The primary endpoint, complete renal remission, was achieved by 29 (32.6%) subjects in the low-dose voclosporin group, 24 (27.3%) subjects in the high-dose group, and 17 (19.3%) in the placebo group. The AURORA study also compared voclosporin (23.7mg twice daily) to placebo in combination with mycophenolate mofetil and low-dose steroids. The primary endpoint was complete renal response at 52 weeks which was defined as a urine protein creatinine ratio of 0.5mg/mg or less, stable renal function (eGFR>60mL/min/1.73m² or no decrease in baseline eGFR above 20%). The primary endpoint was achieved more in the voclosporin group than in the placebo (73 [41%] of 179 patients vs. 40 [23%] of 178 patients; OR 2.65; 95% CI: 1.64-4.27; p<0.0001). Adverse events were comparable among the voclosporin and placebo group (37 [21%] of 178 patients and 38 [21%] of 178 patients). The most common adverse event was pneumonia. Studies found that patients receiving voclosporin had a 50% reduction in urine protein creatinine ratio twice as quickly as those who received the standard of care with mycophenolate mofetil and low dose corticosteroids.

In assessing if this medication is right for the patient, we must consider the risks associated with voclosporin and how they can impact our patient. One risk is acute or chronic nephrotoxicity, this is assessed by making sure the patient's baseline eGFR is above >45 mL/min/1.73m². Risks of nephrotoxicity should also be assessed by reviewing the patients' other medications with nephrotoxicity risk. Voclosporin should not be taken concurrently with strong CYP3A4 inhibitors such as ketoconazole and clarithromycin, cyclophosphamide, or grapefruit products. Baseline blood pressure should also be <165/105 due to risk of hypertension which could further detriment the kidneys. Dose reductions are advised for renal function and blood pressure. If reduced doses do not show improvement or stability of blood pressure and renal function, then it should be discontinued. Baseline QTc should also be assessed before starting voclosporin due to a dose-dependent effect. Assessing other QTc prolonging drugs that the patient takes will also be needed to identify whether this medication is appropriate for initiation. If the patient does not experience therapeutic benefit such as stable renal function by 24 weeks, the medication could be discontinued as the patient will not receive any added benefit at this point.

In conclusion, voclosporin is a great option for patients with LN looking for an oral medication, given blood pressure and renal function are deemed safe for initiation. The risks of voclosporin should be assessed prior to use and regular monitoring at initiation will be needed to determine efficacy in the patient.

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 2. Lupkynis (voclosporin) [prescribing information]. Rockville, MD: Aurinia Pharma US Inc; April 2024.

EXPLORING THE ROLE OF FACTOR XIA INHIBITORS IN ANTICOAGULATION FOR ATRIAL FIBRILLATION



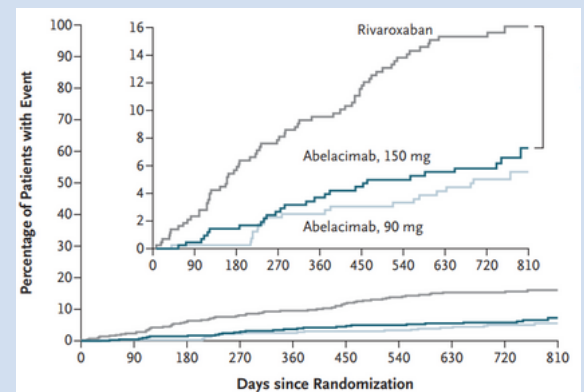
Daniella Ramiro, PharmD

In the United States, there is an estimated 12.1 million people with atrial fibrillation, making it one of the most common cardiac arrhythmias.¹ During atrial fibrillation, the upper chambers of the heart (the atria) are beating irregularly and rapidly which allows blood to pool and prevent it from moving to the lower chambers.¹ The pooled blood has the potential to clot, which can travel to other parts of the body including the vessels, lungs, legs, or the brain – all of which can cause life-changing events including death.

Of those with atrial fibrillation, around 60 to 65% of people are currently prescribed anticoagulation medications. Currently, direct oral anticoagulants (DOACs) such as apixaban (Eliquis) or rivaroxaban (Xarelto), are the medications of choice for atrial fibrillation patients to prevent clots from forming. These medications work by inhibiting factor Xa in the coagulation cascade and thus preventing a downstream of effects that ultimately results in the prevention of fibrin, the material that holds clots together.

While DOACs work on the factor Xa step of the coagulation cascade, there are many other agents that affect the additional steps within this process. A new monoclonal antibody Abecimab, offers a new mechanism as one of the first medications to inhibitor factor XIa within the coagulation cascade. This fully human monoclonal antibody binds to the inactive form of factor XI and blocks its activation earlier in coagulation cascade, which prevents the formation of clots while still preserving the body's ability to clot in response to bleeding or trauma.

The phase 3 AZALEA-TIMI 71 clinical trial published in January 2025 compared abecimab to the commonly used DOAC, rivaroxaban (Xarelto). Participants in this trial were a median age of 74 years with a median CHA2DS2-VASc score of 5 across all groups, indicating a high risk for stroke. Concomitant conditions for these patients included hypertension, diabetes, heart failure, coronary artery disease, as well as a history of either bleeding, ischemic stroke, or transient ischemic attack. Abecimab was administered as a once-monthly, subcutaneous injection while rivaroxaban was administered as its usual form of an oral, daily tablet.



Abecimab demonstrated its anticoagulation ability as the incidence of major or clinically relevant nonmajor events was less than half of the bleeding events seen with rivaroxaban. The figure above depicts that before 90 days of the trial had elapsed, there was a higher percentage of patients with major or clinically relevant nonmajor bleeding when taking rivaroxaban. The curve continues to widen throughout the duration of the study with no overlap in the risk of bleeding between abecimab and rivaroxaban. The curve also depicts the difference in bleeding between a 150 mg and 90 mg dose of abecimab. There was a higher percentage of patients with a bleeding event when utilizing abecimab 150 mg compared to 90 mg; however, there was not much variation in bleeding events as the greatest difference of patients between both doses was approximately 3%.

The trial was stopped early as there was a “greater-than-anticipated reduction in bleeding events” with the monoclonal antibody medication. The presence of any serious adverse events between both medications was nearly the same, with injection site reactions being the only adverse effect specified to abecimab. Further studies involving abecimab need to be conducted to make a more generalizable conclusion as there are other DOACs that this medication can be compared to, as well as other communities that can be impacted with the use of the medication; however, the safety and efficacy of abecimab creates the potential for a new, less frequently administered anticoagulation option for atrial fibrillation patients.

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DECADES OF DEDICATION: TWO PHARMACY PROFESSIONALS RETIRE AFTER YEARS OF SERVICE

After decades of dedicated service to The Valley Hospital, David Dietzel and Lou Spinelli have officially retired, leaving behind a legacy of excellence in the pharmacy department. Both pharmacists were known for their unwavering commitment to patient care and exceptional expertise. David Dietzel, whose career spanned numerous roles within the pharmacy team, became a cornerstone of the department. His attention to detail and understanding of medication management made him a trusted resource for both patients and colleagues. David's retirement marks the end of a remarkable era, but his influence will be felt for years to come.

Lou Spinelli, a long-time member of the Surgery and Anesthesia team, is fondly remembered for his contributions to surgical care. Throughout his career, Lou worked closely with surgical teams to ensure that medications were administered accurately during procedures.



RETIREMENT DINNER FOR DAVID DIETZEL (FIRST SEATED ON THE LEFT).



RETIREMENT DINNER FOR LOU SPINELLI (MIDDLE, FRONT ROW).

His expertise in anesthesia and ability to collaborate across departments helped streamline operations in the operating room. Lou's retirement brings to a close a distinguished chapter in the history of The Valley Hospital. Both David and Lou leave behind a legacy that has shaped the hospital's pharmacy practice, inspiring future professionals in the field.



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HIGHLIGHTING OUR RESIDENTS' MIDYEAR POSTER PRESENTATIONS AT ASHP

Evaluating the Impact of DPYD Testing on 5-Fluorouracil and Capecitabine Toxicity in Patients Receiving Chemotherapy at an Outpatient Infusion Center

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Introduction

Dihydropyrimidine dehydrogenase (DPYD) is an enzyme that causes the breakdown of fluoropyrimidines, such as 5-fluorouracil (5-FU) or capecitabine, allowing it to be excreted by the body. Approximately 2-8% of the population has a DPYD deficiency rendering patients unable to metabolize these antineoplastic agents, resulting in toxicities or death.¹ Testing for DPYD mutations allows physicians to dose adjust chemotherapy regimens containing these agents or avoid them entirely. However, screening for DPYD deficiency is not yet a requirement at many institutions, including Valley Health System, for all patients receiving either 5-FU or capecitabine therapy.

Objective

This study intends to evaluate the relationship between DPYD testing and the preventability of toxicity in patients receiving a chemotherapy regimen containing 5-FU or capecitabine at an outpatient infusion center.

Methods

An IRB-exempt single-center, retrospective review was conducted using patient data from January 1st, 2023 to December 31st, 2023

Inclusion Criteria:

- Age ≥ 18 years old
- Have received at least one dose of 5-FU or capecitabine
- Must have a histologically confirmed diagnosis of cancer

Exclusion Criteria:

- Treated by a non-Valley Medical Group provider
- Those who are contraindicated to receive 5-FU or capecitabine

Primary Outcome: Rate of grade 3 or 4 fluoropyrimidine toxicity including mucositis, diarrhea, and hand-foot syndrome

Secondary Outcome: Rate of hospitalization for fluoropyrimidine toxicity within the last 30 days of 5-FU or capecitabine administration

Patient-Specific Variables Collected: Age, sex, race and/or ethnicity, body surface area, medication received (5-FU or capecitabine), whether DPYD screening was performed prior to treatment or after the first cycle of chemotherapy, DPYD result, cancer diagnosis, ordering prescriber, dose adjustment of 5-FU or capecitabine if applicable, appropriateness of 5-FU or capecitabine dose adjustment if applicable, whether toxicity occurred, and if the patient was hospitalized due to fluoropyrimidine toxicity within 30 days of administration

Statistical Analysis: The primary outcomes, secondary outcomes, and baseline characteristics were analyzed using descriptive statistics.

Results

Figure 1. Type of Cancer Diagnosis

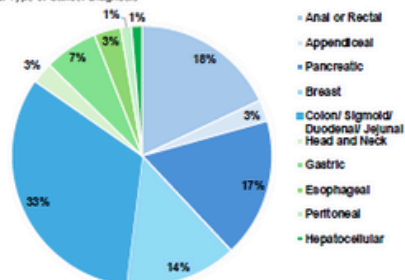


Figure 2. Patients Receiving 5-Fluorouracil vs. Capecitabine

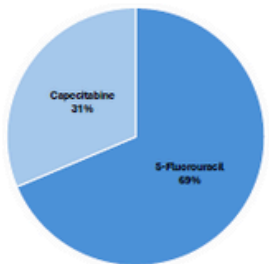


Figure 3. Patients Who Received DPYD Testing vs. No DPYD Testing

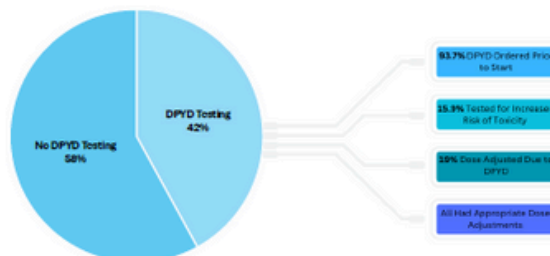


Figure 4. Evidence of Toxicity in Patients Who Received DPYD Testing Prior to Start vs. No DPYD Testing or Testing After the 1st Cycle

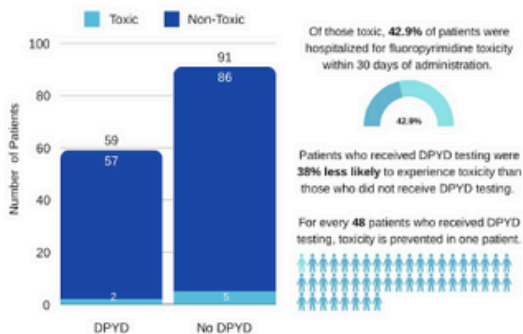


Table 1. Baseline Characteristics of Patient Population

Baseline Characteristics (n=150)	
Age (years), mean ± SD	67.9 ± 11.5
Body Surface Area (m ²), mean ± SD	1.8 ± 0.3
Sex, # (%)	
• Female	73 (48.7%)
• Male	77 (51.3%)
Race or Ethnicity, # (%)	
• White	123 (82%)
• Hispanic or Latino	16 (10.7%)
• Asian	8 (5.3%)
• Black	3 (2.0%)

Table 2. Descriptive Statistical Analysis

Descriptive Statistics	
Relative Risk (RR)	0.62
Relative Risk Reduction (RRR)	0.38
Absolute Risk Reduction (ARR)	2.1%
Number Needed to Treat (NNT)	48
Number Needed to Harm (NNH)	45

Of those who underwent DPYD testing:

40% of individuals who tested for increased risk of toxicity had dose adjustments performed before starting treatment and experienced no toxicity.

75% of individuals who were tested after cycle 1 administration were toxic. This result was statistically significant when using a chi-square test. (p<0.001).

Discussion

Study Limitations:

- Missing documentation of numerical grading of toxicities experienced by patients
- Many patients who received dose reductions after testing as DPYD-deficient experienced grade 2 toxicities, excluding them from this study
- Lack of a single integrative electronic health record that would identify external hospital admissions
- Individuals who received DPYD testing prior to fluoropyrimidine administration and were not treated due to DPYD deficiency were not captured in this data set

Conclusion

- Given 63 patients received DPYD testing, fluoropyrimidine toxicity could have been anticipated or prevented in 4 of these patients if DPYD testing was ordered prior to the start of their first cycle of chemotherapy
- 3 of the 5 patients who did not receive initial DPYD testing that developed toxicity were tested after their first cycle
- Toxicity was prevented in 40% of individuals who had increased risk of toxicity due to dose adjustments made by the provider
- Toxicity could have been prevented in 1 in every 48 patients by considering alternative chemotherapy regimens for their treatment if appropriate
- This study adds to the body of knowledge to support the standardization of DPYD testing in patients receiving fluoropyrimidine therapy
- A follow-up study analyzing the costs of implementing this initiative will be performed to determine its economic value for both the patient and the institution

Disclosures and References

1. Dihydropyrimidine dehydrogenase deficiency. MedlinePlus. September 1, 2015. Accessed August 25, 2024. <https://medlineplus.gov/genetics/condition/dihydropyrimidine-dehydrogenase-deficiency/>
Authors have no conflicts of interests to disclose.

Acknowledgements

We extend our sincere gratitude to Dr. Richard E. Shaw, M.A., Ph.D., FACC, FAHA for his assistance and expertise in the statistical analysis of this research.



Evaluating the Impact of an Ambulatory-Care Pharmacist-Led Medication Refill Management Pilot Program on Primary Care Practices

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Introduction

Fulfilling medication requests is an additional task for physicians that may not take priority due to time constraints. Prompt response to medication refill requests is necessary to promote patient adherence and enhance patients' quality of care. Multiple studies show the importance of pharmacists in medication management as they contribute to improved medication adherence and identification of medication-related issues. Valley Medical Group implemented a pilot program in November 2023, allowing pharmacist-physician collaboration regarding medication refills.

Purpose

This study evaluates how a collaborative relationship between providers and pharmacists affects the operational process and outcomes of a pharmacist-led medication management refill program.

Methods

- Retrospective chart review of medication refill requests sent to pharmacy refill review
- Timeframe: January 1st and June 30th, 2023 and January 1st and June 30th, 2024
- Included medication refill requests for chronic disease state management that includes but is not limited to hypertension, hyperlipidemia, diabetes, GERD, and depression
- Excluded medication refill requests for the following medication classes:
 - Controlled substances
 - Antibiotics
 - Biologics
 - Chemotherapy agents
 - Immunosuppressants/anti-rejection drugs
 - Warfarin
 - Medications for acute/intermittent conditions
 - Injectables
 - Antipsychotics
 - Durable medical equipment
- Data collection:
 - Turnaround time: difference in days from request initiated to request leaving pharmacy or provider's review
 - Provider satisfaction survey that was sent to delegating providers
- Primary outcome: turnaround time of the medication refill request pre- and post-implementation of the refill pilot program
- Secondary outcome: cadence of patient follow-up visits and primary care provider satisfaction post-implementation of the refill pilot program

Results

Figure 1: Pre- and Post-Implementation Refill Pilot Program Turnaround Time

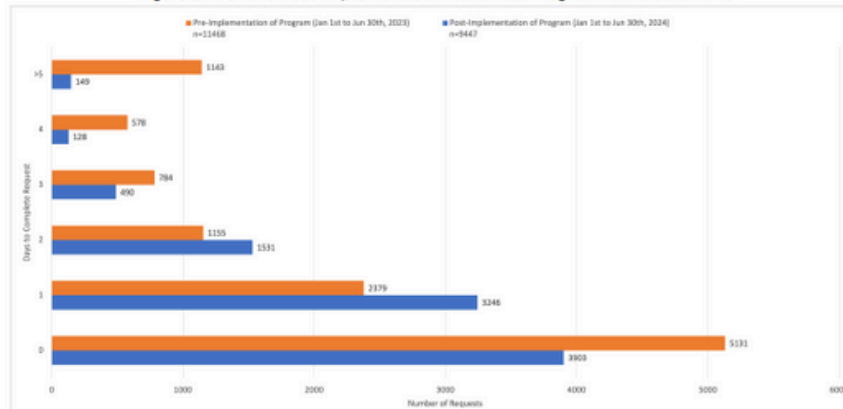


Figure 2: Pharmacist Turnaround Time with Pharmacist Time to First Action

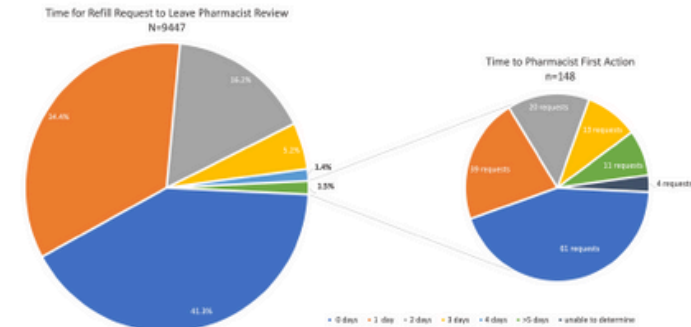


Figure 3: Post-Implementation Refill Requests Requiring Patient Follow-Up

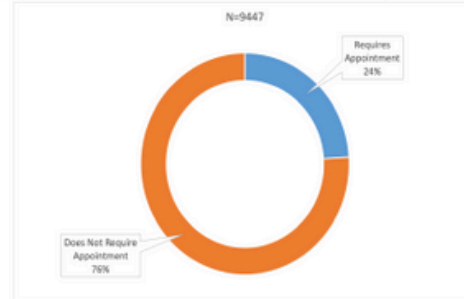
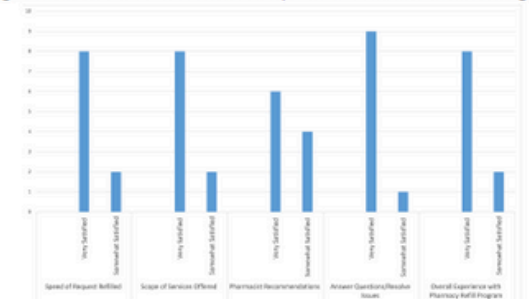


Figure 4: Provider Satisfaction Post-Implementation of Refill Pilot Program



Discussion

The average turnaround time to fulfill requests pre- and post-implementation of the pilot program was 2.00 and 1.10 days, respectively. Figure 1 depicts the program's ability to reduce the number of refill requests responded to in 3 days or longer. Figure 2 depicts delays in refill requests post-implementation of the program which could be attributed to extensive case review involving clinical assessment, contacting patient pharmacies, recommending alternative medication options, inconsistent pharmacist staffing, clarification, and appointment scheduling.

Figure 3 depicts the number of requests that required an office visit and/or lab work scheduled prior to completing the request, as per protocol. Scheduling attempts were initiated for such requests, creating opportunity for closer patient monitoring, problem identification and enhanced chronic disease state management.

A total of 16 surveys were distributed, and 10 providers responded with an average satisfaction of 98%. The surveys included suggestions to adjust workflow, expand pharmacist practice areas, and additional staffing. Provider comments emphasized time saved, demonstrating pharmacist contribution and further potential to provide quality patient care.

Limitations include

- Inconsistent pharmacist staffing during study timeframe
- Satisfaction survey response of 10 out of 16 primary care providers (two practitioners on leave)

Conclusion

Pharmacists have reduced the response time to refill requests and increased patient interaction opportunity. As a result, primary care providers have developed an appreciation for the pharmacist's role within this program, and the positive relationship that has been established has the potential to expand to the remainder of primary care providers within the health system.

Disclosures and References

Authors have no conflicts of interest to disclose



Evaluating the Pharmacist's Role in Time to Discharge in a Community Hospital's Meds-to-Beds Program

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Introduction

In 2017, The Valley Hospital implemented a meds-to-beds program as a quality improvement initiative. A meds-to-beds program is designed to enhance medication access, adherence, and reduction in readmission rate. The program is an integral part of the care team and helps physicians ensure patients receive appropriate and cost-effective medications. Hospital leadership recently noticed delays in the discharge process which triggered the need for reassessment of the various steps including the meds-to-beds program.

Objective

This study explores the potential delay in the hospital discharge process by evaluating pharmacist involvement in fulfilling meds-to-beds prescriptions.

Methods

Inclusion Criteria: Patients who utilize the meds-to-beds service during discharge

Exclusion Criteria: Patients not using meds-to-beds service

Design: Retrospective chart review conducted Monday-Friday, 8am to 8pm, from October 1st to October 28th, 2024.

Prescription processing time

- Collected using the pharmacy dispensing software, McKesson EnterpriseRX
- Reports captured the time, in minutes, for prescriptions to be marked as ready from the time of data entry

Prescription related issues

- Intervention sheets to document issues were provided to pharmacy staff for data collection
- Intervention sheet included date, unit, time it took to resolve the issue, and a short description of the issue
- Issues were broken down into three categories:
 - Clinical:** Drug interactions, DURs, alternate treatment options, direction clarifications, allergies, missing medications charted in EMR, dosage form changes
 - Coordination:** Medications sent to different pharmacy, prescriptions too soon to fill, patient-specific preferences
 - Insurance:** Diagnosis codes missing, prescription not covered, medication overrides, prior authorizations

Primary outcome: The proportion of time to resolve a prescription issue in relation to the total time to process the prescription.

Secondary outcome: Assess the type of interventions being made by the pharmacist.

Results

Primary Outcome

Data points	Outcomes
Total number of RXs	1,917
Total time spent filling RXs	113,305 minutes
Total Issues resolved	85
Total time spent on issues	5,173 minutes

Table 1: Primary outcome data points

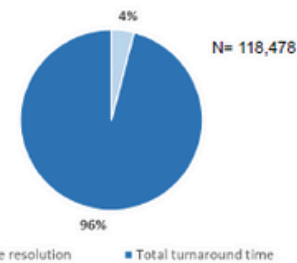


Figure 1: This pie chart represents the percentage of time spent on resolving issues compared to total time filling RXs

Secondary outcome: Number of issues

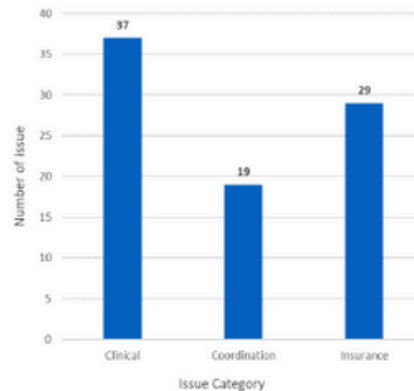


Figure 2: This graph shows the number of issues for each category

Secondary outcome: Time

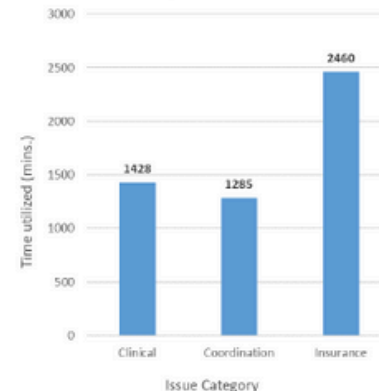


Figure 3: This graph shows the amount of time each type of issue took to resolve.

Week of study	Total RXs filled	Total Issues
Week 1	551	11
Week 2	539	19
Week 3	339	20
Week 4	488	35

Table 2: This table shows the number of prescriptions filled and issues identified per week of the study period. The pharmacy is open for 60 hours per week of the study period.

Discussion

At the conclusion of this study, 1,917 prescriptions were filled and 85 issues were identified by the pharmacy staff. On average, it took about 59 minutes to fill a prescription and 60 minutes to resolve an issue in addition to the time it takes to fill the prescription. The total time resolving an issue consumed about 4% of the pharmacist's time to fill prescriptions. Prescription filling time average was calculated to include all meds-to-beds prescriptions that were filled regardless of if there was an issue. We could not account for the time difference between prescriptions without an issue and prescriptions with an issue. The type of issue identified varied and was categorized based on the description given by the pharmacy staff. Clinical related issues occurred most often, but insurance related issues took the most time to resolve. The frequency of issues encountered, and prescriptions filled did not show a direct correlation. Week 4 contained the most issues which would account for 35 hours of the work week. This amounts to 58% of the total hours that the pharmacy is open Monday-Friday.

Limitations include relying on manual documentation to collect issues, short data collection period (20 days), and data pulled for turnaround time had to be filtered for meds-to-beds prescriptions.

Conclusion

After reviewing the impact of 85 prescription issues on filling time for 1,917 prescriptions, it was determined that about 4 issues occurred per day, taking up to 4 hours of the workday to resolve prescription related issues. This time could negatively impact the time to prescription ready status and delay time to discharge. Future considerations to help reduce time spent on prescription issues could be an implementation of a transitions-of-care pharmacist on the unit. This could enhance the discharge process by reducing the number of issues reaching the pharmacy and make the pharmacist accessible to the care team on the unit.

Disclosure and References

Authors have no conflicts of interest to disclose

