INTRODUCTION

- Schizophrenia affects about 3.2 million individuals in the United States and about 21 million individuals worldwide. Of which, 30% or ~ 6.3 million individuals diagnosed with Schizophrenia are treatment resistant.
- Clozapine, is the most effective antipsychotic for the management of treatment-resistant schizophrenia (TRS).
- However, only 10% of patients with TRS are receiving Clozapine. One of the contributing factors leadings to Clozapine's low prescription rate are it's adverse side effects.
- Clozapine Risk Evaluation and Mitigation Strategy (REMS), is a promising system to monitor the absolute neutrophil counts (ANC). Many evidence-based-practice guidelines have been recommended to prevent other side effects associated with Clozapine, such as, Clozapineinduced gastrointestinal hypo-motility (CIGH).
- However, no system has been implemented to monitor and prevent CIGH.
- CPOS improve compliance with these evidence based practice guidelines and may provide a promising system for systematic Clozapine use.

Objectives

In this study, we explore the effectiveness of Clozapine order sets using Electronic Medical Records (EMR) to:

- 1. Improve compliance to evidence-based practice guidelines.
- 2. Prevent adverse side effects of Clozapine (CIGH).

METHODS

A multistep approach was utilized:

- A Clozapine CPOS, which included ordering of ANC, stool softeners, and a high fiber diet was designed, created and implemented in RUMC's Meditech Software (Figure 2).
- Training was provided to prescribing physicians in the psychiatry department.
- We applied for and obtained an IRB waiver for the study.

Retrospective study:

- Clozapine EMR data from RUMC's psychiatric inpatient unit was analyzed over an 18month period (June 2017-December 2018.
- Compared "order set" vs. "no order set" groups of patients using logistic regression to determine the benefits of CPOS.
- CIGH was defined by the Constipation Assessment Scale (CAS) (Figure 1). Figure 1. Constipation Assessment Scale (CAS) used to define constipation

Assessment				
Constipation Assessment Scale				
Constipation Assessment Scale:	Abd. Distention/Bloating Change in amount of GAS Less Frequent BM Oozing Liquid Stool Rectal Fullness/Pressure Rectal Pain with BM Small Volume of Stool Unable to Pass Stool Straining Sense of difficulty in BM Incomplete Evacuation Hard Lumpy Stools Prolonged Time to Stool Need for manual Maneuvers	NO PROB = 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<u>SOME PROB = 1</u> 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<u>SEVERE PROB = 2</u> 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
*TOTAL SCORE: 🛛 🖾				

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Figure 2. Clozapine Order Set in Meditech Software

- New Orders (5)									
61	cloZAPine (CLOZARIL 25 MG PO bid	.)		3/14/19	1800	New		*	
62	62 Lactulose (Lactulose) 30 ML PO daily PRN CONSTIPATION			3/14/19	1645	New		*	
63	63 Docusate Sodium (Colace) 100 MG PO bedtime			3/14/19	2200	New		*	
64	REGULAR DIET (HOU	SE) (DIET)	R	3/15/19	В	New		*	
65	COMPLETE BLOOD C	OUNT (LAB) QWEEK	R	3/15/19	0600	New		*	
Orders Meds Sets Transfer Notifications Assoc Data Favorites Category Name Cont from Amb Oncology Search Search I Selected Items.									
+ Standard Order Sets				rumonary					
- Psychiatry			<u>+</u>	Surgery					
	ADULT PSYCHIATRIC ADMISSION								
CHILD PSYCHIATRIC ADMIT SET									
CLOZAPINE INITIATION									

RESULIS

- A total of 112 records were retrieved
- Twenty-three did not meet study criteria and were removed.
 - Criteria for data analysis:
 - Patients in the inpatient psychiatry unit
 - Patients that received >1 dose of Clozapine
- "No order set" group: n= 50, with a mean age of 44.4 years; (44% female and 56% male).
- "Order set" group: n=39, with a mean age of 41.2 years (61.5% female and 38.5% male).

Table 1: Demographics of patients in both pre and post interventional groups

	Pre-intervention group	Post-intervention group	Total
Mean Age	44.4	41.2	42.8
Female (%)	22 (44%)	24 (61.5%)	46 (51.7%)
Male	28 (56%)	15 (38.5%)	43 (48.3%)
n-value	50	39	89

• Clozapine CPOS are effective in:

- Ensuring compliance with safe prescribing guidelines [95% CI 0.098-0.526, p< .0001]
- Reducing adverse drug events by 35.41% [95% CI 0.104-0.599; p< .005].
- After Clozapine CPOS intervention, the compliance of ordering:
 - Stool softeners increased from 32% to 91% (p < .0001)
 - High fiber diet increased from 46% to 68% (p < .0001)
 - The percentage of ordering weekly ANCs at the time of the first Clozapine order increased from 18% to 100% (p < .001).

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CONCLUSION

- Clozapine CPOS improves compliance with safe prescribing guidelines and patient outcome.
- More awareness and education of CPOS availability and expansion on the use of Clozapine CPOS in other departments in RUMC should be encouraged.
- Further studies are required to explore effective implementation of medication order sets, in the context of a larger process of patient care practice standards.

Significance:

• Clozapine CPOS will benefit both patients and prescribers to aid in higher prescription rates and in lowering adverse effects.

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• This study has met the federal regulations 45 CFR 46.101 for exemption from IRB review.

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