IV to PO Conversion of Medications: Associated cost savings and reduced patient morbidity

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Study Title

IV to PO Conversion of Medications: Associated cost savings and reduced patient morbidity

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Introduction/Background

The high cost of medication incurred by the hospital substantially contributes to the total cost of inpatient care with inpatient hospital pharmacies estimated to account for between 7% and 10% of a hospitals' total operating cost.[1] According to the American Society of Health-System Pharmacists, the largest portion of any inpatient hospital's pharmacy budget reflects medication cost,[2] representing ~80% of the total pharmacy budget.[1]

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Past studies have shown that conversion from intravenous (IV) to oral (PO) medication when patients are clinically eligible may reduce the costs associated with IV administration.[3] When admitted to the hospital, many patients are initially started on IV medication because their clinical conditions may prohibit the use of PO medication (eg, "nothing-by-mouth" [NPO] status pre/post-surgery or during mechanical

ventilation). When a patient's condition improves and the patient can tolerate PO intake, medications can be transitioned from IV to PO forms.

Conversion from IV to PO may reduce the need for IV access, which carries a higher risk of hospital-acquired bloodstream infections, [4] phlebitis, cellulitis, and severe adverse events associated with infiltration[5] for the patient. Further hospitalization cost saving may be achieved through reduced medication dispensing and administration cost,[6, 7] reduced need for IV access, and reduced frequency of complication such as line infections.[8]

The Problem at Children's Medical Center

In 2019, patients at the Children's Medical Center received approximately 9,500 doses of IV Proton Pump Inhibitors (PPIs). Many of these IV doses were administered to patients, who were on a diet or received other medications by mouth and thus were eligible to receive PO medications. Using two broad assumptions (1. 40-80% of doses could have been safely changed from IV to PO and 2. In 20 to 60% of patients, providers would be compliant with decision support alerts) we calculated an annual potential savings for IV PPIs between $24,000 and $140,000 for these patients (Table 1).

Further, the Children's Medical Center Dallas is one of the leading users of IV acetaminophen in the nation with almost 30,000 doses in 2019. Even if pharmacy splits every IV vial (100mg/100 ml) into four doses on average, we estimate that decision support for switching from IV to PO dosing could generate savings between $33,000 and $200,000 annually (Table 1).

Study Objectives

We seek to create savings by accelerating and increasing the switching of IV medications to PO in eligible patients at the Children's Medical Center by creating alerts to providers that a patient on IV Esomeprazole or IV Acetaminophen, who is receiving a diet or other PO medications, is eligible for PO substitutes. We plan to study the effect of decision support designed to bring about a change from IV to PO dosing in

eligible patients. Providers will receive alerts that preferable will include a link to an order that allows the provider to delete the old order and order the new medication in one action.

Study Design, length of study

All providers with the ability to order medications (physicians, residents, fellows, nurse practitioners, physician assistants) will be targeted by our Clinical Decision Support (CDS) tool. Patients will be randomized using their medical record number (MRN) (odd or even). When a provider opens the chart of an eligible patient with an active order for IV Esomeprazole or IV Acetaminophen for the first time in 24 hours and the patient is either on a diet or is receiving other medications PO, the provider will see an alert: "This patient appears to be eligible for PO medications. If you would you like to switch <IV Esomeprazole or IV Acetaminophen> to a PO dose, please click here." (Figure 1) Alerts will NOT be presented again to the same provider for 24 hours.

We plan to collect baseline data for the 12 months prior to the study retrospectively. Once implemented, the CDS alerts will be active for six months and data collection will occur prospectively. After three months, we plan to conduct a preliminary analysis of results. If the preliminary results show a significant positive (cost savings) effect, we will stop the study early and apply the CDS to all patients.

Study Enrollment, Inclusion/Exclusion Criteria, Identification of Subjects
Study Procedures

All patients at Children's Medical Center will be eligible for our study. For acetaminophen, we will exclude patients in the Newborn Intensive Care Unit (NICU) as only IV acetaminophen is used for the treatment of Patent Ductus Arteriosus. There will be no other exclusion criteria.

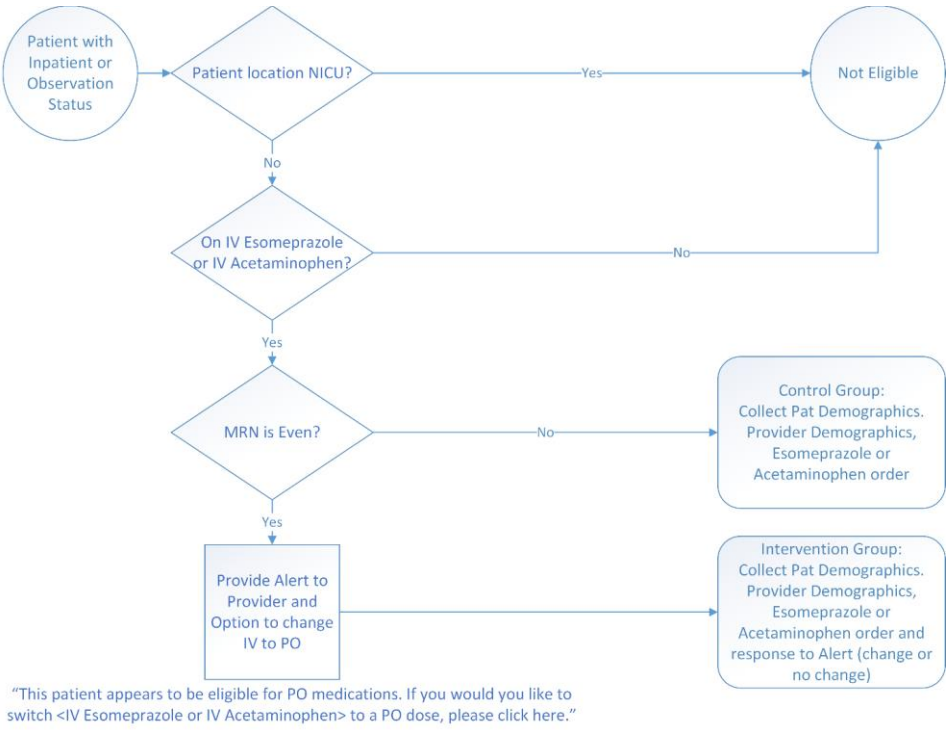

Figure 1: Algorithm to select and randomize patients

In the initial phase, we will collect the following data prior to launching any intervention: Demographics of all patients, who received an order for IV Esomeprazole and IV Acetaminophen in the last year in the Children's Medical Center including the medication, number of administered doses, DOB, Age, Gender, Race, Ethnicity, Insurance status, Zip code, and primary diagnoses. We will also determine the number of IV days (any part of a day where the patient had an IV or central line in place. We will collect the same data for the intervention period.

The intervention consists of two BPAs. Both BPAs will fire when providers enter the record of a patient who has an active order for IV Esomeprazole or IV Acetaminophen and is eligible for PO medications as

determined by an existing diet or active PO medication orders. The intervention BPA will fire on the patients randomized by MRN to the intervention group and the control BPA on patients that are in the control group. The intervention BPA records that it fired and logs the event including the patient and provider demographics. It will also display a recommendation that to switch the patient form IV Esomeprazole and IV Acetaminophen to PO doses. With a single click, the provider can switch to an ordering screen where the PO medication equivalent can be ordered and the existing IV medication order can be discontinued. The BPA records if the provider followed the recommendation. The control BPA is silent to the user and records only that it fired and the patient and provider demographics.

Data Captured

Our analysis will compare pre-study data to data from both groups during the intervention period. Comparing pre-study data to the intervention group will allow the determination of the effect of the intervention. Comparing intervention group to the control group will allow us to see if there is a difference in provider behavior without a prompt (potentially a contamination of providers from being alerted to the IV to PO switch on half of the other patients).

Primary outcome will be the ratio and number of IV PPI and Acetaminophen doses received. Secondary outcomes will be costs of Esomeprazole and Acetaminophen per patient (PO and IV doses), cost savings per alert fired, length of stay, and the number of IV days.

We will collect data for all patients on IV Esomeprazole and Acetaminophen in the control period retrospectively and prospectively during the intervention period for the control and intervention groups. Data will include demographics of all patients, who received an order for IV Esomeprazole and IV Acetaminophen in the Children's Medical Center, the medication, number of administered doses, Age, Gender, Race, Ethnicity, Insurance status, Zip code, length of stay and primary diagnoses. We will also

determine the number of IV days (any part of a day where the patient had an IV or central line in place. In the invention group, we will also record if the alert resulted in a change from IV to PO.

Statistical Considerations

We will use descriptive statistics to describe difference in the groups. To analyze the effect on the ratio of IV and Po doses we will use a two-sample t test.

Data Collection and Management

We will collect data for all patients on IV Esomeprazole and Acetaminophen in the control period retrospectively and prospectively during the intervention period for the control and intervention groups. Data will include demographics of all patients, who received an order for IV Esomeprazole and IV Acetaminophen in the Children's Medical Center, the medication, number of administered doses, Age, Gender, Race, Ethnicity, Insurance status, Zip code, length of stay and primary diagnoses. We will also determine the number of IV days (any part of a day where the patient had an IV or central line in place. In the invention group, we will also record if the alert resulted in a change from IV to PO.

Confidentiality

Data will be transmitted and stored encrypted and will require a password for access. Access will be limited to study personnel. All results will be reported in a de-identified manner. Any collection, cleaning, and management of subject data will be performed in compliance with regulatory standards.

Risk for privacy violations will be minimal.

Safety, risk assessment, benefit to the patient

We believe this study to be safe to patients and provide substantial benefits. Conversion from IV to PO may reduce the need for IV access, which carries a higher risk of hospital-acquired bloodstream infections,

phlebitis, cellulitis, and severe adverse events associated with infiltration for the patient. Further hospitalization cost saving may be achieved through reduced medication dispensing and administration cost, reduced need for IV access, and reduced frequency of complication such as line infections.

Risks from conversion to PO medications are minimal. No conversion is performed unless ordered by a provider adding a safe guard. Effectiveness of PO Esomeprazole and Acetaminophen has been established in the past.

Informed Consent

We are seeking a waiver from obtaining consent as no modifications in care are implemented automatically. All medication changes will be performed by a provider and this study will only provide reminders to providers that patients are eligible for PO medications resulting in minimal risk for harm.

We circulated this proposal to the leadership at Children's Medical Center Dallas for approval and received permission to proceed to the IRB application stage.

PPI Inhibitors and Acetaminophen used at Children's Medical Center

Table 1: PPI Inhibitors and Acetaminophen used at Children's Medical Center

Medication		80% Doses Eligible			60% Doses Eligible			40% Doses Eligible		
		60% compliance	**40% compliance**	**20% compliance**	**60% compliance**	**40% compliance**	**20% compliance**	**60% compliance**	**40% compliance**	**20% compliance**
Pantoprazole		$18	$12	$6	$14	$9	$5	$9	$6	$3
Ibuprofen		$17,798	$11,865	$5,933	$13,348	$8,899	$4,449	$8,899	$5,933	$2,966
Esomeprazole		$143,567	$95,712	$47,856	$107,676	$71,784	$35,892	$71,784	$47,856	$23,928
Acetaminophen		$798,536	$532,358	$266,179	$598,902	$399,268	$199,634	$399,268	$266,179	$133,089
Acetaminophen	4 doses	$199,634	$133,089	$66,545	$149,726	$99,817	$49,909	$99,817	$66,545	$33,272

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