



Value of pharmacy services upon admission to an orthopedic surgery unit

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Main Information

Primary registry identifying number

LBCTR2020124680

Protocol number

LAU.SOP.ER2. 30/Sep/2019.

MOH registration number

Study registered at the country of origin

Yes

Study registered at the country of origin: Specify

Type of registration

Retrospective

Type of registration: Justify

not aware of existence of the registry since it is a new registry.

Date of registration in national regulatory agency

05/12/2020

Primary sponsor

Lebanese American University

Primary sponsor: Country of origin

Lebanon

Date of registration in primary registry

09/12/2020

Date of registration in national regulatory agency

05/12/2020

Public title

Value of pharmacy services upon admission to an orthopedic surgery unit

Acronym

N/A

Scientific title

Value of pharmacy services upon admission to an orthopedic surgery unit

Acronym

N/A

Brief summary of the study: English

This was a prospective single-arm study conducted in a tertiary care teaching hospital in Lebanon between October 2019 and April 2020. The study aimed to assess the impact of pharmacist-conducted medication reconciliation performed within 48 hours of hospital admission to the orthopedic surgical department. Participants were adult inpatients hospitalized for orthopedic surgeries with ≥ 1 outpatient medications. Properly trained pharmacy resident obtained the Best Possible Medication History (BPMH) and led on the reconciliation process. The primary endpoint was the number of reconciliation errors (REs) identified. Descriptive statistics were used to report participants' responses and relevant findings. Linear regression was performed with the number of REs as a continuous dependent variable using Backward method. Results were assumed to be significant when p was < 0.05 .

Brief summary of the study: Arabic





إن الممارسة الحالية في المركز الطبي للجامعة اللبنانية الأمريكية - مستشفى رزق تتمثل في أن يسأل الفريق الطبي المريض و / أو العائلة عن التاريخ الطبي السابق والأدوية الحالية من أجل ضمان باستكمال مناسب للأدوية الحالية التي كانت تأخذها في المنزل أثناء إقامتك في المستشفى وتحسين استخدام الأدوية التي تأخذها في المستشفى. يتم تدريب جميع مقدمي الخدمات الصحية بما في ذلك الممرضات والأطباء والصيادلة على أخذ تاريخ الدواء. من خلال هذا البحث، نود تقييم تأثير التوفيق الدوائي التي يقودها الصيدلي على المرضى البالغين الذين تم إدخالهم إلى المستشفى لعمل جراحي في قسم الجراحة العظمية مقارنة بالمعلومات عن التاريخ المرضي التي يأخذها أعضاء آخرون في الفريق الطبي غير ساعة من دخول المريض ، يقوم الدكتور الصيدلي المقيم بإجراء مقابلات مع المرضى و / أو أفراد الأسرة من أجل الحصول على 48الصيدلي. بعد على تاريخ كامل حول تاريخ المرضى والأدوية الحالية التي يأخذها المريض في المنزل قبل القبول للمستشفى. وهذا يشمل أسئلة حول الحالات الطبية ، والحساسية الدوائية ، والأدوية التي تؤخذ في المنزل التي يحددها الطبيب ، والأدوية في المنزل التي تم شراؤها من الصيدلية دون وصفات طبية وأي أدوية تحتوي على أعشاب طبية أو مكملات غذائية. يسأل الدكتور الصيدلي المقيم أيضًا عن وقت آخر جرعة دواء تم تناولها من كل الأدوية التي يأخذها المريض. يُطلب من كل هذه الأسئلة التأكد من أن الفريق لديه سجل كامل من أجل توفير أفضل رعاية ممكنة في المستشفى.

Health conditions/problem studied: Specify

Orthopedic surgery patients including elective and emergency surgeries.

Interventions: Specify

A post-graduate year 1 pharmacy resident interviewed the eligible patients after obtaining their written informed consent to participate in the study. While interviewing patients for medication history, the pharmacy resident inquired about all prescription and over the counter medications. The pharmacy resident asked both open-ended and closed-ended questions to trigger the patient to remember medications that they may have forgotten to mention such as creams, ointments, inhalers, eye drops, ear drops, vitamins, and herbal or dietary supplements. To ensure complete documentation of the BPMH, the resident also inquired about the level of compliance, the last dose taken, and potential recent changes to select medication regimens. In order to obtain the BPMH, the pharmacy resident relied on more than one information source such as interviewing the family/caregiver, inspecting the medication bottles, or reviewing the patient's previous health record available at the institution. The pharmacy resident documented all the information on the "Medication Reconciliation Data Collection Form" that was developed to guide the BPMH process and record the reconciliation findings. This form included general demographic data, surgery type, total number of home medications and their indications, history of drug allergies, and results of the critical analysis of discrepancies. The different sections of this data collection form and the patient interview tips were adapted from the Medications at Transitions and Clinical Handoffs (MATCH) Toolkit for Medication Reconciliation. 12 Afterwards, the pharmacy resident compared the obtained history from the patient to the medications ordered by the physician for the patient's current admission. When deemed necessary, the pharmacy resident intervened in the management of the patient's medication regimens during the reconciliation process by contacting the physician and clarifying any changes that need to be implemented to the current medication regimens.

Key inclusion and exclusion criteria: Inclusion criteria

Included patients were ≥ 18 years old, admitted for at least 48 hours to the Orthopedic Surgery Department for elective or emergency surgeries, and currently taking at least one regular prescription medication.

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

95

Key inclusion and exclusion criteria: Exclusion criteria

Patients were excluded if they were admitted for less than 2 days or were unable to communicate in English or Arabic.

Type of study

Interventional

Type of intervention

Quality improvement

Type of intervention: Specify type

N/A

Trial scope

Safety

Trial scope: Specify scope

N/A

Study design: Allocation

Single Arm Study

Study design: Masking

N/A

Study design: Control

N/A

Study phase

N/A

Study design: Purpose

Health services research

Study design: Specify purpose

N/A

Study design: Assignment

Study design: Specify assignment



Single

N/A

IMP has market authorization

IMP has market authorization: Specify

Name of IMP

Year of authorization

Month of authorization

Type of IMP

Pharmaceutical class

All

Therapeutic indication

Orthopedic surgery patients (elective and emergency surgeries)

Therapeutic benefit

The primary outcome consisted of the number of REs, defined as any unjustified or unintended discrepancy between the patient's medications prior to admission/surgery, and the inpatient medication list, 24-48 hours after admission.

Secondary outcomes included the number of pharmacy resident's interventions performed to resolve discrepancies.

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

None retained

Biospecimen description

N/A

Target sample size

100

Actual enrollment target size

100

Date of first enrollment: Type

Date of first enrollment: Date





Actual	01/10/2019
Date of study closure: Type	Date of study closure: Date
Actual	30/04/2020
Recruitment status	Recruitment status: Specify
Complete	
Date of completion	
30/04/2020	
IPD sharing statement plan	IPD sharing statement description
No	N/A
Additional data URL	
Admin comments	
Trial status	
Approved	

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
NA	NA

Sources of Monetary or Material Support

Name
NA

Secondary Sponsors

Name
NA



Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Elsy Ramia	LAU-Byblos	Lebanon	03-167962	elsy.ramia@lau.edu.lb	LAU SOP
Scientific	Elsy Ramia	LAU-Byblos	Lebanon	03-167962	elsy.ramia@lau.edu.lb	LAU SOP

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
LAUMCRH	Elsy Ramia, PharmD, MPH, BCPS	Clinical Assistant Professor	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Lebanese American University- University Medical Center Rizk Hospital	30/09/2019	Christine Chalhoub	christine.chalhoub@lau.edu.lb	03212327

Countries of Recruitment

Name
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
Orthopedic surgery	Orthopaedic follow-up care, unspecified (Z47.9)	Orthopedic surgery



Interventions		
Intervention	Description	Keyword
Medication reconciliation	<p>A post-graduate year 1 pharmacy resident interviewed the eligible patients after obtaining their written informed consent to participate in the study. While interviewing patients for medication history, the pharmacy resident inquired about all prescription and over the counter medications. The pharmacy resident asked both open-ended and closed-ended questions to trigger the patient to remember medications that they may have forgotten to mention such as creams, ointments, inhalers, eye drops, ear drops, vitamins, and herbal or dietary supplements. To ensure complete documentation of the BPMH, the resident also inquired about the level of compliance, the last dose taken, and potential recent changes to select medication regimens. In order to obtain the BPMH, the pharmacy resident relied on more than one information source such as interviewing the family/caregiver, inspecting the medication bottles, or reviewing the patient's previous health record available at the institution. The pharmacy resident documented all the information on the "Medication Reconciliation Data Collection Form" that was developed to guide the BPMH process and record the reconciliation findings. This form included general demographic data, surgery type, total number of home medications and their indications, history of drug allergies, and results of the critical analysis of discrepancies. The different sections of this data collection form and the patient interview tips were adapted from the Medications at Transitions and Clinical Handoffs (MATCH) Toolkit for Medication Reconciliation. Afterwards, the pharmacy resident compared the obtained history from the patient to the medications ordered by the physician for the patient's current admission. When deemed necessary, the pharmacy resident intervened in the management of the patient's medication regimens during the reconciliation process by contacting the physician and clarifying any changes that need to be implemented to the current medication regimens.</p>	Medication reconciliation, patient safety, quality improvement, orthopedic surgery

Primary Outcomes		
Name	Time Points	Measure
Number of Reconciliation Errors (REs)	within 48 hours of admission	any unjustified or unintended discrepancy between the patient's medications prior to admission/surgery, and the inpatient medication list, 24-48 hours after admission.

Key Secondary Outcomes		
Name	Time Points	Measure
Number of pharmacy resident's interventions	within 48hours of admission	interventions performed to resolve unintended discrepancies identified.



Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files