

## Role of the Clinical Pharmacist in Reducing Preventable Adverse Drug Events<sup>#</sup>

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### Abstract

According to so many previous studies, lack of sufficient information during prescribing steps may lead to medication errors. Thus, the presence of the clinical pharmacist during routine rounding process in the ward with intervention of patient care plan may reduce the probability of adverse drug events (ADEs). This study evaluate role of the clinical pharmacists, as a member of medical team with the physician, on ADEs and report their interventions in the internal medicine unit. This study was designed to compare between two groups of patients, those receiving care from a rounding team (physician, nurse, and clinical pharmacist) (study or intervention group with 51 patient); and those receiving care from a rounding team (physician and nurse, but without any pharmacist) (control group with 49 patient). The primary outcome measure was preventable ADEs and secondary one involves the time of staying in the hospital and onset of response to therapy. Patients were randomly selected, followed a single-blind design, and evaluated by a senior physicians and clinical pharmacists who document their medical interventions. Specialist physicians accepted (60) of (77) recommendations (i.e. do modifications in drug therapy depending on clinical pharmacist interventions). The most common intervention was recommending dosage or frequency of medication (32.4%), followed by addition of medication (19.5%). The rate of preventable ordering ADEs in the study unit was 77% lower than in the control unit ( $P < 0.05$ ). There was no significant difference ( $p > 0.05$ ) in the cost of drug therapy between patient groups. Patients with ADEs in the control group had an average of 1.5 day longer staying period at the hospital; which was not differ significantly ( $p > 0.05$ ) from the study group. In summary, presence of clinical pharmacist during tour as a full member of the patient care team in internal medicine ward was associated with a substantially lowered rate of ADEs which caused by prescribing errors. Types of errors indicate the need for activation of the clinical pharmacist's interventions.

**Key words:** adverse drug events (ADEs), clinical pharmacist.

### الخلاصة

وفقا لدراسات سابقة فان افتقار المعلومات الدوائية اثناء عملية الوصف الدوائي يسبب الوقوع في اخطاء طبية, لذلك فان تواجد الصيدلاني السريري اثناء الجولة المعتادة للفريق الطبي قد يساهم في التقليل من احتمالية وقوع مثل هذه الاخطاء والمتمثلة بالتأثيرات الجانبية للدواء. كان الهدف من هذه الدراسة تقييم دور الصيدلاني السريري في مساعدة الفريق الطبي للتقليل من التأثيرات الدوائية الممكن تجنبها وتسجيل هذه التداخلات الصيدلانية في ردهات الباطنية. صممت هذه الدراسة لمقارنة دور الصيدلاني السريري في التأثير على علاج مرضى ردهات الباطنية (مجموعة التداخل, ٥١ مريض) مع اولئك الذين لم يكن للصيدلاني السريري دور في تغيير ادويتهم الموصوفة من قبل الطبيب (مجموعة السيطرة, ٤٩ مريض). كان المعيار الاساسي في هذه الدراسة هو معدل حصول التأثيرات الدوائية والممكن تجنبها, اما المعيار الثانوي فكان الفترة الزمنية لمكوث المريض في الردهة ومدى الاستجابة للعلاج الموصوف. تم اختيار المرضى عشوائيا وقيمت حالتهم المرضية من قبل اطباء باطنية اختصاص وتم تسجيل التداخلات الدوائية التي اوصى بها الصيادلة السريريون. بينت النتائج انخفاض في احتمالية حصول التأثيرات الدوائية الممكن تجنبها بنسبة ٧٧٪ وتم تسجيل (٧٧) تداخل صيدلاني قبل منها (٦٠) من قبل الفريق الطبي وكان اكثر هذه التداخلات مرتبط بتغيير الجرعة الدوائية (٣٢,٤ ٪) وازدادة ادوية لم تكن موصوفة مسبقا (١٩,٥ ٪). لم يكن هنالك فرق معنوي في الكلفة العلاجية بين الردهتين, اما الفترة الزمنية لمكوث مرضى مجموعة السيطرة في ردهة الباطنية فكانت اطول وبمعدل يوم ونصف. في ضوء هذه النتائج يمكننا تأكيد الدور الفاعل للصيدلاني السريري في مساعدة الكادر الطبي لاتخاذ القرارات المتعلقة بالادوية الموصوفة والتقليل من مضاعفاتها المستقبلية واضرارها الجانبية.

### Introduction

A medication error is a preventable event that can cause inappropriate use of a product and/or harm to a patient. Medication errors can happen in hospitals, in pharmacies, and at home <sup>(1)</sup>. Failure to obtain sufficient information about the patient or pharmaceutical agents has contributed to medication errors. We can help prevent medication errors by being a well-informed and active partner in patient health care. While

most errors are harmless or are intercepted, some result in adverse drug events (ADEs) <sup>(2)</sup>. Incident rates of medication errors vary widely, the reason for which can be explained by the different study methods and definitions used. The rate of medication errors varies between 2 to 14% for patients admitted to US hospitals, and the majorities are due to poor prescribing <sup>(3)</sup>.

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Medication error has been estimated to kill 7000 patients per annum and accounts for nearly 1 in 20 hospital admissions in the US. The incidence is likely to be similar in the UK. Medication errors (7% of all incidents) were the 2<sup>nd</sup> most common incident documented in the National Audit Commission report on patient safety <sup>(4)</sup>. Lazarou *et al* stated that fatal ADEs, which were defined as any preventable events that lead to inappropriate medication use related to the health care professionals or patients regardless of outcomes, were the sixth leading cause of death in USA in 1998, with 10.9% of all hospital patients experiencing some adverse drug reactions <sup>(5)</sup>. Adverse drug events are an important cause of morbidity and mortality, they are responsible for considerable number of hospital admissions and significantly increase health care costs. In the 20<sup>th</sup> century, great therapeutic advances were accompanied by a growing awareness of the problem of ADEs to medicines among health care professionals <sup>(6)</sup>. When processes are examined, a common root cause of medication errors occurs at the time when decisions about drug therapy are made. Thus, modifying rounding process by adding the expertise of a pharmacist is proposed as a system improvement to addresses the medical problems <sup>(7)</sup>. The presence of clinical pharmacist in the rounding team of ICU has been shown to reduce the incidence of ADEs by two thirds. However, patients admitted to non ICU, like internal ward, also have much comorbidity which requires careful pharmacologic managements <sup>(8)</sup>. Aim of this study was to evaluate the outcomes of the following questions: In the presence of clinical pharmacist, is there a significant reduction in ADEs? Which type of interventions the clinical pharmacist could give? As a secondary outcome measures, is there a significant reduction in the time of hospital staying and onset of response to drug therapy?

## Patients and Methods

This research was achieved at Baghdad Teaching Hospital-Internal Medicine Ward, from January to April 2010. Patients were randomly distributed into two groups: (1) Study or intervention group, which involve physician, nurse and clinical pharmacist, and include 51 patient (2) Control group, which involve physician and nurse, but without clinical pharmacist, and include 49 patient. Baseline and demographic characteristics in both groups were compared statistically (table-1). Most patients within each group have many concurrent disorders ( e.g. , hypertension, CHF, dyslipidaemia, diabetes mellitus,

thromboembolic disorders...etc.). Number of these disorders was calculated and expressed as mean  $\pm$  SD for these co-morbidities. Clinical pharmacists provided patient care services at the bedside. These services included rounding, documenting pharmacotherapy history, and providing discharge counseling which involves patient education and instructions for drug use, dose, time and course of administration, and identification of potential problems and side effects with continuing therapy after discharge. They identified medication-related problems through the review of medication orders, laboratory data and nursing flow sheets in the medical report every morning (retrospective methods), also by evaluating patient medications when they round with the physician (prospective method). Regarding control group patients, any pharmacist was absent in their ward, so patient education about drug therapy was also absent. Primary outcome measures after pharmacist interventions involve preventable ADEs, which were defined as undesired reaction or an injury caused by an error in the use of a medication that may have been prevented by appropriate drug selection or management <sup>(9)</sup>. An intervention documentation form was developed for the pharmacists, based on the interventions identified by Leape *et al* <sup>(8)</sup>. Intervention types and response by the rounding team were documented. The interventions identified by Leape *et al* were (1) clarification of drug order; (2) provision of drug information; (3) recommendation of alternative therapy; (4) identification of drug interaction; (5) identification of "systems error"; (6) identification of drug allergy; (7) approval of non formulary use of a drug; (8) provision of special-order drug; and (9) identification of ADE. We assessed the effect of pharmacist participation with 2 measures: (1) the change in the rate of preventable ADEs in the ordering stage, and (2) the number and acceptance of interventions recommended by the pharmacist. Using pre-established criteria <sup>(10)</sup>, the medical staff also made judgments of severity, preventability, and, if an error was present, the type of error and the stage in the process at which the error occurred. Specialist physicians in the internal medicine reviewed documents for those patients with ADEs identified by the clinical pharmacists to evaluate acceptable and non acceptable recommendations associated with the preventable ADEs. We compared the rate of preventable ADEs in the study unit with the rate of occurrence in the control unit. As a secondary outcome measures, length of stay and time to respond to therapy were both

evaluated. Depending on the drug information of clinical pharmacists, and consequently their role in reduction of medication errors, we expected a shorter period of stay and time to respond to therapy for patient care units that include clinical pharmacist in the rounding process. Study and control group variables were compared using analysis of variance (ANOVA) and chi-square ( $X^2$  analysis). Excel program of Microsoft Office 2007 was used and  $P$ -value less than 0.05 was considered significant.

## Results

One hundred patients were enrolled in this study. Control and study groups were not differ significantly in respect to age, weight, sex, and number of co-morbidities ( $P>0.05$ ), as shown in table (1). Role of clinical pharmacists in evaluating ADEs involved identifying medication-related problems through the review of medication orders, laboratory data and nursing flow sheets in the medical report. Seventy seven drug interventions were provided by the clinical pharmacists during rounding process for patients of the study group. The specialist physicians accepted 60 of these 77 recommendations (i.e. 77.9%) (table-2). These accepted recommendations involved different interventions like decreasing antihypertensive drugs dose, laboratory monitoring of anticoagulant agents, change NSAIDs to less GI disturbance analgesics, avoiding potassium level disturbance, and select the most appropriate drug within the same group. The most common intervention was recommending dosage or frequency of medication (32.4%), followed by addition of medication (19.5%). Pharmacists also made recommendations for drug therapy discharge that could reduce the potential for the problems after discharge. When the control and study group compared during this study, mean number of ADEs (an injuries caused by an error in the use of a medication) for control

group was  $13.0\pm0.2$  (assumed as 100%) and for study group was  $3.0\pm0.1$  (23% relative to control group), so the rate of preventable ordering ADEs in the study group was 77% lower than in the control group (100% - 23%,  $P<0.05$ ) (table-3). There was no significant difference ( $p>0.05$ ) in the therapy cost and number of medications between both groups at the end of this study. Percentage of money spend (cost of medications, IV admixtures, syringes and other medical appliances) was calculated depending on prices that supplied by ministry of health during time of patient staying in the hospital (table-3). In the present study, the way of reporting preventable ADEs depend on patient compliances during the continuous follow up, which were certified by objective methods (like measuring blood pressure, potassium level, INR, endoscopy to detect gastritis, and GSE to detect cause of diarrhea) and subjective methods (like chest palpation, bleeding signs, delirium, and stool frequency). Adverse events shown in table (4) were attributed to drug therapy (not to disease itself, diet type, or any other cause) depending on an official drug guidelines and differential diagnosis achieved by physicians. Table (4) clarified how the preventable ADEs could be avoided with the inclusion of a clinical pharmacist on the rounding team and supports the idea that pharmacists working in a central dispensing area or those available on need to answer questions are less able to assist the physician with prescribing information. When comparing the study and control group with respect to the secondary outcome measures, the control group had an average of 1.5 day longer stay and longer time for resolution of the condition. These figures were not significantly differ from the study group ( $p>0.05$ ). However, the rate of readmission after one month of discharge was 37% less for the study group and shown to be significant statistically ( $p<0.05$ ).

**Table 1 : Demographic data for patient groups.**

Characteristic	Study group (n=51)	Control group (n=49)	P-value
<i>Expressed as mean <math>\pm</math> SD</i>			
Age (year)	54.3 $\pm$ 11.4	57.5 $\pm$ 12.3	>0.05
Weight (kg)	65.2 $\pm$ 9.1	63.7 $\pm$ 10.2	>0.05
Co-morbidities No.	5.3 $\pm$ 1.5	5.7 $\pm$ 1.2	>0.05
<i>Expressed as No. (%)</i>			
Male	15(29.4%)	16(32.6%)	>0.05
Female	36(70.6%)	33(67.4%)	>0.05

**Table 2: Numbers and percentages of total and acceptable interventions achieved by clinical pharmacists within study group.**

Interventions	No. (%) of total interventions	No. (%) of accepted interventions
Dosage or frequency	25 (32.4)	19 (32)
Addition of drug to therapy	15 (19.5)	12 (20)
Therapy problem after discharge	6 (7.8)	5 (8.3)
Deletion of drug from therapy	5 (6.5)	3 (5)
Laboratory monitoring	4 (5.2)	4 (6.6)
Therapeutic alternative	4 (5.2)	3 (5)
IV to oral conversion	4 (5.2)	4 (6.6)
Identification of adverse reaction	4 (5.2)	2 (3.3)
Use of restricted drug	3 (3.9)	3 (5)
Clarification of order	3 (3.9)	2 (3.3)
Drug interaction	2 (2.6)	2 (3.3)
Preferred agent	2 (2.6)	1 (1.6)
Total	77 (100)	60 (100)

#values out of brackets represent no. of total and acceptable interventions

#values inside brackets represent % of total and acceptable interventions

**Table 3 : Variables within patient groups.**

Variable	Study gr.	Control gr.	p-value
No. of ADEs (mean±SD)	3.0±0.1	13.0±0.2	<0.05
No. of medications (mean±SD)	8.85±1.34	7.59±1.26	>0.05
% of money spend (Iraqi Dinar) (mean±SD)	109.000±3.2	124.000±2.7	>0.05

**Table 4 : Description of preventable adverse drug events (ADEs) within study group.**

Medication	Preventable ADEs	Recommendation
Atenolol	bradycardia	Dosage reduction
Labetolol	hypotension	Discontinue
Co-administration of many antihypertensive	hypotension	Discontinue some of antihypertensive drugs
Lisinop+kcl+fruside	hyperkalemia	Discontinue kcl
Warfarin	bleeding	Monitor INR daily
Narcotics	delirium	Use benzodiazepines
NSAIDs (Cox <sub>1</sub> inhibitors)	gastritis	Use paracetamol Use Cox <sub>2</sub> inhibitors
Pencillins high dose	diarrhea	Dosage reduction

## Discussion

The principle cause of medication errors is insufficient information when the prescribing decisions are made, and the later are often made during the rounding process<sup>(11)</sup>. Clinical pharmacists expert in pharmacotherapy and can assist physicians in making prescribing decision. The rounding process involves complement of information to diagnose the medical problem and to develop a treatment plan. This is the step in the patient care process in which the pharmacist may contribute to improving the quality of patient care<sup>(12)</sup>. In previous studies , nearly half of

preventable ADEs resulted from errors in the prescribing process. Prescribing errors frequently have a cascade effect, causing errors downstream in dispensing or administration. The major cause of prescribing errors was physician's lack of essential drug and patient information at the time of ordering<sup>(13)</sup>. One method of providing such information is computerized physician order entry, which has been shown to reduce the rate of serious medication errors by more than half. Evans *et al* have demonstrated that a computer assisted management program for antibiotics can

substantially reduce excessive use and misuse of antibiotics as well as reduce length of hospital stay and costs <sup>(14)</sup>. However, most hospitals do not yet have computerized ordering by physicians, so incorporation of the pharmacist into the patient care team is a more feasible alternative at present, especially in units with high medication use. Typical medical centers and hospitals state that clinical pharmacist, and not any pharmacist, should be included during the rounding process as one strategy to improve medication safety. Thus, the clinical pharmacist would be able to recommend medication and monitoring parameters for the patient. While participating in rounds as a member of the patient care team, the clinical pharmacist reduced ADEs both by preventing errors and by intercepting them <sup>(15)</sup>. Clinical pharmacist prevented errors by providing information about doses, interactions, indications, and drug alternatives to physicians at the time of ordering. He intercepted errors by immediately reviewing all orders and correcting deficiencies before the orders were transmitted to the pharmacy. In addition, the clinical pharmacist prevented nursing medication errors by providing ready consultation to the nursing staff and teaching drug safety <sup>(16)</sup>. In certain interventional study, clinical pharmacists monitored 861 patients' medical records and detected, reported and prevented medication errors in the infectious disease ward of a major referral teaching hospital in Tehran, Iran. During the study period, 112 medication errors (0.13 errors per patient) were detected by clinical pharmacists. Physicians, nurses and patients were responsible for 55 (49.1%), 54 (48.2%), and 3 (2.7%) of medication errors, respectively. Drug dosing, choice, use and interactions were the most frequent causes of error in medication processes, respectively. This study concluded that medication errors occur frequently in medical wards and clinical pharmacists' interventions can effectively prevent these errors <sup>(17)</sup>. Results of our study were consistent with these findings where the rate of ADEs was reduced by 77% in patients with study group (table 3). Leape *et al* research has identified that adding a pharmacist to the rounding team in the ICU reduce preventable ADEs by 72%. It may have been less clear in the ICU population if the drug caused a reduction or if the patient condition deteriorated, thus, contributing to the differences in measuring preventable ADEs <sup>(8)</sup>. However, the percentage of reduction in preventable ADEs with a clinical pharmacist on the rounding team in our study (77%) and Leape *et al* study (72%) was comparable. A

survey of 934 acute care hospitals found that 15% of them had pharmacist participating in the rounding process. Those hospitals that have this service had significantly less drug cost <sup>(18)</sup>. Certain study estimated the financial impact of the 66% reduction in ADEs. The cost of an ADEs has been estimated at \$2000 to \$2500 per event in 1993. However, the cost of a preventable ADE, one due to an error, was estimated at \$4685. At \$4685 each, the cost reduction in single unit would be approximately \$270 000 per year <sup>(19)</sup>. The present study shows that good saving of money, due to decline in drugs cost, can be achieved by reducing preventable ADEs through the effective role of the clinical pharmacist (table 3). We found that patients with control group had period of stay 1.5 day longer than those with study group. This was consistent with the findings published by Senet *et al*, who studied the effect of reducing ADEs on therapeutic cost and time of staying in the hospitals <sup>(20)</sup>. However, there are limitations to our study. First, the changes in the rate of preventable ADEs and drug therapy costs are limited practically over this short-term study (four months). Second, the study was limited to patients admitted to the internal medicine ward and the results can not be generalized to other specialty units, such as cardiology, nephrology, or infectious wards. So, further research is required to evaluate the impact of rounding pharmacists on preventable ADEs in the specialty units. Third, ADEs are more common in teaching hospitals than in community hospitals, so these findings are not generalizable to all types of hospitals. Fourth, pharmacist participation would be more difficult to arrange in units where multiple physicians make rounds at different times. Finally, the success of the pharmacist intervention depends on interpersonal relationships. Thus, the personality and cooperativeness of the pharmacist and the medical staff are critical factors in making this system work, especially at the beginning. The presence of the pharmacist on rounds was well accepted by physicians, as evidenced by the fact that 77.9 % (60 from 77) of the recommendations were accepted (table -2). While staff perceptions were not evaluated systematically in our experience, nurses also accepted this role easily, appreciating the reduction in extra work, such as telephoning physicians to have orders corrected. The pharmacist in this study had to overcome the traditional impression of the medical staff that pharmacists may be primarily concerned with costs. In summary, physician rounding team with a clinical pharmacist in the internal

medicine ward contributes to a significantly lower likelihood of preventable ADEs than a rounding team without a clinical pharmacist. The types of errors indicate the need for continuous education and implementation of clinical pharmacists' interventions.

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