

## Original Research Article

# Impact of pharmacist independent prescription on critical care: A prospective interventional study in Madinah, Saudi Arabia

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## Abstract

**Purpose:** To compare the impact of pharmacist independent prescribers (PIPs) with that of regular physician-based prescriptions in the Madinah Region, Saudi Arabia.

**Methods:** This prospective interventional study was conducted over 4 months and involved 40 critically ill patients in an adult medical intensive care unit (ICU) in a medium-sized non-teaching (private) hospital in the Kingdom of Saudi Arabia (KSA). Data from 20 patients based on typical physician prescriptions were compared with data from 20 patients under PIP prescriptions. The primary outcomes comprised the rate of medication errors (MEs), length of hospital stay (LOS), cost-effectiveness of prescriptions, and patients' status. The secondary outcomes were guideline adherence and mortality rates.

**Results:** There were significant PIP-mediated reductions in MEs. A total of 156 errors were identified: 23 by PIP (14 %) and 133 (86 %) by physicians. Moreover, PIP had 75 % guideline adherence when compared to physicians. The difference in cost-effectiveness was statistically significant in favor of PIP, resulting in a lower LOS of 7½ days compared to the physician group.

**Conclusion:** These results indicate that integrating PIP into a multidisciplinary team will enhance medication use, reduce the rate of MEs, improve cost-effectiveness, and enhance patients' outcomes. Further studies with larger sample size are needed to measure the effect of PIP on mortality rate.

**Keywords:** Pharmacist independent prescriber, Adult intensive care unit, Prescriber in ICUs, Critical care clinical pharmacist, Saudi Arabia

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## INTRODUCTION

The importance of the clinical pharmacist's prescription in improving safe and effective use of medicines is well established in the care of critically ill patients in the UK. Most critical care pharmacists in the UK Clinical Pharmacy are willing to become PIPs in the next three years [1]. However, the concept is new in developing countries, including the Arab world, where chronic diseases like diabetes, cardiovascular diseases, hypertension, and obesity are on the increase due to factors such as poverty, population growth, and public health challenges. Thus, there is need for action to transform pharmacy education and practice in the Arab world [2]. Independent clinical pharmacists in the Arab world who offer crucial support to ICU physicians are often preoccupied with patient care, thereby leaving limited time to follow guidelines or stay updated on therapeutic approaches. This lack of oversight poses challenges in managing medication updates amid critical case conditions [3]. Furthermore, clinical pharmacists in critical care units provide valuable services by assisting physicians to minimize MEs and improve medication safety systems.

Pharmacokinetic changes associated with critically ill patients and the associated impact on pharmacodynamics are crucial when patients in the ICU suffer from major pathophysiological changes, especially sepsis or septic shock, due to systemic inflammatory mediators that promote endothelial leak, extravascular fluid shifts, and hemodynamic instability. These changes in drug pharmacokinetics may cause treatment failure. For example, it has been reported that critically ill patients faced serious challenges due to pharmacokinetic changes when infusions of sedatives and analgesics were titrated to maintain optimal effective doses [4].

Medication errors (MEs) in Saudi hospitals are beginning to reach alarming levels. The number of these errors in Saudi Arabia exceeded 25,000 over five years [5]. The Saudi Central Board of Accreditation for Health Care Institutions (CBAHI) has indicated that these numbers are on the increase in Saudi Arabia. The ICU poses the highest ME risk due to various factors such as severely-sick patients, high-alert meds, age and comorbidities.

Several key issues driving policymakers indicate that pharmacists are key participants in the management of healthcare crises worldwide. These pharmacists may be CPs, PIPs or pharmacist supplementary prescribers (PSP),

although the extent of success may vary according to the pharmacist's role. The main differences between PIP and PSP were described by the General Pharmaceutical Council (GPhC) in 2022. The PIPs prescribe medications, e.g., analgesics, antibiotics, etc., for diagnosed or undiagnosed patients, while PSPs prescribe only for diagnosed patients with a specific clinical management plan added by the treating physician. The GPhC considers PIP more effective and attractive from the point of view of expanding the scope of clinical pharmacists within their clinical competence. The exceptions to this are prescriptions involving the three controlled drugs for the treatment of addiction (cocaine, dipipanone and diamorphine) and unlicensed cannabis-based medicinal products (CBMPs) [6]. In February 2020, Tsuyuki *et al* stated that the expansion of the pharmacists' role in patient care must be carried out in a manner that maximizes the benefits gained from the pharmacists and reflects their positive impact on health care services [7]. In 2019, Girvin highlighted the crucial role of PIPs in managing medical prescriptions. The PIPs refer patients to doctors for urgent situations like severe symptoms, uncontrolled diseases, or unexpected lab results in the hypertension clinic [8]. Rather than being limited to an advisory role, the PIPs serve the purpose of prescribing or un-prescribing medicines [9]. Moreover, the practice of PIP is an 'eye-opening experience' [9], especially in ICUs that use APACHE II score for determining severity of disease classification systems, SOFA & qSOFA scores, and feeding, analgesia, sedation, thromboprophylaxis, head of bed, stress ulcer prophylaxis, glucose control (FASTHUG) mnemonic. Other types of pharmacist independent prescribers are Community Pharmacist Independent Prescriber (CPIP) and Neonatal Intensive Care Unit (NICU) PIP.

Evidence-based medicine (EBM) is crucial, particularly in the ICU. However, globally, the lack of a 'gold standard' in ICUs contributes to varied practices, leading to increased risks, higher costs, and poorer patient outcomes. The standardization of medication practices in critical care is essential for reducing variation, mitigating risks, controlling expenses, and enhancing patient care through user-friendly guidelines tailored by PIP to local protocols [10]. Furthermore, the evidence labelled as Expert Opinion (EO) was indirect and occasionally very low-quality evidence, where the hierarchy of EBM showed that EO was the last choice in decision-making in medicines.

## METHODS

This study prospectively analyzed the impact of PIP on critically ill adult patients in cooperation with ICU physicians. Forty critically ill patients were admitted to the ICU over 4 months in a private 200-bed hospital that operates independently from governmental funding and is considered a non-teaching medium-sized hospital for inpatients. The pre-intervention group comprised 20 patients under conventional physician prescription and clinical pharmacist advisory role only, while the intervention group was made up of 20 patients under PIP prescription in cooperation with physicians. All the levels of illness were managed by PIP, except for cardiac arrest patients who had been exposed to cardiopulmonary resuscitation and were initially managed by conventional physicians, after which PIP managed and modified the prescriptions according to the prevailing situation of the illness.

### Inclusion criteria

Patients in the following categories were included in the study: adults aged > 18 years, medically and critically ill patients with acute or chronic illnesses, male and female patients, and patients with abnormal kidney or liver functions.

### Exclusion criteria

Pregnant women, cardiac arrest patients, critically ill surgical patients, and patients aged < 18 years were excluded.

When practising the advisory role only, the clinical pharmacists took time in the implementation of the interventions for critically ill patients so as to effectively correct any MEs. The aim was to shed light on how the expansion of the clinical pharmacist's scope of practice to PIPs will overcome the delay in implementing the pharmacists' interventions, thereby preventing errors from affecting the patients.

### Data collection and study phases

Patient data such as demographics (name, medical record number (MRN), age, and gender); diagnosis, co-morbidities, medical history, risk factors, allergies, vital signs, lab results, medications, fluids, electrolytes, and culture findings, were collected. During the pre-intervention phase, clinical pharmacists reviewed physician prescriptions for critically ill patients and offered recommendations during ICU rounds without direct prescribing authority. After two months in the intervention phase, the PIPs began managing prescriptions directly in collaboration

with physicians as part of a multidisciplinary team, thereby actively participating in treatment decisions for critically ill patients. On admission, PIPs in the intervention phase used FASTHUG-MAIDENS scores and APACHE II scores. When necessary, creatinine clearance was calculated using the Cockcroft-Gault equation, while hepatic function was calculated using the Child-Pugh score. Patients were followed up until discharge from the ICU.

### Analysis of the most common MEs in ICU

The most common MEs were observed in the ICU, where PIPs were able to prevent or decrease most of these errors through working within the MDT and expanding the scope of prescribing medications. The most common MEs found are presented.

**Table 1:** Common MEs in the ICU

| Common medication errors during ICU admission                                                                                   |
|---------------------------------------------------------------------------------------------------------------------------------|
| Antimicrobial misuse                                                                                                            |
| Dose adjustment in MOF (renal impairment or hepatic dysfunction, either using the creatinine clearance or the Child-Pugh Score) |
| Electrolyte replacement (sodium, potassium, magnesium, calcium, phosphorus)                                                     |
| Improper therapeutic doses (overdose or sub-therapeutic doses)                                                                  |
| Indication without drug                                                                                                         |
| Drug without indication                                                                                                         |
| Lack of monitoring                                                                                                              |
| Insulin dosing errors (IV or SC)                                                                                                |
| Intravenous fluids or acute diuretic therapy                                                                                    |
| Drug-disease interaction                                                                                                        |
| Vasoactive drugs (Noreadrenaline, Dobutamine...)                                                                                |
| Venous thromboembolism (VTE) prophylaxis/stress ulcer prophylaxis                                                               |
| Drug-drug interaction                                                                                                           |
| Prescribing errors                                                                                                              |
| Human Albumin misuse                                                                                                            |

In Table 1. In the pre-intervention phase, the clinical pharmacist examined any recommendations and monitored patients for improvement, deterioration, or newly diagnosed conditions, and wrote down any errors in the medicines prescribed by physicians. Then, the clinical pharmacists recommended changes in the therapeutic plan or doses during or after rounds. However, based on the physicians' point of view and expert opinion, these recommendations may or may not be implemented, may or may not be read, and may or may not be taken into account. In the intervention phase, and after collecting data, PIP personnel attended the rounds with other HCPs to monitor any improvements, deteriorations or newly diagnosed conditions in the cases. Then, after discussion with the MDT, PIP personnel

wrote prescriptions for all critically ill patients according to the latest guidelines and by applying EBM that matched the clinical management plan for each patient, while using clinical sense in cooperation with physicians. Finally, after a total of four months, the results in both groups were subjected to analysis.

Data on therapeutic plan costs were obtained from the database of the pharmacy department, while data on mortality rates were obtained from the database of ICU department.

## Statistics

Data analysis was performed using R version 3.6.1 (2019-07-05). All categorical variables were expressed as Count and percent; numerical data were expressed as median and IQR. Age, Cost, Hospitalization days and number of medication errors were described as median and IQR and compared the physician and PIP with Wilcoxon rank sum test. Gender and Intervention were described as Count and percent and compared by Pearson's Chi-squared test. Diagnosis, Origin, Adherence to standards and Hospitalization Status were described as Count and percent and compared by Fisher's Exact Test. The tests were done after the normality was tested with Shapiro-Wilk normality test, which showed that the data wasn't normally distributed. P-values < 0.05 were considered significant with 95 % confidence interval. Correlations were analyzed using Spearman's rank correlation.

## RESULTS

**Table 2:** Basic demographic data and diagnosis in the two groups of patients (total number of patients was 40 over the 4 months)

|             |                                                                    | Physician |      | PIP   |      | Total | Test                      | P-value |
|-------------|--------------------------------------------------------------------|-----------|------|-------|------|-------|---------------------------|---------|
|             |                                                                    | Count     | %    | Count | %    |       |                           |         |
| Diagnosis   | Acute ischemic stroke                                              | 2         | 5    | 6     | 15   | 8     | Fisher's exact test       | 0.6     |
|             | Decompensated heart Failure with reduced ejection fraction (HFrEF) | 2         | 5    | 2     | 5    | 4     |                           |         |
|             | Diabetic ketoacidosis (DKA)                                        | 5         | 12.5 | 2     | 5    | 7     |                           |         |
|             | Hepatic Encephalopathy                                             | 2         | 5    | 1     | 2.5  | 3     |                           |         |
|             | Pneumonia                                                          | 5         | 12.5 | 4     | 10   | 9     |                           |         |
|             | Septic shock                                                       | 4         | 10   | 5     | 12.5 | 9     |                           |         |
| Gender      | Female                                                             | 7         | 17.5 | 9     | 32.5 | 16    | Pearson's Chi-square test | 0.75    |
|             | Male                                                               | 13        | 32.5 | 11    | 27.5 | 24    |                           |         |
| Nationality | Bangladesh                                                         | 1         | 2.5  | 0     | 0    | 1     | Fisher's exact test       | 0.1995  |
|             | Egypt                                                              | 1         | 2.5  | 0     | 0    | 1     |                           |         |
|             | India                                                              | 0         | 0    | 2     | 5    | 2     |                           |         |
|             | Indonesia                                                          | 1         | 2.5  | 0     | 0    | 1     |                           |         |
|             | KSA                                                                | 12        | 30   | 11    | 27.5 | 23    |                           |         |
|             | Nigeria                                                            | 1         | 2.5  | 0     | 0    | 1     |                           |         |
|             | Pakistan                                                           | 3         | 7.5  | 4     | 10   | 7     |                           |         |
|             | Turkey                                                             | 1         | 2.5  | 0     | 0    | 1     |                           |         |
|             | Yemen                                                              | 0         | 0    | 3     | 7.5  | 3     |                           |         |

## Patients' demographic data in the two groups (pre- and post-intervention groups)

Descriptive statistics were used to analyze the data (frequency and percentages). Forty patients were admitted to the ICU and were recruited through convenience sampling over the 4-month period of study (60 % of the patients were male). The median age in the pre-intervention phase was 60 years (IQR = 16.5), while the median age in the intervention phase was 67 years (IQR = 20). The baseline demographics for the patients who received the medications prescribed by PIP and physicians during the study period are shown in Table 2.

Age, sex, nationality, and diagnosis were mostly similar in the two groups, and there were no significant differences between PIP and physician groups ( $p > 0.05$ ). Therefore, these parameters did not affect the comparison of clinical patients' outcomes between the two groups.

## Medication errors (MES)

Overall, there were 156 MEs in both groups. Physicians were responsible for 86 % of the errors (133/156), while PIPs were responsible for 14 % (23/156). The median numbers of MEs per patient in the physician and PIP groups were 7 (IQR = 3) and 1 (IQR = 1), respectively. There was a highly significant difference in MEs per patient between the two groups ( $p < 0.001$ ).

The most common documented MEs occurred in the physician group during electrolyte replacement.

## Cost-effectiveness

From February to June 2020, the median medication expense per ICU patient over the 4-month study period decreased from 20,224.89 to 2,545.04 SAR. The benefit, which represented the total savings from halting the prescription of inappropriate medications in the PIP group, was calculated by subtracting the two medians, resulting in a value of 17,679.85 SAR. The cost-benefit analysis showed a significant positive economic effect for the PIP ICU group: there were better patient outcomes and lower medication costs than in the physician group ( $p < 0.05$ ).

## ICU length of stay

Median LOS in the physician group was 20½ days (IQR = 46), while the median LOS in PIP group was 13 days (IQR = 22.75;  $p > 0.05$ ). Numerical regression analysis showed that the average LOS was 7½ days shorter for patients in the intervention group than for those in the pre-intervention group ( $p > 0.05$ ). Overall, there was no statistically significant difference in patient ICU LOS between the two groups.

## Patient hospitalization status

In this study, PIPs estimated patient clinical outcomes by measuring the consequences of treatment and disease using discrete indicators such as ME rates, cost effectiveness, and LOS, all of which were influenced by PIP contributions in the ICU. As a result, patient outcomes in the PIP group were improved by 37.5 % (10 % of patients were discharged, and conditions were improved in 27.5 % of patients), when compared with the physicians' group (2.5 % discharged and 12.5 % improved;  $p > 0.05$ ). It is clear that PIPs played an important role in improving patient outcomes. As mentioned earlier, there were no significant differences in age, sex, origin, and diagnosis between the two study groups ( $p > 0.05$ ). Consequently, any improvement or deterioration in patient outcomes in both groups was attributed to the quality of medication prescription.

## Relationship between HCP and adherence to ICU guidelines

A low level of adherence to gold standard international ICU guidelines and local hospital ICU guidelines was observed in this study during the pre-intervention phase. It was found that only 10 % of physician prescriptions adhered to the guidelines, while 75 % of PIP prescriptions were consistent with the guidelines ( $p < 0.001$ ). Furthermore, the adherence levels of the two

groups were analyzed through comparison of the procedures used *vis-à-vis* the guidelines: complete adherence to guidelines (physicians = 5 %; PIPs = 37.5 %), partial adherence to guidelines (physicians = 35 %; PIPs = 12.5 %), and non-adherence to guidelines (physicians = 10 %; PIPs = nil).

## Rate of acceptance of PIPS by physicians

Physicians' acceptance rate of expanding clinical pharmacists' role to PIP in the ICU as independent prescribers was calculated during the study. The results showed that there were 10 different physicians who were assigned to the ICU unit for two different duties, who collectively covered 24 hours of the day: 2 consultants, 4 senior doctors, and 4 junior doctors.

## DISCUSSION

This study evaluated the impact of PIPs on critically ill patients at a tertiary medium-sized, 200-bed hospital. A total of 40 patients participated in the study, with 20 subjects in each group (intervention PIP group and pre-intervention physician group). It was found that the PIPs reduced MEs, ICU costs, and LOS when compared to physicians, leading to improved patient outcomes. The acceptance rate of the proposed expansion in scope, that is, for clinical pharmacists to become independent prescribers in ICU, was 77 %. In a recent study, PIPs who were authorized to care for patients without needing permission achieved an 83.4 % acceptance rate for prescribing anti-microbial agents [11]. In previous studies, PIPs had roles in ME reduction. For example, in a comparison between doctor-issued prescriptions and PIP-issued prescriptions, McFadzeam *et al* demonstrated an 82 % error rate from physicians, when compared to a 17 % error rate from PIPs [12].

In the present study, the ME occurrence rate, which is the most important parameter that affects patient outcomes, was compared before and after implementing PIPs in the ICU, and a 72 % reduction was found when PIPs wrote prescriptions. The median numbers of errors per patient were 7 and 1 for the physician and PIP groups, respectively. In a study, 986 pharmaceutical interventions were reported due to DRPs, and about 50 % of these DRPs were due to MEs in prescriptions by physicians (42.6 %;  $n = 420$ ) [13]. Significant pharmacokinetics and pharmacodynamic changes occur in critically ill patients. The present study revealed high rates of non-adjusted doses, particularly among physicians (45 %), while none were seen among

PIPs. This was attributed to varying medicine distributions in obese burns patients, hypo-albuminemia patients, and patients with lung diseases, e.g., cystic fibrosis. These findings are in agreement with the findings in an earlier study by Jiang *et al*, who reported that 212 out of 233 dose adjustments (90.98 %) recommended by pharmacists for patients receiving continuous renal replacement therapy were accepted by physicians, resulting in saving of \$2,345.98 per patient [14]. In addition, dose adjustments are crucial due to the impact of unbound drug concentrations on distribution and clearance. This may cause therapeutic failure, particularly in critically ill patients with low albumin levels.

The measurement of cost cost-effectiveness of prescriptions is a cornerstone for policymakers and healthcare institutions. In the present study, the implementation of PIP services resulted in median-per-patient cost reductions of 17,679.8 SAR. Similarly, Kaiser and Schmid [15] reported that prescribing physicians increased drug cost per patient by 34 % due to over-prescription and prescription of more expensive medications [15]. Hale *et al* found that PIPs reduced hospitalization medicine costs for surgical and VTE prophylaxis patients [16]. Cost per patient was lower at \$31 when prescribed by doctors, and \$12 lower when prescribed by pharmacists. Therefore, recommending pharmacists for VTE prophylaxis prescription in high-risk surgical cases will be beneficial for decreasing VTE cases and healthcare costs [16].

A comparison of LOS between the physician and PIP groups revealed a decrease in median LOS value in the PIP group [13], relative to the physician group (20½). In addition, IQR was reduced from 46 in the physician group to 22.75 in the PIP group. On average, patients were discharged 7½ days earlier in the PIP group than in the physician group. Therefore, PIP interventions reduced LOS, although this value was not statistically significant, most likely due to the small sample size used.

Additionally, some researchers have reported a non-significant decrease in LOS with CP intervention in an acute unit. This finding is consistent with the results obtained in the present study, in which LOS for the CP group (342 min (95 % CI: 323–362)) was comparable to that of the control group (339 min (95 % CI: 322–357)) [17].

While the mortality rates of the pre-intervention and intervention phases were 15 and 5 %, respectively, the sample size was too small for an accurate estimation of a significant difference between the

two. However, it has been found that CPs working in the adult ICU within the MDT influenced patient mortality rates, improved patient outcomes, and reduced mortality rates [18].

### Limitations of the study

This study has some limitations. There were unclear regulations for PIPs in KSA and insufficient hospital pharmacists to serve as PIPs alongside other duties. Although prices were adjusted to a single year as recommended by financial experts in order to account for price changes, consideration was not given to clinical pharmacists and personnel time investments in the financial analysis when recording and implementing PIP roles and interventions. In addition, it was difficult to record administrative errors, as pharmacists systemically could not verify the administration of the prescribed drugs with the nurses. Furthermore, the validity of the findings may be influenced by the medium-sized hospital setting, the limited number of cases for specific diagnoses, and non-significant results. Therefore, future studies on PIPs in ICU should involve multi-center hospitals with bigger samples, with consideration for factors such as infection control and medication availability.

### CONCLUSION

The results obtained in this study indicate that expansion of the scope of clinical pharmacists from advisory role in MDT to include PIP function in adult ICUs in Saudi Arabia improved use of appropriate medicines and reduced MEs, thereby reducing adverse drug events and enhancing cost effectiveness. It also improved patient outcomes and reduced LOS in the ICU. It may be reasonably concluded that the results of this study have a promising potential to increase the acceptance rate of PIPs by physicians in ICU settings. However, the results need to be validated through large-scale multicenter studies.

### Recommendations

As this study is the first to be published in this area, it is recommended that Arab pharmaceutical societies should advocate expanded roles for clinical pharmacists without the requirement for permission. Regulations must stipulate criteria for autonomy of pharmacists in making prescriptions. Clinical pharmacists require enhanced diagnostic training. Moreover, ICU physicians need time for reading guideline updates so as to improve patient care. The implementation of these recommendations may enhance critical care in the Arab world.

## DECLARATIONS

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### Conflict of interest

No conflict of interest is associated with this work.

### Contribution of authors

We declare that this work was done by the authors named in this article, and all liabilities pertaining to claims relating to the content of this article will be borne by the authors.

### Registration

This study was not registered, as it did not involve the trial of a new drug. Moreover, the study was done under the supervision of the consultant in the ICU after obtaining ethical approval from the hospital and ethics committee.

### Ethical approval

Ethical approval was obtained from the hospital Research Ethics Committee (REC) in line with the guidelines of the National Committee of Bioethics (NCBE; reference no. PH-REC-2020-001).

### Availability of data and materials

The data that support the findings in this study are available from the corresponding author without undue reservation.

### Use of Artificial Intelligence/large language models:

The authors acknowledge the use of <https://contentdetector.ai/sentence-shortener> as shortening tool for the Abstract, Introduction and Discussion sections so as to match the journal guidelines in word count.

### Use of research reporting tool

The authors declare that no research reporting tool was used during the study.

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