Original Article

# Impact of guidelines implementation for the rational use of prophylactic antibiotics in elective cesarean sections at Elqutainah Teaching Hospital

**Sara M. Suliman[1], Bashir A. Yousef[2,3], Afrah A. Hamadelnil[4]**

*[1]Clinical Pharmacy Unit, Elqutainah Teaching Hospital, Quttainah, [2]Department of Pharmacology, Faculty of Pharmacy, University of Khartoum, Khartoum, [3]Department of Pharmacology, Faculty of Pharmacy, Sudan International University, Arkawait, Khartoum, [4]Department of Pharmacology, Faculty of Pharmacy, Omdurman Islamic University, Omdurman, Sudan*

## Abstract

**Background:** The clinical pharmacists have a sensible role in the implementation of guidelines by ensuring proper patient selection and medication use. This study aimed to implement a hospital guideline for the rational use of prophylactic antibiotics in elective cesarean sections (ECS) by establishing compliance with international guidelines regarding prophylactic antibiotic use in ECS at Elqutainah Teaching Hospital in White Nile State, Sudan, and define the area of medication cost-saving. **Methods:** A quasi-experimental design without control group was used from April to June 2018. 195 participants were included, 94 participants before and 101 participants after the intervention and data were collected using a designed checklist by the researchers. The intervention is based on withdrawal metronidazole dosage forms from prophylactic antibiotics for ECS according to international guidelines in antibiotics prophylaxis toward ECS. Finally, the data were compared between pre- and post-intervention. **Findings:** Before intervention; all participants had received intravenous cefuroxime and metronidazole infusions prior ECS and oral cefuroxime or amoxicillin-clavulanic acid, and metronidazole for 7 days upon discharge. While after the intervention, all participants didn't receive any metronidazole dosage forms before and after ECS also didn't receive amoxicillin-clavulanic acid. However, the dosage regimen of cefuroxime didn't change. This intervention was meaningful in minimizing overuse of antibiotics prophylaxis in the ECS, and reducing staff workload along with medication cost. **Conclusions:** Clinical pharmacist intervention was concisely changing the physicians' practice toward using updated guidelines of the rational use of prophylactic antibiotics for ECS.

**Keywords:** Clinical pharmacist, elective cesarean section, intervention program, prophylactic antibiotics

## Introduction

WHO statement that cesarean section (SC) rates have increased in both developed and developing countries is based on the available data.[1] The updated estimation of the trend in SC rates was increased globally, regionally, and nationally from 1990 to 2014, with specification in Africa 4.5%.[2] Two studies were conducted at Sudan, first at Khartoum hospital from October to December 2011, the rate of SC was 43.2%,[3] and the second in Kassala, Eastern Sudan: a community-based study (2014–2015), the rate of SC is 17.8%.[4] Elective CS (ECS) is considered as a clean type of surgical procedure. Meanwhile, antimicrobial prophylaxis is appropriate for elective cesarean delivery.[5]

CS is probably complicated by surgical site infections (SSI), endometritis, and urinary tract infection which increase morbidity and cost.[6] Endometritis has been reported in up to 24% of patients in ECS and up to approximately 60% of patients undergoing emergency SC.[7] Most SSI occurs after

**Address for correspondence:** Dr. Bashir A. Yousef, Department of Pharmacology, Faculty of Pharmacy, University of Khartoum, P.O. Box 1996, Postal Code - 11111 Khartoum, Sudan.
E-mail: bashiralsiddiq@gmail.com

**Received:** 16-10-2019 **Revised:** 03-12-2019
**Accepted:** 12-12-2019 **Published:** 28-01-2020

Access this article online

Quick Response Code:

Website: www.jfmpc.com

DOI: 10.4103/jfmpc.jfmpc_903_19



**How to cite this article:** Suliman SM, Yousef BA, Hamadelnil AA. Impact of guidelines implementation for the rational use of prophylactic antibiotics in elective cesarean sections at Elqutainah Teaching Hospital. J Family Med Prim Care 2020;9:162-7.

discharge from hospital where documentation and follow-up were absent, so according to American College of Obstetrics and Gynecologists (ACOG), all women must be in real contact with a maternal-care provider within 3 weeks minimally up to 12 weeks after birth, and this helps in SSI follow-up.[8] CS represents one of the most essential risk factors for the development of postpartum maternal infection.[6] The main second factors in the CS are presence of ruptured membrane, systemic illness, poor hygiene, obesity, and anemia may be considered.[7] Many international guidelines discuss the appropriateness of selection of prophylactic antibiotics for CS based on many factors including the narrow spectrum of activity, the timing of administration of dose and re-doses, route of administration, availability, and cost.[5-7,9-11]

National Institute for Health and Clinical Excellence (NICE) at 2016 reported that IV cefuroxime is the drug of choice, 750 mg starting dose as surgical prophylaxis in elective and emergency CS, and the second dose rarely indicated in patients with previous risk factors, so the third dose is not given until microbiological advice is considered.[11] Royal Australian and New Zealand College of Obstetricians and Gynecologists (RANZOG) claimed that; there is not any significant benefit of using multiple-dose regimens over the single-dose regimens as supported by ACOG and the American Society of Health-System Pharmacists (ASHP) for procedures lasting less than 2 h, while an additional intraoperative dose may be useful for the patient with excessive blood loss or for whom the duration of surgery is so long.[10] IV preoperative administration of prophylactic antibiotics for CS significantly reduces the incidence of infectious morbidity of maternal postpartum as compared with administration after cord clamp. There were no apparent differences in adverse neonatal outcomes reported.[11]

The collaboration between pharmacists and physicians is highly required to enhance clinical services, and patients care.[12] ASHP and American College of Practice of Clinical Pharmacy have clearly described the role of pharmacists in meeting the primary care needs of patients. One of the primary responsibilities to achieve this is to communicate to physicians towards patient care and to provide comprehensive medication stewardship that optimizes patient outcomes.[13,14]

ECS at Elqutainah Teaching Hospital is done by the physician's own practice that can lead to irrational use of prophylactic antibiotics either pre- and/or postoperatively. In order to assess the role of pharmacists in the physician primary care, this type of interventional study was carried to enhance and apply the rational use of prophylactic antibiotics. Thus, this study aimed to implement a hospital guideline for the rational use of prophylactic antibiotics in ECS and to assess the impact of clinical pharmacist intervention on both the antibiotic utilization while maintaining adherence to guidelines in CS and on medications' cost-saving.

# Methods

## Study design

A quasi-experimental design without control group (the one-group pretest-posttest design).

## Setting

This study was conducted at Elqutainah teaching hospital, White Nile State, Sudan.

## Participants and study size

Women undergoing CS at term from April to June 2018 at the department of obstetrics and gynecology of Elqutainah Teaching Hospital were recruited.

This study design was contained in three phases.

- Phase 1: all the CS' records ($n$ = 94) were collected by using a checklist, for 1 month prospectively from 25/4/2018 to 25/5/2018,
- Phase 2: (interventional phase) was started on 20/5/2018 by verbal contacts with all consultants and registrars separately about updated guidelines of prophylactic antibiotics in ECS. Brochures were given with the details about the prophylactic antibiotics in ECS.
- Phase 3: the CS' records ($n$ = 101) of post-interventional phase were similar to that of phase 1, from period 25/5/2018 to 25/6/2018,

Then, the delivered woman was followed up during the hospital stay on days 15 and 30 upon the clinic visit.

All consultants, specialists, and residents working in the department of obstetrics at Elqutainah hospital and the pregnant woman scheduled to deliver by CS in that attending period were included. Exclusion criteria included pregnant women who had received therapeutic antibiotics to treat bacterial infections before the intervention procedure. All infusions were prepared and administered by anesthesia staff prior to skin incision and by the nurses in the word.

## Variables

The selection of antibiotics, route of administration, dose and re-dose, and time of administration.

## Data sources/measurements

Up to date guidelines (ACOG, RCOG, NICE) in antibiotics prophylaxis toward ECS.

## Bias

No bias was detected due to the total coverage of participants.

## Statistical methods

Statistical Package for Social Sciences (SPSS) version 23 was used for data analysis. The difference between the costs of the two phases was determined using a paired $t$-test.

## Ethical approval

The ethical clearance (FPEC-06-2018) was obtained from the ethical committee of the Faculty of Pharmacy, University of Khartoum on February, 2018. Additional approval for checking the medical records was obtained from Elqutainah Teaching Hospital.

## Results

The study was conducted on 25/4/2018 to 25/6/2018, 1 month before and one month after the intervention. Two consultants and 16 registrars were incorporated in this educational intervention program.

The total participants of this study were 195 women divided into 94 and 101 participants before and after the intervention program, respectively. As demonstrated in Table 1, 20–29 years of age represent the majority of participants (53.3%) [Table 1].

Pre-intervention protocol [Table 2] was as follows: all participants received IV cefuroxime 750 mg before cord clamping and metronidazole infusions 500 mg at (69.1%) before skin incision and (30.9%) after skin incision in six consecutive doses for 48 h. The participants received oral cefuroxime 500 mg (85.1%) or amoxicillin-clavulanic acid 1,000 mg (14.9%) and oral metronidazole 500 mg (100%) for 168 h.

After the intervention, the hospital protocol has followed the guidelines, so all participants didn't receive metronidazole infusions or oral dosage forms. All participants received IV cefuroxime 750 mg in six consecutive doses for 48 h followed by only oral cefuroxime 500 mg for 168 h when discharged [Table 2].

Following the intervention program, all participants were followed up to exclude any symptoms or signs of SSI. The first follow-up step was done at the discharge time. Second and third rounds of follow-up were done on the day 15$^{th}$ and day 30$^{th}$, respectively, by checking them in the hospital and by calling the person who couldn't attend to hospital at the time of the follow-up. Interestingly, all participants didn't develop any symptoms or signs of SSI, which indicated the success of the intervention program without any case of SSI.

As shown in Table 3, the mean of the cost of antibiotics medications/prescription for the pre-intervention protocol was 735 Sudanese pounds (SP)/prescription. While, after the intervention the cost of antibiotics medications was significantly decreased to mean of 505 SP/prescription. Therefore, the net cost-benefit was 23230 SP for 101 participants and then the percentage of cost-saving was 31% for each one.

**Table 1: Age of participants (*n*=195)**

| Age of participants in years (*n*=195) | Frequency |
|---|---|
| <20 | 19.5% |
| 20-29 | 53.3% |
| 30-39 | 24.1% |
| 40-49 | 3.1% |

**Table 2: Selected antibiotic with time administration and dose regimen for pre-intervention and post-intervention phases**

| Drug | Time of administration | Dose regimen |
|---|---|---|
| **Pre-intervention protocol** | | |
| Use of IV cefuroxime | Before cord clamping | 750 mg six doses every 8 h for 48 h |
| Use of metronidazole infusion | Before cord clamping | 500 mg six doses every 8 h for 48 h |
| Use of oral cefuroxime | When discharged | 500 mg every 12 h for 168 h (7 days) |
| Or use of oral amoxicillin-clavulanic acid | When discharged | 1,000 mg every 12 h for 168 h (7 days) |
| Use of oral metronidazole | When discharged | 500 mg every 8 h for 168 h (7 days) |
| **Post-intervention protocol** | | |
| Use of IV cefuroxime | Before cord clamping | 750 mg six doses every 8 h for 48 h |
| Use of oral cefuroxime | When discharged | 500 mg every 12 h for 168 h (7 days) |

**Table 3: Antibiotics cost/prescription for pre-intervention and post-intervention phases**

| Type of antibiotics | Number of doses | Mean of the price of one Sudanese Pound (SP) | Total price SP |
|---|---|---|---|
| **Antibiotics cost pre-intervention** | | | |
| IV cefuroxime | 6 | 50 | 300 |
| Oral cefuroxime | 1 | 205 | 205 |
| IV metronidazole | 6 | 35 | 210 |
| Oral metronidazole | 2 | 10 | 20 |
| Average price/prescription | | | 735 |
| **Antibiotics cost post-intervention** | | | |
| IV cefuroxime | 6 | 50 | 300 |
| Oral cefuroxime | 1 | 205 | 205 |
| Average price/prescription | | | 505** |

**$P$<0.01

## Discussions

Clinical pharmacists are responsible for implementing critical pathways and can help improve patient outcomes by maintaining cost-effective patient care.[15] The results of this study explained that the local rate of overall compliance with the ASHP guidelines in surgical prophylaxis in CS was surprisingly low. Nevertheless, prophylaxis antibiotics used in ECS was meaningful in protective effects for reducing SSI to all women scheduled for ECS. This effect had a sensible reduction in postoperative infectious morbidity and staff workload along with medication costs. Antibiotic prophylaxis in obstetric procedures by the Society of Obstetricians and Gynaecologists of Canada (SOGC) guidelines 2017; all women undergoing elective or emergency CS should receive antibiotic prophylaxis.[6,16] All the participants were received antibiotic prophylaxis for ECS, which was good clinical practice but in out-of-date manner when compared to international standards of evidence-based practice worldwide.[17] Cochrane Database Systematic Review in 2017 reported that antibiotic prophylaxis appears to be effective in preventing postoperative infection in women undergoing elective, vaginal, or abdominal hysterectomy, regardless of the dose regimen.[18]

In this study, pre-intervention data were explained that all participants received the combination of IV cefuroxime and metronidazole infusions for 48 h which was a high level of antibiotic prescriptions toward ECS similar with the study done in 2017 in Medani hospital, which has shown the overuse of antibiotics for ECS, injectable ceftizoxime in combination with gentamicin and metronidazole after cord clamping, it was the most commonly prescribed regimen.[19] The agent used in prevention should not be used to treat the infection; thus, extended-spectrum agents should not be used for prophylaxis but, instead, should be reserved for the treatment of endometritis. Cefuroxime is second generation cephalosporin used for the prevention of infection in ECS. The single dose of IV cefuroxime (additional intraoperative or postoperative doses may be given for prolonged procedures or if there is major blood loss), is substitute with IV clindamycin if the history of allergy to penicillins or cephalosporins. Add IV teicoplanin (or vancomycin) if high risk of methicillin-resistant *Staphylococcus aureus* according to British National Formula, 2018.[20] NICE at 2016 documented that cefuroxime in a dose 750 mg is effective as first dose prophylaxis for ECS without combination with metronidazole after intervention and this finding was similar with hospital practice, and this result means compatibility with international guidelines in the choice of agents, so the intervention based on stopped taken metronidazole in ECS.[9] A prospective cohort study confirmed that cefuroxime is effective in prophylaxis against postoperative infections, but metronidazole appeared ineffective, with no additional risk-reductive effect when combined with cefuroxime.[21] Butt *et al.* explained that after educational intervention, the metronidazole utilization was decreased.[22]

Cefuroxime's first dose was administered by the anesthetist on arrival in the theatre before skin incision 30 min or less to provide adequate tissue concentrations, this practice was similar to the ASHP and other guidelines. Cochrane collaboration was also stated, IV prophylactic antibiotics for CS administered preoperatively significantly decreases the incidence of composite maternal postpartum infectious morbidity as compared with administration after cord clamp.[11] At Ugandan hospital, a randomized clinical trial in evaluating the effect of administration time on the incidence of postoperative infections concluded that, giving prophylactic antibiotics before skin incision reduces the risk of postoperative infection, in particular of endometritis.[23] Hassan Baaqeel conducted a systematic review and meta-analysis resulted in compared with intraoperative administration, preoperative antibiotics significantly reduce the endometritis rate.[24] Despite of the previous studies by Bashir Osman, *et al.* in Soba hospital, Sudan, concluded that there was no difference in the two regimens (pre-incision or post-clamping of the umbilical cord) of ceftizoxime as prophylactic for ESC,[25] and randomized controlled trial in Egypt by Mohamed Kandil, *et al.* was founded that, equal effectiveness of prophylactic antibiotic in reducing the postoperative infectious morbidity after CS when administered before surgery or after cord clamping.[26] S. Kalaranjini *et al.* were documented same findings with administration of single-dose ceftriaxone for ECS.[27]

Laura J, *et al.* showed that the overall rate of postpartum endometritis (PPE) was low 1.6%, with no significant difference between patients who received 1 g cefazoline vs 2 g and 3 g.[28] Retrospective cohort study done by Homa K. *et al.* concluded that preoperative 3 g cefazoline prophylaxis administered to morbidly obese gravid patients didn't reduce SSI,[29] and a resemble result; an ampoule intervention of cefazoline from 2 g to 1 g, led to high compliance with dose reduction.[30] Re-dose in the hospital practice was continued to six consecutive doses of cefuroxime 750 mg for 48 h, not in line with the updated guidelines were explained, only the first dose was recommended,[7] also Siddig has claimed that a single dose of ceftriaxone was sufficient as surgical prophylaxis agent.[31] These collectively support the fact of increasing of cefuroxime dose of more than 750 mg was uselessness, so using a single dose of 750 mg of cefuroxime led to reducing the costs without increasing the risk of maternal infection.

In pre-intervention, participants received oral cefuroxime 500 mg (85.1%), amoxicillin-clavulanic acid 1000 mg (14.9%), and oral metronidazole 500 mg (100%) for 168 h when discharge and in post-intervention, all precipitants received only oral cefuroxime 500 mg for 168 h. No oral medications were recommended in prophylaxis area in all guidelines and Cochrane Collaboration following clinical improvement of uncomplicated endometritis which has been treated with IV therapy, the use of additional oral therapy has not been proven to be beneficial.[32]

The quasi-experimental nature of the study was compulsory based on to follow the discharge participants to exclude SSI and the new SSI definitions, surveillance for SSI continues for 30 days for CS.[33] The participants were followed on the day of

discharge, days 15, and 30 by the consultants. Using data from the intensive follow-up, a 100% reduction in post-cesarean section SSI rates were achieved and sustained up to 30 days prolonged period after implementing to stop metronidazole dosage forms. All participants were absolutely clean from SSI.

This study revealed that pharmacist interventions provide substantial cost-saving (*P* value = 0.0002) in ECS, and the net cost-benefit was 23230 Sudanese pounds for 101 participants with cost-saving of 31% for each one. These findings are similar to previous studies which concluded that a pharmacist intervention led to significant reduction in antibiotic usage and cost,[34] and another study that claimed that an ample intervention of cefazoline from 2 g to 1 g provides more than $4,000 money-saving.[31] One study done in Nigeria in 2019 by Abubakar *et al.* demonstrated that antibiotic stewardship interventions improved compliance and cost for antibiotic utilization for ECS.[35]

## Conclusion

Clinical pharmacist intervention concisely changed the physicians' practice toward updated guidelines for the rational use of prophylactic antibiotics for ECS. The usage of cefuroxime alone as prophylactic antibiotic is sufficient for reducing postpartum infection in ECS. Furthermore, cost-saving at both individual and governmental level was decreased.

### Financial support and sponsorship

Support and assistance were provided by Faculty of Pharmacy, University of Khartoum, Sudan. Also, financial support is provided by Faculty of Pharmacy, Sudan International University.

### Conflicts of interest

There are no conflicts of interest.

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