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Impact of Pharmacist-led Intervention on Early Intravenous to Oral Antibiotics Switch Practice in Surgical Wards of Hospital Sibu

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ABSTRACT

Introduction: Early intravenous to oral antibiotics switch (IVOS) is one of the essential elements in antimicrobial stewardship (AMS). Currently, the decision on the IVOS of antibiotics in Hospital Sibu based on the decision of clinicians in charge. A systematic interventional strategy by a pharmacist is required to facilitate IVOS.

Objective: This study aimed to associate pharmacist's intervention with the practice of early IVOS of antibiotics.

Methods: This study was a cross-sectional study conducted in the surgical wards of Hospital Sibu. In the pre-intervention phase (April to June 2019), pharmacists performed the conventional practice of reviewing medication charts without informing prescribers about the IVOS of antibiotics. In post-intervention phase (August to October 2019), Pharmacists screened the antibiotic prescriptions and intervened by attaching printed checklist which contained IVOS criteria to patients' medical notes on the day patients were eligible for the switch. Besides, IVOS stickers on antibiotic prescriptions serves as reminders.

Results: A total of 68 and 60 subjects recruited in the pre-intervention phase and post-intervention phase, respectively. The percentage of IVOS of antibiotics on the appropriate day was improved to 75.0% in the post-intervention phase compared to 51.5% in the pre-intervention

phase ($p=0.006$). The proportion of IVOS that performed upon discharge reduced significantly in the post-intervention phase (46.7% vs 75.0%, $p=0.001$). Mean antibiotic cost savings increased substantially in the post-intervention phase compared to the pre-intervention phase [MYR41.90 (SD=39.50) vs MYR22.00 (SD=34.93); $p=0.003$]. However, the mean duration of the length of stay during the pre-intervention phase is not statistically significant shorter compared to the mean duration of the length of stay during the post-intervention phase ($p= 0.514$).

Conclusions: Pharmacist initiated printed AMS recommendations might improve the percentage of IVOS of antibiotics on an appropriate day. Further study needs a larger sample size.

Keywords: IVOS, antibiotics, antimicrobial stewardship, pharmacists, surgical ward

INTRODUCTION

Antibiotics are one of the classes of medications that most commonly prescribed nowadays. Therefore, the antibiotics use surveillance is crucial as improper use affects patient from various aspects. According to the Protocol on Antimicrobial Stewardship Program of Pharmaceutical Services Division Malaysia 2014, antibiotics sometimes prescribed for uncertain indications and prolonged duration (1). Antimicrobial resistance (AMR) may happen, leading to extended stay of hospital, increased morbidity and mortality rate and higher healthcare cost (2). Based on the latest report from National Antibiotic Resistance Surveillance (NSAR) 2017, the results showed that there is an increasing trend of antimicrobial resistance. One of the examples is a 3% increase in the rate of vancomycin resistance to *Enterococcus faecium* compared to 2016. Besides, most of the antibiotics tested for *Acinetobacter baumannii*, which includes ampicillin/sulbactam, ceftazidime, imipenem, meropenem, gentamicin, amikacin and polymyxin B also have increased in resistant rate (3).

According to a study by McLaughlin et al. in 2005, out of one-third of patients that received antibiotic therapy, up to 40% of them had it intravenously. However, also up to 40% of the antibiotics were prescribed inappropriately (4). Shrayteh et al. 2014 mentioned that patients in the wards are prescribed with intravenous antibiotics for a more extended period of therapy when oral antibiotic is possible (5). To overcome this issue, the Ministry of Health Malaysia (MOH) developed and introduced the Antimicrobial Stewardship (AMS) protocol in 2015 as a systematic approach to improve the quality use of antibiotics in patients. Several of policies included in the protocol and one of them is the initiation of intravenous (IV) to oral (PO) antibiotic switch program.

Some studies have reported that the effectiveness of a short course of IV therapy for 2-3 days followed by PO therapy for the remaining period was same with a complete course of IV therapy except in patients with severe infections, in critically ill patients, or in patients who are unable to take PO medications (6, 7). According to Mertz et al. (2009), the most suitable time to switch IV to PO antibiotic is on the day 2 - 4 of the IV therapy. This duration allows reassessment to the treatment plan where culture and sensitivity test has been carried out (7).

According to Fischer et al. 2003, some physicians believe that if patients receive a full course of IV antibiotics, patients healed from symptoms earlier as IV antibiotics have a higher bioavailability than their PO counterpart (8). Therefore, physicians usually tend to choose the IV

antibiotics for the patients when patients admit to the hospital and continue until patients discharge from hospital. But the fact is that for most of the antibiotics, either given intravenously or orally, and there will be equivalent clinical outcomes (9).

There are many advantages of early IV-PO switch, such as shorter hospital stay, shorter duration of IV therapy, lesser chance of getting infections associated with IV lines, lower risk of thrombophlebitis and increased patient compliance (5, 10). Besides, this practice also shows the improvement in cost savings as well as reduced workload (7, 11). However, the approach of early IV to PO switch has not been implemented in the hospital setting. Currently, the decision of switching of IVOS in Hospital Sibul based on the decision of clinicians in charged. For example, mostly IV antibiotics will only switch to oral antibiotics upon discharge. Therefore, in this study, we would like to study the impact of a pharmacist-led intervention on early switching from intravenous to oral antibiotics in surgical wards in Hospital Sibul.

We aimed compare the percentage of IV-PO antibiotics switch on the appropriate day, the proportion of IV antibiotic switched/stopped only upon discharge, length of hospital stay and antibiotics cost saving between the pre-intervention group and post-intervention group.

METHODS

Study Type and Design

This study was a cross-sectional interventional study carried out prospectively in the surgical wards of Hospital Sibul. The study involved patients on IV antibiotics that were switchable to oral antibiotics. The IV-PO switch was only eligible for IV antibiotics available in oral formulations or suitable alternatives available in oral forms. The identification of patients suitable for the early switch to oral antibiotics was as shown in Figure 1.

In this study, we applied the convenience sampling method. The pharmacist from the study ward assigned as the study investigator. The pharmacist identified cases eligible for inclusions through daily screening of the medication charts in the ward, except on weekends when ward pharmacy service was unavailable.

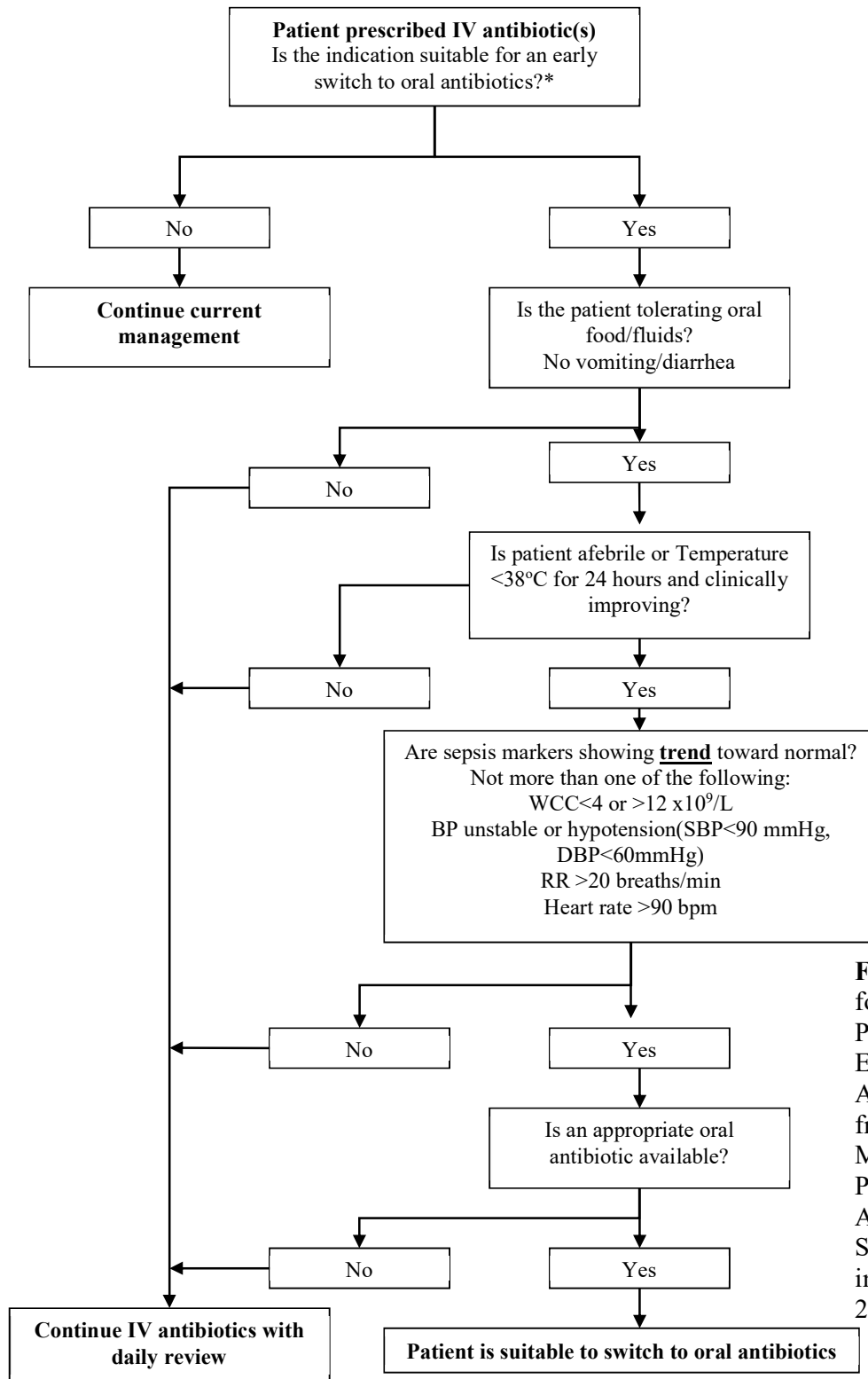


Figure 1. Flowchart for Identification of Patients Suitable for Early Switch to Oral Antibiotic (Adapted from Malaysia Ministry of Health Protocol of Antimicrobial Stewardship Program in Healthcare Facilities 2014)

* Some conditions require prolonged course of IV antibiotics OR high tissue concentration, so are not suitable for early switch. Eg Bone/joint infections, endocarditis, meningitis, S. aureus bacteraemia, cystic fibrosis, deep seated abscess, immunosuppression, melioidosis, prosthetic infection, febrile neutropenia

Study Procedure

There were two phases in the study, pre-intervention and post-intervention (Figure 2). The pre-intervention phase was conducted from April to June 2019, while post-intervention conducted from August to October 2019. The control group recruited during the pre-intervention phase, whereas the patients recruited during the post-intervention phase act as the intervention group. The purpose of recruiting the subjects for different groups at the different time was to eliminate the effect of the intervention on the control group, in which the prescribers' decision for IVOS in the control group might be influenced by pharmacists' recommendation for the intervention group.

In the pre-intervention phase, the investigators reviewed the antibiotic prescriptions in the ward and collected the data of subjects using the data collection form (refer to the Appendix) without informing prescribers about the IVOS. All the patients eligible for IV-PO switch were followed up prospectively by the study investigators. The patients were monitored continuously as per routine and data collected, to prevent bias in the outcomes of comparing the pre-intervention and post-intervention phase.

For post-intervention group, the investigators performed the conventional practice of reviewing antibiotic prescriptions in the wards and verbally informed the prescribers on the day patient eligible for switching to oral antibiotics. A clinical intervention form with the criteria of IV-PO switch and recommendation of a suitable oral antibiotic attached to the medical notes on the day patients eligible for the switch. Doctors required to document on the form whether the switch recommendation was accepted and to state the reasons if the suggestions rejected, within 24 hours of intervention. An IV-PO switch sticker was placed beside the antibiotic prescription in the medication charts as a reminder for IV-PO switching.

Before commencement of the post-intervention phase, all doctors in the study ward were handed a written formal letter by the research investigators in the study ward on the availability of IV-PO switch protocol in the wards one week before the post-intervention phase commenced. The IV-PO protocols also attached to the letters. The study investigators followed up the patients daily until IV-PO switch was done or until patients discharged home (whichever was earlier).

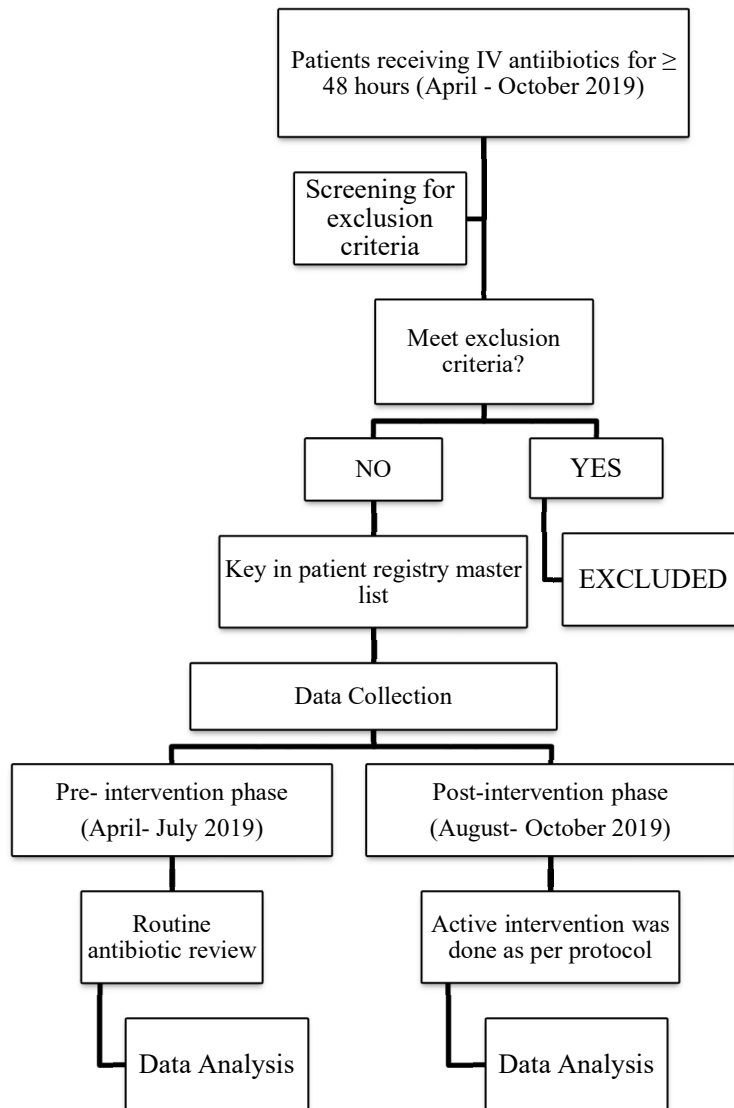


Figure 2. Flowchart for study methodology

Study Participants

We recruited all patients admitted to surgical wards Hospital Sibu who were eligible for IV-PO antibiotics switch. They must age 18 years old and above, received an IV antibiotic for at least 48 hours, had body temperature $<38^{\circ}\text{C}$ for the past 24 hours, normal or decreasing white cell count, tolerating orally and showing clinical improvements from signs of infection. Patients with the following criteria were excluded.

- 1) Oral route compromised (vomiting, nil by mouth, severe diarrhoea, swallowing disorder, unconscious, active gastrointestinal bleeding, malfunction gastrointestinal tract or malabsorption syndrome)

- 2) Continuing sepsis (2 or more of the following: Temperature $>38^{\circ}\text{C}$ or $<36^{\circ}\text{C}$, heart rate $>90\text{bpm}$, respiratory rate $>20/\text{min}$, white cell count $>12 \times 10^9/\text{L}$ or $<4 \times 10^9/\text{L}$)
- 3) Deteriorating clinical condition
- 4) A prolonged course of IV antibiotics needed (e.g., endocarditis, meningitis, *Staphylococcus aureus* bacteraemia, immunosuppression, bone and joint infection, deep abscess, empyema, cystic fibrosis, orbital cellulitis, endophthalmitis, prosthetic infection and melioidosis)
- 5) Febrile with neutropenia
- 6) Absence of oral formulation that fit the susceptibility
- 7) Hypotension (systolic blood pressure $<90\text{mmHg}$, diastolic blood pressure $<60\text{mmHg}$)
- 8) Shock

We obtained the informed consent form each subject involved in the study. The written consent approved by MREC was available in both Malay and English language. A copy of the informed consent given to the study subject, while the original copy filed in the Investigator's Study File. Please refer to Appendix.

Sample Size

Based on the calculation done using Power and Sample Size Calculator (12), the minimum sample size required was 128 patients (pre = 64; post = 64) at 80% certainty with a precision of 0.05 and estimated standard deviation of 2.

Outcome Measurement

The firstly measured the primary outcome of the study was the percentage of IV-PO antibiotics switch on the appropriate day in the pre-intervention group and the post-intervention group. "IV-PO antibiotics switch on the appropriate day" was defined as "yes" if IV antibiotics were switched to PO antibiotics within one day (24 hours) from the date of IVOS criteria met.

The secondary outcomes included the percentage of IV antibiotic switched/stopped only upon discharge, length of hospital stay, and antibiotics cost savings. 'IV antibiotic switched/stopped only upon discharge' was defined as the date of IV antibiotic been switched or stopped the same as the date of discharge. 'Length of hospital stay' defined as the total number of days patient stayed in the hospital from the first day of admission until the day of discharge home.

‘Antibiotics cost savings’ was defined as cost savings incurred by switching IV antibiotic to oral antibiotic, and calculated using the formula: Cost savings = (Cost of IV antibiotics x cost-saving days) – (Cost of oral antibiotics x cost savings days), and the cost-saving days would mean the number of days of oral antibiotics including the duration of discharged oral antibiotics.

Statistical Analysis

We analysed the data using SPSS version 20.0. Chi-square test used to compare the percentage of IV-PO switches on the appropriate day in both pre-intervention and post-intervention groups. The two groups were compared for the percentage of IV antibiotic switched/stopped only upon discharge, the mean length of hospital stay and mean cost of antibiotic used by using independent t-test or chi-square. All p-values < 0.05 were considered significant.

RESULTS AND DISCUSSION

In this study, 91 courses of antibiotics were recruited from 68 patients in the pre-intervention phase, while 92 courses of antibiotics recruited from 60 patients in the post-intervention phase (Table 1).

Table 1. Number of patients screened for inclusion into the study and the numbers excluded

	Pre Phase	Post Phase
Number of patients screened for inclusion	186	116
Excluded as patients younger than 18 years of age	2	1
Excluded as oral route compromised	14	12
Excluded due to continuing sepsis	17	8
Excluded as infection required prolonged a course of IV treatment	67	24
Excluded due to febrile with neutropenia	2	1
Excluded as no suitable alternative	4	1
The patient lost to follow-up	5	7
Transferred to another ward or another hospital	7	2
Patient eligible for inclusion in the study, following the application of exclusion criteria	68	60

The characteristics of the study samples shown in Table 2. No significant difference found for patient gender or age between the pre and post-intervention group. No significant difference

found for the site of infection between both groups. The most frequent site of infection was abdomen infection in both groups, as shown in Table 2 (50.0% vs 61.7% in pre and post-intervention, respectively).

Table 2. Baseline Characteristics

Characteristics	Pre-intervention group	Post-intervention group	P-value
Number of patients, n	68	60	
Number of IV antibiotic courses, n	91	92	
Gender: n (%)			0.352 ^a
Male	44 (64.7)	34 (56.7)	
Female	24 (35.3)	26 (43.3)	
Age (years): mean (SD)	51.7 (18.91)	50.5 (17.50)	0.731 ^b
Site of infection: n(%)			
Abdomen	34 (50.0)	37 (61.7)	0.579 ^a
Skin and Soft Tissue	9 (13.2)	5 (8.3)	
Urinary Tract	12 (17.7)	8 (13.3)	
Others	13 (19.1)	10 (16.7)	

^aChi-square test for independence

^bIndependent *t*-test

Primary Endpoint

The percentage of IV-PO antibiotic switch on the appropriate day was significantly more in the post-intervention group compared to the pre-intervention group (75.0% vs 51.5%, $p=0.006$) (Table 3).

Table 3. Primary outcome: Percentage of IV to PO Antibiotic Switch on Appropriate Day

Variable	Pre-intervention group, n (%)	Post-intervention group, n (%)	X ² statistic ^a (df)	P-value ^a
IV- PO Antibiotic Switch on Appropriate Day	35 (51.5)	45 (75.0)	7.53 (1)	0.006

^aChi-square test for independence

Our results had shown that the implementation of pharmacists' recommendations had significantly improved the percentage of IV-PO antibiotic switch on the appropriate day in the

ward. This finding was following the study by Sze et al. (11), in which the percentage of IV-PO antibiotic switch on the appropriate day was more in the post-intervention group (88.3%) consisting of antimicrobial strategies such as application of clinical intervention form with the criteria of IV-PO switch and reminder sticker by clinical pharmacists, compared to the pre-intervention group (24.1%) where clinical pharmacists reviewed antibiotic prescriptions and verbally informed the prescribers to discuss a switch (11). A similar approach was implemented by Dunn et al. (13), who applied stickers highlighting the patient was on IV antibiotics and applied guidelines to the drug chart by clinical pharmacists had reported improvement in the percentage of IV-PO switch on the appropriate day in the post-intervention group, i.e. 71.7% compared to the pre-intervention group, i.e. 50.6% (13). The use of printed AMS interventions had helped to promote the switch of IV antibiotics to oral antibiotics.

Secondary Endpoints

The mean duration of the length of stay during the pre-intervention phase is shorter compared to the mean duration of the length of stay during the post-intervention phase. However, the results projected were not statistically significant. The results were not in line with similar studies conducted by Sze WT & Kong MC, 2018 and McLaughlin et al., 2005, which reported statistically reduction in length of hospital stay (LOS) through the implementation of IVOS guidelines (11,13). In our study, some IV antibiotics treatment only started for infection after a few days since admission in the hospital and subsequently increased the length of stay in the hospital. There was a case in the post-intervention phase in which the patient LOS was 48 days; however, the IV antibiotic only started one month since admission that might contribute to an outlier in our study. Besides, several other reasons such as co-morbidities and social factors, possibly lengthening stay.

Although the LOS between pre and post-intervention was not significant, our study showed the percentage of IV antibiotics only switched/ stopped upon discharged was significantly reduced from 46.7% to 75% ($p = 0.001$) by comparing pre and post-intervention phase which implied that these printed reminders have growing importance as strategies to promote IV to oral antibiotic switch. Also, the earlier IVOS switch could lead to earlier discharge and thus shortening the LOS.

Table 4. Secondary outcome: Percentage of IV antibiotic switched/stopped only upon discharge, length of hospital stay, antibiotics cost saving

Variable	Pre-intervention group	Post-intervention group	<i>t</i> statistic ^a (<i>df</i>)	χ^2 statistic ^b (<i>df</i>)	<i>P</i> -value
Length of hospital stay (day), mean (SD)	7.3 (6.13)	6.6 (6.13)	0.655 (126)		0.514 ^a
IV antibiotics only switched/ stopped upon discharged, n (%)	51 (75.0)	28 (46.7)		10.830 (1)	0.001 ^b
Antibiotics cost-saving (RM), mean (SD)	22.0 (34.93)	41.9 (39.50)	-0.3030 (126)		0.003 ^a

^aIndependent *t*-test^bChi-square test for independence

The cost-saving between pre-intervention phase and post-intervention phase are statistically significant ($p = 0.003$). The post-intervention phase has reported a higher mean of cost-saving (RM41.90) compared the pre-intervention phase (RM22.00). The total cost saving reported in the post-intervention phase was RM2516.05 in 60 subjects; while the cost saving in the pre-intervention phase was only RM1496.24 in 68 subjects. The report agrees with previous studies such as WT & Kong MC, 2018 that with printed guidelines and intervention by pharmacist could lead to saving in antibiotic expenditure (11). Another study from Taiwan also showed that significant cost saving in both medications cost, as well as inpatient cost with a pharmacist, managed IV to oral switch services (14). The pharmacist-led early intervention of IV antibiotic switch to oral antibiotic significantly reduced the cost of an overall treatment for an infection.

In our study, there were only two cases of re-initiation of IV antibiotic treatment in both of the pre and post phases each due to the relapse of the infection. However, these cases were not able to be followed up due to time constraint. According to Sze et al., which carried out a similar study, reported zero instances of re-initiation of IV antibiotic treatment in their intervention phase (11). Besides that, the study by Dunn et al. also showed a reduced percentage of re-initiation of IV antibiotic in the intervention group (13). Therefore, the implementation of the

IVOS is beneficial in helping with the switch decision as pharmacists helped to screen patient who fulfilled the IVOS inclusion criteria as mentioned previously.

In the post-intervention phase, out of the 60 recruited subjects, 34 switches were initiated by prescribers. Twenty switches performed after a recommendation made by pharmacist while six rejected. In the clinical intervention form attached in the patient medication chart during the post-intervention phase, prescribers required to provide feedback of IVOS. However, only one of the rejected recommendations claimed by prescriber that “patient was not clinically stable yet to change to PO antibiotic”. The other forms were left empty without providing a reason. Throughout the study, there were no adverse drug reactions reported after the IVOS.

LIMITATION OF STUDY

There is a limitation of time in this study to recruit more subjects. There was a difference in the number of subjects recruited in pre and post phases which may affect the outcome of the study. On top of that, due to limitation of time, we were not able to follow up the patient properly, and this led to a loss of follow up and affected the number of subjects in the study.

Besides that, the costs of drug preparation, administration, pharmacists and nursing labour not included in this study. The methods of this study adapted from Sze et al. (11), which was a pre-post-intervention study without a control group due to limitation of time. According to Sze et al., the pre-existing factors and other confounders might affect the result without the use of a control group (11). Therefore, in the future study, it would be suggested to perform research with a control group with sufficient study duration to reflect the actual impact of IVOS.

CONFLICT OF INTEREST

The investigators declared they have no conflict of interest.

CONCLUSION

Printed AMS recommendations initiated by pharmacists had shown to improve the percentage of IV-PO switch on the appropriate day, reduce the proportion of IV antibiotic switch only upon discharge, and increase antibiotic cost savings thus may improve AMS strategies of the hospitals to encourage IV-PO antibiotics switch.

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APPENDIX

Clinical Intervention Form

Antimicrobial Stewardship Programme 2019

Pharmacy Hospital Sibul

Start date of IV antibiotic:

		/			/		
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**assumed day 1 = day of IV antibiotic started*

Does the patient fulfill all criteria?

- 18 years old and above
- On IV antibiotics for ≥ 48 h
- Able to tolerate orally
- Not in sepsis
- White cell counts normalised or decreasing
- Clinical improvement with temperature $<38^{\circ}\text{C}$ for 24h
- Not requiring a prolonged course of IV therapy
- Not hypotensive (SBP not <90 mmHg, DBP not <60 mmHg)
- Not in shock

SWITCH IV TO ORAL?

		/			/		
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This patient has met the criteria for IV to Oral antibiotic switching on which is the Day _____ of IV antibiotic.

Suggest to switch to oral antibiotic _____.

For Medical Officer's Feedback

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

Agree to switch today

Agree to switch on a later day

[pls state reason(s):

_____]

Disagree on early IV-Oral switch for this patient [pls state reason(s): _____]

IV-Oral Switch Reminder Sticker

IVOS							
Date:				Time:			
		/		/			

Data Collection Table

Does the patient fulfil all criteria?

- 18 years and above
- On IV antibiotics for \geq 48hours
- Able to tolerate orally (refer research protocol)
- Not in sepsis (refer research protocol)
- White cell count normalises or decreasing trend

***Assume day 1=day of IV antibiotic started**

- Clinical improvement with temperature $<$ 38°C for 24hours
- Not requiring a prolonged course of IV therapy (refer to research protocol)
- Not hypotensive (SBP not $<$ 90mmHg, DBP not $<$ 60mmHg)
- Not in shock

If Eligible (fulfil ALL criteria), please proceed to data collection

Subject code	Age	Gender	Diagnosis	Admission date	IV antibiotic (AB) Started	Day of criteria for switch met*	Day of a switch to oral*/ Day of antibiotic stopped*	Type of oral AB switched and duration	Date of discharge <i>(Pls remark if prolonged stay due to TB, daily dressing etc.)</i>	Only switched/ stopped upon discharge <i>(yes/no)</i>	IV AB restarted after a switch to oral for the same indication <i>(yes/no/NA)</i>	Adverse events and intercurrent illness occurred after intervention
					Date started							