Implementation of intravenous to oral antibiotic switch therapy guidelines in the general medical wards of a tertiary-level hospital in South Africa

Anida C. van Niekerk1*, Daniel J. L. Venter2 and Shirley-Anne Boschmans1

1Department of Pharmacy, Nelson Mandela Metropolitan University, PO Box 77000, Summerstrand, Port Elizabeth, 6031, South Africa; 2Department of Statistics, Nelson Mandela Metropolitan University, PO Box 77000, Summerstrand, Port Elizabeth, 6031, South Africa

*Corresponding author. Tel: +27-73-809-6884; Fax: +27-41-504-2744; E-mail: anidavn@gmail.com

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Objectives: The design and implementation of an antibiotic intravenous (iv) to oral switch therapy (IVOST) guideline in a Third World health setting.

Methods: The guideline was developed and integrated into daily practice by a ward pharmacist over a period of 7 weeks. Patients were switched once they were deemed clinically stable according to IVOST criteria. The final decision to switch was left to the attending physician. One pre- and two post-implementation audits (150 patient medical records per audit) were compared.

Results: Implementation of the IVOST guideline was successful in increasing \( P < 0.0005 \) the number of patients switched from 16% (19/119) pre-implementation to 43.9% (47/107) immediately after implementation; however, the change was not sustained 3 months after implementation (20.8%; 25/120). The intervention was also successful in decreasing the overall duration of iv therapy \( P < 0.0005 \) from 7.2 ± 3.5 days pre-implementation to 5.2 ± 3.0 days immediately post-implementation. The change was not sustained 3 months after implementation (6.5 ± 3.5 days).

Conclusions: Despite the challenges encountered in a Third World environment, an antibiotic IVOST guideline can be successfully implemented. Continual, active integration of the guideline into daily practice by a ward pharmacist is essential if positive IVOST outcomes are to be maintained.

Keywords: antibiotic guidelines, interventions, ward pharmacists, developing country

Introduction

The recognized frequent misuse and overuse of antibiotics in hospitals, and the impact on therapeutic efficacy, bacterial resistance and costs warrant the implementation of programmes to improve the use of antibiotics in hospitals,1,2 especially in countries with limited resources. One of the methods to improve antibiotic prescribing is by implementing switch therapy. ‘Switch therapy’ is used to describe the conversion of intravenous (iv) to oral therapy, using the same or a different compound, as soon as patients are judged clinically stable, according to specified criteria, without the loss of antimicrobial potency. Other similar terms used include ‘streamlining’, ‘sequential’ therapy and ‘step-down’ therapy.3,4 The benefits of timely and appropriate iv to oral switch are well recognized and include: (i) decreased duration of iv therapy;5–7 (ii) decreased drug acquisition, hospitalization and non-drug costs;8–10 (iii) decreased workload and nursing time;10 (iv) decreased length of hospitalization;8 and (v) decreased side effects associated with iv lines.11,12 Pharmacists’ contributions towards the rational use of antibiotics have been widely described in the literature, and several studies have used pharmacists to design and implement antibiotic guidelines.5,7–9,13 Poor healthcare infrastructure, deficiency of resources, lack of education and training, minimal regulatory control on the supply and quality of antibiotics, inappropriate hygiene, overcrowding, lack of resources for infection control, and a lack of appropriately trained infection control personnel are some of the barriers to the effective implementation and audit of interventions by pharmacists in developing countries.14 These barriers, in addition to a high incidence of HIV infection15,16 and antibiotic resistance,17 are especially prevalent in government sector hospitals in South Africa, which serve 80% of the South African population.18 Moreover, limited pharmacy staff has forced pharmacists to spend minimal time in hospital wards.19

Only a few studies demonstrating the effect of implementing switch criteria in a general population of medical patients have been identified and all of these were conducted in developed countries, such as the UK,18 the USA,9,20 the Netherlands,10,23
Switzerland and Norway. In addition, these studies have not assessed the long-term sustainability of guideline implementation when a pharmacist is not actively integrating switch therapy in the general medical wards on a daily basis.

This paper is therefore aimed at assessing the effect of iv to oral switch therapy (IVOST) guideline implementation on antibiotic prescribing in the medical wards of a South African government hospital. While IVOST guidelines are commonly available and similar studies have been conducted in First World countries, performing such a study in a Third World country is challenging, and it is argued that the implementation of switch therapy by a ward pharmacist (even if only present in the ward for 2 h/day, but on a continuous basis) can reduce unnecessary iv antibiotic use and expenditure, even under difficult and challenging circumstances in a Third World country.

Methods

The implementation of the IVOST guideline and the audit of prescribing practices were undertaken in the four general medical wards of a 500 bed tertiary-level government hospital in South Africa. At the time of implementation there was no clinical ward pharmacist conducting ward rounds; however, two medical officers, two medical interns and five specialists rotated among the study wards. No institutional antibiotic or IVOST guideline was available at the study site.

Ethical approval was obtained from the Nelson Mandela Metropolitan University Ethics Committee (Human) (reference number: H09He0PHA001). Permission to undertake the study was granted by the Medical Superintendent, the Head of Medicine and the Head of the Pharmacy Department at the study hospital. Access to medical records was granted by the Medical Superintendent and, thus, informed consent was not obtained from individual patients. The study was undertaken in accordance with the principles embedded in the Helsinki Declaration.

The IVOST guideline was designed by a ward pharmacist in consultation with the Head of the Pharmacy Department and the Head of Medicine at the study hospital, and approved by the study hospital Pharmacy and Therapeutics Committee (PTC). National and provincial guidelines on antibiotic prescribing in South Africa have limited criteria and information on iv to oral switch and, therefore, the IVOST guideline used was based on a published guideline from the USA and guidelines used by UK National Health Services. A similar guideline was implemented by McLaughlin et al.

The experimental study employed a before-and-after intervention design and a similar design has been employed previously. The study consisted of four components: (i) a pre-implementation audit (3 weeks) to collect baseline data; (ii) an implementation phase (a ward pharmacist visited four general medical wards 2–3 h/day, 3–5 days/week, Monday to Friday over a period of 7 weeks); (iii) an immediate post-implementation audit (3 weeks) to assess the effect of the antibiotic IVOST guideline on iv to oral prescribing patterns when a pharmacist was present; and (iv) a 3 month post-implementation audit (5 weeks) to assess whether the antibiotic IVOST guideline would still be used by medical staff when a pharmacist was no longer present in the wards.

The implementation phase consisted of: (i) a slide show presentation to all medical interns and physicians; (ii) the distribution of IVOST guideline documentation; (iii) a meeting with pharmacists; (iv) the placement of ‘iv to oral’ stickers on patients’ drug prescription charts and physicians’ daily assessment sheets once patients were deemed eligible for switch according to IVOST criteria (Figure S1, available as Supplementary data at JAC Online); and (v) the placement of posters (Figure S1) in applicable areas.

Each audit consisted of the first 150 medical records of patients who were ≥18 years of age, admitted to and discharged from the four general medical wards during the audit periods, and for whom iv antibiotics were prescribed. Audits were identical and carried out retrospectively from the medical records of patients after discharge.

IVOST guideline criteria (Figure S1) in addition to patient progress notes were used to determine whether patients were clinically stable and, thus, eligible for switch. The following IVOST criteria (Figure S1) were used: inability to tolerate oral drugs, presence of sepsis, severe infection or critical illness and any other factors that would have made switch inappropriate. The guideline also recommended the evaluation of patients 72 h after iv antibiotic initiation.

Patients were categorized as either ‘switched’, ‘could have been switched but not switched’ or ‘iv stopped at point that switching became possible’ (Figure 1). If iv therapy was stopped on the day clinical stability was achieved and no oral therapy was initiated, the patients were categorized as ‘iv stopped at point that switching became possible’.

During the three audits the following patients were excluded from the switch group: (i) patients for whom there was a delay (>24 h) before receiving oral therapy after iv therapy was stopped; (ii) patients who were kept on iv >24 h after clinical stability was achieved prior to switching to an oral antibiotic; and (iii) patients who received multiple iv antibiotics simultaneously with only one antibiotic switched to oral while the patient continued on iv therapy with the other agents. Patients who died during hospitalization were excluded from the study.

Inferential statistics employed were the χ2 goodness-of-fit test, Pearson’s χ2 test of independence and analysis of variance (ANOVA). Where only one factor was involved, three or more means were compared using one-way ANOVA. To compare three or more means where two factors were involved, two-way factorial ANOVA was used. Inferential statistics were calculated using Statistica version 9 (Statsoft Ltd). A P value <0.05 was regarded as significant.

Results

Patient characteristics

The three audit groups were similar in terms of the mean age, number of males and females, total number of admission diagnoses, mean number of admission diagnoses per patient, type of admission diagnoses, total number of chronic diseases, and type of chronic diseases. The five most common admission diagnoses were lower respiratory tract infections (26.7%–40%), HIV (13.3%–27.3%), tuberculosis (TB; 19.3%–29.3%), cardiovascular (CV) disease (12%–19.3%) and chronic obstructive pulmonary disease (11.3%–12.7%). The three most common chronic diseases present before admission were CV disease (28%–33.3%), HIV (20%–26.7%) and TB (11.3%–17.3%).

Incidence of switch therapy

The implementation was successful in increasing (P<0.0005) the number of patients switched (pre-implementation audit 16% (19/119) and immediate post-implementation audit 43.9% (47/107)). This improvement was, however, not sustained, as the number of switched patients decreased again during the 3 month post-implementation audit (20.8%; 25/120) once the ward pharmacist was no longer actively promoting switch therapy in the medical wards (Figure 1).

Antibiotics prescribed, time to clinical stability, observation period after switch and length of hospital stay

The five most common iv antibiotics used at this study site were ampicillin (21.5%; 134/622), amoxicillin/clavulanic acid
Physicians (sustained (Table 1). The number of prescriptions for which a audits (decreased (received by non-switched patients after clinical stability hospital than non-switched patients (3.9–4.5 days) (Table 1). This is one of the reasons why there was no difference in the mean length of hospitalization between the three audits (P=0.609) (Table 1). However, as expected, switched patients spent less time in hospital than non-switched patients (P<0.0005).

**Duration of iv antibiotic therapy**

Although the duration of iv antibiotic therapy decreased by 2.0 days from the pre-implementation audit to the immediate post-implementation audit, it increased by 1.3 days during the 3 month post-implementation audit (P<0.0005) (Table 1). A shorter duration of iv therapy was recorded for switched versus non-switched patients (P<0.0005). The duration of iv therapy received by non-switched patients after clinical stability decreased (P<0.0005), but the change was unfortunately not sustained (Table 1). The number of prescriptions for which a duration was specified by physicians decreased between the pre-implementation and the immediate post-implementation audits (P=0.001), as did the duration of treatment specified by physicians (P=0.003) (Table 1).

**Cost implications**

The immediate calculated drug-acquisition cost saving for the switched groups increased (P<0.0005) (Table 1). The estimated drug-acquisition cost saving for the non-switched groups was lowest during the immediate post-implementation audit (P<0.0005), obviously because more patients in this audit were already switched. A total amount of £1414.41 was saved for switched patients during the immediate post-implementation audit and a further £635.63 could have been saved if non-switched patients had also been switched (Table 1).

**Combined use of iv antibiotics and oral medications**

Because the ability to tolerate oral medication was used as a criterion for switching patients (Figure S1), it was worthwhile to record the number of oral drug prescriptions prescribed for and received by patients on iv antibiotic therapy. The number of oral drug prescriptions issued to patients on iv antibiotic therapy was similar in the three audits (pre-implementation, n=597; immediate post-implementation, n=569; and 3 month post-implementation, n=537) (P=0.204). Furthermore, the fact that a large number of patients in each audit (90.7%–97.3%) received oral drugs while on iv antibiotic therapy indicated that few patients had gastrointestinal absorption problems.

**Discussion**

To our knowledge, this is the first study conducted in a Third World country with a high incidence of HIV investigating the suitability of switching antibiotic therapy from the iv to the oral route.

The significant increase in the number of switched patients from 16% to 43.9%, which decreased to 20.8% 3 months after implementation, justified the need for a ward pharmacist, despite the availability of guidelines. The increase in the switch incidence for this study was close to that reported by Servinc et al. (28% versus 29%). Additionally, pharmacists’ day-to-day contact with other healthcare staff has been shown to be important for the reinforcement of adherence to guidelines.

Patients had a shorter time to clinical stability immediately after implementation, which could be attributed to the increased awareness of switch among physicians who, during the immediate post-implementation audit, switched patients or stopped iv therapy earlier. Hunter and Dormaier also made the observation that physicians tend to stop iv therapy on the day of clinical stability rather than switching patients to oral therapy. The mean time to clinical stability in this study (3.8–4.5 days) correlated with previous studies that also reported 2.0–4.0 days as the appropriate time for iv therapy to be reassessed. The reduction in time to clinical stability might raise the question of whether...
antibiotics were given for either too long (unnecessary use) or too short (risk of relapse) a period. However, the decision to switch was left to the attending physician and, thus, it was assumed that patients were appropriately switched according to the discretion of the physician with the help of the switch criteria (Figure S1).

Most of the switched patients were observed in hospital after switch. This could be linked to the high incidence of comorbid

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pre-implementation</th>
<th>Immediate post-implementation</th>
<th>3 month post-implementation</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of iv therapy (days)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>all patients</td>
<td>mean ± SD</td>
<td>7.2 ± 3.5</td>
<td>5.2 ± 3.0</td>
<td>6.5 ± 3.5</td>
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<td>switched patients</td>
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<td>7: 1 – 25</td>
<td>5: 1 – 14</td>
<td>6: 1 – 21</td>
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<td>mean ± SD</td>
<td></td>
<td>3.2 ± 1.4 (n = 19)</td>
<td>4.1 ± 1.8 (n = 47)</td>
<td>3.7 ± 2.1 (n = 25)</td>
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<tr>
<td>non-switched patients</td>
<td>mean ± SD</td>
<td>8.2 ± 3.1 (n = 100)</td>
<td>7.3 ± 2.7 (n = 60)</td>
<td>8 ± 3.1 (n = 95)</td>
</tr>
<tr>
<td>Time to clinical stability (days)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>all patients</td>
<td>mean ± SD</td>
<td>4.7 ± 2.5</td>
<td>3.8 ± 2.0</td>
<td>4.1 ± 2.0</td>
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<tr>
<td>switched patients</td>
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<td>4: 1 – 9</td>
<td>4: 1 – 10</td>
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<td>4.1 ± 1.8 (n = 47)</td>
<td>3.7 ± 2.1 (n = 25)</td>
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<tr>
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<td>4.5 ± 2.3 (n = 100)</td>
<td>3.9 ± 1.8 (n = 60)</td>
<td>4.2 ± 1.7 (n = 95)</td>
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<td>Observation period after switch (days)</td>
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<td>3.9 ± 5.0 (n = 60)</td>
<td>4 ± 3.9 (n = 25)</td>
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<td>5: 0 – 20</td>
<td>3: 0 – 14</td>
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<td>Duration of iv therapy after clinical stability for non-switched patients (days)</td>
<td>mean ± SD</td>
<td>3.8 ± 2.4 (n = 100)</td>
<td>3.3 ± 1.8 (n = 60)</td>
<td>3.9 ± 2.5 (n = 95)</td>
</tr>
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<td>3: 0 – 8</td>
<td>3: 0 – 16</td>
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<tr>
<td>Number of iv antibiotic prescriptions for which duration was specified (n=total number of prescriptions)</td>
<td>mean ± SD</td>
<td>40 (n = 204)</td>
<td>19 (n = 213)</td>
<td>18 (n = 204)</td>
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<td>Duration specified by physicians (days)</td>
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<tr>
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<td>6.9 ± 3.1 (n = 40)</td>
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<tr>
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<td></td>
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<td>3: 2 – 10</td>
<td>7: 2 – 10</td>
</tr>
<tr>
<td>Length of hospital stay (days)</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>all patients</td>
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<td>10.7 ± 7.0</td>
<td>11.3 ± 7.3</td>
</tr>
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<td>9: 2 – 40</td>
<td>10: 2 – 43</td>
</tr>
<tr>
<td>mean ± SD</td>
<td></td>
<td>8 ± 5.0 (n = 19)</td>
<td>8.9 ± 5.6 (n = 47)</td>
<td>9 ± 4.5 (n = 25)</td>
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<td>non-switched patients</td>
<td>mean ± SD</td>
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<td>12.9 ± 8.0 (n = 60)</td>
<td>12.4 ± 7.2 (n = 95)</td>
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<td>Total antibiotic acquisition costs (£)®</td>
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<td>3445.15</td>
<td>3165.55</td>
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<tr>
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<tr>
<td>Total amount saved (£)®</td>
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<tr>
<td>switched groups</td>
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<td>1414.41 (n = 47)</td>
<td>520.85 (n = 25)</td>
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<tr>
<td>non-switched groups</td>
<td>mean ± SD</td>
<td>805.59 (n = 100)</td>
<td>635.63 (n = 60)</td>
<td>970.41 (n = 95)</td>
</tr>
</tbody>
</table>

^aP value calculated using one-way ANOVA.
^bP value calculated using Pearson’s χ² test of independence.
^cStatistical calculations were carried out in South African Rand (ZAR), but values are reported in pounds (calculated using 1 ZAR = 0.09 pounds).
conditions, such as HIV, or socioeconomic factors (a lack of transport, absence of reliable family members and/or the absence of a safe environment for continued care). Other reasons could include: (i) physicians reluctant to discharge patients; (ii) patients not assessed on a daily basis; and (iii) physicians waiting for the results of diagnostic tests. Similar to previous studies, a reduction in the length of hospital stay was not observed even though the duration of iv therapy decreased immediately after implementation. Possible reasons include: (i) the previously mentioned observation period after switch; (ii) a high incidence of concomitant chronic conditions; and (iii) the application of the guideline to a population with a wide variety of infections. The median length of hospitalization for patients in this study (9.0–10.0 days) (Table 1) was close to the median length of hospitalization reported by Viale et al. (11.0 days).

The decreases in the number of prescriptions for which iv antibiotic duration was specified by physicians and the mean duration of iv antibiotic therapy specified could be attributed to the presence of a ward pharmacist, which resulted in physicians not indicating the duration or decreasing the duration of iv treatment, as they thought it unnecessary if iv therapy was to be re-evaluated 72 h after initiation, according to the IVOST guideline. The significant decrease in the duration of iv antibiotic therapy for non-switched patients after clinical stability indicated that even patients who were not switched on the day of clinical stability received shorter iv antibiotic courses. Essentially, the significant decrease in the duration of iv therapy led to substantial drug-acquisition cost savings of up to £1414.41 in the immediate post-implementation audit.

A recent survey revealed that pharmacists in the USA regard gastrointestinal functionality as one of the most important criteria for switching from iv to oral therapy. This implies that since >90% of patients in each audit received oral medication while on iv antibiotic therapy, the number of patients switched could have been even higher. This study has taken into account that certain clinical conditions, such as infective endocarditis, require iv therapy even though the patient can take oral medication (due to the pharmacokinetic/pharmacodynamic criteria of the antibiotic). The IVOST guideline (Figure S1) included serious infections as a reason for the continuation of iv therapy and it was assumed that physicians applied these criteria to all patients on iv antibiotic therapy.

Challenges pertaining to Third World countries

The high incidence of HIV in this study (13.3%–27.3%) posed a challenge due to a lack of previous studies for comparison. Previous studies either: excluded patients with HIV (or immunosuppression); reported that immunosuppressed patients were ‘sometimes’ eligible for switch only after consultation with an infectious disease specialist; included HIV patients in the study, but the incidence was low, ranging from 1.9% to 13%; or did not mention HIV or immunosuppression at all.

HIV infection may have made physicians reluctant to switch patients from iv to oral. This is substantiated by the observation that during the immediate post-implementation audit (when most patients were switched) more HIV patients were present in the non-switched group compared with the switched group \(P=0.034\). In addition, some patients with HIV were observed in hospital for longer after switch, increasing the length of hospitalization. A further complicating factor was the expected high incidence of TB observed (19.3%–29.3%), which also contributed to an increased workload.

In South African government hospitals, electronic patient databases have not been implemented and paper records are still used. This was one of the challenges encountered in this study. Interpreting paper records was time consuming, and often contributed to confusion between admission diagnoses and previously diagnosed chronic diseases. Inefficient and unorganized filing systems increased the risk of missed data. The absence of an electronic patient database made it difficult to retrieve a patient’s history of antibiotic consumption, and eliminated the options of randomization, determining the 30 day mortality and recording readmission to hospital.

The high workload accompanied by staff shortages contributed to missed doses, the absence of daily assessments and forced inexperienced medical interns to practise without appropriate supervision. The absence of daily assessments could have led to patients achieving clinical stability in the absence of the physician, resulting in less accurate clinical stability data. A similar observation was made by Looi and Black, who noticed that the number of times patient charts were reviewed declined as the number of patients seen increased.

Due to cost and inappropriate use, the study site had limited oral antibiotics and an infectious disease specialist was not available to assist the researchers with analysis. Some antibiotics that are available in the South African private sector, e.g. iv and oral levofloxacin, iv and oral moxifloxacin, and oral cefuroxime axetil, were not available on the study hospital formulary. To further complicate matters, several antibiotics were out of stock at different stages during the study. The ward pharmacist was not a permanent staff member at the study hospital and this could have affected guideline acceptance.

Strengths of the study

This is the first South African study measuring the impact of an IVOST guideline on prescribing patterns. The three audit groups showed sufficient similarity to be appropriate for comparison. Only two other studies compared three groups, but did not evaluate the long-term sustainability of IVOST guideline implementation whereas this study conducted a third audit to determine whether positive outcomes could be sustained without the presence of a ward pharmacist. This study used a variety of methods to implement switch: (i) the involvement of physicians and pharmacists; (ii) audit and feedback; (iii) guideline distribution; (iv) a poster campaign; and (v) a ward pharmacist. A combination of methods to implement switch has been shown to be more successful than one method alone. The number of patients included in the study was also comparable to that in previous studies.

Recommendations for Third World countries

Considering the limited resources in Third World countries, the most important recommendation for a hospital is to have an optimally functioning PTC. Medical staff often fail to realize the importance of an active PTC and as a group the PTC can: (i) enforce the periodical auditing of medical practice, as it is a
tool through which a vast amount of information on the inappropriate use of medication can be identified; (ii) develop institutional, up-to-date antibiotic guidelines that incorporate local resistance patterns; (iii) organize educational sessions; (iv) promote effective communication among staff members; (v) ensure the continuous management and supervision of inexperienced staff; (vi) provide a channel through which staff members can convey their grievances and provide suggestions; and (vii) employ a ward pharmacist. Whether or not a functioning PTC exists, it is essential to ensure that a pharmacist spends at least 2–3 h/day in the wards, even with staff shortages and especially during stock shortages, as this would enhance physicians’ accessibility to the recommendations regarding replacement therapy. In addition, the implementation of switch by a ward pharmacist could increase awareness among physicians, leading to more frequent assessment of patients. Even though not measured in this study, it can be assumed that the overall reduction in iv antibiotic use would lead to a reduction in iv device-associated infections, as this is an important reason for using the oral rather than the iv route. Lastly, pharmacy schools in Third World countries should provide the option for pharmacists to specialize in the area of infectious diseases.

Conclusions

Even with limited resources and a high incidence of HIV, the implementation of the IVOST guideline in the medical wards of a South African government hospital positively affected prescribing patterns during the immediate post-implementation audit. The study was successful in increasing the number of patients switched, which led to a decrease in the unnecessary use of iv antibiotics and substantial cost saving. Unfortunately, these positive outcomes were not sustained when the pharmacist was no longer present in the ward actively implementing switch therapy. Based on these results, it can be recommended that South African government hospital PTCs consider using ward pharmacists, on a continual daily basis for 2–3 h/day, for the integration and reinforcement of IVOST guidelines. This study indicated that even under challenging circumstances, pharmacists working in developing countries can make a positive contribution towards the appropriate use of antibiotics and bring about considerable cost savings.

As the impact of iv to oral switch on the incidence of iv device-related infections and rate of relapse were not assessed in the current study, it can be recommended that future studies of this kind include investigating these aspects.

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Transparency declarations

None to declare.

Supplementary data

Figure S1 is available as Supplementary data at JAC Online (http://jac.oxfordjournals.org/).

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